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

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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

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

FARM CREDIT ADMINISTRATION

12 CFR Part 652

RIN 3052–AC56

Federal Agricultural Mortgage Corporation Funding and Fiscal Affairs; Farmer Mac Investment Management; Effective Date

AGENCY: Farm Credit Administration.

ACTION: Notice of effective date.

SUMMARY: The Farm Credit Administration (FCA), through the FCA Board, issued a final rule amending its regulations governing investment management practices of the Federal Agricultural Mortgage Corporation. In accordance with the law, the effective date of the final rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session.

DATES: *Effective Date:* Under the authority of 12 U.S.C. 2252, the regulation amending 12 CFR part 652 published on November 5, 2012 (77 FR 66375) is effective December 31, 2012.

FOR FURTHER INFORMATION CONTACT:
Joseph T. Connor, Associate Director for Policy and Analysis, Office of Secondary Market Oversight, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4280, TTY (703) 883–4434; or
Jennifer A. Cohn, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, Virginia 22102–5090, (703) 883–4020, TTY (703) 883–4020.

SUPPLEMENTARY INFORMATION: The Farm Credit Administration (FCA), through the FCA Board, issued a final rule amending its regulations governing investment management practices of the Federal Agricultural Mortgage Corporation. In accordance with 12 U.S.C. 2252, the effective date of the final rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulations is December 31, 2012.

(12 U.S.C. 2252(a)(9) and (10))

Dated: January 8, 2013.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2013–00548 Filed 1–14–13; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0483; Airspace Docket No. 12–ANM–13]

Establishment of Class D and Class E Airspace; Camp Guernsey, WY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class D airspace and Class E airspace at Camp Guernsey, WY. The establishment of an air traffic control tower has made this action necessary for the safety and management of Instrument Flight Rules (IFR) operations at Camp Guernsey Airport.

DATES: Effective date, 0901 UTC, March 7, 2013. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT:
Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

History

On September 12, 2012, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish controlled airspace at Camp Guernsey Airport, Camp Guernsey, WY (77 FR 56174). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class D airspace and Class E airspace designations are published in paragraphs 5000 and 6002, respectively, of FAA Order 7400.9W dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR Part 71.1. The Class D airspace and Class E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class D airspace and Class E airspace extending upward from the surface, at Camp Guernsey Airport, Camp Guernsey, WY, to accommodate the newly established air traffic control tower. Controlled airspace is established within a 5-mile radius of the airport, with a segment extending from the 5-mile radius to 6.5 miles north of the airport to provide the necessary airspace for IFR operations at Camp Guernsey Airport, Camp Guernsey, WY.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 discusses the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the

safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes controlled airspace at Camp Guernsey Airport, Camp Guernsey, WY.

Except for some editorial changes better explaining the airspace, this rule is the same as published in the NPRM.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures,'' paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air)

Adoption of the Amendment

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

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9W, Airspace Designations and Reporting Points, dated August 8, 2012, and effective September 15, 2012 is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

ANM WY D Camp Guernsey Airport, WY [New]

Camp Guernsey Airport, WY
(Lat. 42°15′35″ N., long. 104°43′42″ W.)

That airspace extending upward from the surface to and including 6,900 feet MSL within a 5-mile radius of Camp Guernsey Airport, and within 1.5 miles each side of the 340° bearing of the airport, extending from the 5-mile radius to 6.5 miles north of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E airspace designated as surface areas.

* * * * *

ANM WY E2 Camp Guernsey Airport, WY [New]

Camp Guernsey Airport, WY
(Lat. 42°15′35″ N., long. 104°43′42″ W.)

Within a 5-mile radius of Camp Guernsey Airport, and within 1.5 miles each side of the 340° bearing of the airport, extending from the 5-mile radius to 6.5 miles north of the airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in Seattle, Washington, on January 8, 2013.

Rex MacLean,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2013–00558 Filed 1–14–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 381

[Docket No. RM13–4–000]

Annual Update of Filing Fees

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule; annual update of Commission filing fees.

SUMMARY: In accordance with 18 CFR 381.104, the Commission issues this update of its filing fees. This notice provides the yearly update using data in the Commission's Management, Administrative, and Payroll System to calculate the new fees. The purpose of updating is to adjust the fees on the basis of the Commission's costs for Fiscal Year 2012.

DATES: *Effective Date:* February 14, 2013.

FOR FURTHER INFORMATION CONTACT: Raymond D. Johnson Jr., Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE., Room 42–66, Washington, DC 20426, 202–502–8402.

SUPPLEMENTARY INFORMATION:

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

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User assistance is available for eLibrary and other aspects of FERC's Web site during normal business hours. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

(Issued January 9, 2013)

The Federal Energy Regulatory Commission (Commission) is issuing this notice to update filing fees that the Commission assesses for specific services and benefits provided to identifiable beneficiaries. Pursuant to 18 CFR 381.104, the Commission is establishing updated fees on the basis of the Commission's Fiscal Year 2012 costs. The adjusted fees announced in this notice are effective February 14, 2013. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, that this final rule is not a major rule within the meaning of section 251 of Subtitle E of Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. 804(2). The Commission is submitting this final rule to both houses of the United States Congress and to the Comptroller General of the United States.

The new fee schedule is as follows:

Fees Applicable to the Natural Gas Policy Act

1. Petitions for rate approval pursuant to 18 CFR 284.123(b)(2). (18 CFR 381.403)	$12,130

Fees Applicable to General Activities

1. Petition for issuance of a declaratory order (except under Part I of the Federal Power Act). (18 CFR 381.302(a))	$24,370

2. Review of a Department of Energy remedial order:

AMOUNT IN CONTROVERSY	
$0–9,999. (18 CFR 381.303(b))	$100

AMOUNT IN CONTROVERSY—Continued

$10,000–29,999. (18 CFR 381.303(b))	600
$30,000 or more. (18 CFR 381.303(a))	35,580

3. Review of a Department of Energy denial of adjustment:

AMOUNT IN CONTROVERSY

$0–9,999. (18 CFR 381.304(b))	$100
$10,000–29,999. (18 CFR 381.304(b))	600
$30,000 or more. (18 CFR 381.304(a))	18,650

4. Written legal interpretations by the Office of General Counsel. (18 CFR 381.305(a))	$6,990

Fees Applicable to Natural Gas Pipelines

1. Pipeline certificate applications pursuant to 18 CFR 284.224. (18 CFR 381.207(b))	* $1,000

Fees Applicable to Cogenerators and Small Power Producers

1. Certification of qualifying status as a small power production facility. (18 CFR 381.505(a))	$20,960
2. Certification of qualifying status as a cogeneration facility. (18 CFR 381.505(a))	$23,720

List of Subjects in 18 CFR Part 381

Electric power plants,Electric utilities, Natural gas, Reporting and recordkeeping requirements.

Anton Porter,

Executive Director.

In consideration of the foregoing, the Commission amends Part 381, Chapter I, Title 18, Code of Federal Regulations, as set forth below.

PART 381—FEES

■ 1. The authority citation for Part 381 continues to read as follows:

Authority: 15 U.S.C. 717–717w; 16 U.S.C. 791–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; 49 U.S.C. 60502; 49 App. U.S.C. 1–85.

§ 381.302 [Amended]

■ 2. In 381.302, paragraph (a) is amended by removing ''$24,860'' and adding ''$24,370'' in its place.

§ 381.303 [Amended]

■ 3. In 381.303, paragraph (a) is amended by removing ''$36,290'' and adding ''$35,580'' in its place.

§ 381.304 [Amended]

■ 4. In 381.304, paragraph (a) is amended by removing ''$19,030'' and adding ''$18,650'' in its place.

§ 381.305 [Amended]

■ 5. In 381.305, paragraph (a) is amended by removing ''$7,130'' and adding ''$6,990'' in its place.

§ 381.403 [Amended]

■ 6. Section 381.403 is amended by removing ''$12,370'' and adding ''$12,130'' in its place.

§ 381.505 [Amended]

■ 7. In 381.505, paragraph (a) is amended by removing ''$21,380'' and adding ''$20,960'' in its place and by removing ''$24,200'' and adding ''$23,720'' in its place.

[FR Doc. 2013–00590 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

* This fee has not been changed.

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in February 2013. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective February 1, 2013.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for February 2013.[1]

The February 2013, interest assumptions under the benefit payments regulation will be 0.75 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for January 2013, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during February 2013, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE–EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 232 is added to the table to read as follows:

Appendix B to Part 4022—Lump Sum Interest Rates For PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
232	2–1–13	3–1–13	0.75	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 232 is added to the table to read as follows:

Appendix C to Part 4022—Lump Sum Interest Rates For Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
232	2–1–12	3–1–13	0.75	4.00	4.00	4.00	7	8

Issued in Washington, DC, on this 8th day of January 2013.

Laricke Blanchard,

Deputy Director for Policy, Pension Benefit Guaranty Corporation.

[FR Doc. 2013–00632 Filed 1–14–13; 8:45 am]

BILLING CODE 7709–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–OAR–2012–0943, FRL–9769–4]

RIN 2060

Findings of Failure To Submit a Complete State Implementation Plan for Section 110(a) Pertaining to the 2008 Ozone National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is finding that 28 states, the District of Columbia and the Commonwealth of Puerto Rico have not made complete state implementation plan (SIP) submissions to address certain SIP elements, as required by the Clean Air Act (CAA). Specifically, the EPA is determining that these states have not submitted complete SIPs that provide the basic CAA program elements as necessary to implement the 2008 8-hour ozone national ambient air quality standards (NAAQS). The EPA refers to these SIP submissions as ''infrastructure'' SIPs. By this action, the EPA is identifying states that either have not made any submission to address the applicable elements or have made a complete submission to address some applicable elements but did not make a complete submission for other applicable elements. The EPA recognizes that its efforts to reconsider the 2008 8-hour ozone NAAQS delayed and complicated the efforts of some states to develop and submit these infrastructure SIPs, but at this time the EPA is nevertheless required by court order to make these findings. These findings of failure to submit establish a 24-month deadline for the EPA to promulgate federal implementation plans (FIPs) to address the outstanding SIP elements unless, prior to that time, the affected states submit and the EPA approves, a SIP that corrects the deficiency.

DATES: The effective date of this rule is February 14, 2013.

FOR FURTHER INFORMATION CONTACT: General questions concerning this notice should be addressed to Dr. Karl Pepple: telephone (919) 541–2683, email *pepple.karl@epa.gov;* or Mr. Lynn Dail: telephone (919) 541–2363, email *dail.lynn@epa.gov,* Office of Air Quality Planning and Standards, Air Quality Policy Division, Mail Code C539–02, 109 TW Alexander Drive, Research Triangle Park, NC 27709.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Notice and Comment Under the Administrative Procedure Act (APA)

Section 553 of the APA, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that there is good cause for making this rule final without prior proposal and opportunity for comment because no significant EPA judgment is involved in making a finding of failure to submit SIPs, or elements of SIPs, required by the CAA, where states have made no submissions, or incomplete submissions, to meet the requirement. Thus, notice and public procedure are unnecessary. The EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

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

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2012–0943. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue 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 Office of Air and Radiation Docket and Information Center is (202) 566–1742.

C. Contact Information

For questions related to a specific state, the District of Columbia or the Commonwealth of Puerto Rico, please contact the appropriate EPA Regional Office:

Regional offices	States
EPA Region I: Dave Conroy, Air Program Branch Manager, Air Programs Branch, EPA New England, 1 Congress Street, Suite 1100, Boston, MA 02203–2211.	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont.
EPA Region II: Raymond Werner, Chief, Air Programs Branch, EPA Region II, 290 Broadway, 21st Floor, New York, NY 10007–1866.	New Jersey, New York and Puerto Rico.
EPA Region III: Donna Mastro, Air Program Manager, Air Quality Planning Branch, EPA Region III, 1650 Arch Street, Philadelphia, PA 19103–2187.	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia and West Virginia.
EPA Region IV: R. Scott Davis, Air Program Manager, Regulatory Development Section, EPA Region IV, Sam Nunn, Atlanta Federal Center, 61 Forsyth Street SW., 12th Floor, Atlanta, GA 30303.	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee.
EPA Region V: John Mooney, Air Program Branch Manager, Air Programs Branch, EPA Region V, 77 West Jackson Street, Chicago, IL 60604.	Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin.
EPA Region VI: Guy Donaldson, Chief, Air Planning Section, EPA Region VI, 1445 Ross Avenue, Dallas, TX 75202–2733.	Arkansas, Louisiana, New Mexico, Oklahoma and Texas.
EPA Region VII: Joshua A. Tapp, Branch Chief, Air Planning and Development Branch, EPA Region VII, 11201 Renner Blvd., Lenexa, KS 66219.	Iowa, Kansas, Missouri and Nebraska.
EPA Region VIII: Monica Morales, Air Program Manger, Air Quality Planning Unit, EPA Region VIII Air Program, 1595 Wynkoop St. (8P–AR), Denver, CO 80202–1129.	Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming.
EPA Region IX: Doris Lo, Acting Air Program Manager, Air Planning Office, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105.	Arizona, California, Hawaii and Nevada.
EPA Region X: Debra Suzuki, Air Program Manager, Air Planning Unit, EPA Region X, Office of Air, Waste, and Toxics, Mail Code AWT–107, 1200 Sixth Avenue, Seattle, WA 98101.	Alaska, Idaho, Oregon and Washington.

D. How is this preamble organized.

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II. Background and Overview

On March 12, 2008, the EPA promulgated new NAAQS for ozone.[1] The agency revised the previous 8-hour primary ozone standard of 0.08 parts per million (ppm) to 0.075 ppm. The EPA also revised the secondary 8-hour standard to the level of 0.075 ppm making it identical to the revised primary standard. In September 2009, the EPA announced it would reconsider the 2008 8-hour ozone NAAQS and informed the states of this plan. On January 19, 2010, the EPA extended by 1 year the deadline for promulgating initial area designations for the 2008 ozone NAAQS. However, in September 2011, the EPA announced its decision to merge the reconsideration of the 2008 NAAQS with the next scheduled 5-year review of the ozone NAAQS, and advised the states that the 2008 NAAQS would be implemented.

The CAA section 110(a) imposes an obligation upon states to make a SIP submission with respect to the 2008 8-hour ozone NAAQS. CAA section 110(a)(1) requires states to submit SIPs that provide for the implementation, maintenance and enforcement of a new or revised NAAQS within 3 years following the promulgation of the new or revised NAAQS, or within such shorter period as the EPA may prescribe.[2] Section 110(a)(2) lists specific requirements that states must meet in these SIP submissions, as applicable. The EPA refers to this type of SIP submission as the ''infrastructure'' SIP. The requirements for infrastructure SIPs include basic SIP

[1] *See* 73 FR 16436, March 27, 2008, National Ambient Air Quality Standards for Ozone, Final Rule.

[2] The EPA has not prescribed a shorter period for the 2008 8-hour ozone NAAQS.

elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. The contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS necessarily affect the content of the submission. The content of such a SIP submission may also vary depending upon what provisions the state's existing SIP already contains. Two elements identified in section 110(a)(2) are not governed by the 3-year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area requirements are not due within 3 years after promulgation of a new or revised NAAQS, but rather are due at the time the nonattainment area plan requirements are due pursuant to section 182.[3] These requirements are: (i) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a nonattainment area new source review permit program for major sources as required in part D of title I of the CAA; and (ii) submissions required by section 110(a)(2)(I) which pertains to the nonattainment planning requirements of part D of title I of the CAA. Therefore, this action does not cover these specific SIP elements in section 110(a)(2). This action does cover the requirement that infrastructure SIPs provide for a minor source permitting program. In the case of the 2008 8-hour ozone NAAQS, the period during which the EPA was making efforts to reconsider the 2008 NAAQS with the expectation of revising it in the near term extended about 6 months beyond March 12, 2011, the normal deadline for submission of infrastructure SIPs. The EPA therefore did not prepare and issue timely guidance for the states to assist them in preparing their submissions. Also, states were given the impression that if the NAAQS were revised as a result of the reconsideration, the 3-year deadline would reset. However, given that the NAAQS have not been revised, March 12, 2011, remains the legally applicable deadline for infrastructure SIPs for the 2008 8-hour ozone NAAQS.

The EPA recognizes that many states would have developed and made timely infrastructure SIP submissions for purposes of the 2008 8-hour ozone NAAQS but for the uncertainty of the submission date requirement as a result of the EPA's efforts to reconsider that NAAQS, the EPA's associated interim advice to states regarding implementation of those NAAQS, and the lack of guidance from the EPA regarding what such infrastructure submissions should include. The EPA believes that many states in fact have SIPs in place that meet all or many of the basic program elements required in section 110(a)(2), as a result of their earlier SIP submissions in connection with previous ozone NAAQS and NAAQS for other pollutants. Since the September 2011 announcement that the 2008 8-hour NAAQS would be implemented, many states have been working to prepare infrastructure SIP submissions documenting that this is the case (and supplementing the SIP with new provisions when needed) and to complete required public comment opportunity steps. About one-half of the states have successfully made complete submissions and a number of others are less than a month away from doing so. Some states are on track to make a submittal somewhat later.

As of early 2012, which was only a few months after the announcement that the deadline for infrastructure SIPs would not reset and thus had already passed on March 12, 2011, many states had not yet submitted an infrastructure SIP for the 2008 8-hour ozone NAAQS. Litigants filed a mandatory duty lawsuit alleging: (i) That the EPA had failed to take timely mandatory action under section 110(k) on infrastructure SIPs submitted by Kentucky and Tennessee; and (ii) that the EPA had failed to make completeness findings or findings of failure to submit for many other states that had not yet submitted such infrastructure SIP submissions as of that point in time. On October 17, 2012, the court granted summary judgment to the litigants against the EPA and ordered the EPA to take certain actions, including making findings of failure to submit for any of the listed states that had not yet made an infrastructure SIP submission.[4] The court ordered the EPA to sign a final rule issuing these findings of failure to submit for each of the states listed in the order for each of the listed infrastructure SIP elements, no later than January 4, 2013. The EPA interprets the court's order to require a determination whether or not each of the listed states has made a complete infrastructure SIP submission for the listed elements of section 110(a)(2), as applicable, and if the state in question has not made such a complete submission for one or more relevant elements of section 110(a)(2), to make a finding of failure to submit with respect to any such element. Whether or not a submittal is ''complete'' pertains to the requirements in section 110(k)(1)(B) and EPA's regulations at 40 CFR 51 Appendix V. Thus, the EPA is making findings of failure to submit, in whole or in part, based upon whether the states at issue have made a complete infrastructure SIP for the relevant elements of section 110(a)(2).[5]

The EPA also is not issuing in this notice any findings of failure to submit SIPs addressing section 110(a)(2)(D)(i)(I) of the CAA. The EPA has historically interpreted section 110(a)(1) of the CAA as establishing the required submittal date for SIPs addressing all of the ''interstate transport'' requirements in section 110(a)(2)(D) including the provisions in section 110(a)(2)(D)(i)(I) regarding significant contribution to nonattainment and interference with maintenance. The DC Circuit's recent opinion in *EME Homer City Generation* v. *EPA,* 696 F.3d 7, 31 (D.C. Cir. 2012), however, concluded that a SIP cannot be deemed to lack a required submission or deemed deficient for failure to meet the 110(a)(2)(D)(i)(I) obligation until after the EPA quantifies that obligation. This decision is not yet final as the mandate has not been issued and the EPA has petitioned for rehearing *en banc,* asking the full court to reconsider that conclusion. Nonetheless, during the pendency of the appeal, the EPA intends to act in accordance with the holdings in the

[3] Nonattainment area plans required by part D title I of the CAA for the 2008 8-hour ozone NAAQS are due by various dates as established throughout subpart 2 of part D, i.e., reasonably available control measures are due in 2 years under 182(b)(2), reasonable further progress plans are due in 3 years under 182(b)(1), and attainment demonstrations are due in 4 years under 182(c)(2). The EPA has interpreted these dates to run from the effective dates of the nonattainment designations, *see* 68 FR 32802, 32816–817 (June 2, 2003) (''subpart 2 SIP submittals will be due as a general matter by the same period of time after designation and classification under the 8-hour standard as provided in subpart 2 for areas designated and classified at the time of enactment of the 1990 CAA.'') The designations for the 2008 ozone standard were effective on July 20, 2012. *See* 77 FR 30088 (May 21, 2012) and 77 FR 34221 (June 11, 2012). The EPA notes that it has recently become aware that in several actions on ozone infrastructure SIPs the EPA incorrectly indicated that nonattainment SIPs would be due according to schedules established under section 172. Those statements were incorrect and the result of inadvertently using language applicable to particulate matter SIPs in ozone SIP actions. Section 172 sets SIP submittal dates only for SIPs subject to subpart 1 of part D. Section 182 sets the dates for ozone SIPs which are governed by subpart 2 of part D.

[4] *WildEarth Guardians* v. *Lisa P. Jackson,* U.S. District Court for the Northern District of California, Case No.:11–CV–5651 YGR and Consolidated Case No.: 11–CV–05694 YGR.

[5] The court also ordered the EPA to sign a final rule or rules taking action on infrastructure SIP submittals from Tennessee and Kentucky. The date for these final actions was subsequently extended by the court to March 4, 2013. These actions will be addressed in separate **Federal Register** notices.

EME Homer City opinion. Therefore, at this time the EPA is not making findings that states failed to submit SIPs to comply with section 110(a)(2)(D)(i)(I).

After excluding SIP elements required by CAA sections 110(a)(2)(C) to the extent that subsection refers to a nonattainment area new source review permit program for major sources as required in part D of title I of the CAA, 110(a)(2)(I) regarding plans for nonattainment areas, and 110(a)(2)(D)(i)(I) regarding interstate transport affecting attainment and maintenance of the NAAQS, as explained above, the remaining elements that are relevant to this action are the requirements of CAA sections 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M).

For those states that have not yet made an infrastructure SIP submittal and those states that have made a submittal that was not complete with respect to each relevant element of section 110(a)(2), as applicable, the EPA is making a finding of failure to submit. For those states that have not made any submittal, the EPA is making a finding with respect to all of the relevant section 110(a)(2) SIP elements. For those states that have made a SIP submittal, but whose submittal is incomplete for some or all of the relevant section 110(a)(2) elements, as applicable, the EPA is issuing findings of failure to submit only with respect to those specific elements which a state has not yet submitted a complete SIP submission to meet. For both sets of states, these findings reflect submissions received or not received as of January 3, 2013.

These findings establish a 24-month deadline for the promulgation by the EPA of a FIP, in accordance with section 110(c)(1). These findings of failure to submit do not impose sanctions, or set deadlines for imposing sanctions as described in section 179 of the CAA, because these findings do not pertain to the elements of a part D, title I plan for nonattainment areas as required under section 110(a)(2)(I) and because this action is not a SIP call pursuant to section 110(k)(5).

The EPA is not making any finding in this notice regarding 22 states that have submitted infrastructure SIPs that have become complete by operation of law under CAA section 110(k)(1)(B) or have already been determined by the EPA to be complete for all elements relevant to this action. These states are Alaska, Alabama, Colorado, Connecticut, Florida, Georgia, Idaho, Indiana, Kentucky, Maryland, Mississippi, New Hampshire, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Virginia and West Virginia. Arizona and Illinois have made submissions that have been determined by the EPA to be complete except for elements related to prevention of significant deterioration (PSD). Also, the infrastructure SIP submitted by Delaware was determined by the EPA to be incomplete for all elements prior to this notice; the EPA is anticipating that Delaware will submit a revised SIP soon. Also, New Mexico has submitted an infrastructure SIP covering Bernalillo County that has already been approved by the EPA. The submission date and completeness status of the infrastructure SIP for each of these states are provided in Table 1, for informational purposes only.

TABLE 1—INFRASTRUCTURE SIPS (AND SIP ELEMENTS) FOR THE 2008 8-HOUR OZONE NAAQS THAT HAVE BECOME COMPLETE BY OPERATION OF LAW, DETERMINED TO BE COMPLETE OR DETERMINED TO BE INCOMPLETE OR APPROVED PRIOR TO TODAY'S ACTION

State	Date of receipt by the EPA (and date shown on the submittal)	Completeness status
Alaska	Section 110(a)(2)(D)(i)—April 4, 2011 (submission was dated March 29, 2011); other sections—March 8, 2012 (submission is dated March 2, 2012).	Complete by operation of law.
Alabama	August 23, 2012 (submission is dated August 20, 2012).	Determined to be complete on December 14, 2012.
Arizona	December 27, 2012 (submission is dated December 27, 2012).	Determined to be complete for relevant elements except those related to PSD on January 4, 2013.
Colorado	December 31, 2012 (submission is dated December 31, 2012).	Determined to be complete on January 2, 2013.
Connecticut	December 28, 2012 (submission is dated December 28, 2012).	Determined to be complete on January 3, 2013.
Delaware	February 1, 2012 (submission is dated January 17, 2012).	Determined to be incomplete on March 29, 2012.
Florida	November 3, 2011 (submission is dated October 31, 2011).	Complete by operation of law.
Georgia	March 8, 2012 (submission is dated March 6, 2012).	Complete by operation of law.
Idaho	June 28, 2010 (submission is dated June 25, 2010).	Complete by operation of law.
Illinois	December 31, 2012 (submission is dated December 31, 2012).	Determined to be complete for relevant elements except those related to PSD on January 2, 2013.
Indiana	December 15, 2011 (submission is dated December 12, 2011).	Complete by operation of law.
Kentucky	July 23, 2012 (submission is dated July 17, 2012).	Determined to be complete on December 14, 2012.
Maryland	December 31, 2012 (submission is dated December 27, 2012).	Determined to be complete on January 2, 2013.
Mississippi	August 17, 2012 (submission is dated July 26, 2012).	Determined to be complete on December 18, 2012.

TABLE 1—INFRASTRUCTURE SIPS (AND SIP ELEMENTS) FOR THE 2008 8-HOUR OZONE NAAQS THAT HAVE BECOME COMPLETE BY OPERATION OF LAW, DETERMINED TO BE COMPLETE OR DETERMINED TO BE INCOMPLETE OR APPROVED PRIOR TO TODAY'S ACTION—Continued

State	Date of receipt by the EPA (and date shown on the submittal)	Completeness status
New Hampshire	December 31, 2012 (submission is dated December 31, 2012).	Determined to be complete on January 3, 2013.
New Mexico (for Bernalillo County only)	August 25, 2010 (submission is dated August 16, 2010).	Final approval (77 FR 58032, September 19, 2012).
North Carolina	November 9, 2012 (submission is dated November 2, 2012).	Determined to be complete on November 15, 2012.
Ohio	December 27, 2012 (submission is dated December 27, 2012).	Determined to be complete on January 2, 2013.
Oregon	Section 110(a)(2)(D)(i)—June 28, 2010 (submission is dated June 23, 2010); other sections—December 28, 2011 (submission is dated December 19, 2011).	Complete by operation of law.
Rhode Island	January 2, 2013 (submission is dated January 2, 2013).	Determined to be complete on January 3, 2013.
South Carolina	October 28, 2011 (submission is dated October 24, 2011).	Complete by operation of law.
Tennessee	October 21, 2009 (submission is dated October 19, 2009).	Complete by operation of law.
Texas	December 19, 2012 (submission is dated December 13, 2012).	Determined to be complete on December 20, 2012.
Virginia	July 26, 2012 (submission is dated July 23, 2012).	Determined to be complete on December 10, 2012.
West Virginia	February 21, 2012 (submission is dated February 17, 2012).	Complete by operation of law.

The EPA is finding that the 25 states not listed in Table 1, Arizona, Illinois, New Mexico, the District of Columbia and the Commonwealth of Puerto Rico, as identified in section III of this notice, have not made a complete infrastructure submission to meet certain requirements of section 110(a)(2) that are relevant to this action, as applicable, for the 2008 8-hour ozone NAAQS. The EPA is committed to working with these states and areas to expedite the needed submissions and to working with all the states to review and act on their infrastructure SIP submissions in accordance with the requirements of the CAA.

III. Findings of Failure To Submit for States That Failed To Make an Infrastructure SIP Submittal in Whole or in Part for the 2008 8-hour Ozone NAAQS

The EPA is making findings that certain states have failed to submit a complete infrastructure SIP that provides certain basic program elements of section 110(a)(2) necessary to implement the 2008 8-hour ozone NAAQS, by January 3, 2013, as identified for each below. The EPA is by this action starting a 24-month deadline by which time the EPA must promulgate a FIP for each affected state to address the identified section 110(a)(2) requirements, unless the state submits and EPA approves a SIP revision that corrects the deficiency before the EPA promulgates a FIP for the state, in accordance with section 110(c)(1). This action will be effective 30 days after publication, on February 14, 2013.

The following states and territories failed to make a complete submittal to satisfy certain of the requirements of section 110(a)(2).

Region I

Maine did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M).

Massachusetts did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four subsections for the PSD-related and notification-related requirements only) are already addressed for Massachusetts through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections.

Vermont did not submit a SIP to address the requirements of 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M).

Region II

New Jersey did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four subsections for the PSD-related and notification-related requirements only) are already addressed for New Jersey through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections. The EPA anticipates that New Jersey will propose a SIP for public comment that certifies New Jersey's existing EPA-approved SIP, meets all the requirements of the infrastructure SIP elements included in today's finding that are not related to PSD or to notification.

New York did not submit a SIP to address the requirements of section

110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). A SIP proposed for public comment by New York certifies that New York's existing EPA-approved SIP, including its PSD program, meets all the requirements of the infrastructure SIP elements included in today's finding.

The *Commonwealth of Puerto Rico* did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four subsections for the PSD-related and notification-related requirements only) are already addressed for the Commonwealth of Puerto Rico through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections.

Region III

The *District of Columbia* did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four sections for the PSD-related and notification-related requirements only) are already addressed for the District of Columbia through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections.

Pennsylvania did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four subsections for the PSD-related and notification-related requirements only) are already addressed for Allegheny County through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections in Allegheny County.

Region V

Illinois did not submit a complete SIP to address the requirements of section 110(a)(2)(C) and (J) to the extent these refer to PSD permitting programs required by part C of title I of the CAA. Illinois also failed to submit a complete SIP to address the PSD-related requirement of section 110(a)(2)(D)(i)(II) to the extent it refers to interference with other states' PSD permitting programs required by part C by sources in Illinois. Illinois also failed to submit a complete SIP to address the requirement of section 110(a)(2)(D)(ii) to the extent it refers to notification to other states. Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four subsections for the PSD-related and notification-related requirements only) are already addressed for Illinois through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections.

Michigan did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M).

Minnesota did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four subsections for the PSD-related and notification-related requirements only) are already addressed for Minnesota through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections.

Wisconsin did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M).

Region VI

Arkansas did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M).

Louisiana did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M).

New Mexico did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M) for all portions of the state other than Bernalillo County.

Oklahoma did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M).

Region VII

Iowa did not submit a complete SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). On December 17, 2012, the state by letter submitted a document that describes the actions the state has taken to address the infrastructure SIP requirements for the 2008 8-hour ozone NAAQS, to demonstrate that the state is taking necessary and possible steps needed to ensure that its rules and procedures are sufficient to implement the new standards. However, while the state provided this document to the public for comment on December 6, 2012, that comment period does not close until January 8, 2013. In addition, the state has scheduled a public hearing on this submission for January 8, 2013, as required by CAA section 110(a)(1) and 40 CFR 51.102. The EPA anticipates that Iowa will submit a complete SIP soon after conclusion of the public comment period.

Kansas did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it

refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). The EPA anticipates that Kansas will submit a SIP to address these requirements after conclusion of the public comment period currently underway.

Missouri did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). The EPA anticipates that Missouri will submit a SIP to address these requirements soon.

Nebraska did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). The EPA anticipates that Nebraska will submit a SIP to address these requirements after conclusion of the public comment period currently underway.

Region VIII

Montana did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by CAA part C title I, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M).

North Dakota did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). The state anticipates undergoing rulemaking and public notice early in 2013.

South Dakota did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). The state anticipates undergoing rulemaking and public notice early in 2013.

Utah did not submit a complete SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). On December 12, 2012, the state by letter submitted documents that summarize the state's existing infrastructure SIP elements and explain that these elements satisfy the state's obligation for the 2008 ozone NAAQS. However, the state had not yet completed a public comment process on this submission, although the state has provided these documents to the public for a comment period between December 18, 2012, and January 18, 2013. As a result, the December 12, 2012, submittal has not yet satisfied the requirement for public notice and opportunity for a public hearing established in CAA section 110(a)(1) and 40 CFR 51.102. *See also* CAA section 110(l). The state's letter offers its position that because all of the elements in the existing infrastructure SIP were previously subject to a public comment process, including the opportunity for public hearing(s), when they were first submitted for the EPA's approval and incorporation into the SIP, no public comment requirements should apply to the December 12, 2012, submittal. Utah's position is inconsistent with the plain text of section 110(a)(1) of the CAA. Section 110(a)(1) first provides that ''[e]ach State shall, *after reasonable notice and public hearings,* adopt and submit to the Administrator, within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a [primary NAAQS] (or any revision thereof) * * * a plan [i.e., infrastructure SIP] which provides for implementation, maintenance, and enforcement of such primary standard.'' The clause ''after reasonable notice and public hearings'' is most naturally read as imposing that procedure on the immediately following phrase, ''adopt and submit,'' the direct object of which is the infrastructure SIP itself. Utah's position would instead apply the phrase ''after reasonable notice and public hearings'' to SIP revisions submitted before the promulgation of the new or revised primary NAAQS, despite the complete absence of a reference to those earlier SIP revisions in section 110(a)(1). Any possible residual ambiguity is removed by the last sentence of section 110(a)(1), which requires an infrastructure SIP for a secondary NAAQS to be considered (unless a separate public hearing is provided) ''at the hearing required by the first sentence of this paragraph.'' The only possible interpretation of this sentence is that there must be an opportunity for public hearing for the infrastructure SIPs for both the primary and secondary NAAQS. As explained in an EPA memorandum,[6] the requirement in the CAA and EPA rules for public notice and opportunity for a hearing is to inform the public that the SIP is being revised and allow for comment as to whether the state regulations satisfy the relevant specific obligation under the CAA, in this case the new obligation stemming from the promulgation of the revised 2008 ozone NAAQS. Finally, draft submittals are not considered plan submittals under the CAA because they have not been adopted by the state. Consequently, Utah's SIP submittal does not qualify for a finding of completeness. Because the requirements for public notice and opportunity for a hearing apply to Utah's December 12, 2012, submittal, the EPA's determination in this action that the submittal did not satisfy those requirements is also a determination that the December 12, 2012, submittal is incomplete in its entirety under the criteria in 40 CFR part 51, Appendix V, specifically the criteria in subsections 2.1(f) and (g). As Utah's submittal did not meet the minimum criteria in Appendix V, we are treating the state as not having made the required infrastructure SIP submission. *See* CAA section 110(k)(1)(C).

Wyoming did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). The state anticipates undergoing rulemaking and public notice early in 2013.

Region IX

Arizona did not submit a complete SIP to address the requirements of section 110(a)(2)(C) and (J) to the extent these refer to the Prevention of Significant Deterioration (PSD) permitting programs required by part C, title I of the CAA for sources in Maricopa County, Pima County, and Pinal County. Arizona did not submit a complete SIP to address the PSD-related requirements of section 110(a)(2)(D)(i)(II) to the extent it refers to interference with other states' PSD permitting programs required by part C by sources in these counties. Arizona did not submit a complete SIP to address the requirement of section 110(a)(2)(D)(ii) to the extent it refers to

[6] *See* Attachment B, ''Regional Consistency for the Administrative Requirements of State Implementation Plan Submittals and the Use of 'Letter Notices' '', Memorandum from Janet McCabe, Deputy Assistant Administrator for the Office of Air & Radiation, to EPA Regional Administrators, April 6, 2011.

notification to other states for sources in these counties. Finally, did not submit a complete SIP to address the requirement of section 110(a)(2)(K) for the same counties. In Pinal County, PSD sources are subject to a SIP-approved PSD program but the state has not yet submitted SIP revisions to address PSD requirements for the 2008 8-hour ozone NAAQS. In Maricopa and Pima counties, sections 110(a)(2)(C), (D)(i)(II), (D)(ii), (J) and (K) (in all five subsections for the PSD-related and notification-related requirements only) are currently addressed by an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to these PSD-related and notification-related requirements in Maricopa and Pima counties.

California did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four subsections for the PSD-related and notification-related requirements only) are already addressed for some portions of California through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections in those portions of California.

Hawaii did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four subsections for the PSD-related and notification-related requirements only) are already addressed for Hawaii through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections.

Nevada did not submit a complete SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to PSD permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). On December 20, 2012, the state by letter submitted documents that summarize the state's existing infrastructure SIP elements. The state's letter offers its position that ''[s]ince no revisions for the Nevada infrastructure SIP for the 1997 ozone NAAQS are required to meet the infrastructure SIP requirements of the 2008 ozone NAAQS'', no public notice requirements should apply at this time for the revised ozone standard. The state's letter also requested that the EPA act on these submittals pursuant to the ''parallel processing'' procedures set forth in 40 CFR part 51, Appendix V. The state has not yet completed a public comment process on this submission, but the state letter provided information on the schedule for public comment periods and public hearings for three geographic subdivisions of the state indicating that all steps in the public comment processes would be finished by the end of February 2013. The state letter maintains that the EPA can make a completeness finding on Nevada's submittal under section 2.3 of 40 CFR part 51, Appendix V. For the reasons explained below, the EPA disagrees with both rationales offered by the state and hereby finds that Nevada has failed to submit a complete SIP to address the infrastructure SIP requirements of CAA section 110(a)(2) for the 2008 8-hour ozone NAAQS. Nevada's first rationale that no public comment process is needed because no revisions for the Nevada infrastructure SIP for the 1997 ozone NAAQS are required to meet the infrastructure SIP requirements of the 2008 ozone NAAQS is inconsistent with the plain text of section 110(a)(1) of the CAA. Section 110(a)(1) first provides that ''[e]ach State shall, *after reasonable notice and public hearings,* adopt and submit to the Administrator, within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a [primary NAAQS] (or any revision thereof) * * * a plan [i.e., infrastructure SIP] which provides for implementation, maintenance, and enforcement of such primary standard.'' The clause ''after reasonable notice and public hearings'' is most naturally read as imposing that procedure on the immediately following phrase, ''adopt and submit,'' the direct object of which is the infrastructure SIP itself. Nevada's position would instead apply the phrase ''after reasonable notice and public hearings'' to SIP revisions submitted before the promulgation of the new or revised primary NAAQS, despite the complete absence of a reference to those earlier SIP revisions in section 110(a)(1). Any possible residual ambiguity is removed by the last sentence of section 110(a)(1), which requires an infrastructure SIP for a secondary NAAQS to be considered (unless a separate public hearing is provided) ''at the hearing required by the first sentence of this paragraph.'' The only possible interpretation of this sentence is that there must be an opportunity for public hearing for the infrastructure SIPs for both the primary and secondary NAAQS. As explained in an EPA memorandum,[7] the requirement in the CAA and EPA rules for public notice and opportunity for a hearing is to inform the public that the SIP is being revised and allow for comment as to whether the state regulations satisfy the relevant specific obligation under the CAA, in this case the new obligation stemming from the promulgation of the revised 2008 ozone NAAQS. Finally, draft submittals are not considered plan submittals under the CAA because they have not been adopted by the state. Consequently, Nevada's SIP submittal does not qualify for a finding of completeness. Regarding Nevada's second rationale based on the parallel processing provisions of section 2.3 of 40 CFR part 51, Appendix V, the EPA agrees that this section provides for EPA to propose an approval action for a draft SIP submittal accompanied by a request for parallel processing as a way to reduce the time elapsed before final approval can be given after completion of the public comment process. However, draft submittals are not considered plan submittals under the CAA because they have not been adopted by the state. Consequently, a draft SIP submittal accompanied by a request for parallel processing under 40 CFR part 51, Appendix V does not qualify for a finding of completeness.[8] Because the requirements for public notice and opportunity for a hearing apply to Nevada's December 20, 2012, submittal, the EPA's determination in this action that the submittal did not satisfy those requirements is also a determination that the December 20, 2012, submittal is incomplete in its entirety under the criteria in Appendix V, Part 51 of Title 40 of the Code of Federal Regulations, specifically the criteria in subsections 2.1(f) and (g). As Nevada's submittal did not meet the

[7] *See* Attachment B, ''Regional Consistency for the Administrative Requirements of State Implementation Plan Submittals and the Use of 'Letter Notices' '', Memorandum from Janet McCabe, Deputy Assistant Administrator for the Office of Air & Radiation, to EPA Regional Administrators, April 6, 2011.

[8] *See* Memorandum from John Calcagni, Air Quality Management Division, OAQPS, to EPA Air Division Directors, Regions I through X, ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (Act) Deadlines,'' October 28, 1992.

minimum criteria in Appendix V, we are treating the state as not having made the required infrastructure SIP submission. *See* CAA section 110(k)(1)(C).

Region X

Washington did not submit a SIP to address the requirements of section 110(a)(2)(A), (B), (C) to the extent it refers to enforcement, to permitting programs for minor sources and to permitting programs required by part C of title I of the CAA, (D)(i)(II), (D)(ii), (E)–(H) and (J)–(M). Regarding this finding, sections 110(a)(2)(C), (D)(i)(II), (D)(ii) and (J) (in all four subsections for the PSD-related and notification-related requirements only) are already addressed for Washington through an existing PSD FIP that remains in place. Therefore, this action will not trigger any additional FIP obligations with respect to the PSD-related and notification-related requirements in these four subsections.

As noted earlier, the EPA is committed to working with these states and areas to expedite the needed submissions and to review and act on their infrastructure SIPs submission in accordance with the requirement of the CAA.

IV. Statutory and Executive Order Reviews

A. Executive Orders 12866: Regulatory Planning and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under EO 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* This final rule does not establish any new information collection requirement apart from that already required by law. This rule relates to the requirement in the CAA for states to submit SIPs under section 110(a) to satisfy certain infrastructure and general authority-related elements required under section 110(a)(2) of the CAA for the 2008 8-hour ozone NAAQS. Section 110(a)(1) of the CAA requires that states submit SIPs that implement, maintain and enforce a new or revised NAAQS which satisfy the requirements of section 110(a)(2) within 3 years of promulgation of such standard, or such shorter period as the EPA may provide.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating and verifying information, processing and maintaining information and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. 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 the CFR are listed in 40 CFR Part 9.

C. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the APA or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions. For the purpose of assessing the impacts of this final rule on small entities, small entity is defined as: (1) A small business that is a small industry entity as defined in the U.S. Small Business Administration (SBA) size standards (*See* 13 CFR 121); (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this rule will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. This action relates to the requirement in the CAA for states to submit SIPs under section 110(a) to satisfy certain infrastructure and general authority-related elements required under section 110(a)(2) of the CAA for the 2008 ozone NAAQS. Section 110(a)(1) of the CAA requires that states submit SIPs that implement, maintain and enforce a new or revised NAAQS which satisfies the requirements of section 110(a)(2) within 3 years of promulgation of such standard, or such shorter period as EPA may provide.

D. Unfunded Mandates Reform Act of 1995 (UMRA)

This action contains no federal mandate under the provisions of Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1538 for state, local and tribal governments and the private sector. The action imposes no enforceable duty on any state, local or tribal governments or the private sector. Therefore, this action is not subject to the requirements of section 202 and 205 of the UMRA.

This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This action relates to the requirement in the CAA for states to submit SIPs under section 110(a) to satisfy certain infrastructure and general authority-related elements required under section 110(a)(2) of the CAA for the 2008 ozone NAAQS. Section 110(a)(1) of the CAA requires that states submit SIPs that implement, maintain and enforce a new or revised NAAQS which satisfies the requirements of section 110(a)(2) within 3 years of promulgation of such standard, or such shorter period as the EPA may provide.

E. Executive Order 13132: Federalism

EO 13132, titled ''Federalism'' (64 FR 43255, August 10, 1999), requires the EPA to develop an accountable process to ensure ''meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the EO to include regulations that have ''substantial direct effects on the states, or the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.'' This final rule does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in EO 13132. The CAA establishes the scheme whereby states take the lead in developing plans to meet the NAAQS. This rule will not

modify the relationship of the states and the EPA for purposes of developing programs to implement the NAAQS. Thus, EO 13132 does not apply to this rule.

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

EO 13175, titled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires the EPA to develop an accountable process to ensure ''meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications.'' This final rule does not have tribal implications, as specified in EO 13175. This rule responds to the requirement in the CAA for states to submit SIPs under section 110(a) to satisfy certain elements required under section 110(a)(2) of the CAA for the 2008 8-hour ozone NAAQS. Section 110(a)(1) of the CAA requires that states submit SIPs that provide for implementation, maintenance and enforcement of a new or revised NAAQS, and which satisfy the applicable requirements of section 110(a)(2), within 3 years of promulgation-of such standard, or within such shorter period as the EPA may provide. No tribe is subject to the requirement to submit an implementation plan under section 110(a) within 3 years of promulgation of a new or revised NAAQS and the court order requiring this final action does not affect any tribe or its implementation plan.

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

The EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it is making findings that certain states have failed to submit a complete SIP that provides certain basic program elements of section 110(a)(2) necessary to implement the 2008 8-hour ozone NAAQS.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in EO 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs the EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impracticable. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS. This action does not involve technical standards. Therefore, EPA did not consider the use of any VCS.

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

EO 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the United States. The EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not directly affect the level of protection provided to human health or the environment. This notice is making a finding that certain states have failed to submit a complete SIP that provides certain of the basic program elements of section 110(a)(2) necessary to implement the 2008 8-hour ozone NAAQS.

K. Congressional Review Act

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 rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. 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). This rule will be effective February 14, 2013.

L. Judicial Review

Section 307(b)(1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final agency actions by the EPA under the CAA. This section provides, in part, that petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit (i) when the agency action consists of ''nationally applicable regulations promulgated, or final actions taken, by the Administrator,'' or (ii) when such action is locally or regionally applicable, if ''such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.''

This final rule consisting of findings of failure to submit certain required infrastructure SIP provisions is ''nationally applicable'' within the meaning of section 307(b)(1). First, this rule affects many states, the District of Columbia and the Commonwealth of Puerto Rico. Second, the action affects states across the U.S. that are located in nine of the 10 EPA Regions, 10 different federal circuits and multiple time zones. Third, the rule addresses a common core of knowledge and analysis involved in formulating the decision and a common interpretation of the requirements of 40 CFR 51 appendix V applied to determining the completeness of SIPs in states across the country.

This determination is appropriate because in the 1977 CAA Amendments that revised CAA section 307(b)(1), Congress noted that the Administrator's determination that an action is of ''nationwide scope or effect'' would be appropriate for any action that has ''scope or effect beyond a single judicial circuit.'' H.R. Rep. No. 95–294 at 323–324, reprinted in 1977 U.S.C.C.A.N. 1402–03. Here, the scope and effect of this action extends to numerous judicial circuits because the action affects states throughout the country. In these circumstances, section 307(b)(1) and its legislative history authorize the Administrator to find the rule to be of ''nationwide scope or effect'' and thus to

indicate that venue for challenges to be in the D.C. Circuit. Accordingly, the EPA is determining that this is a rule of nationwide scope or effect. In addition, pursuant to CAA section 307(d)(1)(V), the EPA is determining that this rulemaking action will be subject to the requirements of section 307(d). Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the District of Columbia Circuit Court within 60 days from the date final action is published in the **Federal Register**. Filing a petition for review by the Administrator of this final action does not affect the finality of the action for the purposes of judicial review nor does it extend the time within which a petition for judicial review must be filed, and shall not postpone the effectiveness of such rule or action. Thus, any petitions for review of this action must be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date final action is published in the **Federal Register**.

List of Subjects in 40 CFR Part 52

Approval and promulgation of implementation plans, Environmental protection, Administrative practice and procedures, Air pollution control, Incorporation by reference, Intergovernmental relations and Reporting and recordkeeping requirements.

Dated: January 4, 2013.

Gina McCarthy,

Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2013–00566 Filed 1–14–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

45 CFR Part 5b

[Docket Number NIH–2011–0001]

Privacy Act, Exempt Record System; Withdrawal

AGENCY: Department of Health and Human Services, National Institutes of Health.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) published in the **Federal Register** of August 28, 2012, a direct final rule to exempt a new system of records from certain provisions of the Privacy Act of 1974 in order to protect the integrity of NIH research misconduct proceedings and to protect the identity of confidential sources in such proceedings. The comment period for this direct final rule closed November 13, 2012. HHS is withdrawing the direct final rule because the agency has received significant adverse comment.

DATES: The direct final rule published at 77 FR 51933, August 28, 2012, is withdrawn effective January 10, 2013.

FOR FURTHER INFORMATION CONTACT: Karen Pla, the NIH Privacy Act Officer, by email at *KarenPla@nih.gov* or by telephone on 301–402–6201; and/or Jerry Moore, the NIH Regulations Officer, by email at *jm40z@nih.gov* or by telephone on 301–496–4607.

SUPPLEMENTARY INFORMATION: HHS and NIH published in the **Federal Register** of August 28, 2012 (77 FR 51933), a direct final rule to exempt a new system of records, 09–25–0223, ''NIH Records Related to Research Misconduct Proceedings, HHS/NIH,'' from certain provisions of the Privacy Act of 1974 in order to protect the integrity of NIH research misconduct proceedings and to protect the identity of confidential sources in such proceedings. HHS is withdrawing the direct final rule because the agency has received significant adverse comment.

Authority: Therefore, pursuant to 5 U.S.C. 301 and 552a, the direct final rule published on August 28, 2012 (77 FR 51933) is withdrawn.

Dated: January 10, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–00726 Filed 1–10–13; 4:15 pm]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 21

[Docket No. FDA–2011–N–0252]

Office of the Secretary

45 CFR Part 5b

Privacy Act, Exempt Record System; Withdrawal

AGENCY: Office of the Secretary, Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) are withdrawing the direct final rule that August 28, 2012. HHS/FDA published the direct final rule to exempt scientific research misconduct proceedings records from certain requirements of the Privacy Act of 1974 in order to protect records compiled in the course of misconduct inquiries and investigations, and to safeguard the identity of confidential sources. The comment period closed on November 13, 2012. HHS/FDA is withdrawing the direct final rule because the Agency received significant adverse comment.

DATES: *Effective Date:* The direct final rule published at 77 FR 51910, August 28, 2012, is withdrawn effective January 10, 2013.

FOR FURTHER INFORMATION CONTACT: Frederick Sadler, Division of Freedom of Information, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–8975, *Frederick.Sadler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: HHS and FDA are withdrawing the direct final rule that published in the **Federal Register** of Tuesday, August 28, 2012 (77 FR 51910). HHS/FDA published the direct final rule to exempt scientific research misconduct proceedings records from certain requirements of the Privacy Act of 1974 in order to protect records compiled in the course of misconduct inquiries and investigations, and to safeguard the identity of confidential sources. The comment period closed on November 13, 2012. HHS/FDA is withdrawing the direct final rule because the Agency received significant adverse comment.

Authority: Therefore, under 5 U.S.C. 552a, the direct final rule published on Tuesday, August 28, 2012, 77 FR 51910, is withdrawn.

Dated: January 10, 2013.

Approved:

Kathleen Sebelius

Secretary, Department of Health and Human Services.

[FR Doc. 2013–00723 Filed 1–10–13; 4:15 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 2, 22, and 52

[FAC 2005–64; FAR Case 2011–028; Correction; Docket 2011–028, Sequence 1]

RIN 9000–AM21

Federal Acquisition Regulation; Nondisplacement of Qualified Workers Under Service Contracts

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule; correction.

SUMMARY: DoD, GSA, and NASA are issuing a correction to the applicability date of FAR Case 2011–028; Nondisplacement of Qualified Workers Under Service Contracts, which was published in the **Federal Register** at 77 FR 75766, December 21, 2012.

DATES: *Effective Date:* January 18, 2013.

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, Procurement Analyst, at 202–501–0650, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite FAC 2005–64; FAR Case 2011–028; Correction.

SUPPLEMENTARY INFORMATION:

Correction

In rule FR Doc. 2012–30592 published in the **Federal Register** at 77 FR 75766, December 21, 2012, make the following correction:

On page 75766, in the third column, under **DATES**, *Applicability Date,* remove ''paragraph (c)'' and add ''paragraph (d)'' in its place.

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

Dated: January 8, 2013.

Laura Auletta,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–00655 Filed 1–14–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

[Docket No. 110427267–2708–02]

RIN 0648–BB04

Endangered and Threatened Species: Designation of a Nonessential Experimental Population for Middle Columbia River Steelhead above the Pelton Round Butte Hydroelectric Project in the Deschutes River Basin, OR

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

ACTION: Final rule.

SUMMARY: We, the National Marine Fisheries Service (NMFS), are issuing a final rule to authorize the continued release of Middle Columbia River (MCR) steelhead (*Oncorhynchus mykiss*) that are currently being reintroduced as part of an ongoing reintroduction effort into the upper Deschutes River basin in portions of Jefferson, Crook, and Deschutes Counties, Oregon, and designate them as a nonessential experimental population (NEP) under the Endangered Species Act (ESA) of 1973. The geographic boundaries of the NEP extend upstream from Round Butte Dam on the Deschutes River (about river mile (RM) 110, river kilometer (rkm) 177) and all accessible reaches of the Deschutes River and its tributary Whychus Creek; on the Crooked River from its confluence with the Deschutes River upstream to Bowman Dam (RM 70, rkm 113) and all accessible tributaries between these points; and on the Metolius River from its confluence with the Deschutes River upstream to all accessible tributaries between these points. This NEP designation will have an expiration date 12 years from the effective date of this final rule. We anticipate providing a notice in the **Federal Register** about 1 year before the NEP designation is set to expire to provide adequate notice to the public.

DATES: The effective date of this rule is January 15, 2013.

ADDRESSES: This final rule, along with the Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI), is available at *http://www.regulations.gov.* Comments and supporting documentation used in the preparation of this final rule are also available for inspection, by appointment, during normal business hours at the National Marine Fisheries Service, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR 97232.

FOR FURTHER INFORMATION CONTACT: Scott Carlon, NMFS, 1201 NE Lloyd Blvd., Portland, OR 97232 (503–231–2379) or Marta Nammack, NMFS, 1315 East-West Highway, Silver Spring, MD 20910 (301–713–1401).

SUPPLEMENTARY INFORMATION:

Context

On March 25, 1999, we listed the Middle Columbia River (MCR) steelhead distinct population segment (DPS) as threatened under the Endangered Species Act (ESA) (16 U.S.C. 1531–1544) (64 FR 14517). The MCR steelhead DPS range covers approximately 35,000 square miles (90,650 sq km) of the Columbia plateau of eastern Oregon and eastern Washington. The Deschutes River in central Oregon is one of six major river basins supporting steelhead in this DPS. Since 1968, the Pelton Round Butte Hydroelectric Project (hereafter, Pelton Round Butte Project) on the Deschutes River has blocked steelhead from accessing nearly 200 miles (322 km) of historical spawning and rearing habitat.

In this rulemaking, we are authorizing the continued release of the MCR steelhead currently being reintroduced to the upper Deschutes River basin and designating this population as a NEP. This reintroduction is a requirement of the new hydropower license for the Pelton Round Butte Project in Central Oregon, and thus will continue regardless of this designation. The licensees, Portland General Electric Company and the Confederated Tribes of the Warm Springs Reservation of Oregon, are conducting the reintroduction program in cooperation with the State of Oregon, NMFS, the U.S. Forest Service (USFS), the U.S. Fish and Wildlife Service (FWS), U.S. Bureau of Land Management (BLM), Jefferson and Deschutes Counties, Oregon, and 10 other stakeholder groups. This reintroduction is one of many recovery actions being implemented by NMFS, Federal and state agencies, and other partners throughout the threatened species' historical range. While passage and reintroduction have commenced under the authority of a license issued under the Federal Power Act, we are authorizing the continued release of the steelhead and designating the population as a NEP. We are also providing alternative protective measures for the NEP, under the authority of the ESA.

The purpose of this designation is to temporarily lift certain ESA liability and consultation requirements to allow time for local landowners and municipalities to develop well-informed conservation measures to support the reintroduction effort in the Upper Deschutes River basin. Information gained during the early stages of the reintroduction effort will help us focus conservation measures on the areas needing support, and how best to provide that support. For example, knowing where the steelhead spawn will inform determinations about what improvements are most important for that specific habitat, and what kinds of activities could be detrimental to spawning steelhead.

The specific stock chosen to initiate steelhead reintroduction is from the Round Butte Hatchery, and was not listed at the time it was chosen. After the new license was issued in June 2005 and reintroduction planning was largely completed, we included the Round Butte Hatchery steelhead stock as part of the threatened group of steelhead (71 FR 834; January 5, 2007).

In the proposed rule (76 FR 28715, May 18, 2011), we stated that the NEP designation would expire after three successive generations of MCR steelhead had been passed above the Pelton Round Butte Project. Three generations equates to about 12 years. At the time of the proposed rulemaking, it was not known when adult steelhead would first be passed above the Pelton Round Butte Project, so the expiration date was also not known. However, adult MCR steelhead from juvenile outplants in the NEP area are now returning to the Pelton Round Butte Project, and the first of these adults were released into the NEP area in late October 2012. Consequently, we can now provide the expiration date, which is 12 years from the effective date of this rule.

Some local landowners and one municipality are working to develop a Habitat Conservation Plan (HCP) for certain activities above the Pelton Round Butte Project. This HCP is likely to be completed sooner than the expiration date for the NEP designation. However, the HCP covers only a subset of the activities and area affected by the reintroduction. Thus, other local entities may consider developing conservation measures to address potential ESA liability. We expect that the fixed-duration NEP designation will encourage local landowners and municipalities to develop conservation measures in a timely manner, as full ESA protections for a threatened species will once again apply to the steelhead after the NEP designation expires. In addition, we expect that information gained during the NEP designation period will help inform conservation measures so that they can be refined through adaptive management.

This NEP will occur in portions of Deschutes, Jefferson, and Crook Counties, Oregon. The geographic boundaries of the NEP would extend upstream from Round Butte Dam on the Deschutes River and all accessible reaches of the Deschutes River (to MCR steelhead) and its tributary, Whychus Creek; on the Crooked River from its confluence with the Deschutes River upstream to Bowman Dam (RM 70, rkm 113) and all accessible tributaries between these points; and on the Metolius River from its confluence with the Deschutes River upstream to all accessible tributaries between these points. While this area is part of its historical range, MCR steelhead fish passage to the area was abandoned in about 1968.

Section 10(j) of the ESA allows the Secretary of Commerce (Secretary) to authorize the release of an experimental population of an endangered or threatened species outside the species' current range if the Secretary determines that the release will further the species' conservation. This designation will further the conservation of the species because it will build support for the reintroduction effort among local landowners, encourage those landowners and municipalities to complete conservation measures within the set time-period, and ensure that the conservation measures are focused on supporting the reintroduction based on information gathered during the NEP designation. Since we listed the MCR steelhead DPS as threatened, there has been great concern and uncertain support for reintroduction by local landowners and municipalities in the Upper Deschutes River basin. Consistent with Congressional intent of section 10(j), the NEP designation provides a flexible management tool to help build support for the reintroduction while promoting species conservation by allowing local landowners and municipalities to focus on developing conservation measures that promote the reintroduction effort. The expiration date supports the determination that this action will further the conservation of the species because it will encourage these entities to complete the needed conservation measures in a time certain. Without an expiration date, local landowners and municipalities would not have the same incentive to develop and implement conservation measures needed to support the reintroduction. We anticipate providing a notice in the **Federal Register** about 1 year before the NEP designation is set to expire to provide notice to the public.

The Secretary may designate an experimental population when, and at such times as, the population is wholly separate geographically from nonexperimental populations, as required in ESA section 10(j). In this action, we are designating an experimental population that is geographically separate from the nonexperimental ESA-listed MCR steelhead population, due to the dams that block access both upstream and downstream to the area where the species will have experimental status. The MCR steelhead will only be considered experimental when they are above Round Butte Dam (the last dam, moving upstream, in the three-dam complex). All MCR steelhead that are above the dams will be in the NEP geographic area, and will be part of the NEP. MCR steelhead below the dams will not be part of the NEP because they are not in the geographic area. This is a clear geographic boundary. It also recognizes the life cycle of MCR steelhead—that they spawn in streams, travel into the ocean to grow to maturity, and return to their natal streams to spawn. In this case, the MCR steelhead designated as an NEP will be geographically separated from the larger DPS of MCR steelhead while above Round Butte Dam, but will intermingle with more steelhead as they travel downstream of the Pelton Round Butte Project, while in the ocean, and on part of their journey upstream.

Background

The Deschutes River basin above the Pelton Round Butte Project was once home to native runs of summer steelhead, Chinook salmon, sockeye salmon, and Pacific lamprey. Before hydroelectric and irrigation development, steelhead used the Deschutes River up to Big Falls, Whychus Creek (a Deschutes River tributary above the Pelton Round Butte Project), and the Crooked River watershed. Within the Crooked River watershed, steelhead were documented in McKay, Ochoco, Horseheaven, Newsome, Drake, Twelvemile, and Beaver Creeks, and the North Fork Crooked River (Nehlsen, 1995). The completion of Ochoco Dam east of Prineville in 1920 blocked steelhead access into most of the Ochoco Creek watershed, and the completion of Bowman Dam on the Crooked River in 1961 stopped fish passage into the upper Crooked River watershed. On the

Deschutes River, the Pelton and Reregulating Dams were completed in 1958. Even though these dams had fish passage, steelhead numbers in the upper Deschutes River basin, though still significant, had declined by that time (Nehlsen, 1995). Available information suggests peak annual escapements in the 1950s were at least 1,600 adult summer steelhead and 800–900 (Montgomery, 1955) adult spring Chinook salmon (with perhaps twice this number harvested downstream). After completion of Round Butte Dam (the most upstream dam) in 1964, fish passage decreased dramatically, and, by 1968, was abandoned in favor of a hatchery program to mitigate lost passage and habitat. The runs could not be sustained primarily because reverse surface currents (surface currents moving upstream in the Metolious arm of Lake Billy Chinook) confused smolts attempting to migrate seaward through Lake Billy Chinook, the reservoir behind Round Butte Dam. Most of the smolts failed to find their way from the head of the reservoir downstream to a fish collector installed at Round Butte Dam (Korn *et al.,* 1967). As a result of this decline and other factors, and following a comprehensive study of west coast steelhead, we subsequently listed the MCR steelhead as a threatened DPS under the ESA (64 FR 14517; March 25, 1999).

There has long been an interest in reestablishing anadromous fish runs in the upper Deschutes River subbasin. This interest strengthened in recent years as technological innovations advanced and hydrodynamic modeling suggested that surface currents could be altered to favor the downstream passage of smolts. The relicensing of the Pelton Round Butte Project provided the opportunity to implement these innovations in order to attempt to reestablish anadromous fish runs upstream.

The Federal Energy Regulatory Commission issued a new license for the Pelton Round Butte Project (Project No. P–2030) on June 21, 2005, to Portland General Electric Company (PGE) and the Confederated Tribes of the Warm Springs Reservation of Oregon (CTWS), who are joint licensees (Licensees). The Warm Springs Power and Water Enterprises manages hydropower for the CTWS. The license requires fish passage around the Pelton Round Butte Project, and incorporates the terms of a Settlement Agreement (which includes agreement on license articles for fish passage in support of reintroduction) entered into by the Licensees and 20 other parties, including all levels of government, CTWS, and environmental groups. The license establishes a Fish Committee, which is made up of the PGE, CTWS' Natural Resource Management Services, NMFS, Oregon Department of Fish and Wildlife (ODFW), the FWS, and other agencies and entities. Details regarding the responsibilities of the Licensees with respect to fish passage and reintroduction are in the Fish Passage Plan, included as Exhibit D to the Settlement Agreement. These responsibilities include fish passage at the Pelton Round Butte Project, a wide variety of test and verification studies, and longer term monitoring efforts. The license includes a schedule for meeting those obligations.

Steelhead reintroduction has commenced consistent with the Fish Passage Plan, and the donor steelhead are from a captive bred population. This population is propagated to mitigate lost fisheries due to failed fish passage after the Pelton Round Butte Project was originally constructed. The hatchery fish being used for the ongoing reintroduction are excess stock, and therefore are not needed to help recovery.

Because the Pelton Round Butte Project does not provide volitional passage, the license requires construction and operation of a Selective Water Withdrawal structure that is now in place and operating at Round Butte Dam. The structure has already begun to help guide smolts to an associated fish screening and collection facility, and provide downstream passage for juveniles. This structure and its operation are also central elements of the Fish Passage Plan, as well as additional measures supporting reintroduction. Returning adult steelhead are being collected in traps below the Reregulating Dam and transported for release above Round Butte Dam. These released adults will have NEP status once transported above the dams and in the NEP geographic area (but do not have that status when they are below the dam).

The juvenile fish are marked as they leave the NEP area and thus can be identified by trap operators when they return as adults. For the time period of this rule, marked adult fish (i.e. fish that originated in the NEP) are likely to be the predominant if not only category of fish released above Round Butte Dam. The Fish Passage Plan (developed during the FERC relicensing process) is primarily focused on the release of adult marked fish and, although it provides for the future possibility of wild adult fish releases, that potential will depend on availability of wild spawners and the successful performance of the fish passage program at the Pelton Round Butte Project.

Statutory and Regulatory Framework

Congress made significant changes to the ESA in 1982, including the addition of section 10(j), which provides authority to reintroduce populations of listed species as ''experimental populations.'' Previously, we had authority to reintroduce populations into unoccupied portions of a listed species' historical range. However, local citizens often opposed these reintroductions because they were concerned about potential liability for harming these animals, and the placement of restrictions and prohibitions on Federal and private activities. Section 10(j) was designed to address this by providing greater flexibility in the application of ESA protections to experimental populations. H.R. Rep. No. 567, 97th Cong. 2d Sess. 34 (1982). Under section 10(j) of the ESA, the Secretary can authorize the release of an ''experimental'' population outside the species' current range, where: (1) The experimental population is geographically separate from the nonexperimental population; and (2) release of the experimental population will further the conservation of the listed species. The determination of whether experimental populations are ''essential'' or ''nonessential'' to the continued existence of the species must be based on the best scientific and commercial data available.

The ESA provides that species listed as endangered or threatened are afforded protection primarily through the prohibitions of section 9 and the consultation requirements of section 7. Section 9 of the ESA prohibits the take of an endangered species. The term ''take'' is defined by the ESA as ''to harass, harm, pursue, hunt, shoot, wound, trap, capture, or collect, or attempt to engage in any such conduct.'' 15 U.S.C. 1532(19). Section 7 of the ESA provides procedures for Federal interagency cooperation and consultation to conserve federally listed species, ensure their survival, help in recovery of these species, and to protect designated critical habitat necessary for the listed species' survival. It also mandates that all Federal agencies determine how to use their existing authorities to further the purposes of the ESA to aid in recovering listed species. In addition, ESA section 7 requires that Federal agencies will, in consultation with NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species, or result in the

destruction or adverse modification of designated critical habitat. Section 7 of the ESA does not apply to activities undertaken on private land unless they are authorized, funded, or carried out by a Federal agency.

For the purposes of section 7 of the ESA, section 10(j) requires that we treat NEPs as a species proposed to be listed, unless they are located within a National Wildlife Refuge or National Park, in which case they are treated as threatened, and section 7 consultation requirements apply. When NEPs are located outside a National Wildlife Refuge or National Park, only two provisions of section 7 apply—section 7(a)(1) and section 7(a)(4). In these instances, NEP designations provide additional flexibility in developing conservation and management measures, because they allow NMFS to work with the action agency early to develop conservation measures, instead of analyzing an already well-developed proposed action provided by the agency in the framework of a section 7(a)(2) consultation. Additionally, for populations of listed species that are designated as nonessential, section 7(a)(4) of the ESA only requires that Federal agencies confer (rather than consult) with NMFS on actions that are likely to jeopardize the continued existence of a species proposed to be listed. These conferences are advisory in nature, and their findings do not restrict agencies from carrying out, funding, or authorizing activities.

Experimental population designations must be done through a rulemaking that identifies the population and states whether the population is essential or nonessential to the continued existence of the species. Through section 4(d) of the ESA, a threatened designation allows the NMFS greater discretion in devising management programs and special regulations for such a population, including take prohibitions. Section 4(d) of the ESA allows us to adopt regulations necessary to provide for the conservation of a threatened species. MCR steelhead are currently included in NMFS' 4(d) rule that imposes section 9 take liability for threatened anadromous fish, at 50 CFR 203. Through this rulemaking, we are using our authority under section 4(d) to create a different set of protective regulations, specific to the experimental steelhead population above Round Butte Dam. In effect, we would be modifying the current 4(d) rule as it applies to MCR steelhead. For this NEP only, we would allow take if the take is incidental to an otherwise lawful activity, such as agricultural activities, and is unintentional and not due to negligent conduct.

The FWS has regulations for experimental population designation, 50 CFR 17 subpart H, that provide definitions, considerations in finding that the designation would further the conservation of the species, and information to be included in the designation. These regulations state that, in making the determination that the designation would further the conservation of the species, the Secretary must consider the effect of taking the eggs or young from another population, the likelihood that the experimental population will become established, the effect the designation would have on the species' overall recovery, and the extent to which the experimental population would be affected by activities in the area. Under the FWS regulations, a regulation designating the experimental population must include: a clear means to identify the experimental population; a finding based on the best available science indicating whether the population is essential to the continued existence of the species; management restrictions, protective measures, or other management concerns; and a periodic review of the success of the release and its effect on the conservation and recovery of the species. The FWS regulations also state that any experimental population shall be treated as threatened for purposes of establishing protective regulations under ESA section 4(d), and the protective regulations for the experimental population will contain applicable prohibitions and exceptions for that population.

While we do not have regulations regarding designation of experimental populations, many of the considerations in FWS's regulation are generally applicable to this designation and consistent with the statutory criteria. Where applicable, we have applied the considerations in our decision regarding designation, and provide the rationale in the preamble.

Biological Information

''Steelhead'' is the name commonly applied to the anadromous (migratory) form of the biological species *O. mykiss.* The common names of the non-anadromous, or resident, form are rainbow trout and redband trout. The species *O. mykiss* exhibits perhaps the most complex suite of life history traits of any species of Pacific salmonid. These fish can be anadromous or freshwater residents, and under some circumstances yield offspring of the opposite form. Steelhead can spawn more than once, whereas all other *Oncorhynchus* except cutthroat trout (*O. clarki*) spawn once and then die.

When we originally listed the MCR steelhead as threatened on March 25, 1999 (64 FR 14517), it was classified as an evolutionarily significant unit (ESU) of salmonids that included both the anadromous and resident forms, but not hatchery fish. Since then, we revised our species determinations for West Coast steelhead under the ESA, delineating anadromous, steelhead-only distinct population segments (DPS). We listed the MCR steelhead DPS as threatened on January 5, 2006 (71 FR 834). Rainbow trout and redband trout are not listed under the ESA, and are under the jurisdiction of the states unless they are listed, at which time they would come under the jurisdiction of the FWS. We published a final Critical Habitat designation for MCR steelhead on September 2, 2005, with an effective date of January 2, 2006 (70 FR 52630).

As noted previously, the MCR steelhead DPS extends over an area of about 35,000 square miles (90,650 square km) in the Columbia plateau of eastern Washington and eastern Oregon. The DPS includes all naturally spawned populations of steelhead in drainages upstream of the Wind River, Washington, and the Hood River, Oregon (exclusive), up to, and including, the Yakima River, Washington, excluding steelhead from the Snake River Basin (64 FR 14517, March 24, 1999; 71 FR 834, January 5, 2006). Major drainages that support steelhead in this DPS are the Deschutes, John Day, Umatilla, Walla Walla, Yakima, and Klickitat river systems. Most of the region is privately owned (64 percent), with the remaining area under Federal (23 percent), tribal (10 percent), and state (3 percent) ownership. Most of the landscape consists of rangeland and timberland, with significant concentrations of dryland agriculture in parts of the range. Irrigated agriculture and urban development are generally concentrated in valley bottoms. Human populations in these regions are growing. Steelhead produced in seven artificial propagation programs are considered part of the DPS, and are therefore also listed as threatened (71 FR 834, January 5, 2006). These programs are the Touchet River Endemic Summer Steelhead Program, the Yakima River Kelt Reconditioning Program (in Satus Creek, Toppenish Creek, Naches River, and Upper Yakima River), and the Umatilla River and Deschutes River steelhead hatchery programs.

Within the range of West Coast steelhead, spawning migrations occur throughout the year, with seasonal peaks of activity. The runs are usually named for the season in which the peak occurs. Most steelhead can be categorized as one of two run types, based on their sexual maturity when they re-enter freshwater and how far they go to spawn. In the Pacific Northwest, summer steelhead enter freshwater between May and October, and require several months to mature before spawning; winter steelhead enter freshwater between November and April with well-developed gonads and spawn shortly thereafter. Summer steelhead usually spawn farther upstream than winter steelhead (Withler, 1966; Roelofs, 1983; Behnke, 1992).

The steelhead that occur in the Deschutes Basin are summer run. Spawning occurs from late winter through spring, and juveniles typically rear in freshwater for 2 years (may range 1–4 years) before migrating to the Pacific Ocean. About half of the adults return after 1 year in the ocean and the other half returns after 2 years.

Throughout much of its historical range, the decline of steelhead has been attributed to habitat degradation and fragmentation, the blockage of migratory corridors, poor water quality, angler harvest, entrainment (the incidental withdrawal of fish and other aquatic organisms in water diverted out-of-stream for various purposes) into diversion channels and dams, and introduced nonnative species. Specific land and water management activities that may negatively impact steelhead populations and habitat, if not implemented in accordance with best management practices, include the operation of dams and other diversion structures, forest management practices, livestock grazing, agriculture, agricultural diversions, road construction and maintenance, mining, and urban and rural development.

Factors Affecting Listing Middle Columbia River Steelhead as Threatened

Section 4(a)(1) of the ESA and NMFS implementing regulations (50 CFR part 424) establish procedures for listing species as threatened or endangered. According to this direction, the Secretary must determine if a species is endangered or threatened based on any one or a combination of the following factors: (1) The present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms; or (5) other natural or human-made factors affecting its continued existence (Busby *et al.,* 1996; NMFS, 1999).

In our initial determination to list the MCR steelhead species, we found that all five section 4(a)(1) factors had played a role in the decline of the West Coast salmon and steelhead ESUs. These factors may or may not still be limiting recovery in the future when we reevaluate the status of the species to determine whether the protections of the ESA are no longer warranted and the species may be delisted. Findings leading to the listing of West Coast salmon and steelhead, including MCR steelhead, include:

(1) *The present or threatened destruction, modification, or curtailment of its habitat or range:* Salmon and steelhead have experienced declines in abundance over the past several decades as a result of loss, damage, or change to their natural environment. Water diversions, forestry, agriculture, mining, and urbanization have eliminated, degraded, simplified, and fragmented habitat. Hydroelectric development on the mainstem Columbia River modified natural flow regimes and impaired fish passage. Tributary obstructions also restrict or block salmon and steelhead access to historical habitats.

(2) *Overutilization of the steelhead and salmon for commercial, recreational, scientific, or educational purposes:* Overfishing in the early days of European settlement led to the depletion of many salmonid stocks before extensive modifications and degradation of natural habitats, and exploitation rates following the degradation of many aquatic and riparian ecosystems were higher than many populations could sustain. Today, steelhead harvest continues on the Columbia River, tributaries, and Pacific Ocean; however, fishery impacts have declined significantly because of changes in fishery management.

(3) *Disease or predation:* Introductions of non-native species and habitat modifications have resulted in increased predator populations in numerous rivers. Predators on adult and juvenile steelhead include walleye, California sea lions, and seabirds including Caspian terns.

(4) *Inadequacy of existing regulatory mechanisms:* Various Federal, state, county, and tribal regulatory mechanisms are in place to reduce habitat loss and degradation caused by human use and development. Many of these mechanisms have been improved over the years to slow habitat degradation and destruction. Protective efforts directed toward addressing the many factors that adversely impact MCR steelhead and habitat—water quality and quantity, safe migration, riparian vegetation, food, predation dynamics and complex stream channels, and floodplain connectivity—will aid in improving these factors.

(5) *Other natural or human-made factors affecting its continued existence:* Variability in ocean and freshwater conditions can have profound impacts on the productivity of salmonid populations and, at different times, have exacerbated or mitigated the problems associated with degraded and altered riverine and estuarine habitats.

Relationship of the Proposed Experimental Population to Recovery Efforts

The 2009 Middle Columbia River Steelhead Recovery Plan (NMFS 2009) has the overarching aim of removing the MCR steelhead DPS from the threatened and endangered species list. The suite of strategies and actions proposed in the Plan will protect and improve ecosystem functions and restore normative ecological processes to levels that support recovery of MCR steelhead populations. The strategies and actions were developed by planning teams comprised of natural resource specialists for the Fifteenmile, Deschutes, John Day, Umatilla, and Walla Walla watersheds. The actions reflect direction identified in regional and local plans, recent modeling and research findings, and local expert input provided by the planning team members. Together, these strategies and actions call for maintaining high quality habitats and their productive capacity, improving ecosystem processes and habitats that are impaired but are currently important to productive capacity, and restoring habitat through passive and active measures.

Recovery criteria specific to the Deschutes include eight kinds of tributary habitat conservation measures that could mitigate adverse impacts. We organized the habitat actions and associated information for each population by the conservation measures, or habitat strategies:

(1) Protect and conserve natural ecological functions that support the viability of populations and their primary life history strategies throughout their life cycle;

(2) Restore passage and connectivity to habitats blocked or impaired by artificial barriers and maintain properly functioning passage and connectivity;

(3) Maintain and restore floodplain connectivity and function;

(4) Restore degraded and maintain properly functioning channel structure and complexity;

(5) Restore riparian condition and large woody debris recruitment and maintain properly functioning conditions;

(6) Restore natural hydrograph to provide sufficient flow during critical periods;

(7) Improve degraded water quality and maintain unimpaired water quality; and

(8) Restore degraded and maintain properly functioning upland processes to minimize unnatural rates of erosion and runoff.

The recovery scenario described in the MCR steelhead recovery plan states that the Deschutes Eastside and Westside populations should reach a viable status. The Westside population existed historically in Whychus Creek and the upper Deschutes River below Big Falls. The Eastside population, as determined by the Interior Columbia Technical Recovery Team, did not extend above Pelton Round Butte historically. The Plan recognizes that successful reintroduction of MCR steelhead and their natural production above the Pelton Round Butte Project could contribute substantially to recovery in two ways, by: (1) Restoring production from the Whychus Creek drainage, part of the historical Westside Deschutes population that currently is limited to major tributaries below the Pelton Round Butte Project; and (2) reestablishing production in the Crooked River drainage, identified by the Interior Columbia Technical Recovery Team as a separate extirpated historical population. If successful, these reintroductions and restoration of natural production could contribute substantially to population status and therefore to the viability of the MCR steelhead DPS.

The MCR steelhead recovery plan also includes an ambitious restoration and protection program for currently accessible habitats in tributaries below the Pelton Round Butte Project. As a result, it is possible that the Westside Deschutes population could reach minimum viability levels without access to habitat above the Pelton Round Butte Project if there is an increase in actions aimed at further improving natural production from accessible habitats below the project. Furthermore, the Mid-Columbia Steelhead Recovery Plan recognizes that a future delisting decision for the DPS should consider not only the specific biological criteria incorporated into the current plan, but also the general principles underlying those criteria, advances in risk assessment, management actions in place to address threats, and considerations for the status of all of the components in the DPS. Therefore, while the reintroduction program furthers recovery, it is one of many measures to assist achieving this goal.

Does the Designation Further the Conservation of the Species?

Under ESA section 10(j), the Secretary may designate listed species as experimental if doing so furthers the conservation of the species. The underlying premise of section 10(j) is to allow local communities to support, and work with NMFS and FWS, on reintroducing listed species into historical habitat. The designation is consistent with the statutory purpose because it provides regulatory flexibility that will allow local communities to focus on work to support the reintroduction in a productive way. Reintroducing MCR steelhead above the Pelton Round Butte Project supports recovery of the DPS. This rule supports the reintroduction effort by allaying landowners' fear of potential ESA take liability, and allows them to work to support the reintroduction by encouraging them to develop conservation measures in a set time period. Therefore, the designation of MCR steelhead that are a part of the ongoing reintroduction program as an experimental population furthers their conservation by encouraging completion of conservation measures well tailored to support the program.

This designation is expected to promote well tailored conservation measures to support reintroduction because during the time period that the 10(j) rule will be in effect, increasing amounts of relevant data will be collected to inform conservation measures. Without the rule, HCPs hurriedly created to avoid take liability would not benefit from this information. On the other hand, without any time limit, there would not be an incentive to complete HCPs. Thus a balance has to be struck. Twelve years, or three generations, of data is designed to account for some variable environmental conditions the NEP will experience, and give a solid basis for knowing what kinds of conservation measures will provide strong support for the reintroduction effort. For example, once we know the main spawning areas after collecting this information from three generations of spawning adults, we can craft conservation measures to protect those areas. Conservation measures typically include adaptive management components, and those measures that are completed before the expiration date likely would include an adaptive management component that would allow us to modify these measures based on this information. In addition, the expiration date adds another conservation aspect to the designation by encouraging development and completion of the conservation measures before expiration of the NEP designation.

We weighed these benefits against any potential harm caused by this rule. With respect to the HCP, the designation may create a disincentive for completing the HCP on its current trajectory, which is less than 12 years; however, the HCP does not cover all activities and geographies and so the rule allows non-HCP entities the opportunity and timeframe to also develop and implement conservation measures. Additionally, there is potential harm associated with the reduced ESA section 7 and section 9 protections during the time period of the designation. Yet, while the ESA regime applicable to above-dam entities will temporarily change, past experience suggests that they are likely to continue to take actions that promote steelhead conservation. Even before the steelhead for the reintroduction program were listed under the ESA (i.e., before there was ESA liability), local landowners began implementing certain conservation measures to support the reintroduction, and there is no reason to expect this to change when the landowners are again not subject to ESA liability. Furthermore, the fixed timeframe for the rule provides an incentive for landowners to continue their trend toward fish conservation measures, and thus also provides a counterbalance to any incentive in the opposite direction. It is also worth noting that the MCR steelhead that have been reintroduced to date appear to be doing reasonably well in their historic habitat despite ongoing activities in the area.

Finally, the premise of 10(j) is to provide flexibility in ESA protections to facilitate the greater benefit of promoting reintroduction. Thus, even if there is some potential harm to the nonessential reintroduced fish as a result of the reduced ESA protections, it does not inherently undermine the conservation benefit to the species. In this case, we have weighed the benefits of developing sound conservation measures in a time certain fashion versus the potential for some harm and determined that, on balance, the designation of the population as experimental, together with reductions in certain ESA protections, would

further the conservation of the species. This conclusion is informed by the same considerations that we evaluated in determining that the NEP population is ''nonessential'', as set out below.

Is the Experimental Population Essential or Nonessential?

Under ESA section 10(j)(2)(B), the Secretary must ''identify the [proposed] population and determine, on the basis of the best available information, whether or not such population is essential to the continued existence of an endangered species or a threatened species.'' 15 U.S.C. 1539(j)(2)(B). First, we considered the importance of the experimental population to recovery of MCR steelhead generally. While the reintroduction effort is a significant recovery effort, it is not the only one and not the key to whether recovery can be achieved for this steelhead DPS. Successful implementation of restoration efforts across all major population groups in the DPS could reduce risks and improve viability even absent reintroduction above the Pelton Round Butte Project.

Another factor we considered is that the juvenile steelhead used for this reintroduction effort at the outplant stage are surplus hatchery stock. The hatchery program exists to mitigate lost MCR steelhead upstream habitat, but the steelhead used in the reintroduction program are excess hatchery fish and are beyond what is needed for the mitigation. In addition, returning adults will primarily, if not solely, be the marked adults associated with those hatchery outplants. Even in the unlikely event that adult wild fish would be placed upstream, it would only occur consistent with species conservation objectives as set out in the Fish Passage Plan, and means that the NEP is doing very well. Thus, the potential loss of some of the NEP fish will not appreciably reduce the likelihood of survival and recovery for this DPS. Therefore, this experimental population will be designated as nonessential because this population is not essential to the continued existence of the DPS.

Location of Proposed NEP

ESA section 10(j) requires that the experimental population be designated only when, and at such times, as it is geographically separate from nonexperimental populations of the same species. The NEP geographic area includes all waters that could support steelhead above Round Butte Dam. It includes portions of the Deschutes River basin above Round Butte Dam, which is the most upstream development of the three-dam Pelton Round Butte Project. Specifically, the NEP area includes all accessible reaches of the Deschutes River downstream to Round Butte Dam; the Whychus Creek subbasin; the Metolius River subbasin; and the Crooked River subbasin from Bowman Dam downstream (including the Ochoco and McKay Creek watersheds) to its point of confluence with the Deschutes River.

This NEP area is distinct from the areas where MCR steelhead are otherwise found. The nearest steelhead population to the NEP area is found in the Deschutes River below the Pelton Round Butte Project. Other steelhead populations near the NEP area include fish in the following tributaries of the lower Columbia River: the Lewis River, entering the lower Columbia at RM 84, (rkm 135), the Willamette River at RM 101 (rkm 163), and the Hood River at RM 165 (rkm 366).

The Round Butte Dam serves as the line of demarcation between the experimental population and the rest of the steelhead population. This geographic boundary is clearly defined by the presence of Round Butte Dam, with all steelhead above the dam being part of the experimental population and all steelhead below the dam not part of the experimental population. This approach to providing a clear geographic separation recognizes that anadromous fish migrate and mingle during the migration. Because anadromous populations of steelhead migrate to the Pacific Ocean and return to their natal streams to spawn, fish that originally were part of the experimental population will commingle with other fish in the lower Deschutes and Columbia Rivers, and may stray into any of the lower Columbia River tributaries or into Deschutes River tributaries below the Pelton Round Butte Project and spawn. Nevertheless, the steelhead will be experimental when, and at such times as, they are above Round Butte Dam, and not experimental when they are downstream of the dam, even if they were originally part of the reintroduced stock.

The Round Butte Dam provides a clear geographic boundary in large part because of the passage barrier it represents, both upstream and downstream. All juvenile steelhead smolts leaving the NEP boundary are collected for passage in a fish collection facility at Round Butte Dam. Likewise, when steelhead return to spawn, they must be trapped and manually relocated into the NEP area. As indicated above, marked adult steelhead from the experimental population are likely to be the predominant if not the only category of fish released above Round Butte Dam within the time period of this rule, though any fish released above the dam will have NEP status while in that area.

The NEP area is outside the current range of MCR steelhead because there is currently no self-sustaining population in the NEP geographic area; and if the releases stopped at this point, MCR steelhead would disappear from the NEP area. In summary, the section 10(j) requirement that the experimental population be wholly separate geographically from the nonexperimental populations of the same species is met here because the NEP area is outside the range of the currently existing DPS, and is clearly defined by Round Butte Dam, which is impassable to steelhead. The NEP area includes all streams above Round Butte Dam capable of supporting steelhead. All steelhead above the dam are in the experimental population, and all steelhead below the dam are not part of the experimental population.

Time Frame for NEP Designation

We are establishing an expiration date for the NEP designation because we want to provide an incentive for private landowners and local government entities to complete conservation measures in a certain time frame, while providing time to gather useful information on the reintroduction effort. Information gathered during the 12-year timeframe will be progressively incorporated into the development of the conservation measures so they will best support the reintroduction program. This set time frame for the NEP designation furthers the conservation of the species because it is expected to provide strong encouragement to complete conservation measures that support the reintroduction by a date certain. The NEP designation period will expire 12 years from the effective date of this final rule.

We are using a timeframe of 12 years because this approximately represents three generations of returns to the NEP area. On average, one generation of steelhead is about 4 years (2 years freshwater rearing, 1 year in the ocean, and roughly 9–11 months for adult migration, holding, and spawning), so three generations will be 12 years. We recognize that variations in freshwater rearing and ocean growth will occur.

The proposed timeframe reflects our view that it will be useful to have information on three generations of steelhead to understand how well the reintroduction program is working and how best to craft conservation measures to support the program. As we discussed in the Does the Designation

Further the Conservation of the Species section, the timeframe of three generations allows an adequate amount of data to be collected on the reintroduction program. It is enough time to account for the kind of environmental variability mentioned above, such as variations in stream and ocean conditions. The time frame also allows time for this information to be used as the basis of conservation measures tailored toward supporting this reintroduction. This amount of information will allow all parties, private and governmental, to work together to develop conservation measures that are specifically focused on addressing needs of steelhead in the Upper Deschutes River basin. For conservation measures completed before expiration of the designation, such as potentially the HCP currently being developed, an adaptive management component could be used to address the need to modify the measures based on this information. This component will maximize the benefit of the conservation measures and strengthen the reintroduction program, and will result in a strong program for this recovery measure.

Without an expiration date, development and completion of conservation measures may continue for a longer time. In general, 12 years is a reasonable amount of time to complete development of conservation measures because there is still a lot of information needed, and the issues are complex and involve many parties. That said, the HCP could be completed before the NEP designation expires. We would like to strongly encourage development and implementation of conservation measures that will support the reintroduction, and this expiration date is meant to provide that encouragement while also ensuring that the measures are based on good information.

Management Considerations and Protective Measures

The aquatic resources in the NEP area are managed by the USFS, BLM, Bureau of Reclamation (BOR), the State of Oregon, municipalities, and private landowners. Multiple-use management of these waters would continue under the NEP designation. We do not expect that continuing these agricultural, recreational, municipal, and other activities by private landowners within and near the NEP area will cause significant harm to the NEP. The main factors we took into account in considering appropriate protective measures are: (1) A significant number of upstream irrigators are developing or already implementing certain conservation measures; (2) Federal agencies have already consulted under section 7 of the ESA on various actions in the area and are implementing actions that do not cause jeopardy and minimize incidental take; (3) fish used for the reintroduction will be excess hatchery fish, and loss of some of them will not harm survival and recovery of the steelhead; and (4) enough steelhead are already surviving to provide information necessary for the initial stages of the reintroduction program. These factors all lead to the conclusion that, for a 12-year period, the reintroduction effort can continue successfully while allowing some take of the steelhead in the experimental population because enough fish will survive to support successful reintroduction. Therefore, for the time period of the designation, incidental take, as provided in the next paragraph, will not harm the recovery program.

Incidental Take: Although MCR steelhead are already covered by a NMFS 4(d) rule at 50 CFR 203, this action would modify that protection. In this final rule, under the authority of ESA section 4(d), incidental take of steelhead within the experimental population area would be allowed, provided that the take is incidental to an otherwise lawful activity, such as agricultural activities, unintentional, and not due to negligent conduct. One example is recreational fishing that is consistent with State fishing regulations that have been coordinated with NMFS. As recreational fishing for species other than steelhead is popular within the NEP area, we expect some incidental take of steelhead from this activity, but as long as it is incidental to the recreational fishery, and in compliance with ODFW fishing regulations and Tribal regulations on land managed by the CTWS, such take will not be a violation of the ESA.

Special Handling: NMFS, ODFW, and CTWS employees and authorized agents acting on their behalf may handle MCR steelhead for: Scientific purposes, to relocate steelhead within the NEP area, to aid sick or injured steelhead, and to salvage dead steelhead. PGE and CTWS employees and authorized agents acting on their behalf for the purpose of monitoring and evaluating the ongoing reintroduction under the FERC license for the Pelton Round Butte Project may handle MCR steelhead in the NEP area. Deschutes Valley Water District employees and agents acting on their behalf for the purpose of monitoring and evaluating the Opal Springs Hydroelectric Project (FERC No. 5891) may handle steelhead. However, non-authorized personnel will need to acquire permits from NMFS and ODFW for these activities.

Monitoring and Evaluation

As a requirement under its Federal license to operate the Pelton Round Butte Project, the Licensees will monitor over the 50-year term of the license. Some of this monitoring relates directly to the MCR steelhead reintroduction program. The licensees will collect data to gauge long-term progress of the reintroduction program and to provide information for decision-making and adaptive management for directing the reintroduction program. Fish passage, fish biology, aquatic habitat, and hatchery operations will be the primary focus of the monitoring (PGE and CTWSRO, 2004; ODFW and CTWSRO, 2008).

Fish passage monitoring will focus on addressing a variety of issues important to successful reintroduction. These issues consist of measuring fish passage efficiency, including smolt reservoir passage, collection efficiency at the fish collection facility, smolt injury and mortality rates, adult collection, and adult reservoir passage to spawning areas. Passive integrated transponder tags and radio tags will be used to evaluate and monitor fish passage effectiveness. Biological evaluation and monitoring will concentrate on adult escapement and spawning success, competition with resident species, predation, disease transfer, smolt production, harvest, and sustainability of natural runs. Habitat monitoring will focus on long-term trends in the productive capacity of the reintroduction area (e.g., habitat availability, habitat effectiveness, riparian condition) and natural production (the number, size, productivity, and life history diversity) of steelhead in the NEP area above Round Butte Dam.

Monitoring at the fish hatchery will focus on multiple issues important to the quality of fish collected and produced for use in the reintroduction program. ODFW and CTWS' Natural Resource Services are primarily responsible for monitoring hatchery operations. This will consist mainly of broodstock selection; disease history and treatment; pre-release performance such as survival, growth, and fish health by life stage; the numerical production advantage provided by the hatchery program relative to natural production; and success of the hatchery program in meeting conservation program objectives.

While this monitoring is being conducted for purposes of making the reintroduction effort successful, we will

use the information to also determine if the experimental population designation is causing any harm to MCR steelhead and their habitat, and then, based on this and other available information, determine if the designation needs to be removed before the expiration date. There is no need for additional monitoring because this effort will provide all the information necessary.

Unrelated to the monitoring and evaluation for the ongoing reintroduction, NMFS conducts status reviews of listed anadromous fish populations roughly every 5 years to determine whether any species should be removed from the list or have its listing status changed. We anticipate the next status review of the MCR steelhead DPS to occur in or about 2015. We further anticipate that the status of the ongoing reintroduction program would be a consideration of NMFS' analysis of the Cascades Eastern Slope Tributaries major population group and DPS as a whole. While we cannot reasonably determine at this time what effect the new status review would have on this experimental population designation, we do not anticipate any changes to the designation.

Summary of Comments and Responses

We requested written comments from the public on the proposed rule and draft EA published on May 18, 2011 (76 FR 28715), on all issues of concern to the public. We also requested comments on five specific questions regarding (1) the use of a specific expiration date; (2) the efficacy of a 12-year designation; (3) the effects of current and future actions on the NEP within the NEP area; (4) current programs within the NEP area that protect fish or aquatic habitats; and (5) additional management measures that we have not considered. We also contacted other Federal agencies and tribes and invited them to comment on the proposed rule. The comment period was open from May 18, 2011, until July 18, 2011.

A number of parties combined their respective comments into one submittal; thus, we received eight separate filings of comments from a total of 18 parties. For clarity, we treat each filing as one commenter in our summary and response to comments below. Commenters included natural resource agencies, non-governmental organizations, and private entities. All of the parties supported the reintroduction program, but had varying comments on the proposed rule. Two commenters responded directly to the five questions we asked in the proposed rule, while others provided comments on different issues. The comments generally addressed issues regarding whether an expiration date is appropriate; the choice of a 12-year time frame is the correct amount of time; if hatchery or wild fish should be used; and whether a 4(d) rule would be more appropriate. Some commenters questioned the need for the expiration date, suggesting that 12 years was not necessary to achieve the purpose and need for the NEP designation; one party also questioned whether the designation was too broad to address a narrow set of concerns. Others suggested eliminating the expiration date and to keep the rule in place until the MCR steelhead DPS is delisted. Some parties suggested the promulgation of a new 4(d) rule, or limit (we use the term ''limit'' in connection with 4(d) rules because our 4(d) rules limit the take liability for threatened species, if the entity covered by the limit meets the proper criteria included in the specific limit), would be more appropriate.

We reviewed all comments received, and provide our response to all the substantive issues regarding the proposed rule and draft EA. Our responses to the substantive comments on the proposed rule are provided below, and where appropriate, we made changes in this final rule in response to the comments. Substantive comments we received on the EA were addressed in Appendix A1 of the Final EA, and where appropriate, we made changes to the EA in response to comments.

Public Comments

The first five sets of comments are in response to the five questions we asked in our proposed rule. The rest of the comments are additional ones raised by the commenters.

(1) Use of a Specific Expiration Date

Comment 1: Two commenters disagreed with the concept of having an expiration date on the designation. While both commenters recommended against use of an expiration date, both did provide suggestions to help alleviate their concerns without eliminating the expiration date concept completely. One commenter suggested that the designation either be left in place until the MCR steelhead DPS is delisted, or be tied biologically to development of a self-sustaining run of MCR steelhead above the Project. This commenter also suggested that if we decide to keep the expiration date, then we should promulgate a 4(d) rule to become effective when the designation expires, to address potential ESA liability. The other commenter suggested setting a time to reevaluate the status of the reintroduced population and determine at that time whether the designation should be terminated. A third commenter stated that, if we go forward with the rule, a limited time frame for the NEP was absolutely necessary. This commenter went on to say that the time frame should be shortened. We respond to the use of a time frame in this response, and provide our rationale for our choice of the number of years, in our response to the second question.

Response: Section 10(j) of the ESA specifically states that the experimental population designation must further the conservation of the species. In this case, use of an expiration date promotes this objective by setting an end date after which ESA take prohibitions will again be in effect. Local landowners and municipalities have a very clear time frame, which they are encouraged to put to good use to develop focused conservation measures that support the reintroduction effort. Without such a time limit, there would be little incentive to develop and implement conservation measures because there would be no potential take liability. The rationale for our choice of 12 years for the expiration date is provided in detail in our response to the second comment.

While we recognize that FWS has not included an expiration date in its designations, in this case, it is appropriate to further the conservation of the species. This expiration date furthers the stated intent of Congress in the ESA, 16 U.S.C. 1531(a)(5), to encourage interested parties to develop and maintain conservation programs. This expiration date also furthers the specific intent of Congress when amending the ESA to add section 10(j) to provide broad discretion and flexibility to the Secretaries of Commerce and Interior in managing populations so as to reduce opposition to release of listed species outside their current range. The expiration date associated with this NEP designation of the reintroduced MCR steelhead satisfies the intent of Congress by providing local entities temporary relief of certain potential ESA section 9 take liabilities to allow time to build support for the reintroduction program among local landowners and municipalities, and to provide an incentive to complete and implement conservation plans and other conservation measures in a time certain. The designation will allow local entities adequate time and flexibility to assess and mitigate impacts, if any, to the reintroduced population of MCR steelhead, and do these without the concern of certain ESA section 9 take liabilities. It will also allow time for the reintroduction monitoring and

evaluation programs to develop information on the status of the reintroduction while under the NEP designation. The expiration is designed to encourage entities to complete, in a time certain, necessary conservation measures to support the reintroduced population.

After considering the suggested alternatives to removing the expiration date, we did not accept any of them because they are not appropriate means to achieve the goal of acting as an incentive to local landowners and municipalities to complete and implement conservation measures in a time certain:

(1) Keeping the designation in place until the species improves to the point of delisting removes incentives to complete conservation measures within a time certain. Delisting depends on many more factors than supporting the reintroduction in the upper Deschutes River, and would not provide any certainty for an expiration date.

(2) Tying the expiration date of the designation to completion of a self-sustaining run of MCR steelhead also removes incentives to complete conservation measures in a time certain. This idea would work against successful development of a self-sustaining run because the conservation measures are needed to support the reintroduction program. Without the conservation measures, it would likely take much longer to achieve the goal of a self-sustaining run.

(3) Completion of an ESA 4(d) rule, or limit, at the end of the expiration date would considerably weaken the incentive to complete the conservation measures by the expiration date of the designation because it would perpetuate most of the limits on ESA take liability for local entities.

(4) Including an option to reevaluate the NEP designation before it expires does not provide the private or public sector certainty for planning and operating their facilities and lands, and also removes the incentive to complete the conservation measures in a time certain. A reevaluation option also could be a disincentive to complete the conservation measures in 12 years because of the possibility of an extension of time.

We agree with the commenter who stated that the time limit is necessary here because it provides an incentive to complete conservation measures that support the reintroduction program in a time certain. As stated above in this response, a time limit in this case serves an important conservation function because it lifts certain ESA take liabilities for the local community for a set period of time, during which the community is strongly encouraged to develop and implement conservation measures that support reintroduction.

(2) 12-Year Time Frame

Comment 2: We received one comment that the 12-year time frame is too short, and another that 12 years is too long. One commenter stated that the 12-year period is the minimum time needed to identify whether the establishment of a self-sustaining population is possible, and also that 12 years is insufficient to include variability in ocean conditions, and to assess the effectiveness of the reintroduction program and conservation measures. The commenter stated that we should wait until supplementation has stopped and upstream passage is completed at Opal Springs Dam. This commenter also requested that NMFS promulgate a 4(d) rule to be effective when the NEP designation expires. The other commenter strongly urged NMFS to limit the designation to no more than 7 years because this shorter time frame would be more of an incentive to complete conservation measures sooner. This commenter also stated that they did not understand the connection between the 12-year time frame and data needed for development of conservation measures.

Response: We agree with the first commenter that 12 years of monitoring and evaluation is too short to take into account decadal and interdecadal variations in the ocean environment. However, we disagree that this information on decadal ocean conditions is necessary for conservation measures supporting the reintroduction program in the Upper Deschutes River basin. The conservation measures will assist the reintroduction effort by supporting the part of the MCR steelhead's life that is spent in rivers, not the ocean. While ocean conditions play a role in the numbers of MCR steelhead that return to the NEP area, this designation and the conservation measures to support the reintroduction are focused on the part of MCR steelhead life that is spent in fresh water. However, we anticipate that information resulting from these conservation measures will be instructive regarding the effectiveness of the NEP designation in terms of conserving MCR steelhead in the NEP area.

We disagree with the commenter that we need to wait to gather information on the reintroduction program after supplementation has stopped and passage is completed at Opal Springs Dam. We need the completion of conservation measures to help achieve a self-sustaining run of MCR steelhead in the NEP area, and waiting to develop conservation measures until the population is self-sustaining would reduce the likelihood of ever reaching that goal. The data gathered in the next 12 years will be sufficient to inform supportive conservation measures in the Upper Deschutes River basin that are needed to increase the likelihood of success for the reintroduction because the data will focus the conservation measures on areas that are needed most by the MCR steelhead. Information gathered after that time, and also toward the end of the 12 years, will be used to modify the conservation measures through adaptive management, as well as to form the basis of additional conservation measures. Additionally, because this commenter misunderstood the draft EA's purpose and need statement, we clarified the language in the EA.

The monitoring and evaluation programs for the reintroduction are being conducted by the joint licensees for the Pelton Project. These programs include, to name a few, habitat use and productivity, fish passage efficiency and survival, smolt to adult return ratios, adult migration and spawning effectiveness, spawning locations, and water quality changes in Lake Billy Chinook and the lower Deschutes Rivers. This monitoring effort will be most concentrated during the NEP period but may continue at a reduced effort for many years after the NEP expires. The reintroduction program will continue for the life of the Pelton Round Butte Project's license.

As stated in our first response to comments, we disagree with the concept of implementing an ESA 4(d) rule at the end of the designation because it would be a disincentive to complete conservation measures in a time certain.

We partly disagree with the one commenter who stated that a shorter time frame or 7 years for the designation would be a better incentive for timely completion of conservation measures, and would also be sufficient time to complete the local irrigation district's and City of Prineville's HCP, as well as other conservation measures.

We agree that a NEP period of 7 years would be an incentive to complete the HCP in a shorter period of time. However, there are other considerations that support our choice of 12 years instead of 7 years. For local entities who are not participating in the HCP development effort, and who believe their operations may have impacts on MCR steelhead that are being

reintroduced, a shorter timeframe may not allow adequate time for identifying their effects, determining conservation measures to address those effects, and finding funds, if needed, to complete the necessary measures. Furthermore, a 7-year timeframe would not allow sufficient time for the monitoring and evaluation programs to develop information on the reintroduction to support development of conservation measures tailored to support the reintroduction. After considering the reasons provided by both commenters for choosing at least 12 years or shortening the expiration date to 7 years, we consider the 12-year expiration date to be appropriate, for the following reasons. Our choice of 12 years is based on the biology of the MCR steelhead, time needed to incorporate data into the conservation measures, and time needed to develop and implement conservation measures that support the reintroduction program. First, the biological basis for the 12 years is that it will allow for monitoring of three generations of MCR steelhead in their historical habitat above the Project. This is enough time to determine where they chose to spawn and rear, and also enough time to account for year-to-year variability in stream and other environmental conditions. These data should be used to develop conservation measures focused on supporting the reintroduction by mitigating specific effects in areas that are important to the MCR steelhead. Conservation measures typically have an adaptive management component, so they could be completed before the 12 years are up and can be modified through adaptive management if needed, based on new information.

(3) The Effect of Current and Future Actions on the NEP in the NEP Area

Comment 3: One commenter noted that we did not provide information about future ESA section 7 consultations (consultation with Federal agencies) and expressed concern with the NEP's effects on those future actions as well as existing section 7 consultations. The commenter also provided a list of actions that would require ESA section 7 consultations. This commenter specifically called out NMFS' existing section 7 consultation with the BOR on the Deschutes Basin Projects, and questioned how the status of this consultation would be affected by the NEP designation. Another commenter noted that it has undertaken an assessment of its activities and their effects on MCR steelhead for the purpose of developing an HCP. This commenter also noted that many conservation measures have already been completed or are being implemented in the NEP area.

Response: We asked Federal agencies that have previously conducted ESA section 7 consultations in the NEP area about ongoing or potential future actions, and we reviewed agency Web sites. These agencies include the Forest Service, BLM, BOR, Army Corps of Engineers and the Federal Highway Administration.

Three ESA section 7 consultations in particular were underway while this final rule was being developed, and they should be completed before this final rule's effective date. These consultations are commonly referred to as ''programmatic consultations'' because they apply to programs implemented by various Federal agencies in Oregon, Washington, and Idaho, including the NEP area. Many individual actions are typically carried out under the auspices of these programs. Programmatic consultations are designed to streamline ESA compliance and accelerate actions carried out under each program. Consultation and implementation of the individual actions is accelerated because actions carried out under these programs must include all appropriate minimization measures required by the Federal agency as part of its program, and must satisfy the terms and conditions in the incidental take statement issued by NMFS for the various programs. Some actions may still need to undergo an individual ESA section 7 consultation. The three relevant ongoing section 7 consultations are:

- *Reinitiation on the Aquatic Restoration Biological Opinion (ARBO):* This is a consultation on a number of individual actions which, when grouped together, represent programs that may occur at many sites across lands managed by the Forest Service and BLM in Washington and Oregon, and the Coquille Indian Tribe in Oregon (the Bureau of Indian Affairs is the consulting agency). All proposed activity categories comply with the Record of Decision and Standards and Guidelines of the Northwest Forest Plan, INFISH and PACFISH (USFS and BLM aquatic and riparian area management strategy to protect habitat for Pacific anadromous salmonids and resident fish species), and respective National Forest Land and Resource Management Plans and BLM Resource Management Plans.
- *Reinitiation on the Bonneville Power Administration's Habitat Improvement Program in Oregon, Washington, and Idaho:* This is a consultation on the effects of the Bonneville Power Administration's Habitat Improvement Program (HIP) in the Columbia River basin. The HIP is designed to mitigate the effects of the Federal Columbia River Power System on fish, wildlife, and their habitat. Consultation on this program is designed to streamline the process for ESA compliance for a number of the most common salmon and steelhead habitat improvement projects (e.g., fish passage at manmade barriers, screening water diversions, placement of large woody debris, riparian fencing, and spawning gravel augmentation).
- *Reinitiation on the Farm Services Agency's Conservation Reserve Enhancement Program:* This consultation addresses the effects of the Department of Agriculture's Farm Services Agency Conservation Reserve Enhancement Program (CREP). In Oregon, CREP is designed to address agriculture-related impacts by establishing conservation practices on agricultural lands using funding from Federal, state, and tribal governments as well as non-government sources. It is a voluntary program with the goal of enhancing riparian habitat on agricultural lands along streams within the boundaries of water quality management area plans and along streams that support listed fish species under the ESA, as well as addressing stream water quality issues (primarily temperature).

We do not expect this final rule to have material implications for these consultations because the proposed actions and associated conservation measures are very broad in geographic scope and species covered and not focused only on MCR steelhead in the upper Deschutes. Thus, we do not expect that the Federal agencies implementing these programs would make specific changes to their actions or implementation thereof with respect to only the NEP population and area. This logic also applies to programmatic ESA section 7 consultations in the NEP area that have already been completed. For example, section 7 consultations on Federal land management plans will often result in terms and conditions on activities affecting water quality and fish habitats to conserve listed species, and other Federal and state water quality laws and fish habitat requirements apply to these plans, too.

Furthermore, to the extent that a completed consultation is determined to no longer apply to the NEP population, or activities in the NEP area are treated differently by an action agency after consultation is completed, the conservation benefit of this final rule is not inherently undermined. As explained above with respect to section 9 take liability, the underlying premise

of ESA section 10(j) is to provide flexibility in ESA protections to facilitate reintroductions and associated benefits to the species. Thus, even if there is some potential harm to the reintroduced fish as a result of the reduced ESA protections, this must be weighed against the benefits of developing sound conservation measures in a time certain fashion. We have undertaken that weighing exercise and determined that, on balance, the designation of the population as experimental, together with reductions in certain ESA protections, would further the conservation of the species. This conclusion is informed by the same considerations that we evaluated in determining that the NEP population is ''nonessential'', as set out above.

Concerning the existing ESA section 7 consultation between NMFS and the BOR on the BOR's Deschutes Basin Projects, the commenter noted language in the biological opinion stating that consultation must be reinitiated if fish passage were established at the Pelton Round Butte Project, and asked what the NEP designation means for reinitiation. There is now a need to evaluate how reinitiation requirements apply to the Deschutes Basin Projects consultation. That is an analysis and determination that will be undertaken in the context of the specific consultation and in coordination with the action agency.

NMFS is aware of certain future Federal actions in the NEP area. The Deschutes National Forest is proposing a flood plain restoration action on Whychus Creek, a tributary to the Deschutes River and part of the NEP area. Additionally, the Federal Highway Administration is planning an action in the Metolius River basin for 2014. However, while this river basin is included in the NEP area, steelhead are not being reintroduced here. Also, the BLM is planning to remove Stearns Dam on the Crooked River. This is the last fish passage barrier remaining on the Crooked River and once removed, volitional migration by both adult and juvenile steelhead will be allowed up to Bowman Dam. Even though this is a beneficial action, construction activity in the water during dam removal could impact fish in the area. Finally, the installation of new fish passage facilities is proposed at Opal Springs Dam on the lower Crooked River; this action would be authorized by the Federal Energy Regulatory Commission.

Under the terms of 10(j), there is no section 7 consultation obligation for non-essential experimental populations. Thus, such actions in the NEP area will not be subject to section 7 consultation obligations during the NEP period if only MCR steelhead would be affected. However, because the NEP is treated as a species proposed for listing, Federal agencies are required to confer with NMFS when the Federal action is likely to jeopardize the proposed species, pursuant to section 7(a)(4) of the ESA. As set out in section 402.10 of the consultation regulations, the conference may be conducted in accordance with formal consultation procedures if requested by the action agency and deemed appropriate by NMFS. During such a conference, NMFS is required to make advisory recommendations on ways to minimize or avoid adverse effects. As outlined above, any resulting impact on the NEP population is factored into the overall analysis as to whether the designation benefits the MCR steelhead species. Upon expiration of the NEP, section 7 consultation obligations will once again apply to Federal actions that may affect NEP.

Lastly, we acknowledge the importance of the other commenter's statements about private conservation programs that have already begun. We recognize the efforts by the irrigation districts and municipalities to evaluate their activities that may affect MCR steelhead, and the significant work that has been accomplished (e.g., piping and lining irrigation canals to conserve water, screening water diversions) and is ongoing (e.g., habitat conservation planning).

(4) Current Programs Within the NEP Area That Protect Fish or Aquatic Habitats

Comment 4: One commenter noted that it has already implemented numerous conservation programs to conserve water and improve fish habitat. This commenter also provided a list of these existing programs implemented by some of the irrigation districts in the NEP area. Another commenter merged its response to questions 3 and 4 and we addressed their concerns in our response to their comments in question 3.

Response: We recognize and support the effort by local irrigation districts to conserve water, both the completed conservation projects and ones still under development. We appreciate these early conservation actions that support the reintroduction program, and plan to continue working with these entities and others to support the reintroduction of salmon and steelhead. Regarding the second commenter's concerns about the effect of the NEP designation on the section 7 consultation requirement, we provided a lengthy response in our response to question 3.

(5) Additional Management Measures That We Have Not Considered

Comment 5: One commenter raised concerns about the potential to pass wild fish during the NEP designation time frame, and cautioned against putting them into the NEP area with fewer ESA protections.

Response: As set out above, the Fish Passage Plan (developed during the FERC relicensing process) is primarily focused on the release of adult marked fish that are the progeny of the excess hatchery fish, and, although it provides for the future possibility of wild adult fish releases, that potential will depend on availability of wild spawners and the successful performance of the fish passage program at the Pelton Round Butte Project. Thus, for the time period of this rule, marked adult fish are likely to be the only category of fish released above Round Butte Dam, and the possibility of any wild adults being returned would only occur consistent with species conservation objectives as set out in the Fish Passage Plan.

(6) Use of ESA 4(d) Instead of 10(j), Rationale for 10(j), and Use of 4(d) When the Designation Expires

Comment 6: Two commenters acknowledged that allaying community concerns by providing relief from ESA section 9 take prohibitions, and supporting the reintroduction program are legitimate goals. They suggest a different way to meet those goals, to use only the authority under ESA section 4(d) to address local landowner and municipality concerns about potential ESA take liability. One of these commenters states that we can achieve the same goals with a 4(d) limit, and still would provide more protections for the MCR steelhead because we could still designate critical habitat and section 7 consultations for Federal agencies would still apply. One other commenter suggested that we prepare a 4(d) rule or limit to be effective when the 10(j) designation expires.

Response: Before issuing the proposed rule, we considered the proper tool to address local concerns about potential ESA liability resulting from the ongoing reintroduction of threatened MCR steelhead above the Project into historical habitat. The two options that we considered were: (1) Use of a new ESA 4(d) rule, or limit; and (2) authorization of the continued release of the MCR steelhead as an experimental population under section 10(j) of the ESA with tailored limits on take. Both options are discretionary, and the ESA provides for both. Each option has slightly different effects, as noted by the

commenter. We have exercised our discretion to use the regulatory tool of 10(j) combined with a modified take prohibition because it seems best suited to the situation at hand. As evidenced in the legislative history, this is exactly the type of situation that Congress had in mind when it provided the regulatory flexibilities of 10(j) to promote local landowner support for reintroductions of listed species. Here, the broad effect of the NEP designation will give more relief, flexibility and time to the local landowners and communities in the NEP area to work with NMFS, ODFW, CTWS, local watershed councils, or other conservation entities in assessing and correcting impacts, if any, they may have on MCR steelhead, by developing conservation measures; and the time limit would reinstate full protection under the ESA for a threatened species within a reasonable amount of time.

Additionally, we have previously elected to craft our 4(d) limits for threatened Pacific salmon so that they apply to activities across large geographic scales, and potentially many entities. As a matter of policy, this approach is considered desirable for Pacific salmon and, by contrast, it is considered undesirable to signal a different approach whereby 4(d) rules are applied to discrete areas and situations such as the reintroduction of fish in the upper Deschutes.

In summary, we have decided to use our authority under section 10(j) to provide regulatory relief to landowners and other entities in the area of the reintroduced MCR steelhead; and we will not use 4(d) at the time the designation expires because it would remove the incentive to complete the conservation measures in a time certain, as explained in our response to comments 1 and 2.

(7) Use of Hatchery or Wild Stock

Comment 7: One commenter urged us to use only hatchery stock for the reintroduction, and another commenter stated that only wild fish should be used to reestablish a self-sustaining population of MCR steelhead above the Pelton Round Butte Project.

Response: The commenters' remarks are more appropriately directed at the reintroduction program and associated Fish Passage Plan, and not the NEP designation because the reintroduction is being conducted under a separate authority and process, and will continue regardless of this designation. The NEP designation is being applied to the ongoing reintroduction, which began in 2007, and will continue according to the fish passage plan that is part of the Federal Energy Regulatory Commission license for the Pelton Round Butte Project. This designation only changes the ESA status of MCR steelhead in the NEP area for a period of 12 years and does not influence which stock is used. We address above the implications of using hatchery stock in the context of the 10(j) statutory criteria, and address the remote possibility of passing wild fish above the dams in our response to comment 5.

(8) Passage Needed at Opal Springs Dam

Comment 8: One commenter suggested that passage at Opal Springs Dam, located in the Crooked River Gorge, was necessary for the reintroduction of MCR steelhead to be successful. Thus, the 12-year NEP period should be extended or done away with altogether, because it was unknown when passage could be achieved at Opal Springs Dam.

Response: A portion of the Crooked River makes up part of the NEP area and we agree that access to the Crooked River is very important for the reintroduction. The details of the reintroduction program are separate from the designation, and the designation is meant to help the reintroduction succeed by encouraging local support for the program and completion of conservation measures in a time certain. The designation, with its 12-year expiration date, is not tied to completion of a successful program. The Opal Springs Hydroelectric Project currently blocks adult steelhead, and other species, from volitionally accessing most of the Crooked River. A settlement agreement on fish passage was completed in August 2011. The owners of this hydropower project are seeking funds to complete construction of an adult fish passage facility, and are currently developing an interim passage program so that returning adult steelhead can be collected and released above the project.

(9) General Support for the Designation

Comment 9: Three commenters stated general support for the rule. Two of them provided an explanation that it will foster local cooperation to recover listed species, and will encourage completion of the HCP and other conservation measures.

Response: We agree that the rule will foster local support for the reintroduction program that will aid in recovery of the MCR steelhead. This support includes completion of the HCP and other conservation measures supporting the reintroduction.

Conclusion

After review of the comments and further consideration, we have decided to adopt the proposed rule that was published in the **Federal Register** (76 FR 28715) on May 18, 2011, with only non-substantive editorial changes. Minor modifications were made to remove unnecessary regulatory language and provide clarity. The modifications make no change to the substance of the rule.

Findings

The statutory criteria for designating an experimental population under ESA section 10(j) are met for this designation.

(1) *Further the conservation of the species.* Based on the best available scientific information, we find that the continued release of MCR steelhead above the Pelton Round Butte Project as an NEP will further the conservation of the species for the following reasons. We expect that this will encourage private landowners, as well as local, state and Federal entities, to continue to develop and expand implementation of effective conservation actions throughout the geographic NEP range and in areas affecting environmental conditions in the geographic NEP range. Our expectation that this will occur is an important factor in finding that this rule furthers the conservation of the species.

Providing a 12-year term for the NEP designation will further the conservation of the species because conservation actions can be based on site-specific biological and environmental information gathered during that 12-year term. Conservation measures, any completed HCPs, and other permits, authorizations, or approvals developed during the 12-year term that are based on the best available scientific information and include measures designed to protect or conserve MCR steelhead in the geographic NEP range should include appropriate adaptive management components that may require modification, expansion, or adjustment of their conservation and mitigation actions to take new site specific biological and environmental information into account.

(2) *Geographically separate from non-experimental populations.* The NEP will be geographically separated from nonexperimental populations by Round Butte Dam (the most upstream dam of the three-dam hydropower complex), which does not allow volitional passage. The MCR steelhead will only be

considered experimental when they are above Round Butte Dam.

(3) *Non-essential designation.* This experimental population is nonessential because it is not key to whether recovery can be achieved for this steelhead DPS. In addition, juvenile outplants are made up solely of excess hatchery stock that are not necessary for the survival and recovery of the species, and returning adults passed in the NEP area will be predominantly, if not solely, from the same stock.

Information Quality Act and Peer Review

In December 2004, the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review pursuant to the Information Quality Act (Section 515 of Public Law 106–554). The Bulletin was published in the **Federal Register** on January 14, 2005 (70 FR 2664). The Bulletin established minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation with regard to certain types of information disseminated by the Federal Government. The peer review requirements of the OMB Bulletin apply to influential or highly influential scientific information disseminated on or after June 16, 2005. There are no documents supporting this final rule that meet this criteria.

Classification

Regulatory Planning and Review (Executive Order (E.O.) 12866)

In accordance with the criteria in E.O. 12866, OMB has determined this final rule is not a significant rulemaking action.

This final rule will not create inconsistencies with other agencies' actions or otherwise interfere with an action taken or planned by another agency. Federal agencies most interested in this rulemaking are the USFS, BLM, and BOR. Because of the substantial regulatory relief provided by the NEP designation, we believe the reestablishment of steelhead in the areas described would not conflict with existing human activities or hinder public utilization of the area.

This final rule also would not materially affect entitlements, grants, user fees, or loan programs, or the rights and obligations of their recipients.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed rule, if adopted, would not have a significant economic effect on a substantial number of small entities. None of the public comments submitted to NMFS addressed this certification, and no new information has become available that would change this determination. As a result, no final regulatory flexibility analysis is required and none has been prepared.

Takings (E.O. 12630)

In accordance with E.O. 12630, this final rule does not have significant takings implications. A takings implication assessment is not required because this rule: (1) Would not effectively compel a property owner to have the government physically invade their property, and (2) would not deny all economically beneficial or productive use of the land or aquatic resources. This final rule would substantially advance a legitimate government interest (conservation and recovery of a listed fish species) and would not present a barrier to all reasonable and expected beneficial use of private property.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

OMB regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), require that Federal agencies obtain approval from OMB before collecting information from the public. A Federal 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. This final rule does not include any new collections of information that require approval by OMB under the Paperwork Reduction Act.

National Environmental Policy Act

In compliance with all provisions of the National Environmental Policy Act of 1969 (NEPA), we have analyzed the impact on the human environment and considered a reasonable range of alternatives for this final rule. We made the draft EA available for public comment along with the proposed rule, received one set of comments, and responded to those comments in an Appendix to the EA. We have prepared a final EA on this proposed action and have made it available for public inspection (see **ADDRESSES** section).

Government-to-Government Relationship With Tribes

E.O. 13175, Consultation and Coordination with Indian Tribal Governments, outlines the responsibilities of the Federal Government in matters affecting tribal interests. If we issue a regulation with tribal implications (defined as having 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), we must consult with those governments, or the Federal Government must provide funds necessary to pay direct compliance costs incurred by Tribal governments. Accordingly, we engaged in a technical consultation with the CTWS on December 7, 2012, and discussed the rule and their recommendations. The CTWS' recommendations were incorporated into this final rule.

Furthermore, Secretarial Order 3206 acknowledges the trust responsibility and treaty obligations of the United States toward recognized tribes and tribal members, as well as its government-to-government relationship with tribes. The order requires NMFS to carry out its ESA responsibilities in a manner that harmonizes the Federal trust responsibility to tribes, tribal sovereignty, and statutory missions of the Department of Commerce, and that strives to ensure that tribes do not bear a disproportionate burden for the conservation of listed species to avoid or minimize the potential for conflict and confrontation.

The CTWS are co-managers of natural resources and share management responsibilities and rights for fisheries in the Columbia Basin. In the Deschutes River basin, MCR steelhead have important cultural, religious, tribal subsistence, ceremonial, and commercial value for the CTWS. The CTWS is engaged in the ongoing reintroduction as one of the Licensees, through the Warm Springs Power and Water Enterprises, and as a member of the Pelton Fish Committee, through the Natural Resources Management Services. Moreover, the CTWS own about 28 percent of the land included in the NEP.

Energy Supply, Distribution, or Use (E.O. 13211)

On May 18, 2001, the President issued E.O. 13211 on regulations that significantly affect energy supply, distribution, and use. E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking any action that promulgates or is expected to lead to the promulgation of a final rule or regulation that (1) is a significant regulatory action under E.O. 12866 and

(2) is likely to have a significant adverse effect on the supply, distribution, or use of energy.

This final rule is not expected to significantly affect energy supplies, distribution, and use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required. We did not receive any comments regarding energy supplies, distribution, and use.

References Cited

A complete list of all references cited in this final rule is available upon request from National Marine Fisheries Service (see **FOR FURTHER INFORMATION CONTACT**).

List of Subjects in 50 CFR Part 223

Endangered and threatened species, Exports, Imports.

Dated: January 9, 2013.

Alan D. Risenhoover,

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

For the reasons set out in the preamble, 50 CFR part 223 is amended as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531–1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

§ 223.211 [Removed and Reserved]

■ 2. Section 223.211 is removed and reserved.

§§ 223.212 through 223.300 [Reserved]

■ 3. Add reserved §§ 223.212 through 223.300.

■ 4. Add § 223.301 to read as follows:

§ 223.301 Special rules—marine and anadromous fishes.

(a) Middle Columbia River steelhead (*Oncorhynchus mykiss*).

(1) The Middle Columbia River steelhead located in the geographic areas identified in paragraph (a)(4) of this section comprise a nonessential, experimental population (NEP).

(2) *Take of this species that is allowed in the NEP area.* (i) Taking of Middle Columbia River (MCR) steelhead that is otherwise prohibited by paragraph (a)(3) of this section and 50 CFR 223.203(a), provided that the taking is unintentional; not due to negligent conduct; and incidental to, and not the purpose of, the carrying out of an otherwise lawful activity. Examples of otherwise lawful activities include recreational fishing, recreation, agriculture, forestry, municipal usage, and other similar activities, which are carried out in accordance with Federal, state, and local laws and regulations as well as applicable tribal regulations.

(ii) Handling of MCR steelhead in the NEP area by NMFS, Oregon Department of Fish and Wildlife (ODFW) and the Confederated Tribes of the Warm Springs Reservation of Oregon (CTWS) employees and authorized agents acting on their behalf for scientific purposes and by the Portland General Electric Company (PGE) and CTWS employees and authorized agents acting on their behalf for the purpose of monitoring and evaluating the ongoing reintroduction under the Federal Energy Regulatory Commission (FERC) license for the Pelton Round Butte Hydroelectric Project (FERC No. 2030).

(iii) Taking of MCR steelhead incidental to any activities related to or associated with the operation and maintenance of Pelton Round Butte Hydroelectric Project's (FERC Project No. 2030) Round Butte Dam by PGE or CTWS as administered under a license issued by FERC. Acceptable forms of taking of steelhead include, but are not limited to, mortality, stranding, injury, impingement at Round Butte Dam facilities, or delay in up- or downstream passage associated with or caused by any of the following activities. Activities related to the operation and maintenance of Round Butte Dam include, but are not limited to:

(A) Hydroelectric generation;

(B) Maintenance of project facilities;

(C) Provision of upstream and downstream fish passage,

(D) Fish handling at fish separation and counting facilities;

(E) Fish conservation activities;

(F) Fish handling, tagging, and sampling in connection with FERC approved studies; and

(G) Approved resource protection, mitigation, and enhancement measures.

(iv) Handling MCR steelhead by Deschutes Valley Water District employees and agents acting on their behalf for the purpose of monitoring and evaluating the Opal Springs Hydroelectric Project (FERC No. 5891).

(v) Take incidental to any activities related to or associated with the operation and maintenance of the Opal Springs Hydroelectric Project (FERC Project No. 5891) as administered under a license issued by FERC and the Settlement Agreement Concerning License Amendment for Fish Passage, dated October 2011.

(vi) Take of MCR steelhead by any person with a valid permit issued by NMFS and a valid permit issued by the ODFW for educational purposes, scientific purposes, and the enhancement of propagation or survival of the species, zoological exhibition, and other conservation purposes consistent with the ESA.

(3) *Take of this species that is not allowed in the NEP area.* (i) Except as expressly allowed in paragraph (a)(2) of this section, the taking of MCR steelhead is prohibited within the NEP geographic area, as provided in 50 CFR 223.203(a).

(ii) No person shall possess, sell, deliver, carry, transport, ship, import, or export, by any means whatsoever, MCR steelhead taken in violation of this paragraph (a)(3)(ii) and 50 CFR 223.203(a).

(4) *Geographic extent of the nonessential experimental population of Middle Columbia River steelhead.* (i) The geographic range of this experimental population is all accessible reaches upstream of Round Butte Dam on the Deschutes River, including tributaries Whychus Creek, Crooked River and Metolius River. More specifically, the geographic range includes all accessible reaches of the Deschutes River downstream to Round Butte Dam; the Whychus Creek subbasin; the Metolius River subbasin; and the Crooked River subbasin from Bowman Dam downstream (including the Ochoco and McKay Creek watersheds) to its point of confluence with the Deschutes River.

(ii) Round Butte Dam is the downstream terminus of this NEP. When MCR steelhead are below the Round Butte Dam, they will be outside the NEP area and thus considered part of the nonexperimental population.

(5) *Review and evaluation of nonessential experimental population.* As a requirement under its Federal license to operate the Pelton Round Butte Project, Portland General Electric Company and the Confederated Tribes of the Warm Springs Reservation of Oregon will conduct monitoring over the 50-year term of the license. This monitoring will include collecting information on the reintroduction program that NMFS will use in evaluating the NEP designation.

(6) *Time frame for NEP designation.* This NEP designation will expire on January 15, 2025.

(b) [Reserved]

[FR Doc. 2013–00700 Filed 1–14–13; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 78, No. 10
Tuesday, January 15, 2013

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 905

[Doc. No. AMS–FV–12–0045; FV12–905–1 PR]

Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would increase the assessment rate established for the Citrus Administrative Committee (Committee) for the 2012–13 and subsequent fiscal periods from $0.0072 to $0.008 per 4/5 bushel carton of citrus handled. The Committee locally administers the marketing order which regulates the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida. Assessments upon citrus handlers are used by the Committee to fund reasonable and necessary expenses of the program. The fiscal period begins August 1 and ends July 31. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by January 25, 2013.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the Internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Corey E. Elliott, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 325–8793, or Email: *Corey.Elliott@ams.usda.gov* or *Christian.Nissen@ams.usda.gov.*

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

SUPPLEMENTARY INFORMATION: This rulemaking is issued under Marketing Order No. 905, amended (7 CFR part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Order 12866.

This rulemaking has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, Florida citrus handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as proposed herein would be applicable to all assessable citrus beginning on August 1, 2012, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule would increase the assessment rate established for the Committee for the 2012–13 and subsequent fiscal periods from $0.0072 to $0.008 per 4/5 bushel carton of citrus.

The Florida citrus marketing order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers and handlers of Florida citrus. They are familiar with the Committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2007–08 and subsequent fiscal periods, the Committee recommended, and USDA approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on July 17, 2012, and unanimously recommended 2012–13 expenditures of $223,500 and an assessment rate of $0.008 per 4/5 bushel carton of citrus. In comparison, last year's budgeted expenditures were also $223,500. The assessment rate of $0.008 is $0.0008 higher than the rate currently in effect.

The Committee estimates 2012–2013 production to be approximately 27.3 million 4/5 bushel cartons, down from the 29.5 million 4/5 bushel cartons estimated for last year. At the current

assessment rate, assessment income would equal only $196,560, an amount insufficient to cover the Committee's anticipated expenditures. The assessment rate increase would generate additional revenue and would help offset the amount of reserves needed to fund the budget. Therefore, the Committee recommended increasing the assessment rate.

The major expenditures recommended by the Committee for the 2012–13 year include $116,200 for salaries, $25,000 for Florida Department of Agriculture and Consumer Services (FDACS) manifesting, and $18,250 for a retirement plan. Budgeted expenses for these items in 2011–12 were the same as recommended for 2012–13 budgeted expenditures, respectively.

The assessment rate recommended by the Committee was derived by reviewing anticipated expenses, expected shipments of Florida citrus, interest income, and available reserves. Citrus shipments for the year are estimated at 27.3 million 4/5 bushel cartons which should provide $218,400 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve would be adequate to cover budgeted expenses. Funds in the reserve (approximately $34,000) would be kept within the maximum permitted by the order of not to exceed one half of one fiscal period's expenses as stated in § 905.42.

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee would continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2012–13 budget and those for subsequent fiscal periods would be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

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

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

There are approximately 45 handlers subject to regulation under the marketing order and approximately 8,000 producers of citrus in the production area. Small agricultural service firms are defined by the Small Business Administration (SBA) as those whose annual receipts are less than $7,000,000, and small agricultural producers are defined as those having annual receipts less than $750,000 (13 CFR 121.201).

Based on industry and Committee data, the average annual f.o.b. price for fresh Florida citrus during the 2010–11 season was approximately $12.16 per 4/5 bushel carton, and total fresh shipments were approximately 30.4 million cartons. Using the average f.o.b. price and shipment data, about 55 percent of the Florida citrus handlers could be considered small businesses under SBA's definition. In addition, based on production data, grower prices as reported by the National Agricultural Statistics Service, and the total number of Florida citrus growers, the average annual grower revenue is below $750,000. Thus, assuming a normal distribution, the majority of handlers and producers of Florida citrus may be classified as small entities.

This proposed rule would increase the assessment rate established for the Committee and collected from handlers for the 2012–13 and subsequent fiscal periods from $0.0072 to $0.008 per 4/5 bushel carton of citrus. The Committee unanimously recommended 2012–13 expenditures of $223,500 and an assessment rate of $0.008 per 4/5 bushel carton of citrus. The proposed assessment rate of $0.008 is $0.0008 higher than the 2011–12 rate. The quantity of assessable citrus for the 2012–13 season is estimated at 27.3 million cartons. Thus, the $0.008 rate should provide $218,400 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve fund, would be adequate to meet this year's anticipated expenses.

The major expenditures recommended by the Committee for the 2012–13 year include $116,200 for salaries, $25,000 for Florida Department of Agriculture and Consumer Services (FDACS) manifesting, and $18,250 for a retirement plan. Budgeted expenses for these items in 2011–12 were the same as recommended for 2012–13 budgeted expenditures, respectively.

As previously stated, the Committee estimates the 2012–2013 production to be approximately 27.3 million 4/5 bushel cartons, down from the 29.5 million 4/5 bushel cartons estimated for last year. At the current assessment rate, assessment income would equal only $196,560, an amount insufficient to cover the Committee's anticipated expenditures. The assessment rate increase would generate additional revenue and would help offset the amount of reserves needed to fund the budget. Therefore, the Committee recommended increasing the assessment rate.

The Committee reviewed and unanimously recommended 2012–13 expenditures of $223,500. Prior to arriving at this budget, the Committee considered information from the Committee's Executive Subcommittee. Alternative expenditure levels were discussed by this group. The assessment rate of $0.008 per 4/5 bushel carton of citrus was then determined by reviewing anticipated expenses, total expected shipments of citrus, interest income, and the available reserves. The increased assessment rate should provide $218,400 in assessment income. This is approximately $5,100 below the anticipated expenses, which the Committee determined to be acceptable.

A review of historical information and preliminary information pertaining to the upcoming crop year indicates that the grower price for the 2012–13 season could range between $3.83 and $10.13 per 4/5 bushel carton of citrus. Therefore, the estimated assessment revenue for the 2012–13 crop year as a percentage of total grower revenue could range between .08 and .2 percent.

This action would increase the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to producers. However, these costs would be offset by the benefits derived by the operation of

the marketing order. In addition, the Committee's meeting was widely publicized throughout the Florida citrus industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the July 17, 2012, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0189 Generic Fruit Crops. No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large Florida citrus handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

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

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

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

A 10-day comment period is provided to allow interested persons to respond to this proposed rule. Ten days is deemed appropriate because: (1) The 2012–13 fiscal period began on August 1, 2012, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable citrus handled during such fiscal period; (2) the Committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis; and (3) handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years.

List of Subjects in 7 CFR Part 905

Grapefruit, Oranges, Reporting and recordkeeping requirements, Tangelos, Tangerines.

For the reasons set forth in the preamble, 7 CFR part 905 is proposed to be amended as follows:

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

■ 1. The authority citation for 7 CFR part 905 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 905.235 is revised to read as follows:

§ 905.235 Assessment rate.

On and after August 1, 2012, an assessment rate of $0.008 per 4/5 bushel carton or equivalent is established for Florida citrus covered under the order.

Dated: January 9, 2013.

David R. Shipman,

Administrator, Agricultural Marketing Service.

[FR Doc. 2013–00599 Filed 1–14–13; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0013; Directorate Identifier 2012–CE–046–AD]

RIN 2120–AA64

Airworthiness Directives; GROB–WERKE Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for GROB–WERKE Model G115EG airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as cracks in the elevator trim tab arms on several Grob G 115 airplanes, which could result in failure of the part and consequent loss of control. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by March 1, 2013.

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

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

For service information identified in this proposed AD, contact Grob Aircraft AG, Lettenbachstrasse 9, D–86874 Tussenhausen-Mattsies, Germany; phone: +49 (0) 8268 998 139; fax: +49 (0) 8268 998 200; email: *productsupport@grob-aircraft.de;* Internet: *www.grob-aircraft.com/index.php/g-115e.html.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Taylor Martin, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4138; fax: (816) 329–4090; email: *taylor.martin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments

to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0013; Directorate Identifier 2012–CE–046–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No. 2012–0155, dated August 20, 2012 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

On several Grob G 115 aeroplanes, elevator trim tab arms Part Number (P/N) 115E–3758 have been found cracked, from a rear mounting hole (either L/H or R/H) to the rear edge of the trim tab arm.

This condition, if not detected and corrected, could lead to further crack propagation, possibly resulting in failure of the part and consequent loss of control of the aeroplane.

For the reasons described above, this AD requires repetitive inspections of the elevator trim tab arm to detect cracks and, if detected, replacement of the part with a serviceable part.

This AD also provides an optional terminating action for the repetitive inspections.

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

Relevant Service Information

Grob Aircraft has issued Service Bulletin No. MSB1078–186/3, dated August 3, 2012. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the Proposed AD

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

Costs of Compliance

We estimate that this proposed AD will affect 0 products of U.S. registry. We also estimate that it would take about 3 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $372 per product.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $627 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

Grob-Werke: Docket No. FAA–2012–0013; Directorate Identifier 2012–CE–046–AD.

(a) Comments Due Date

We must receive comments by March 1, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to GROB–WERKE G115EG airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 55: Stabilizers.

(e) Reason

This AD was prompted by the discovery of cracks in the elevator trim tab arms on several Grob G 115 airplanes, which could result in failure of the part and consequent loss of control. We are issuing this proposed AD to detect cracks and prevent the part from failing.

(f) Actions and Compliance

Unless already done, do the following actions following Grob Aircraft Service Bulletin No. MSB1078–186/3, dated August 3, 2012.

(1) Within the next 50 hours time-in-service (TIS) after the effective date of this AD and repetitively thereafter at intervals not to exceed 200 hours TIS, inspect elevator trim tab arms, part number (P/N) 115E–3758, using a nondestructive testing (NDT) method such as a dye-penetrant or eddy-current.

Note for paragraph (f)(1) of this AD: There must be a more significant nondestructive testing (NDT) method of inspection beyond a visual inspection to accomplish the inspection requirements in paragraph (f)(1) of this AD.

(2) If during any inspection required in paragraph (f)(1) of this AD a crack is found, before further flight, replace the affected elevator trim tab arm with an airworthy part.

(3) Replacement at any time of an elevator trim tab arm with an airworthy part that has a P/N other than P/N 115E–3758, will terminate the repetitive requirement in paragraph (f)(1) of this AD.

(g) Credit for Actions Accomplished in Accordance With Previous Service Information

This AD provides credit for the actions required in this AD if already done before the effective date of this AD following Grob Aircraft Service Bulletin No. MSB1078–186/2, dated March 28, 2012; Grob Aircraft Service Bulletin No. MSB1078–186/1, dated March 8, 2012; or Grob Aircraft Service Bulletin No. MSB1078–186, dated February 15, 2012.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Taylor Martin, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4138; fax: (816) 329–4090; email: *taylor.martin@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(i) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2012–0155, dated August 20, 2012; and Grob Aircraft Service Bulletin No. MSB1078–186/3, dated August 3, 2012, for related information. For service information related to this AD, contact Grob Aircraft AG, Lettenbachstrasse 9, D–86874 Tussenhausen-Mattsies, Germany; phone: +49 (0) 8268 998 139; fax: +49 (0) 8268 998 200; email: *productsupport@grob-aircraft.de;* Internet: *www.grob-aircraft.com/index.php/g-115e.html.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on January 8, 2013.

John Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–00667 Filed 1–14–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. FAA–2012–0929; Notice No. 13–02]

RIN 2120–AJ17

Prohibition on Personal Use of Electronic Devices on the Flight Deck

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The proposed rule would prohibit flightcrew members in operations under part 121 from using a personal wireless communications device or laptop computer for personal use while at their duty station on the flight deck while the aircraft is being operated. This rule, which conforms FAA regulations with recent legislation, is intended to ensure that certain non-essential activities do not contribute to the challenge of task management on the flight deck or a loss of situational awareness due to attention to non-essential tasks.

DATES: Send comments on or before March 18, 2013.

ADDRESSES: Send comments identified by docket number FAA–2012–0929 using any of the following methods:

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

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this proposed rule, contact Nancy Lauck Claussen, Air Transportation Division (AFS–200), Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–8166; email *Nancy.L.Claussen@faa.gov.*

For legal questions concerning this action, contact Nancy Sanchez, Office of the Chief Counsel, Regulations Division, AGC–200, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3073; email *Nancy.Sanchez@faa.gov.*

SUPPLEMENTARY INFORMATION: See the ''Additional Information'' section for information on how to comment on this proposal and how the FAA will handle comments received. The ''Additional Information'' section also contains related information about the docket, privacy, the handling of proprietary or confidential business information. In addition, there is information on obtaining copies of related rulemaking documents.

Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. 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.

This rulemaking is promulgated under the authority described in 49 U.S.C. 44701(a)(5), which requires the Administrator to promulgate regulations and minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security, and 49 U.S.C. 44732(d), which requires the Administrator to issue a final rule to carry out the prohibition of personal use of electronic devices on the flight deck by flightcrew members.

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I. Overview of Proposed Rule

The FAA Modernization and Reform Act of 2012 was enacted on February 14, 2012. Section 307 of the Act, Prohibition on Personal Use of Electronic Devices on the Flight Deck, makes it ''unlawful for a flight crewmember of an aircraft used to provide air transportation under part 121 of title 14, Code of Federal Regulations, to use a personal wireless communications device or laptop computer while at the flight crewmember's duty station on the flight deck of such an aircraft while the aircraft is being operated.'' The legislation also states that this prohibition does not apply to the use of a personal wireless communications device or laptop computer for a purpose directly related to operation of the aircraft, or for emergency, safety-related, or employment-related communications, in accordance with procedures established by the air carrier and the FAA. The FAA is proposing to amend part 121 to conform to this legislation. The FAA proposes to amend 14 CFR 121.542 to add language to prohibit flightcrew members operating under part 121 from using a personal wireless communications device or a laptop computer for personal use while at their duty station on the flight deck while the aircraft is being operated. The amended regulatory language will clarify that the prohibition on use of a personal wireless communications device or laptop computer does not apply to the use of a personal wireless communications device or laptop computer for a purpose directly related to the operation of the aircraft, or for emergency, safety-related, or employment-related communications, in accordance with procedures established by the air carrier and approved by the FAA.

II. Background

A. Related Rule

In 1981, the FAA published the Elimination of Duties and Activities of Flightcrew Members Not Required for the Safe Operation of Aircraft Final Rule.[1] This rule, better known as the ''Sterile Cockpit'' rule, required air carriers operating under parts 121 and 135, as well as flightcrew members in those operations, to ensure that the environment on the flight deck was free from potentially dangerous distractions. The final rule states that air carriers shall not require their flightcrew members to perform non-safety related duties during critical phases of flight and that flightcrew members shall not conduct non-safety related activities which could cause distractions on the flight deck during critical phases of flight. In addition, the rule further states that the pilot-in-command shall not permit any activity during a critical phase of flight which would distract flightcrew members from the performance of their duties which, in effect, extends the sterile cockpit provisions to other crewmembers, such as flight attendants.

The 1981 rule defines the critical phases of flight as all ground operations involving taxi, take-off and landing, and all other flight operations conducted below 10,000 feet, except cruise flight.

The personal use of personal wireless communications devices and laptop computers for non-safety related activities is prohibited by the broad restrictions in the current ''Sterile Cockpit'' rule during ground operations involving taxi, take-off and landing, and all other flight operations conducted below 10,000 feet. The proposed requirements in this NPRM would extend the prohibition on personal use of personal wireless communications devices and laptop computers to all phases of flight.

B. Statement of the Problem

Several recent incidents involving a breakdown of sterile cockpit discipline have prompted Congress to address this issue in the FAA Modernization and Reform Act of 2012. In one instance, two pilots were using their personal laptop computers during cruise flight and lost situational awareness, leading to a 150 mile fly-by of their destination. In another instance, a pilot sent a text message on her personal cell phone during the taxi phase of the flight, after the aircraft pushed back from the gate and before the take-off sequence. These incidents illustrate the potential for such devices to create a hazardous distraction during critical phases of flight.

This rule is intended to ensure that certain non-essential activities do not contribute to the challenge of task management on the flight deck and do not contribute to a loss of situational awareness due to attention to non-essential activities, as the previously discussed incidents highlight. Situational awareness is an attention based phenomenon that reflects the flightcrew's knowledge of where the aircraft is in regard to location, air traffic control, weather, regulations, aircraft status, and other factors. A lack of situational awareness can affect a pilot's ability to perform effectively regarding aircraft handling, aircraft systems, aircraft mode awareness, environmental hazards, standard operating procedures, and attention to required tasks. When loss of situational awareness occurs, there can be critical consequences, such as missing information from one source when concentrating on another source, altitude or course deviations, dominance of visual cues to the extent that pilots may not hear certain aural warnings, misinterpreting ATC instructions, or experiencing task overload.

An individual can lose situational awareness due to attentional tunneling and attention to non-essential activities. Attentional tunneling is becoming absorbed in a task to the exclusion of other visual and aural inputs, and is also a factor in the breakdown of task management. This is operationally

[1] 46 FR 5500 (Jan. 19, 1981).

described as ''the allocation of attention to a particular channel of information, diagnostic hypothesis, or task goal, for a duration that is longer than optimal, given the expected cost of neglecting events on other channels, failing to consider other hypotheses, or failing to perform other tasks.'' [2]

The ''party'' situation, when a person at a loud crowded party usually listens to one conversation and can easily ignore all others, is a commonplace example of attentional tunneling.[3] In some ways, attentional tunneling helps people handle a situation with a high number of visual and aural inputs. However, it can also block important visual and aural information. Because flightcrew members must attend to many safety-related tasks during aircraft operations and must manage those tasks effectively, attentional tunneling can introduce risks into the system.

Additionally, flightcrew members could lose situational awareness when a personal electronic device used on the flight deck is inconsistent with the type certified flight deck design philosophy. The inconsistency could provide distraction, confusion, and ultimately contribute to a loss of situational awareness.[4]

C. National Transportation Safety Board Recommendation

In its recommendations to the FAA regarding the Colgan accident in 2009, the NTSB concluded that because of the continuing number of accidents involving a breakdown in sterile cockpit discipline, collaborative action by the FAA and the aviation industry to promptly address this issue was warranted.

Therefore, the NTSB recommended (A–10–30) that the FAA require all part 121, 135, and 91K operators to incorporate explicit guidance to pilots, including checklist reminders as appropriate, prohibiting the use of personal portable electronic devices on the flight deck.[5]

In response to NTSB recommendation A–10–30, the FAA issued Information for Operators (InFO) 10003, Cockpit Distractions, on April 26, 2010. The NTSB responded that this action did not fully address the recommendation because the InFO was advisory only.[6] With this proposed rulemaking, the FAA will amend current regulations to prohibit the use of personal wireless communications devices and laptop computers by flightcrew members during all aircraft operations to address this type of distraction on the flight deck.

III. Discussion of the Proposal

A. Requirements

The proposed requirements would prohibit the personal use of a personal wireless communications device or laptop computer while a flightcrew member is at his or her duty station during all ground operations involving taxi, takeoff and landing, and all other flight operations. The proposed rule does not prohibit the use of personal wireless communications devices or laptop computers if the purpose is directly related to operation of the aircraft, or for emergency, safety-related, or employment-related communications and the use is in accordance with air carrier procedures approved by the Administrator.

The FAA clarifies that ''emergency'' communications are those related to the safe operation of the aircraft and its occupants, not a flightcrew member's personal emergency. Additionally, the FAA clarifies that ''employment-related'' communications are not at the discretion of the pilot but are part of FAA approved operational procedures regarding the use of personal wireless communications devices or laptop computers. For example, in the previously noted situation with pilots who became distracted when using a personal laptop while discussing the air carrier's flight scheduling software, the flight schedules may have been ''employment-related,'' but the personal use of laptop computers during the discussion was not part of FAA approved operational procedures and would be prohibited by the proposed rule.

B. Current Air Carrier Programs

Several air carriers currently have FAA approved programs or are in the process of developing programs for FAA approval where laptop computers and personal wireless communications devices, such as tablets, are used by flightcrew members for work related activities during flight operations. In some cases, air carriers own the laptop computers and/or personal wireless communications devices used by flightcrew members. In other cases, flightcrew members own the laptop computer and/or personal wireless communications devices.

The FAA clarifies that the provisions of the proposed rule do not require an ''ownership'' test regarding the laptop computer or personal wireless communications device. These devices can be owned by the air carrier or the flightcrew member. The provisions of the proposed rule require a ''use'' test. These devices (regardless of who owns them) may not be used for personal use (e.g. personal communications, personal emails, leisure activities, etc) while the flightcrew member is at his or her duty station while the aircraft is being operated.

C. Operational Timeframes for Prohibition

Section 307 of the Act states that it is unlawful to use a device for personal use ''while the aircraft is being operated''. The meaning of an ''aircraft being operated'' as it pertains to some FAA regulations is very broad, to include being parked at the gate while passengers are boarding. The FAA clarifies that for the purposes of this rule, the meaning of an ''aircraft being operated'' mirrors the definition of ''flight time'' in 14 CFR 1.1. Therefore, the prohibition on the personal use of laptop computers and personal wireless devices commences at taxi (movement of the aircraft under its own power) and ends when the aircraft is parked at the gate at the end of the flight segment.

D. Personal Wireless Communications Device

Section 307 of the Act defines ''personal wireless communications device'' as a device through which personal wireless services (as defined in Section 332(c)(7)(C)(i) of the Communications Act of 1934) are transmitted.[7] The Communications Act of 1934 states that personal wireless services means commercial mobile services, unlicensed wireless services, and common carrier wireless exchange access service.

In general, wireless telecommunications is the transfer of information between two or more points that are not physically connected. In the proposed rule, the FAA retains the same broad category because a list of specific devices would ignore the reality of evolving technology. This broad category of devices includes, but is not limited to, devices such as cell phones,

[2] Wickens, C.D., Alexander, A.L. *Attentional tunneling and task management in synthetic vision displays.* The International Journal of Aviation Psychology, 19(3), 182–199 (2009).

[3] Cherry, E.C., *On human communication: A review, a survey, and a criticism.* Cambridge: Technology Press, MIT; New York: John Wiley (1957).

[4] See 76 FR 6088 (Feb. 3, 2011).

[5] *http://www.ntsb.gov/doclib/reports/2010/aar1001.pdf.*

[6] The NTSB closed recommendation A–10–30 as unacceptable on June 14, 2012. Summaries of the NTSB and FAA letters on A–10–30 can be found at *http://www.ntsb.gov/SafetyRecs/Private/history.aspx?rec=A-10-030&addressee=FAA.*

[7] *See* 47 U.S.C. 332(c)(7)(C)(i).

smartphones, personal digital assistants, tablets, e-readers, gaming systems, netbook computers, and notebook computers.

IV. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this proposed rule.

The Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this proposed rule. The reasoning for this determination follows:

The FAA Modernization and Reform Act of 2012, enacted on February 14, 2012, includes Section 307, Prohibition on Personal Use of Electronic Devices on the Flight Deck. The FAA is proposing to amend part 121 to conform to this legislation. The proposed rule would prohibit flightcrew members in operations under part 121 from using a wireless communications device or laptop computer for personal use while at their duty station on the flight deck while the aircraft is being operated. This proposed rule is intended to ensure that certain non-essential activities do not contribute to the challenge of task management on the flight deck and do not contribute to a loss of situational awareness due to attention to non-essential activities. The FAA expects that this proposed rule reflects current sterile cockpit operating procedures and therefore does not impose more than a minimum cost on any regulated entity.

The FAA has, therefore, determined that this proposed rule is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is not ''significant'' as defined in DOT's Regulatory Policies and Procedures.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions. Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The FAA Modernization and Reform Act of 2012 was enacted on February 14, 2012. Section 307 of the Act, Prohibition on Personal Use of Electronic Devices on the Flight Deck, the FAA is proposing to amend part 121 to conform to this legislation. The proposed rule would prohibit flightcrew members in operations under part 121 from using a wireless communications device or laptop computer for personal use while at their duty station on the flight deck while the aircraft is being operated. This rule is intended to ensure that certain non-essential activities do not contribute to the challenge of task management on the flight deck and do not contribute to a loss of situational awareness due to attention to non-essential activities. While this proposed rule affects small entities, it merely revises existing FAA rules and does not impose any cost on any regulated entity.

Therefore, the FAA certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. The FAA solicits comments regarding this determination.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and has determined that it would have only a domestic impact and therefore no affect on international trade.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $143.1 million in lieu of $100 million. This proposed rule does not contain such a mandate.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there would be no new requirement for information collection associated with this proposed rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

G. Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312f and involves no extraordinary circumstances.

V. Executive Order Determinations

A. Executive Order 12866 and 13563

See the ''Regulatory Evaluation'' discussion in the ''Regulatory Notices and Analyses'' section elsewhere in this preamble.

B. Executive Order 13132, Federalism

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have Federalism implications.

C. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it would not be a ''significant energy action'' under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

VI. Additional Information

A. Comments Invited

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

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

B. Availability of Rulemaking Documents

An electronic copy of rulemaking documents may be obtained from the Internet by—

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

2. Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies* or

3. Accessing the Government Printing Office's Web page at *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Commenter's must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced in item (1) above.

List of Subjects in 14 CFR Part 121

Air carriers, Aircraft, Airmen, Aviation safety, Safety, Transportation.

VII. The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend chapter I of title 14, Code of Federal Regulations as follows:

PART 121—OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

■ 1. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 40119, 41706, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44732, 46105.

■ 2. Amend § 121.542 by adding paragraph (d) to read as follows:

§ 121.542 Flight crewmember duties.

* * * * *

(d) During all flight time as defined in 14 CFR 1.1, no flight crewmember may use, nor may any pilot in command permit the use of, a personal wireless communications device or laptop computer while at a flight crewmember duty station unless the purpose is directly related to operation of the aircraft, or for emergency, safety-related, or employment-related communications, in accordance with air carrier procedures approved by the Administrator.

Issued in Washington, DC, on January 9, 2013.

John M. Allen,

Director, Flight Standards Service.

[FR Doc. 2013–00608 Filed 1–14–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2012–0552]

RIN 1625–AA08

Special Local Regulation; West Palm Beach Triathlon Championship, Intracoastal Waterway, West Palm Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to issue a special local regulation on the waters of the Intracoastal Waterway, in West Palm Beach, Florida, during the West Palm Beach Triathlon Championship, on Saturday, June 1, 2013. Approximately 1,500 participants are anticipated to participate in the triathlon. The special local regulation is necessary to ensure the safety of the triathlon participants, participant vessels, and the general public during the swim portion of the event. Persons and vessels, except those participating

in the event, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative.

DATES: Comments and related material must be received by the Coast Guard on or before March 1, 2012. Requests for public meetings must be received by the Coast Guard on or before January 20, 2012.

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

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

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Lieutenant Junior Grade Mike H. Wu, Sector Miami Prevention Department, Coast Guard; telephone (305) 535–7576, email *Mike.H.Wu@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number USCG–2012–0552 in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number USCG–2012–0552 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before January 20, 2012 using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish special local regulations: 33 U.S.C. 1233. The purpose of the rule is to ensure the safety of life and property on navigable waters of the United States during the West Palm Beach Triathlon Championship.

C. Discussion of Proposed Rule

On June 1, 2013, Game One Sports Marketing Group is hosting the West Palm Beach Triathlon Championship. The races will be held on the waters of the Intracoastal Waterway, in West Palm Beach, Florida. Approximately 1,500 participants are anticipated to participate in the triathlons. No spectator vessels are anticipated to be present during the races.

The special local regulation encompasses certain navigable waters of the Intracoastal Waterway in West Palm Beach, Florida. The special local regulation will be enforced from 6:30 a.m. until 8:30 a.m. on June 1, 2013. All persons and vessels, except those participating in the races, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative.

Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Miami by telephone at (305) 535–4472, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative. The Coast Guard will provide notice of the special local regulation by Local Notice to Mariners, Broadcast Notice to Mariners,

and on-scene designated representatives.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

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

The economic impact of this proposed rule is not significant for the following reasons: (1) The special local regulation will be enforced for a maximum of two hours; (2) non-participant persons and vessels may enter, transit through, anchor in, or remain within the regulated areas during the respective enforcement period if authorized by the Captain of the Port Miami or a designated representative; (3) non-participant persons and vessels not authorized to enter, transit through, anchor in, or remain within the regulated areas may operate in the surrounding areas during the respective enforcement period; and (4) the Coast Guard will provide advance notification of the special local regulation to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to enter, transit through, anchor in, or remain within that portion of the Intracoastal Waterway encompassed within the special local regulation from 6:30 a.m. until 8:30 a.m. on June 1, 2013. For the reasons discussed in the Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

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

5. Federalism

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

6. Protest Activities

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

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children From Environmental Health Risks

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a special local regulation issued in conjunction with a marine event. This rule is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add a temporary § 100.35T07–0552 to read as follows:

§ 100.35T07–0552 Special Local Regulation; West Palm Beach Triathlon Championship, Intracoastal Waterway, West Palm Beach, FL.

(a) *Regulated area.* The following regulated area is established as a special local regulation. All waters of the Intracoastal Waterway in West Palm Beach, Florida between the Flagler Memorial Bridge to the Royal Palm Way Bridge.

(b) *Definition.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state and local officers designated by or assisting the Captain of the Port Miami in the enforcement of the regulated area.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative. Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port Miami by telephone at (305) 535–4472, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated areas is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative.

(2) The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) Enforcement date. This rule will be enforced from 6:30 a.m. until 8:30 a.m. on June 1, 2013.

Dated: December 26, 2012.

J.B. Pruett,

Captain, U.S. Coast Guard, Acting Captain of the Port Miami.

[FR Doc. 2013–00515 Filed 1–14–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

Proposed Priority—National Institute on Disability and Rehabilitation Research—Disability and Rehabilitation Research Project—Inclusive Cloud and Web Computing

CFDA Number: 84.133A–01.

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Proposed priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this notice proposes a priority for a Disability and Rehabilitation Research Project (DRRP) on inclusive Cloud and Web computing. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2013 and later years. We take this action to focus research attention on areas of national need. We intend this priority to contribute to improved employment outcomes for individuals with disabilities.

DATES: We must receive your comments on or before February 14, 2013.

ADDRESSES: Address all comments about this notice to Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue SW., room 5133, Potomac Center Plaza (PCP), Washington, DC 20202–2700.

If you prefer to send your comments by email, use the following address: *marlene.spencer@ed.gov.* You must include the phrase ''Proposed Priority for Inclusive Cloud and Web Computing'' in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Marlene Spencer. Telephone: (202) 245–7532 or by email: *marlene.spencer@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This proposed priority is in concert with NIDRR's Long-Range Plan (Plan). The Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: *www2.ed.gov/legislation/FedRegister/other/2006-1/021506d.pdf.*

Through the implementation of the Plan, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training methods to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms for integrating research and practice; and (6) disseminate findings.

This notice proposes a priority that NIDRR intends to use for a DRRP competition in FY 2013 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities, if needed. Furthermore, NIDRR is under no obligation to make an award using this priority. The decision to make an award will be based on the quality of applications received and available funding.

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the

notice of final priority, we urge you to identify clearly the specific topic that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in room 5133, 550 12th Street SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop methods, procedures, and rehabilitation technology, that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Disability and Rehabilitation Research Projects

The purpose of NIDRR's DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, are to improve the effectiveness of services authorized under the Rehabilitation Act, by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: research, training, demonstration, development, dissemination, utilization, and technical assistance.

An applicant for assistance under this program must demonstrate in its application how it will address, in whole or in part, the needs of individuals with disabilities from minority backgrounds (34 CFR 350.40(a)). The approaches an applicant may take to meet this requirement are found in 34 CFR 350.40(b). Additional information on the DRRP program can be found at: *www.ed.gov/rschstat/research/pubs/res-program.html#DRRP.*

Program Authority: 29 U.S.C. 762(g) and 764(a).

Applicable Program Regulations: 34 CFR part 350.

Proposed Priority:

This notice contains one proposed priority.

DRRP on Inclusive Cloud and Web Computing.

Background:

The World Wide Web (Web) has become a fundamental tool for employment, education, civic participation, entertainment, and purchase of goods and services. However, participation in such activities on the Web for people with disabilities lags behind that for the general population. For example, Web use often requires broadband access, but the National Broadband Plan states that only 42 percent of people with disabilities use broadband at home, compared to 65 percent of people nationwide (Federal Communications Commission, 2010).

One reason for this disparity is that the Web infrastructure is not set up to address disability access issues seamlessly across all of its functions (Global Public Inclusive Infrastructure, n.d.). Additionally, software and devices (e.g., computer, smart phone, tablet) used to access the Web are often inaccessible for people with disabilities, and individuals with disabilities have limited access to technical assistance with selecting, setting up, and using appropriate technologies. Furthermore, people with disabilities often are required to purchase separate accessibility software and assistive devices for each device they use to access the Web, which adds to the economic burden of Web use by people with disabilities (Lyle, 2010).

Cloud computing, a technology used to store, access, and process information on the Web, has the potential to enhance Web participation by people with disabilities by providing an infrastructure that better supports accessibility for this population. International efforts are underway to develop a cloud-based infrastructure for the Web that includes options for disability access within its general structure—a change from the current, more inaccessible structure, where individuals with disabilities must set up their personal Web-enabled devices (e.g., smartphones) to meet their specific needs. The goal of this effort is to enable individuals with disabilities to log onto any Web-enabled device and have their user profiles and accessibility needs automatically recognized and appropriate tools activated, which would reduce the need for individuals to set up assistive technologies on each Web-enabled device they use. Three international projects addressing this need are described at Global Public Inclusive Infrastructure (n.d.), Cloud4all (n.d.), and Fluid (n.d.).

In order to support this effort, NIDRR has identified some (but not all) of the research questions that must be answered (see Table 1), together with possible computer science approaches to addressing them. Answering these and other relevant questions successfully will require collaboration between people with disabilities and experts in both disability and computer science fields relevant to cloud and Web accessibility and structure.

TABLE 1—RESEARCH QUESTIONS OF IMPORTANCE IN DEVELOPING ACCESSIBLE CLOUD AND WEB COMPUTING INFRASTRUCTURE

Research questions	Possible computer science approaches
How to make content and interactions easier to understand for people with mental disabilities.	Natural language processing.
How to make it easier for people with disabilities to log on to the Web	Authentication technology.

TABLE 1—RESEARCH QUESTIONS OF IMPORTANCE IN DEVELOPING ACCESSIBLE CLOUD AND WEB COMPUTING INFRASTRUCTURE—Continued

Research questions	Possible computer science approaches
How to change the presentation of information on Web pages to respond to difficulties encountered by people with disabilities.	Adaptive user interfaces.
How to manage user profiles and accessibility options over time, as technology evolves.	Federated information management.
How to make software more easily modifiable to meet individual needs	Software architecture.
How to improve the ability of software tools to identify accessibility problems in documents.	Automated user interface testing.
How to enable people with disabilities to share accessibility experiences and approaches.	Social computing.
How to incorporate specific accessibility features (e.g., closed captioning, volume control, video description, screen reader technology, accessible user interfaces) into an inclusive Web infrastructure.	Software design.

Sources: Jurafsky and Martin (2008); Cranor (2011); Jameson (2009); Haas *et al.* (2009); Fowler (2004); Li *et al.* (2007); Erickson (2011); Nielsen-Bohlman *et al.* (2004); Meiselwitz *et al.* (2009); Hurst *et al.* (2011); GPII (n.d.); Brajnik (2009); National Council on Disability (2011); Twenty-First Century Communications and Video Accessibility Act of 2011, Pub. L. 111–260.

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Twenty-First Century Communications and Video Accessibility Act of 2011, Public Law 111–260.

Proposed Priority:

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for a Disability and Rehabilitation Research Project (DRRP) on Inclusive Cloud and Web computing. The DRRP must contribute to the development of an inclusive cloud and Web infrastructure that incorporates options for disability access within its general structure.

To contribute to this initiative, the DRRP must—

(1) Identify, design, prototype, and assess promising methods and systems for, and technical approaches to designing, a cloud and Web infrastructure that addresses the needs of individuals with disabilities. The DRRP must address at least one of the research questions outlined in Table 1 above. Applicants may also choose to address additional research questions not reflected in Table 1. In that case, the application must fully explain how work on the additional topic or topics proposed by the applicant will advance disability access in cloud and Web infrastructure design.

(2) Conduct knowledge translation activities (e.g., training, technical assistance, dissemination, collaboration) in order to facilitate use of the research results by key stakeholders (e.g., individuals with disabilities, computer scientists, other researchers and software developers working on accessibility technology, policy makers, international partners).

(3) Demonstrate meaningful involvement by key stakeholder groups (e.g., individuals with disabilities, computer scientists, software developers and researchers working on accessibility technology, policy makers, international partners) in order to maximize the relevance and usability of the research conducted under this priority. Involvement may include, but is not limited to, participation in a multidisciplinary research team, advisory board, focus group, or other participatory action research method.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications

that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority:

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

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

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing this proposed priority only upon a reasoned determination that its benefits would justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Program have been well established over the years, as projects similar to the one envisioned by the proposed priority have been completed successfully. Establishing a new DRRP based on the proposed priority would generate new knowledge through research and development and improve the lives of individuals with disabilities. The new DRRP would generate, disseminate, and promote the use of new information that would improve employment opportunities for individuals with disabilities.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or computer disc) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 9, 2013.

Michael Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2013–00577 Filed 1–14–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

Proposed Priority—National Institute on Disability and Rehabilitation Research—Disability and Rehabilitation Research Project—Center on Knowledge Translation for Technology Transfer

CFDA Number: 84.133A–08.

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Proposed priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under the Disability and Rehabilitation Research Projects (DRRP) and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this notice proposes a priority for a DRRP to serve as the Center on Knowledge Translation for Technology Transfer (Center). The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2013 and later years. We take this action to focus research attention on areas of national need. We intend this priority to contribute to improved outcomes for individuals with a disability.

DATES: We must receive your comments on or before February 14, 2013.

ADDRESSES: Address all comments about this notice to Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue SW., room 5133, Potomac Center Plaza (PCP), Washington, DC 20202–2700.

If you prefer to send your comments by email, use the following address: *marlene.spencer@ed.gov.* You must include the phrase ''Proposed Priority for DRRP to serve as the Center'' in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Marlene Spencer. Telephone: (202) 245–7532 or by email: *marlene.spencer@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This notice of proposed priority is in concert with NIDRR's currently approved Long-Range Plan (Plan). The currently approved Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8166), can be accessed on the Internet at the following site: *http://www2.ed.gov/legislation/FedRegister/other/2006-1/021506d.pdf.*

Through the implementation of the currently approved Plan, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

This notice proposes a priority that NIDRR intends to use for a DRRP competition in FY 2013 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities, if needed. Furthermore, NIDRR is under no obligation to make an award using this priority. The decision to make an award will be based on the quality of applications received and available funding.

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priority, we urge you to identify clearly the specific topic that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in room 5133, 550 12th Street, SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, and to develop methods, procedures, and rehabilitation technology that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Disability and Rehabilitation Research Projects

The purpose of NIDRR's DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, are to improve the effectiveness of services authorized under the Rehabilitation Act by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: research, training, demonstration, development, dissemination, utilization, and technical assistance.

Additional information on the DRRP program can be found at: *www.ed.gov/rschstat/research/pubs/res-program.html#DRRP.*

Program Authority: 29 U.S.C. 762(g) and 764(a).

Applicable Program Regulations: 34 CFR part 350.

Proposed Priority:

This notice contains one proposed priority.

DRRP to Serve as the Center on Knowledge Translation for Technology Transfer (Center).

Background:

Knowledge translation (KT) is a process to ensure that new knowledge and products gained through research and development will ultimately be used to improve the lives of individuals with disabilities and further their participation in society. Technology transfer is a subset of knowledge translation that focuses on ensuring that

technology-based knowledge and products will be transferred into tangible benefits for individuals with disabilities through commercialization, engineering standards, freeware, and other tangible applications.

Under section 200(3) of the Rehabilitation Act, NIDRR is charged with promoting the transfer of rehabilitation technology to individuals with disabilities. NIDRR carries out this responsibility through the Rehabilitation Engineering Research Centers (RERC) and Small Business Innovation Research (SBIR) programs. NIDRR has long required RERCs to develop technology transfer plans. In analyzing grantee performance information, NIDRR determined that it would be useful to provide technical assistance to grantees to improve the rates of technology transfer. NIDRR's concerns were supported by findings from a recent retrospective case study analysis indicating that, while a majority of development projects supported by RERC grants result in prototypes, only a quarter of those projects have evidence of transfer into broader uses (Lane, 2008). More information on technology research funded by NIDRR can be found at: *www.naric.com/research/pd/results.cfm?type=priority&display=detailed&criteria=Technology for Access and Function.*

Transfer of rehabilitation technology products is often difficult because of the small market for each product. Often, the broader technology transfer field does not provide guidance that is directly applicable to technology transfer in the rehabilitation technology area. Thus, there is a need to continue to build a body of knowledge that will advance understanding and practices of technology transfer for rehabilitation technology products.

To support, promote, and improve the technology transfer of its RERC, SBIR, and other technology grantees, NIDRR will fund a Disability and Rehabilitation Research Project (DRRP) on Knowledge Translation for Technology Transfer.

References:

Lane, J. (2008). Delivering on the 'D' in R&D: Recommendations for Increasing Transfer Outcomes From Development Projects. Assistive Technology Outcomes and Benefits, Fall 2008 Special Issue. Retrieved 10/15/2012 from *www.atia.org/files/public/ATOBSIF2008.pdf.*

Proposed Priority:

The Assistant Secretary for Special Education and Rehabilitative Services establishes a priority for a Disability and Rehabilitation Research Project to serve as the Center on Knowledge Translation for Technology Transfer (Center). The Center must conduct rigorous research, development, technical assistance, dissemination, and utilization activities to increase successful technology transfer of rehabilitation technology products and devices developed by NIDRR-funded technology grantees.

In planning and conducting all activities, the Center must partner with relevant stakeholders such as NIDRR's technology grantees, trade and professional associations, industry representatives, individuals with disabilities, and others.

Under this priority, the Center must be designed to contribute to the following outcomes:

(a) Increased rate of successful technology transfer of rehabilitation technology products developed by NIDRR-funded technology grantees to the marketplace, into engineering standards, or into other intended applications;

(b) Increased understanding among rehabilitation engineers and others engaged in disability research and development of technology transfer processes and practices that lead to successful transfer of rehabilitation technology products to the marketplace, into engineering standards, or into other intended applications;

(c) Increased capacity of NIDRR's technology grantees to plan and to engage in technology transfer activities.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority:

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563:

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

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

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and

taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing this proposed priority only upon a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Programs have been well established over the years in that similar projects have been completed successfully. This proposed priority would generate new knowledge through research and development. Another benefit of this proposed priority is that the establishment of new DRRPs would improve the lives of individuals with disabilities. The new DRRP would generate, disseminate, and promote the use of new information that would improve employment opportunities for individuals with disabilities.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 9, 2013.

Michael Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2013–00580 Filed 1–14–13; 8:45 am]

BILLING CODE 4000–01–P

FEDERAL COMMUNICATIONS COMMISSION

[MB Docket No. 07–294; FCC 12–166]

Promoting Diversification of Ownership in the Broadcasting Services

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, the Commission seeks further comment on its requirement that licensees and other entities filing the FCC Form 323, Ownership Report for Commercial Broadcast Station, provide an FCC Registration Number (FRN) generated by the Commission's Registration System (CORES) (CORES FRN) for attributable individuals reported on the Form 323. The *Sixth Further Notice of Proposed Rulemaking* (Sixth FNPRM) also seeks comment on the Commission's proposal to eliminate the ''Special Use'' FRN for individuals reported on the Form 323 and on a proposal to amend the Form 323–E, Ownership Report for Noncommercial Educational Broadcast Station to require filers to report the CORES FRN for individuals with attributable interests in licensees reported on the Form 323–E. The Commission also invites comment on whether it should extend the CORES FRN requirements, as they apply to entities and individuals, to any non-attributable interest holders that the Commission might ultimately conclude should be reported on the Form 323, as proposed by the *Fifth Further Notice of Proposed Rulemaking* (Fifth FNPRM). Finally, comment is sought on a proposal to extend the biennial ownership report filing period and on proposed revisions to the Form 323 as submitted in comments in the *Review of Media Bureau Data Practices* proceeding.

DATES: The Commission must receive written comments on or before February 14, 2013 and reply comments on or before March 1, 2013. Written comments on the Paperwork Reduction Act (PRA) proposed information collection requirements must be submitted by the public, Office of Management (OMB) and other interested parties on or before March 18, 2013.

ADDRESSES: You may submit comments, identified by MB Docket. No. 07–294, by any of the following methods:

- *Federal Communications Commission's Web Site: http://fjallfoss.fcc.gov/ecfs2/.* 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* or phone 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Judith Herman of the Media Bureau, Industry Analysis Division, at (202) 418–2330. For additional information concerning the

Paperwork Reduction Act information collection requirements contained in the *Notice of Proposed Rulemaking* contact Cathy Williams at (202) 418–2918 or send an email to *PRA@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Sixth Further Notice of Proposed Rulemaking in MB Docket No. 07–294, FCC 12–166, adopted December 21, 2012, and released January 3, 2013. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. These documents will also be available via ECFS (*http://fjallfoss.fcc.gov/ecfs/*) and may be purchased from the Commissions copy contractor, BCPI, Inc. at their Web site *http://www.bcpi.com* or call 1–800 378–3160.

Initial Paperwork Reduction Act of 1995 Analysis

This *Notice of Proposed Rulemaking* may result in a new or revised information collection requirement. If the Commission adopts any new or revised information collection requirements, the Commission will publish a notice in the **Federal Register** inviting the public to comment on the requirement, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501–3520). In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the commission seeks further comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

Summary of the Sixth Further Notice of Proposed Rulemaking

I. Introduction

1. In this *Sixth FNPRM,* we seek further comment on the Commission's requirement that licensees and other entities filing the FCC Form 323, Ownership Report for Commercial Broadcast Station, provide an FCC Registration Number (FRN) generated by the Commission's Registration System (CORES) (CORES FRN) for attributable individuals reported on Form 323. Obtaining a CORES FRN requires users to identify themselves uniquely. This unique identification is achieved by requiring users to submit their taxpayer identification number (TIN), which for entities is generally their employer identification number (EIN) and for individuals is generally their social security number (SSN). As discussed below, unique identification of entities and individuals filing and being reported on Form 323 is crucial to ensuring the accuracy and reliability of Form 323 data and the usefulness of those data to the Commission and other researchers.

2. We seek comment herein also on eliminating the interim, ''Special Use'' FRN alternative to obtaining a CORES FRN for individuals reported on Form 323. The Commission has long required licensees and other entities filing Form 323 to obtain and provide a CORES FRN. The revised Form 323, adopted in 2009 pursuant to the *323 Order,* 74 FR 25163 (2009), and the *323 MO&O,* 74 FR 56131 (2009) in this proceeding, requires filers to obtain and include a CORES FRN not only for themselves but also for entities and individuals whose attributable interests are reported on the form. Two parties sought reconsideration of the requirement to obtain CORES FRNs for individuals holding attributable interests, arguing that the CORES FRN requirement for individuals is overly burdensome and raises privacy and data security issues and that the Commission provided inadequate notice of this requirement. To address the concerns of the petitioners and others who raised this issue in comments, the Media Bureau implemented a ''Special Use'' FRN as an alternative, temporary measure to obtaining a CORES FRN for individuals holding attributable interests reported on the form. The Special Use FRN allows Form 323 filers to obtain an FRN for use with Form 323 for such individuals without submitting a TIN through CORES. As a rule, all filers must provide an FRN for all persons and entities reported on Form 323. If, after using diligent and good-faith efforts, a filer is unable to obtain or does not have permission to use an SSN in order to generate an FRN for an individual holding an attributable interest in the licensee, the filer may use the Special Use FRN. Filers who use a non-SSN based Special Use FRN will be deemed fully compliant with the Form 323 filing obligation for purposes of the 323 filing, and the lack of SSN-based FRNs in response to Section II, Question 3(a) and will not subject Respondents to enforcement action. We now seek comment on eliminating this temporary measure. We also seek comment on our proposal to permit filers to use a Special Use FRN solely in instances where the filer is unable to obtain a CORES FRN from an individual with reportable interests.

3. In addition, we seek comment on our proposal to amend the Form 323–E, Ownership Report for Noncommercial Educational Broadcast Station, to require filers to report a CORES FRN for individuals with attributable interests in licensees reported on this form. Further, we seek comment on whether we should extend the CORES FRN requirements, as they apply to entities and individuals, to any non-attributable interest holders that we might ultimately conclude should be reported on Form 323, as proposed in the *Fifth FNPRM.* Finally, we seek comment on our proposal to extend the biennial ownership report filing period and on the proposed revisions to Form 323 submitted in comments in the *Review of Media Bureau Data Practices* proceeding.

II. Background

4. It has been a longstanding goal of the Commission to promote diverse ownership of broadcast stations, including ownership by women and minorities. In order to gather accurate and usable data about these and other ownership categories, the Commission substantially revised its biennial ownership reporting form in 2009. As the Commission previously has stated, the changes to the filing requirements and the modifications to the form are intended to facilitate long-term comparative studies of broadcast station ownership. In addition, the changes address flaws in the data collection process identified by the United States Government Accountability Office (GAO) and by researchers who have attempted to use the data submitted on previous versions of Form 323. In 2008, GAO cited several shortcomings with the Commission's data collection process: (1) Exemptions from the biennial filing requirement for certain types of broadcast stations; (2) inadequate data quality procedures; and (3) problems with data storage and retrieval. To address GAO's concerns and to improve the quality and suitability of the data for the Commission's use, the Commission adopted several significant changes. First, it set a uniform ''as of'' date of October 1 for the ownership data being reported in the biennial filing and established a uniform filing deadline for the data of November 1. Thus, all filers must report their ownership interests as they exist on the ''as of'' date of the filing year and submit their reports no later than one month thereafter. These uniform dates make it possible to discern statistically valid trends in minority and female ownership over time, which was not possible using the previous rolling filing procedures, and ensure timely collection of the data. Second, the Commission also expanded

the class of licensees that must file the report biennially to include sole proprietors and partnerships of natural persons as well as low-power television and Class A licensees.

5. Third, the Commission delegated to the Media Bureau authority to (1) Revise Form 323's electronic interface so that the ownership data incorporated into the database are searchable, and can be aggregated and cross-referenced; (2) build additional checks into Form 323 to perform verification and review functions; and (3) conduct audits to ensure the accuracy of the Form 323 reports. The Commission also stated that ''to further improve the ability of researchers and other users of the data to cross-reference information and construct complete ownership structures, we will require each attributable entity above the licensee in the ownership chain to list on Form 323, the [CORES] FRN of the entity in which it holds an attributable interest.'' This requirement to reference the next layer down in an ownership chain by using a unique identifier, the FRN, fulfills a need for unmistakable identity in the face of often complex ownership structures involving numerous parties and multiple layers or links in the ownership chain, a need which cannot be fulfilled by identification based entirely on names and addresses. In other words, the Commission concluded that without a single, unique identifier, researchers could not confirm the accuracy of aggregated records. While the Commission believed that these measures would resolve concerns regarding the usefulness of the data, it nevertheless delegated authority to the Media Bureau staff to revisit the CORES FRN issue if it determined that additional changes were necessary. In response, the Media Bureau revised and improved the instructions and questions in all sections of the form in order to (1) Clarify the information sought in the form, (2) ensure that the data are collected in machine-readable formats that can be incorporated in database programs used to prepare economic and policy studies, and (3) simplify completion of the form by giving respondents menu-style or checkbox-style options to enter data. The Bureau also included built-in edit checks and pre-fill capabilities to assure greater accuracy and ease of completion.

6. On August 11, 2009, the Commission submitted the revised Form 323 to the Office of Management and Budget (OMB) for approval pursuant to the Paperwork Reduction Act (PRA) requirements and published the **Federal Register** notice initiating a 60-day comment period. Among other things, the revised form required each filer to include a CORES FRN of entities one step above and one step below it in the ownership chain and to identify the CORES FRNs of its attributable officers, directors, and shareholders reported on the form. Many of the commenters in their comments to OMB objected to having to report CORES FRNs for individuals holding attributable interests, arguing that in order to obtain a CORES FRN from these individuals, they would need to provide SSNs to the Commission, a requirement that they claimed triggers privacy, data security, and identity theft concerns. Commenters also suggested that obtaining and reporting CORES FRNs for these individuals would be onerous and would present a hardship to filers, and that in some cases, filers might be unable to obtain a CORES FRN for all individual attributable interest holders because the individuals are unwilling to either obtain the FRN themselves or provide their SSN to the filer for the purpose of obtaining an FRN. Additionally, commenters criticized the Commission for failing to seek comment on requiring these individuals to obtain CORES FRNs prior to including this requirement on the revised form submitted for OMB approval. They also claimed that the decision was inconsistent with the CORES FRN requirement applicable to wireless licensees, who, they alleged, are not required to provide CORES FRNs or other similar information for officers, directors, and board members. Two Petitions for Writs of Mandamus were filed with the Court of Appeals for the D.C. Circuit to stay the FCC from implementing revisions to the form. Both were denied.

7. On October 6, 2009, the Commission submitted a letter to OMB in response to the comments. The FCC's response explained that requiring CORES FRNs on Form 323 is an integral part of the Commission's effort to ''improve the quality, reliability, and usability of the collected data by eliminating inconsistencies and inadequacies in the data submitted.'' The Reply Letter identified the CORES FRN as a key tool for ensuring that the ownership data is matched with specific owners. Also, without the CORES FRNs, the Commission explained that it would be unable to accurately determine the identity of a person when variations of a single name or other spelling irregularities appear from form to form. The Reply Letter also noted that the FRN has been used as a unique identifier for reports that collect data on individuals and entities that hold attributable interests in wireless services and concluded that requiring filers to provide a CORES FRN for individual attributable interest holders on the Form 323 ''will allow the Commission to harmonize its processes between different licensing divisions and directly improve the quality and usefulness of the collected data * * *.'' The Reply Letter rejected allegations that the Commission failed to comply with the notice requirements of the PRA. After the Commission submitted the revised form to OMB, the Commission issued a further order, the *323 MO&O,* and explained that each filer was required to identify the CORES FRNs of its attributable officers, directors, and shareholders, explaining ''[i]n the process of modifying Form 323 on delegated authority, the Bureau determined that it was necessary to expand the class of [CORES] FRNs to be included to ensure the usefulness of the data.''

8. On October 19, 2009, OMB approved the revised Form 323, including the requirement that filers identify the CORES FRN for individuals holding an attributable interest in the licensee. After several delayed filing deadlines, the Commission set July 8, 2010, as the first biennial filing deadline using the revised form. Generally, the Bureau's experience during the filing process was that most filers complied with the CORES FRN requirement. Nevertheless, in response to industry concerns about filers' ability to obtain FRNs from all individuals holding attributable interests due to individuals' concerns about privacy, security, and identify theft, the Bureau allowed filers, as an interim measure, to obtain a Special Use FRN for individuals reported on the form in lieu of obtaining a CORES FRN. Individuals do not need to provide an SSN in order to generate the Special Use FRN.

9. In December 2010, the Commission initiated a rulemaking proceeding in which it proposes to update CORES in an effort to enhance the Commission's data collection efforts and to improve customer interface with CORES. In the Notice of Proposed Rulemaking, the Commission noted that, ''[s]ince the creation of CORES, entities have been able to obtain multiple FRNs in order to permit different members of their corporate family to obtain their own individual FRNs, regardless of whether those entities have different taxpayer identification numbers * * *'' The Commission stated that it has had difficulty using CORES to identify all FRNs held by the same entity when entities have not provided TINs or have provided inconsistent TINs. It also

observed that some filers erroneously invoked exceptions to the general requirement to provide a TIN and that these entities or individuals also would be difficult to track. The Commission has proposed several options to resolve these issues. In addition, the Commission has asked whether it should expand the availability of ''special use'' FRNs for purposes other than the filing of Form 323.

10. In July 2011, the Court of Appeals for the Third Circuit, as part of its review of the Commission's media ownership rules, vacated and remanded certain aspects of the *Diversity Order.* The court concluded that the Commission's decision to adopt a revenue-based eligible entity definition to facilitate ownership diversity was arbitrary and capricious because the Commission did not show how such a definition specifically would assist minorities and women, who were among the intended beneficiaries of this action. The court also remanded each of the measures adopted in the *Diversity Order* that relied on the revenue-based definition. The court found that the eligible entity definition was not supported by ''data attempting to show a connection between the definition chosen and the goal of the measures adopted—increasing ownership of minorities and women,'' stressing that regulations seeking to increase female and minority ownership must be based upon reliable data. The court stated, ''At a minimum, in adopting or modifying its rules the FCC must 'examine the relevant data and articulate a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made.' '' The court also made plain that ''[i]f the Commission requires more and better data * * * it must get the data.'' The court stated that the actions taken in the *Order and Fourth FNPRM* to reliably analyze minority and female ownership ''will, however, lay necessary groundwork for the Commission's actions on remand.''

III. Discussion

11. By this *FNPRM,* we seek to supplement the record regarding the use of CORES FRNs. First, we tentatively affirm the Commission's prior determination that the use of CORES FRNs as unique identifiers is necessary in order to improve the quality of the data collected on Form 323, and we propose to discontinue the Special Use FRN for Form 323. We propose to require all individual attributable interest holders to obtain a CORES FRN and to require all Form 323 filers to provide the CORES FRN for these individuals. Second, we seek comment on whether we should require the individual and entities holding non-attributable interests that would be reportable on the Form 323 under the proposal set forth in the *Fifth FNPRM* to obtain a CORES FRN and require all Form 323 filers to report these CORES FRNs. Third, we seek comment on revising Form 323–E to include the same CORES FRN and attributable interest reporting obligations as those applicable to Form 323. Finally, we seek comment on proposed revisions to the Form 323 submitted in comments in the *Review of Media Bureau Data Practices* proceeding.

12. *Elimination of Special Use FRN for Form 323.* Special Use FRNs do not afford the Commission a reliable means of tracing a reported interest holder to a unique individual and their use therefore undermines the purpose of our data collection effort, which seeks to accurately ascertain the nature and extent of minority and female ownership of broadcast properties. Without the ability to track an FRN to a unique individual, it may be difficult, if not impossible, to accurately cross-reference broadcast ownership interests. The Third Circuit has highlighted the importance of collecting reliable data to support the Commission's rulemaking initiatives.

We seek comment on the use of the CORES FRN as a means of associating non-unique information (names, addresses, race, gender, and ethnicity) with a unique identifier for data quality, searchability, cross-referencing, and aggregation purposes solely for use with FCC Form 323 as a means of identifying attributable interests. How effective, relatively speaking, is the CORES FRN as a unique identifier for the Commission's purposes? If no unique numeric or other identifier is associated with an ownership record, how can researchers and other members of the public adequately verify and/or make use of the collected data? How can complete ownership structures be compiled reliably? What alternatives are there to the use of the CORES FRN as a unique identifier? We invite comment on other measures the Commission could use as a unique identifier in lieu of the CORES FRN and its underlying TIN basis.

13. We tentatively affirm the Commission's prior determination that the use of CORES FRNs as unique identifiers is necessary in order to improve the quality of the data collected on Form 323, and we propose to eliminate the availability of Special Use FRNs and require the universal use of CORES FRNs for all biennial and non-biennial Form 323s. We tentatively conclude that such unique identification is essential to providing the kind of searchable and manipulable database needed to support accurate and reliable studies of ownership trends. We also tentatively conclude that the reporting of CORES FRNs on Form 323 that are obtained after supplying the Commission with a TIN is superior to reporting the Special Use FRNs now permitted for individuals. We seek comment on these tentative conclusions, and particularly encourage those who may have used the dataset created from the first set of Form 323 biennial filings that were required to include FRNs for attributable entities and individuals to address these issues. Furthermore, the use of CORES FRNs is consistent with Commission precedent in the wireless services context, as applicable to attributable interest holders. We seek comment on any justifications to treat broadcasters differently with respect to CORES FRN requirements.

14. We note that other government agencies also use SSNs when necessary to ensure program integrity and for statistical and research purposes. For example, the Census Bureau uses SSNs reported on income tax returns in order to prepare annual population estimates for states and counties to determine immigration rates between localities. The Department of Agriculture has statutory authority to collect the SSNs of both food stamp recipients and officers and owners of retail and wholesale food concerns that accept and redeem food stamps. The Small Business Administration (SBA) requires that applicants for SBA-backed loans provide their past business and personal income tax returns, which contain their SSNs. The Department of Housing and Urban Development (HUD) requires SSNs as a condition of eligibility for participation in HUD programs involving loans, grants and other assistance. The Veterans Administration requires individuals to provide their SSNs to be eligible for compensation or pension benefits programs. The Treasury collects the SSNs of all savings bond purchasers. The Department of Labor requires all workers compensation claimants to provide an SSN. The Department of Homeland Security uses SSNs in its E-Verify database as the basis for its employment verification system. Health and Human Services collects SSNs to verify citizenship status. Agencies also collect and share SSNs for purposes of collecting debts owed to the government, as well as using employees'

SSNs for activities such as payroll, wage reporting, and providing employee benefits. We seek comment on the use of SSNs as unique identifiers by other governmental agencies as it relates to the Commission's proposed CORES FRN requirement for individuals.

15. Although we are seeking comment in our separate CORES proceeding on measures to improve the CORES FRN system and the possible expansion of special use FRNs, we tentatively conclude that it is not necessary to await the outcome of that proceeding to improve further the Form 323 data collection process by discontinuing the Special Use FRN for Form 323. Unlike many of our filing obligations, the fundamental objective of the biennial Form 323 filing requirement is to track trends in media ownership by individuals with particular racial, ethnic, and gender characteristics. In this context, it is especially critical to ensure that we can identify uniquely each individual reported on the form. As noted above, the Commission cannot ensure that each individual is assigned only one Special Use FRN and that it is used consistently throughout the Form 323 reporting process because no unique identifier is available to track the Special Use FRN back to a single individual. For instance, CDBS does not have any mechanism to prevent a filer from obtaining multiple Special Use FRNs for the same individual. In contrast, even though multiple CORES FRNs can be obtained by the same individual or entity, the SSN or TIN underlying these FRNs generally permits the Commission to identify the specific person or entity using any such FRNs in a Commission report or form. Because CORES FRNs are backed by a TIN whereas Special Use FRNs are not backed by any unique identifier, the CORES FRN offers a superior means of sorting and aggregating Form 323 data. We seek comment on these views.

16. We also seek comment on the costs and benefits of eliminating the Special Use FRN for Form 323. Commenters objecting to the CORES FRN requirement for individuals with attributable interests that are reported on the form argue that the requirement would be burdensome. In the Reply Letter, the Commission disagreed that the process is as onerous as commenters describe. Filers must only register one time to obtain a CORES FRN, which can be used for current and all future Form 323 filings and other Commission filings. The CORES database registration process takes only a few moments to complete and users easily can obtain previously-registered CORES FRNs using the search tool in CORES. Moreover, in addition to not being a burdensome requirement, the CORES FRN is an essential part of the Commission's effort to improve the reliability, quality, and usability of the data collected, as the Commission as noted in identifying the CORES FRN as a key tool for ensuring that ownership data are matched with specific owners. Is the requirement to obtain a CORES FRN for individual attributable interest holders onerous on small businesses? On large corporations? On individuals? A small number of commercial broadcast licenses are held by governmental entities, tribal organizations, and not-for-profit groups. Is compliance with the CORES FRN requirement more burdensome for these entities? What factors contribute to any difficulties businesses may have in complying with the CORES FRN requirement? On balance, we believe the benefits of the proposed revisions will outweigh any costs. We seek comment on this analysis. Commenters should describe the benefits and any costs associated with eliminating the Special Use FRN or with any alternative proposal, explain any underlying assumptions, submit all relevant data and, if possible, quantify the potential effects.

17. We also seek comment on whether we should continue to allow filers to obtain a Special Use FRN solely in instances where, after reasonable and good faith efforts, they are unable to obtain a CORES FRN from an individual with reportable interests. We expect that filers will either obtain a CORES FRN for such individuals after obtaining the individuals' SSNs in order to do so, or, if the individuals are reluctant to disclose their SSNs to the filer, to instruct such individuals how to obtain a CORES FRN on their own. As we have noted before, this latter approach would avoid the need for individuals to disclose their SSNs to any party other than the Commission. In the event that an individual is unwilling to provide the filer with sufficient information for it to obtain a CORES FRN and is unwilling to obtain and provide a CORES FRN separately, we wish to ensure that a filer will still be able to timely file a Form 323 and to report the recalcitrant attributable interest holder. To permit this and to identify individuals who have failed to provide the required FRN, we seek comment on whether we should reserve the use of special use FRNs solely for those cases in which an individual with a reportable interest has failed to provide a responsible filer with a valid CORES FRN or to provide the filer with the means of obtaining one. We note that in such instances, the Commission can use its enforcement authority to impose a forfeiture against such individuals. In this connection, we also seek comment on whether we should require filers to notify individuals with reportable interests of the Commission's enforcement authority in such instances.

18. We also invite comment on any privacy concerns the CORES FRN requirement may raise as it relates to Form 323 and the identification of attributable interests. CORES FRNs are intended to provide a unique identification system for entities and individuals that does not require the disclosure of a TIN or SSN on Commission applications and forms. TIN data are needed only to obtain a CORES FRN in the first instance and those data are secured by the Commission and not used publicly. Does this requirement raise any potential adverse consequences? We invite comment in particular on the applicability of the Privacy Act to the CORES FRN requirement. The Commission does not consider sole proprietors and officers and directors to be persons who are subject to the Privacy Act of 1974, as amended, since they are acting in an entrepreneurial capacity. In addition, the Commission already has adopted Privacy Act Systems of Records for the CORES system and for the Form 323 requirement, which apply to any personally identifiable information required by the Form 323 and by CORES in connection with the FRN registration process. We tentatively conclude that the Privacy Act does not bar our adoption of the CORES FRN proposals discussed in this Further Notice. To the extent commenters believe the requirement presents a risk of any adverse consequences affecting individuals' privacy, what is the degree of risk involved and is it outweighed by the benefits of obtaining more accurate and verifiable ownership data?

19. We also invite comment as to whether it is necessary to clarify that any individual with reportable interests must obtain an FRN. Currently, our rules do not explicitly require these individuals to obtain an FRN. Rather, the Form 323 requires licensees and other respondents to report the FRN of individuals holding attributable interests. A requirement for individuals with reportable interests to obtain FRNs would address concerns that filers may be unable to obtain FRNs from unwilling individual attributable interest holders. In this regard, we seek comment on Petitioner Koerner &

Olender's request to ''redefine or reinterpret'' § 1.8002 of our rules, which establishes the Commission's generic FRN requirement, to include within the scope of the rule the holders of interests reportable on Form 323. Section 1.8002 states that persons ''doing business'' with the Commission must obtain an FRN and lists examples of the types of activities or interests that trigger the requirement. It does not state that the listed categories are the only circumstances under which an entity or individual must obtain an FRN. In the wireless context, the Commission has determined that individuals holding attributable interests in wireless licensees are ''doing business with'' the Commission and that wireless licensees must provide the FRNs for such individuals on the Form 602, FCC Ownership Disclosure Information for the Wireless Telecommunications Services. Should we amend § 1.8002 to explicitly include any interests of individuals or entities that are reportable on Form 323, either because the holders of these interests are deemed to be ''doing business'' with the Commission or because the Commission has, for other reasons, determined that these interest-holders should obtain an FRN? We seek comment on these matters, including comments on the costs and benefits of any rule amendment.

20. *Requiring CORES FRNs for additional reportable interests.* In the *Fifth FNPRM,* we are concurrently seeking comment on whether to expand the biennial ownership reporting requirement to include interests, entities and individuals that are not attributable because of (a) the single majority shareholder exemption and (b) the exemption for interests held in eligible entities pursuant to the higher EDP threshold. We propose herein that if the Commission requires these interest holders to be reported on the biennial ownership form, they should be required to obtain and provide CORES FRNs. We seek comment on what impact such a requirement would have on these interest holders and whether the benefits of unique identification described above are equally applicable to individuals subject to such a requirement. Would a CORES FRN requirement for these interest holders present different burdens for small businesses, other types of firms, or individuals? Would this requirement present privacy concerns? As requested above, commenters should address in detail the costs and benefits of expanding the existing FRN requirements to the additional interests at issue in the *Fifth FNPRM.*

21. *Reporting FRNs on Form 323–E.* We also seek comment on our proposal to require that CORES FRNs be provided for all entities and individuals reported on Form 323–E, Ownership Report for Noncommercial Broadcast Stations. In the *323 Fourth FNPRM,* the Commission sought comment on whether to modify the Form 323–E to include gender, race, or ethnicity data questions, similar to the revisions adopted in the *323 Order* in order to further the Commission's goal of advancing diversity of ownership in the broadcast industry. NPR objects to extending the CORES FRN requirement to Form 323–E, contending that it raises ''unique privacy issues and administrative burdens'' for the noncommercial sector. In comments submitted in response to the *323 Fourth FNPRM,* NPR states that in many instances the governing board members are elected officials, or political appointees, who are volunteers that are not compensated for their services. Therefore, NPR argues that none of these board members would hold any equity interest in the station and would not provide meaningful ''ownership'' information to the Commission. We seek comment on this view. Are there unique attributes of noncommercial broadcasters, or of the ownership structure of noncommercial entities, that would make the application of an FRN requirement for their officers and directors particularly burdensome? Generally, we seek comment on the benefits, potential costs or other effects, and possible alternatives to imposing the same CORES FRN requirements on Form 323–E filers and holders of reportable interests as those applicable to Form 323 filers and attributable interest holders. Are there other advantages or drawbacks to applying these requirements to the Form 323–E? If the Commission elects not to include a CORES FRN requirement for individuals with attributable interests reported on Form 323–E, how can it ensure the accuracy of the data submitted? What alternatives to the CORES FRN, if any, are available that could provide sufficient data verification? We invite comment on these issues. Commenters should describe the benefits and costs of applying the existing FRN requirements to the Form 323–E or any alternative proposal, explain any underlying assumptions, submit all relevant data and, if possible, quantify the potential effects.

22. *Due date for Biennial Ownership Reports.* Currently, 47 CFR 73.3615(a) requires biennial reports to be filed by November 1 of odd-numbered years and states that each report must be accurate as of October 1 of the year in which it is filed. In order to provide parties with additional time to complete and submit their reports, we propose to move the due date from November 1 to December 1, with the October 1 ''as of'' date unchanged. We believe that providing filers with an additional 30 days to produce the Form 323 report will lead to more accurate reporting, and will not significantly delay the collection of data. We seek comment on this proposal.

23. *Proposals submitted in the Review of Media Bureau Data Practices proceeding.* We also are seeking comment on proposals regarding the Form 323 that were submitted in the *Review of Media Bureau Data Practices* proceeding, which was initiated ''to improve the way the Commission collects, uses and disseminates data.'' In that proceeding, the Bureau encouraged commenters to provide recommendations regarding: (1) The use and rationale of its existing data collections, (2) additional data that should be collected, (3) how it can improve the collection and analysis process for its existing collections, and (4) how it may improve the dissemination of its reports and analyses. Based on its experiences completing the revised Form 323, NAB suggests that the Commission modify the electronic version of Form 323 to allow for cross-referencing to information on other reports. Second, NAB suggests that an entity with several wholly-owned licensee subsidiaries should be able to list all of the licensees (and their respective stations) in Section I, Item 7. We seek comment on this proposal and ask whether it should be limited to wholly-owned subsidiary licensees or whether a parent entity instead should be able to list all the licensees in which it has an attributable interest (and their respective stations) in Section I, Item 7. We believe that such a change will significantly reduce the filing burdens on some entities, without compromising the data collected. NAB also proposes that the Bureau consider eliminating Section II–B, Item 3(c) as duplicative. NAB further suggests that the Commission modify the instructions to Form 323 to eliminate inconsistent information, such as the instructions for Section II–B, Items 1, 3(a), and 3(c). MMTC recommends simplifying the public display of Form 323 filings; requiring only one Form 323 filing per station with all the racial/ethnic/gender ownership of the attributable interest holders; creating a separate filing

category for transfers to bankruptcy trustees, debtors-in-possession or trusts; and changing from a biennial filing to an annual filing requirement. Accordingly, we seek comment on these proposals regarding Form 323, including the costs and benefits of these proposals.

IV. Procedural Matters

24. *Ex Parte Rules.* The proceeding this FNPRM initiates shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with § 1.1206(b). In proceedings governed by § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

25. *Comments and Reply Comments.* 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://fjallfoss.fcc.gov/ecfs2/.*
- Paper Filers: Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.

26. *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Initial Regulatory Flexibility Analysis

27. As required by the Regulatory Flexibility Act of 1980, as amended (''RFA''), the Commission has prepared this Initial Regulatory Flexibility Analysis (''IRFA'') of the possible economic impact on small entities by the policies and rules proposed in this *Sixth FNPRM.* Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the *FNPRM.* The Commission will send a copy of the *FNRPM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (''SBA''). In addition, the *FNPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.

28. *Need for, and Objectives of, the Proposed Rules.* The *FNPRM* invites comment on the Commission's prior determination that the use of CORES FRNs as unique identifiers is necessary in order to improve the quality of the data collected on the Form 323 and on the proposal to eliminate the ''Special Use'' FRN feature for the Form 323. The *FNPRM* also seeks comment on the burdens of eliminating the Special Use FRN, of requiring all individual holders of interests reportable on the Form 323 to obtain an FRN through the Commission's Registration System (CORES), and of requiring all filers of Form 323 to report the FRNs for these individuals. The *FNPRM* invites comment on the use of social security numbers as unique identifiers by other governmental agencies as it relates to the Commission's proposed CORES FRN requirement for individuals.

29. The objective of the information collection undertaken to establish a CORES FRN is to obtain a special, unique identifier that will allow the Commission and researchers to cross-reference information and create complete ownership structures in order to promote its long standing goal to promote diverse ownership of broadcast stations, including by women and minorities.

30. The *FNPRM* also notes that the Commission, in the *Fifth FNPRM,* is concurrently seeking comment on whether to expand the biennial ownership reporting requirement to include interests, entities and individuals that are not attributable because of (a) the single majority shareholder exemption and (b) the exemption for interests held in eligible entities pursuant to the higher EDP threshold. If the Commission requires these interest holders to be reported on the biennial ownership form, the Commission proposes, in this *FNPRM,* that these interest holders should be required to obtain and provide CORES FRNs. The *FNPRM* invites comment on the impact of this requirement on these interest holders and whether the benefits of unique identification described in the *FNPRM* are equally applicable to individuals subject to such a requirement. As described at paragraph 13 of the *FNPRM,* a unique identifier is essential to providing the searchable database necessary to support accurate and reliable studies of ownership trends.

31. The *FNPRM* also seeks comment on the Commission's proposal to require

that CORES FRNs be provided for all entities and individuals reported on Form 323–E, Ownership Report for Noncommercial Broadcast Stations. Based on potential unique attributes of noncommercial entities, the Commission seeks comment on whether the proposed data collection imposes a significant burden for such entities, which may be smaller entities by nature. The Commission also seeks comment on the usefulness, potential effects, and possible alternatives to imposing the same CORES FRN requirements on Form 323–E filers and holders of reportable interests as those applicable to Form 323 filers and attributable interest holders.

32. The *FNPRM* also seeks comment on a proposal to amend the Commission's rules to clarify that an individual with reportable interests must obtain a CORES FRN. The Commission also invites comment on whether the Commission should reserve the use of Special Use FRNs solely for cases in which an individual with a reportable interest has failed to provide the filer with sufficient information for it to obtain a CORES FRN and is unwilling to obtain and provide a CORES FRN separately. The Commission also seeks comment on whether it should require filers to notify individuals with reportable interests of the Commission's enforcement authority to impose a forfeiture against such individuals.

33. The Commission invites comment on its proposal to extend the filing period for the Biennial Ownership Reports by moving the due date from November 1, to December 1, with the October 1 ''as of'' date unchanged. The *FNPRM* also invites comment on the proposed revisions to Form 323 that were submitted in the *Review of Media Bureau Data Practices* proceeding. The Commission also seeks comment on NAB's proposal in that proceeding that an entity with several wholly-owned licensee subsidiaries should be able to list all of the licensees and respective stations in Section I, Item 7 of the Form 323 and asks whether the proposal should be limited to wholly-owned subsidiary licensees or whether a parent entity instead should be able to list all the licensees in which it has an attributable interest in Section I, Item 7.

34. *Legal Basis.* This *FNPRM* is adopted pursuant to sections 1, 2(a), 4(i)–(j), 257, and 303(r), of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i, j), 257, 303(r).

35. *Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply.* The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction'' under Section 3 of the Small Business Act. In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

36. *Television Broadcasting.* In this context, the application of the statutory definition to television stations is of concern. The Small Business Administration defines a television broadcasting station that has no more than $14 million in annual receipts as a small business. Business concerns included in this industry are those ''primarily engaged in broadcasting images together with sound.'' The Commission has estimated the number of licensed commercial television stations to be 1,387. According to Commission staff review of the BIA Kelsey Inc. Media Access Pro Television Database as of May 2, 2012, 1070 (77 percent) of the 1,399 commercial television stations in the United States have revenues of $14 million or less. The Commission has estimated the number of licensed noncommercial educational television stations to be 396. We do not have revenue data or revenue estimates for noncommercial stations. These stations rely primarily on grants and contributions for their operations, so we will assume that all of these entities qualify as small businesses. We note that in assessing whether a business entity qualifies as small under the above definition, business control affiliations must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by any changes to the filing requirements for FCC Form 323 or Form 323–E, because the revenue figures on which this estimate is based do not include or aggregate revenues from affiliated companies.

37. An element of the definition of ''small business'' is that the entity not be dominant in its field of operation. The Commission is unable at this time and in this context to define or quantify the criteria that would establish whether a specific television station is dominant in its market of operation. Accordingly, the foregoing estimate of small businesses to which the rules may apply does not exclude any television stations from the definition of a small business on this basis and is therefore over-inclusive to that extent. An additional element of the definition of ''small business'' is that the entity must be independently owned and operated. It is difficult at times to assess these criteria in the context of media entities, and our estimates of small businesses to which they apply may be over-inclusive to this extent.

38. *Radio Broadcasting.* The Small Business Administration defines a radio broadcasting entity that has $7 million or less in annual receipts as a small business. Business concerns included in this industry are those ''primarily engaged in broadcasting aural programs by radio to the public.'' According to Commission staff review of the BIA Kelsey Inc. Media Access Radio Analyzer Database as of May 2, 2012, about 10,750, (97 percent) of 11,093 commercial radio stations in the United States have revenues of $7 million or less. The Commission has estimated the number of licensed noncommercial radio stations to be 3,712. We do not have revenue data or revenue estimates for these stations. These stations rely primarily on grants and contributions for their operations, so we will assume that all of these entities qualify as small businesses. We note that in assessing whether a business entity qualifies as small under the above definition, business control affiliations must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by any changes to filing requirements for FCC Form 323 or Form 323–E, because the revenue figures on which this estimate is based do not include or aggregate revenues from affiliated companies.

39. In this context, the application of the statutory definition to radio stations is of concern. An element of the definition of ''small business'' is that the entity not be dominant in its field of operation. We are unable at this time and in this context to define or quantify the criteria that would establish whether a specific radio station is dominant in its field of operation. Accordingly, the foregoing estimate of small businesses to which the rules may apply does not exclude any radio station from the definition of a small business on this basis and is therefore over-inclusive to that extent. An additional element of the definition of ''small business'' is that the entity must be independently owned and operated. We note that it is difficult at times to assess these criteria in the context of media entities, and our estimates of small businesses to which

they apply may be over-inclusive to this extent.

40. *Class A TV and LPTV Stations.* The rules and policies adopted herein apply to licensees of low power television (''LPTV'') stations, including Class A TV stations and, as well as to potential licensees in these television services. The same SBA definition that applies to television broadcast licensees would apply to these stations. The SBA defines a television broadcast station as a small business if such station has no more than $14 million in annual receipts. As of March 31, 2012, there are approximately 479 licensed Class A stations and 2,001 licensed LPTV stations. Given the nature of these services, we will presume that all of these licensees qualify as small entities under the SBA definition. We note, however, that under the SBA's definition, revenue of affiliates that are not LPTV stations should be aggregated with the LPTV station revenues in determining whether a concern is small. Our estimate may thus overstate the number of small entities since the revenue figure on which it is based does not include or aggregate revenues from non-LPTV affiliated companies.

41. *Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements.* There may be changes to reporting or recordkeeping requirements if the Commission eliminates the ''Special Use'' FRN requirement. We do not anticipate any other changes in recording or recordkeeping requirements for commercial broadcast entities, as we are proposing to maintain the existing requirement. In addition, there may be a change in reporting or recordkeeping compliance for noncommercial entities if a CORES FRN requirement is adopted for the Form 323–E. *See,* paragraph 21.

42. *Steps Taken to Minimize Significant Impact on Small Entities, and Significant Alternatives Considered.* The RFA requires an agency to describe any significant alternatives that might minimize any significant economic impact on small entities. Such alternatives may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

43. As noted, we are directed under law to describe any such alternatives we consider, including alternatives not explicitly listed above. The *Notice* proposes to continue to require individuals reported on a Form 323 to obtain a CORES-registered FRN and to eliminate the ''Special Use'' FRN. In the alternative, the Commission could decide not to eliminate the Special Use FRN for the Form 323, or it could defer these actions until a later time. While the option to retain the CORES FRN requirement and to eliminate the Special Use FRN might result in an increased burden on those required to obtain and provide a CORES FRN, the benefits of having a unique identifier for data quality, searchability, cross-referencing and aggregation purposes in order to further the Commission's goal of advancing diversity of ownership in the broadcast industry outweigh the burdens. The CORES FRN as a unique identifier is necessary to improve the quality of the data collected on the Form 323. The Commission also seeks comment on whether the Special Use FRN should be available solely in instances where, after reasonable and good faith efforts, filers are unable to obtain a CORES FRN from an individual with reportable interests. This alternative could reduce the burden for those filers who are unable to, after reasonable and good faith efforts, to obtain a CORES FRN from an individual attributable interest holder, while ensuring that the filer will be able to timely submit the Form 323 and allowing the Commission to identify the individual with a reportable interest that has failed to provide a CORES FRN.

44. In the *FNPRM,* the Commission proposes that CORES FRNs be reported for the two classes of non-attributable interests that would be reportable if the Commission adopts the pending proposal in the *Fifth FNPRM* to make these interests reportable. In the alternative, the Commission could decide not to extend the CORES FRN requirement to these interests if they are deemed reportable, or the Commission could defer these actions until a later time. While the option to extend the CORES FRN to these classes of non-attributable interests might impose an increased burden on those required to obtain and provide a CORES FRN, the benefits of having a unique identifier for data quality, searchability, cross-referencing and aggregation purposes in order to further the Commission's goal of advancing diversity of ownership in the broadcast industry outweigh the burden of obtaining a CORES FRN.

45. In the *FNPRM,* the Commission proposes to impose a CORES FRN requirement for all entities and individuals reported on the Form 323–E, Ownership Report for Noncommercial Broadcast Stations in order to further the Commission's goal of advancing diversity of ownership in the broadcast industry. In the alternative, the Commission could decide not to expand the CORES FRN requirement to the holders of attributable interests in non-profit licensees that file Form 323–E, or the Commission could defer this action until a later date. While the option to extend the CORES FRN requirement to entities and individuals reported on the 323–E could impose an increased burden on those required to obtain and provide a CORES FRNs the benefits of having a unique identifier for aggregating data related to non-commercial licensees outweighs the burdens associated with obtaining a CORES FRN.

46. The *FNPRM* proposes to amend the Commission's rules to clarify that an individual with reportable interests must obtain a CORES FRN. The Commission seeks comment on how to reduce or eliminate the costs imposed by this proposal to amend the Commission's rules on small businesses. The Commission invites comment on its proposal to extend the filing deadline for the Biennial Ownership Reports. By providing filers with additional time to file the Biennial Ownership Report, this proposal will reduce the burden on filers. The Commission also seeks comment on the recommendations regarding the Form 323 from NAB and other commenters in the *Media Bureau Data Practices* proceeding and the costs and benefits associated with these proposals for small businesses.

47. *Federal Rules that May Duplicate, Overlap, or Conflict With the Proposed Rules.* None.

V. Ordering Clauses

48. Accordingly, *it is ordered* that, pursuant to the authority contained in sections 1, 2(a), 4(i)–(j), 257, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i)–(j), 257, and 303(r), this *Sixth Further Notice of Proposed Rulemaking is adopted.*

49. *It is further ordered* that, pursuant to the authority contained in sections 1, 2(a), 4(i,j), 257, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i,j), 257, 303(r), *notice is hereby given* of the proposals described in this *Sixth Further Notice of Proposed Rulemaking.*

50. *It is further ordered* that the Commission's Consumer & Governmental Affairs Bureau, Reference

Information Center, *shall send* a copy of the *Sixth Further Notice of Proposed Rulemaking,* including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

51. *It is further ordered,* that the Emergency Petition for Immediate Revision of Instructional/Informational Materials Relative to Form 323, filed on September 14, 2011 by Fletcher, Heald & Hildreth, P.L.C., *is dismissed.*

Federal Communications Commission.

Cecilia Sigmund,

Acting Associate Secretary.

[FR Doc. 2013–00578 Filed 1–14–13; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket Nos. 07–294, 06–121, 02–277, 04–228; MM Docket Nos. 01–235, 01–317, 00–244; FCC 09–92]

Promoting Diversification of Ownership in the Broadcasting Services

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission seeks comment on whether to collect information from holders of equity interests in a licensee that would be attributable but for the single majority shareholder exemption and from holders of interests that would be attributable but for the higher EDP thresholds adopted in the *Diversity Order,* published May 16, 2008, for purposes of determining attribution of certain interests in eligible entities.

DATES: The Commission must receive written comments on or before February 14, 2013 and reply comments on or before March 1, 2013. Written comments on the Paperwork Reduction Act (PRA) proposed information collection requirements must be submitted by the public, Office of Management (OMB) and other interested parties on or before March 18, 2013.

ADDRESSES: You may submit comments, identified by MB Docket. No. 07–294, by any of the following methods:

• *Federal Communications Commission's Web Site: http://fjallfoss.fcc.gov/ecfs2/.* 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* or phone 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Judith Herman of the Media Bureau, Industry Analysis Division, at (202) 418–2330. For additional information concerning the Paperwork Reduction Act information collection requirements contained in the *Notice of Proposed Rulemaking* contact Cathy Williams at (202) 418–2918 or send an email to *PRA@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Fifth Notice of Proposed Rulemaking* in MB Docket No. 07–294 is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. These documents will also be available via ECFS (*http://fjallfoss.fcc.gov/ecfs/*) and may be purchased from the Commissions copy contractor, BCPI, Inc. at their Web site *http://www.bcpi.com* or call 1–800 378–3160.

Initial Paperwork Reduction Act of 1995 Analysis

This *Notice of Proposed Rulemaking* may result in a new or revised information collection requirement. If the Commission adopts any new or revised information collection requirements, the Commission will publish a notice in the **Federal Register** inviting the public to comment on the requirement, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501–3520). In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the commission seeks further comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

I. Introduction

1. The Commission seeks comment on whether to collect information from holders of equity interests in a licensee that would be attributable but for the single majority shareholder exemption and from holders of interests that would be attributable but for the higher EDP thresholds adopted in the *Diversity Order,* published May 16, 2008, 73 FR 28361, for purposes of determining attribution of certain interests in eligible entities. In the *323 Order,* 74 FR 25163 (2009), the Commission determined that, in order to measure the extent of minority and female ownership of broadcast outlets and assess the need for and effectiveness of any policies designed to promote minority and female ownership, it is important to obtain information on holders of certain nonattributable interests, as well as on holders of attributable interests. The Commission concluded that while it considers only attributable interest holders in determining whether licensees are in compliance with our media ownership rules, the balance struck in defining what interests should be counted for purposes of implementing our ownership rules may not be appropriate for collecting data on interests held by minorities and women. As noted above, we did not receive comments on this issue prior to adopting these conclusions. Therefore, in order to obtain a complete record on this question, we are commencing a Further Rulemaking on whether to expand the reporting requirements to include certain nonattributable entities. Specifically, we seek comment on whether to collect information from holders of equity interests in a licensee that would be attributable but for the single majority shareholder exemption and from holders of interests that would be attributable but for the higher EDP thresholds adopted in the *Diversity Order* for purposes of determining attribution of certain interests in eligible entities.

2. The single majority shareholder exemption provides that a minority shareholder's voting interests will not be attributed where a single shareholder holds more than 50 percent of the outstanding voting stock of the corporation in question. In the *323 Order,* the Commission explained why reporting of information about minority shareholders in a corporation with a single majority shareholder is important: ''For purposes of assessing levels of minority ownership * * * we believe that we should err on the side of comprehensiveness based on criticisms of the current collection scheme. The minority interests that are exempt from attribution under the single majority shareholder exemption can be quite substantial—nearly 50%. Including these interest holders would make the data set more complete and help determine whether nonattributable interests could be a source of attributable minority and female owners in the future. Thus, collection of this

information will be useful in assessing whether we need to take additional measures to increase minority ownership and in justifying any measures that we decide to take.'' The FCC proposes to require that voting stock interests that would be attributable but for the single majority stockholder exemption be reported on the biennial Form 323.

3. As is the case now, whether the holders of these direct or indirect interests in licensees that are held in vertical ownership chains will have to file a Form 323 themselves or will simply have their interest reported on a Form 323 filed by another entity would depend on the nature of the shareholder. Individuals holding such interests in licensees or in entities that hold interests in licensees would be reported on the Form 323 filed by the entity in which they hold the interest and would not have to file a form themselves. Corporations, partnerships, or other entities holding such interests in licensees or in entities that directly or indirectly hold interests in licensees, however, would both be reported on the Form 323 filed by the entity in which they hold the interest and would be required to file a Form 323 on their own behalf, using the same biennial Form 323 as all other filers would use and following the same format and instructions. The distinction made here between individuals and entities for purposes of the Form 323 filing obligation is the same distinction that applies under the current rules. The Commission seeks comment on this proposal.

4. Under the Commission's EDP standard, an interest is deemed attributable if, aggregating both equity and debt, the interest exceeds 33 percent of the total asset value (all equity plus all debt) of a broadcast station licensee, cable television system, daily newspaper or other media outlet subject to the Commission's broadcast multiple ownership or cross-ownership rules—and the interest holder also: (1) Holds an attributable interest in another media outlet in the same market that is subject to the multiple or cross-ownership rules; or (2) supplies over 15 percent of the total weekly broadcast programming hours of the station in which the interest is held. In the *Diversity Order,* the Commission adopted a mechanism to allow an interest holder to exceed the 33 percent threshold without triggering attribution if the investment would enable an ''eligible entity'' (as that term is defined in the *Diversity Order*) to acquire a broadcast station, provided that: (1) The combined equity and debt of the interest holder in the eligible entity is less than 50 percent; or (2) the total debt of the interest holder in the eligible entity does not exceed 80 percent of the asset value of the station being acquired by the eligible entity and the interest holder does not hold any equity interest, option or promise to acquire an equity interest, option or promise to acquire an entity interest in the eligible entity or any related entity.

5. In order to obtain more complete ownership data, the Commission proposes that interest that would be attributable but for the recently adopted EDP exemption for certain investments in eligible entities be reported on the biennial Form 323. In the *323 Order,* the Commission noted that it ''did not premise its relaxation of the EDP attribution rule on a finding that such an interest holder is unable to exert significant influence in the licensee but rather on a policy decision that relaxing the EDP rule is necessary to facilitate access to capital by eligible entities, including minority- and female-owned businesses.'' The Commission also noted that it already has determined that interests that exceed 33 percent EDP threshold confer on the interest holder an ability to influence a licensee's operations. While we do not believe there are many ownership interests held pursuant to this exemption, they are clearly interests within the scope of our concern in this proceeding. For this reason, we propose to require that they be reported. With respect to which interest holders will be report and which will also file Form 323, we propose to apply the same distinction discussed in paragraph 18 of the *5th FNPRM.* Thus, individuals holding these interests would have to be reported by the entity in which the interest is directly held but would not themselves have to file the separate ownership reports and be reported by the entity in which the interest is directly held.

6. Will collection of race, ethnicity, and gender data on the holders of these two nonattributable interests further the Commission's goals to obtain reliable data on the precise status of minority and female ownership? NAB suggests that information from nonattributable entities will not provide the Commission with any useful information on the current status of minority and female ownership of broadcast stations. We seek comment on this view. NAB states that by excluding these interests from its attribution rules, the Commission has already determined that such interests fail to confer sufficient influence over a licensee's operations. Therefore, NAB questions how the ownership information will further the Commission's stated goals. We seek comment on NAB's position and on all aspects of our proposals.

7. We also seek comment on any adverse consequences of requiring reporting of individuals holding these nonattributable interests and of requiring entities holding these nonattributable interests to file separate Form 323s. We seek comment specifically on NAB's concern that the reporting requirement will deter investment in the broadcast industry by increasing investors' administrative and financial burdens and by requiring disclosure of information that they would otherwise consider private. CBS argues that the potential costs and other burdens of compliance with these reporting requirements could persuade nonattributable investors to invest elsewhere or even divest their existing ownership interests. We seek comment on these contentions. In the *323 Order,* the Commission explained that our attribution rules seek to identify financial interests in licensees that convey the potential and incentive to exert significant influence over core licensee functions, and thus should be counted under the multiple ownership rules. At the same time, however, the Commission noted that it has sought to target the attribution rules precisely so as to avoid impeding capital flow to broadcasters. The Commission concluded that, in this instance, the concern about impeding capital flow does not apply, and noted that the Commission's goal is to collect information so that we can accurately assess and effectively promote diversity of ownership in the broadcast industry. We seek comment on whether a reporting requirement of non-attributable interests would adversely affect capital investment in broadcasting.

8. We seek comment on whether expanding the reporting requirements to include the two non-attributable interests we have identified will result in undue burdens on licensees, and in particular, small entities. The Commission recognized that it must balance the goal of collecting more comprehensive and more accurate data with the goal of minimizing burdens on respondents. In the *323 Order,* the Commission explained that broadcasters are familiar with and accustomed to keeping records in accordance with the Commission's existing attribution rules, which provide useful, fairly bright-line criteria to determine which interests must be reported and which interests do not need to be reported. CBS suggests that broadcasters often do not possess

the reportable information because publicly traded companies may have limited knowledge of the demographic information of a majority of shareholders, and may not know the underlying beneficial owners when the stocks are held by banks or other financial institutions. We seek comment on whether licensees or other entities required to file revised Form 323 currently possess information on minority shareholders of single majority shareholder corporations. If not, what is the burden of collecting this information? Will licensees, parent corporations, or other entity filers have to obtain specialized counsel and conduct additional surveys to comply with the reporting requirement, as suggested by CBS? We seek comment on whether the benefits of obtaining comprehensive minority and female ownership data outweigh the increased burden on respondents. Are alternatives available to reduce the filing burden without reducing the accuracy or completeness of the data?

9. We also seek comment on NAB's suggestion that, if the Commission adopts the reporting requirement discussed above, it should limit the reportable information to race, gender, and ownership percentage of the nonattributable investors, rather than full reporting of their names, addresses, familial relationships, and other media holdings. Would data thus limited provide the Commission and outside researchers with sufficient information to conduct studies? If information on nonattributable media holdings is omitted, as suggested by NAB, would the Commission lack sufficient information to accurately determine the universe of minority and female ownership in broadcasting?

II. Procedural Matters

10. *Ex Parte Rules.* The proceeding this *5th Further Notice of Proposed Rulemaking* initiates shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

11. *Comments and Reply Comments.* 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://fjallfoss.fcc.gov/ecfs2/.*
- Paper Filers: Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.

12. *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Initial Regulatory Flexibility Analysis

13. As required by the Regulatory Flexibility Act of 1980, as amended (''RFA''), the Commission has prepared this Initial Regulatory Flexibility Analysis (''IRFA'') of the possible economic impact on small entities by the policies and rules proposed in this *Fifth FNPRM.* The RFA, *see* 5 U.S.C. 601–612, was amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (''SBREFA''), Public Law 104–121, Title II, 110 Stat. 857 (1996). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the first page of this document. The Commission will send a copy of the Notice, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (''SBA'').

14. *Need for, and Objectives of, the Proposed Rules.* The *Fifth FNPRM* invites comment on proposed revisions to FCC Form 323 that would require entities that hold financial interests that would constitute attributable interests in the licensee (1) but for the single majority shareholder attribution exemption or (2) the higher Equity/Debt Plus threshold adopted in the Diversity Order for purposes of attributing certain interests in eligible entities to file ownership reports biennially and would require reporting in biennial ownership reports of individuals that hold such interests. Consistent with current filing requirements, an individual holding an ownership interest is not required to file Form 323. The objective of the information collection is to obtain comprehensive ownership data to further the Commission's goal to design

policies to advance diversity in the broadcast industry.

15. *Legal Basis.* This *Fifth FNPRM* is adopted pursuant to sections 1, 2(a), 3, 4(i)–(j), 257, and 303(r), of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 153, 154(i, j), 257, 303.

16. *Description and Estimate of the Number of Small Entities To Which the Proposed Rules Will Apply.* The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental entity'' under Section 3 of the Small Business Act. In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definition of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.'' A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

17. *Television Broadcasting.* In this context, the application of the statutory definition to television stations is of concern. The Small Business Administration defines a television broadcasting station that has no more than $14 million in annual receipts as a small business. Business concerns included in this industry are those ''primarily engaged in broadcasting images together with sound.'' This category description states: ''These establishments operate television broadcasting studios and facilities for the programming and transmission of programs to the public.'' In the *Fifth NPRM,* the Commission noted that upon review of the BIA Kelsey Inc. Media Access Pro Television Database, as of August 14, 2009 there were about 923 (72 percent) of the 1,289 commercial television stations in the United States with revenues of $14 million or less. These statistics will be updated in a subsequent FRFA. The Commission notes that in assessing whether a business entity qualifies as small under the above definition, business control affiliations must be included. ''[Businesses] are affiliates of each other when one [business] controls or has the power to control the other or a third party or parties controls or has the power to control both.'' The Commission's estimate, therefore, likely overstates the number of small entities that might be affected by any changes to the filing requirements for FCC Form 323, because the revenue figures on which this estimate is based do not include or aggregate revenues from affiliated companies.

18. An element of the definition of ''small business'' is that the entity not be dominant in its field of operation. The Commission is unable at this time and in this context to define or quantify the criteria that would establish whether a specific television station is dominant in its market of operation. Accordingly, the foregoing estimate of small businesses to which the rules may apply does not exclude any television stations from the definition of a small business on this basis and is therefore over-inclusive to that extent. An additional element of the definition of ''small business'' is that the entity must be independently owned and operated. It is difficult at times to assess these criteria in the context of media entities, and the Commission's estimates of small businesses to which they apply may be over-inclusive to this extent.

19. *Radio Broadcasting.* The Small Business Administration defines a radio broadcasting entity that has $7 million or less in annual receipts as a small business. Business concerns included in this industry are those ''primarily engaged in broadcasting aural programs by radio to the public.'' According to Commission staff review of the BIA Kelsey Inc. Media Access Radio Analyzer Database as of August 14, 2009, there were about 10,660 (96 percent) of 11,100 commercial radio stations in the United States with revenues of $7 million or less. These statistics will be updated in a subsequent FRFA. The Commission notes that in assessing whether a business entity qualifies as small under the above definition, business control affiliations must be included. ''[Businesses] are affiliates of each other when one [business] controls or has the power to control the other, or a third party or parties controls or has the power to control both.'' The Commission's estimate, therefore, likely overstates the number of small entities that might be affected by any changes to the ownership rules, because the revenue figures on which this estimate is based do not include or aggregate revenues from affiliated companies.

20. In this context, the application of the statutory definition to radio stations is of concern. An element of the definition of ''small business'' is that the entity not be dominant in its field of operation. The FCC is unable at this time and in this context to define or quantify the criteria that would establish whether a specific radio station is dominant in its field of operation. Accordingly, the foregoing estimate of small businesses to which the rules may apply does not exclude any radio station from the definition of a small business on this basis and is therefore over-inclusive to that extent. An additional element of the definition of ''small business'' is that the entity must be independently owned and operated. The Commission notes that it is difficult at times to assess these criteria in the context of media entities, and the Commission's estimates of small businesses to which they apply may be over-inclusive to this extent.

21. *Class A TV and LPTV stations.* The rules and policies adopted herein apply to licensees of Class A TV stations and low power television (''LPTV'') stations, as well as to potential licensees in these television services. The same SBA definition that applies to television broadcast licensees would apply to these stations. The SBA defines a television broadcast station as a small business if such station has no more than $14.0 million in annual receipts. As of June 30, 2009, there were approximately 553 licensed Class A stations and 2,386 licensed LPTV stations. Given the nature of these services, the Commission will presume that all of these licensees qualify as small entities under the SBA definition. These statistics will be updated in a subsequent FRFA. The Commission notes, however, that under the SBA's definition, revenue of affiliates that are not LPTV stations should be aggregated with the LPTV station revenues in determining whether a concern is small. The Commission's estimate may thus overstate the number of small entities since the revenue figure on which it is based does not include or aggregate revenues from non-LPTV affiliated companies.

22. *Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements.* The Commission anticipates that changes in recording or recordkeeping requirements for commercial broadcast entities would result from the changes in the Commission's Form 323 necessary to implement the proposal to collect additional investor information. Entities holding two types of nonattributable interests, as described in

the *Fifth FNPRM,* would be required to file Form 323, and individuals holding these interests would have to be reported on Form 323.

23. *Steps Taken to Minimize Significant Impact on Small Entities, and Significant Alternatives Considered.* The RFA requires an agency to describe any significant alternatives that might minimize any significant economic impact on small entities. Such alternatives may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

24. As noted, the Commission is directed under law to describe any such alternatives it considers, including alternatives not explicitly listed above. The *Fifth FNPRM* seeks comment on the tentative conclusion that obtaining certain nonattributable financial interests would further its goal to design policies to advance diversity in the broadcast industry. In the alternative, the Commission could defer until a later time collection of such information or not require reporting of such information. The *Fifth FNPRM* also seeks comment on whether the proposed data collection would impose a significant reporting, recordkeeping, or other compliance burden on commercial broadcast entities, especially smaller entities, and whether there are alternative ways to minimize burdens from this proposed reporting requirement.

25. *Federal Rules that May Duplicate, Overlap, or Conflict With the Proposed Rules*

None.

III. Ordering Clauses

26. Accordingly, *it is ordered* that, pursuant to the authority contained in sections 1, 2(a), 4(i)–(j), 257, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i)–(j), 257, and 303(r), the *Fifth FNPRM is adopted.*

27. *It is further ordered* that, pursuant to the authority contained in sections 1, 2(a), 4(i, j), 257, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i, j), 257, 303(r), *notice is hereby given* of the proposals described in this *Fifth FNPRM.*

28. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of the *Fifth FNPRM,* including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

29. *It is further ordered* that the Commission *shall send* a copy of the *Fifth FNPRM* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Federal Communications Commission.

Cecilia Sigmund,

Associate Secretary (Acting).

[FR Doc. 2013–00574 Filed 1–14–13; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 78, No. 10
Tuesday, January 15, 2013

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Adoption of Recommendations

AGENCY: Administrative Conference of the United States.

ACTION: Notice.

SUMMARY: The Administrative Conference of the United States adopted three recommendations at its Fifty-seventh Plenary Session. The appended recommendations address reforms to 28 U.S.C. 1500, third-party programs to assess regulatory compliance, and inflation adjustment for civil penalties.

FOR FURTHER INFORMATION CONTACT: For Recommendation 2012–6, Emily Bremer; for Recommendation 2012–7, David Pritzker; for Recommendation 2012–8, Stephanie J. Tatham. For all three recommendations the address and phone number are: Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW., Washington, DC 20036; Telephone 202–480–2080.

SUPPLEMENTARY INFORMATION: The Administrative Conference Act, 5 U.S.C. 591–596, established the Administrative Conference of the United States. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by Federal agencies and makes recommendations for improvements to agencies, the President, Congress, and the Judicial Conference of the United States (5 U.S.C. 594(1)). For further information about the Conference and its activities, see *http://www.acus.gov.*

At its Fifty-seventh Plenary Session, held December 6–7, 2012, the Assembly of the Conference adopted three recommendations. Recommendation 2012–6, ''Reform of 28 U.S.C. Section 1500,'' urges Congress to repeal Section 1500, which divests the U.S. Court of Federal Claims of jurisdiction when a plaintiff has claims against the government based on substantially the same operative facts pending in another court, and replace it with a provision that would create a presumption that in such circumstances, later-filed actions would be stayed. The Administrative Conference Member from the Department of Justice filed a separate statement noting the Department's disagreement with the recommendation, which is printed following the recommendation.

Recommendation 2012–7 addresses issues that arise when agencies develop programs in which third parties assess whether regulated entities are in compliance with regulatory standards and other requirements. In some areas of regulation, Congress has directed agencies to develop a third-party program; in others, regulatory agencies have developed programs under existing statutory authority. The recommendation sets forth guidance for federal agencies that are establishing, or considering establishing, such programs.

Recommendation 2012–8, ''Inflation Adjustment Act,'' addresses agency adjustments to civil monetary penalties under the Federal Civil Penalties Inflation Adjustment Act, codified as amended at 28 U.S.C. 2461 note. The recommendation urges Congress to change the current statutory framework by which agencies periodically adjust their penalties to address three provisions that result in penalty adjustments that may not track the actual rate of inflation. It also advises agencies to adjust their penalties for inflation as required by the law.

The Appendix (below) sets forth the full texts of these three recommendations. The Conference will transmit them to affected agencies and to appropriate committees of the United States Congress. The recommendations are not binding, so the relevant agencies, the Congress, and the courts will make decisions on their implementation.

The Conference based these recommendations on research reports that it has posted at: *http://www.acus.gov/events/57th-plenary-session/.* A video of the Plenary Session is available at the same web address, and a transcript of the Plenary Session will be posted once it is available.

Dated: January 10, 2013.

Paul R. Verkuil,

Chairman.

Appendix—Recommendations of the Administrative Conference of the United States

Administrative Conference Recommendation 2012–6

Reform of 28 U.S.C. 1500

Adopted December 6, 2012

The Administrative Conference of the United States has long had an interest in ensuring appropriate judicial review of Government actions and in considering related questions regarding jurisdiction and forum. For example, the Conference's seminal Recommendation 69–1 recommended amendment of the Administrative Procedure Act—subsequently enacted by Congress—to waive sovereign immunity and thereby permit citizens ''to challenge in courts the legality of acts of governmental administrators.'' [1] Recommendation 68–7 encouraged Congress to revise the general ''federal question'' provision in Title 28 of the U.S. Code in order to eliminate the jurisdictional-amount requirement for district court actions seeking review of federal administrative actions.[2] The Conference has also recommended ways to improve procedures in suits involving the federal government.[3]

Building upon the principles underlying such Recommendations, the Conference addresses another bar to judicial review which deprives some litigants of their rights—28 U.S.C. 1500 (Section 1500). Section 1500 prohibits consideration by the United States Court of Federal Claims of otherwise cognizable claims while the plaintiff has litigation against the United States or an officer thereof ''pending in any other court'' and arising from substantially the same operative facts.[4]

[1] Administrative Conference of the United States, Recommendation 69–1, ''Statutory Reform of the Sovereign Immunity Doctrine,'' 1 ACUS 23 (1969).

[2] Administrative Conference of the United States, Recommendation 68–7, ''Elimination of Jurisdictional Amount Requirement in Judicial Review,'' 1 ACUS 22 (1968).

[3] *E.g.,* Administrative Conference of the United States, Recommendation 80–5, *Eliminating or Simplifying the ''Race to the Courthouse'' in Appeals From Agency Action,* 45 FR 84954 (Dec. 24, 1980); Administrative Conference of the United States, Recommendation 82–3, *Federal Venue Provisions Applicable to Suits Against the United States,* 47 FR 30706 (June 18, 1982).

[4] Section 1500 of Title 28 of the United States Code reads in full:

The United States Court of Federal Claims shall not have jurisdiction of any claim for or in respect to which the plaintiff or his assignee has pending in any other court any suit or process against the United States or any person who, at the time when

Continued

With its origins in the Reconstruction era, the statutory predecessor to Section 1500 arose against the backdrop of a proliferating number of suits, in multiple fora, by residents of the Confederacy who sought compensation from the United States for property (typically, cotton) seized during the Civil War.[5] To curb this duplicative litigation, Congress enacted legislation divesting the Court of Claims (the trial court predecessor to the Court of Federal Claims) of jurisdiction when a plaintiff had a related action against the United States or an officer thereof pending in another court. This legislation was reenacted several times, most recently in 1948 as Section 1500 of the Judicial Code, and the provision's jurisdictional limitation has remained essentially unchanged.[6] Though the ''cotton claimants'' are long gone, Section 1500's restrictions on the jurisdiction of the Court of Federal Claims remain.

Application of Section 1500 in the context of modern-day federal court jurisdiction and complex litigation, however, causes serious problems for courts and litigants alike. Plaintiffs confront difficult questions of forum selection and timing when the same set of operative facts arguably gives rise to two or more claims against the United States—for which Congress has otherwise waived sovereign immunity—but the Court of Federal Claims has exclusive jurisdiction over one or more claims, and another federal court has exclusive jurisdiction over the other claims. Does a claim sound properly in contract (within the exclusive jurisdiction of the Court of Federal Claims) or in tort (within the exclusive jurisdiction of district courts)? Where the answer is not clear or could be both, the choice of any other court for an initial filing could result in dismissal of a claimant's subsequent suit in the Court of Federal Claims under Section 1500. When a plaintiff prosecutes a challenge to agency action in district court based on the Administrative Procedure Act (which may necessarily precede pursuit of any monetary relief for the same claim in the Court of Federal Claims) appellate proceedings on his or her Administrative Procedure Act litigation could well carry past the Court of Federal Claims' six-year statute of limitations. Thus, in conjunction with the statute of limitations, Section 1500 may foreclose full recovery for plaintiffs prosecuting meritorious claims in good faith.

Section 1500 affects a wide variety of plaintiffs with many different kinds of claims. Federal employees, property owners, businesses, local governments, and Indian tribes may be affected. The statute may present intractable jurisdictional conundrums for sophisticated litigants and *pro se* plaintiffs alike. Examples of the diverse parties and claims affected include:

- A federal employee's claims under the Equal Pay Act were transferred to and dismissed by the Court of Federal Claims for lack of jurisdiction because the Title VII claims with which the action was filed in district court were considered ''pending'' under Section 1500, even though the district court already had entered summary judgment on all non-transferred claims.[7]
- Characterizing the result as ''neither fair nor rational,'' the Court of Federal Claims dismissed a Fifth Amendment-based takings claim filed *pro se* by property owners and that had been transferred from a district court tort action, despite finding that the uncertain legal distinction between tort and takings actions made plaintiffs' confusion about the appropriate forum ''understandable.''[8]
- A government contractor's bid protest action was rejected by the Court of Federal Claims as jurisdictionally lacking because the plaintiff had previously sued in district court under the Administrative Procedure Act—even though the district court had already dismissed on the ground that the plaintiff's exclusive remedy was in the Court of Federal Claims.[9]
- A local government sued by the United States over taxation of certain federal office buildings counterclaimed for the taxes it believed it was owed. The counterclaims were transferred to the Court of Federal Claims—and dismissed under Section 1500.[10]
- An Indian tribe suing in the Court of Federal Claims for breach of trust had its claims dismissed under Section 1500 because it had filed a related action in the district court on the same day.[11]

Because of the barrier it imposes on some plaintiffs pursuing cognizable claims against the United States, Section 1500 has been strongly criticized by litigants, courts, and legal scholars as overly harsh, anachronistic, unfair, and in need of reform.[12]

On the other hand, some of the aims attributed to Section 1500 have modern relevance. In *United States* v. *Tohono O'odham Nation,* the Supreme Court held that Section 1500 applies to any claim filed in the Court of Federal Claims that shares substantially the same operative facts as a claim pending in another court.[13] The decision thus reversed Federal Circuit precedent that allowed the Court of Federal Claims to retain jurisdiction over a claim under Section 1500 if a plaintiff sought different relief in the Court of Federal Claims than it sought in another forum. This had the effect of expanding the range of cases to which Section 1500 could be found to apply. The Supreme Court faulted the Federal Circuit for saying that it ''could not identify 'any purpose that § 1500 serves today.' ''[14] The Court remarked that ''the statute's purpose is clear from its origins with the cotton claimants—the need to save the Government from burdens of redundant litigation—and that purpose is no less significant today.''[15]

In *Tohono,* the Supreme Court also observed that ''[i]f indeed the statute leads to incomplete relief'' or causes undue hardship for plaintiffs, citizens are ''free to direct their complaints to Congress.''[16] After careful consideration and consultation with affected parties over eighteen months, including the Department of Justice, the Conference accepts the Court's invitation to approach Congress. While Section 1500's purpose as articulated in *Tohono* has legitimate aspects, the Conference's research reveals that the statute is an undesirably blunt tool for reducing the duplicative burdens that may arise from simultaneous litigation. Federal courts have both the authority and the competence to use measures such as stays, transfers, and the doctrine of preclusion to prevent double recoveries and ease the burdens of simultaneous litigation on the Government without unfairly depriving plaintiffs of the opportunity to pursue all potentially meritorious claims against the United States.[17] Replacing Section 1500 with a context-specific judicial management tool for simultaneous litigation in different fora would also better serve Congress's various waivers of sovereign immunity.

Accordingly, the Administrative Conference recommends that Congress repeal Section 1500. The Conference further recommends that Congress replace Section 1500 with a provision that permits plaintiffs to bring congressionally authorized suits arising from the same set of operative facts in the Court of Federal Claims and other federal courts at the same time, but also contains a presumptive stay mechanism to mitigate any burden on the courts or parties from simultaneous litigation.[18] As a general

the cause of action alleged in such suit or process arose, was, in respect thereto, acting or professing to act, directly or indirectly under the authority of the United States.

28 U.S.C. 1500 (2012). *See also United States* v. *Tohono O'odham Nation,* 131 S. Ct. 1723, 1731 (2011) (''Two suits are for or in respect to the same claim, precluding jurisdiction in the [Court of Federal Claims], if they are based on substantially the same operative facts, regardless of the relief sought in each suit.'').

[5] *See, e.g., Keene Corp.* v. *United States,* 508 U.S. 200, 206 (1993).

[6] *Id.*

[7] *Griffin* v. *United States,* 590 F.3d 1291 (Fed. Cir. 2009).

[8] *Vaizburd* v. *United States,* 46 Fed. Cl. 309, 311–12 (Fed. Cl. 2000).

[9] *Vero Technical Support* v. *United States,* 94 Fed. Cl. 784 (Fed. Cl. 2010).

[10] *United States* v. *County of Cook,* 170 F.3d 1084, 1091–92 (Fed. Cir. 1994).

[11] *Passamaquoddy Tribe* v. *United States,* 82 Fed. Cl. 256 (Fed. Cl. 2008). Notably, if the plaintiff tribe had filed its district court action one day later, it would have been permitted to proceed simultaneously in both the Court of Federal Claims and district court under Federal Circuit precedent. *See Tecon Engineers, Inc.* v. *United States,* 170 Ct. Cl. 389 (Ct. Cl. 1965).

[12] Emily S. Bremer & Jonathan R. Siegel, *The Need to Reform 28 U.S.C. § 1500* (2012) (report to the Administrative Conference of the U.S.) (collecting criticism of Section 1500), *available at www.acus.gov.*

[13] *Tohono,* 131 S. Ct. at 1731.

[14] *Id.* at 1729.

[15] *Id.* at 1730.

[16] *Id.* at 1731.

[17] *E.g.,* 28 U.S.C. 1631; *see also Court of Federal Claims Technical and Procedural Improvements Act, Hearing on S. 2521 Before the S. Comm. on the Judiciary,* 102nd Cong. 59 (Apr. 29, 1992) (statement of Hon. Loren Smith, Chief Judge, U.S. Claims Court) (observing that repeal of Section 1500 would save ''wasteful litigation over non-merits issues'' and that the ''Court can stay duplicative litigation, if the matter is being addressed in another forum, or proceed with the case, if the matter appears to be stalled in the other forum'').

[18] This position comports with that of the Judicial Conference of the United States in 1995, which dropped its historical opposition to the repeal of

rule, the later-filed action should be the subject of the presumptive stay. Nonetheless, the Administrative Conference recognizes that a stay presumption may not be appropriate in all situations. In the absence of other compelling considerations, the presumption of a stay should not apply where the parties agree that the later-filed action should proceed.

In various situations, the interests of justice may override the presumption favoring a stay in the later-filed action. Such a situation might exist, for example, where a decision in the first-filed action is dependent on the outcome of a later-filed action, or where the later-filed action requires factual discovery from witnesses who might not be available in the future. Alternatively, a plaintiff might have a strong interest in obtaining prompt resolution in the Court of Federal Claims of a claim for just compensation stemming from an agency decision, even though the ultimate validity of the decision remains at issue in an earlier-filed district court action. These examples are not intended to be exhaustive.

The Administrative Conference also recommends that repeal of the current Section 1500 apply to claims pending at the time the Recommendation is enacted.[19] Elimination of Section 1500's jurisdictional bar for current litigants would directly serve their fairness interests, without substantially impairing the Government's reliance interests or disrupting the orderly progress of any pending litigation. A specific pronouncement by Congress on this important issue would also avoid unnecessary litigation over the application of the repeal legislation.

Recommendation

1. Congress should repeal 28 U.S.C. 1500 (2012).

2. Congress should enact a new statute as follows:

28 U.S.C. Section 1500.

Presumption of Stay. Whenever a civil action is pending in the United States Court of Federal Claims, or on appeal from the Court of Federal Claims, and the plaintiff or his assignee also has pending in any other court (as defined in section 610 of this title) any claim against the United States or an agency or officer thereof involving substantially the same operative facts, the court presiding over the later-filed action shall stay the action, in whole or in part, until the first action is no longer pending. If such actions or appeals were filed on the same day, regardless of the time of day, the United States Court of Federal Claims action shall be treated as having been filed first. This provision shall not apply if the parties otherwise agree or if the stay is not or ceases to be in the interest of justice.

3. The public law that enacts the provision in paragraph two should contain the following additional provision:

EFFECTIVE DATE—[The presumptive stay provision] shall apply to all claims pending on or after the date of its enactment, unless the later-filed action is pending in a court of appeals or the Supreme Court. No claim in a case pending on or after the date of enactment of this Act shall be subject to the jurisdictional bar previously imposed by former Section 1500 of Title 28, United States Code prior to the enactment of this Act.

Separate Statement of Government Member Elana Tyrangiel, Acting Assistant Attorney General, U.S. Department of Justice

The preamble to the Administrative Conference of the United States (ACUS) Recommendation entitled ''Reform of 28 U.S.C. Section 1500'' states: ''After careful consideration and consultation with affected parties over eighteen months, including the Department of Justice, the Conference accepts the Court's invitation to approach Congress [to recommend replacing the existing Section 1500 with a substitute provision formulated by ACUS].'' The Department of Justice writes separately to make clear that it did not support adoption of the recommendation, and that the Department believes ACUS's proposed statutory substitute has serious flaws.

Administrative Conference Recommendation 2012–7

Agency Use of Third-Party Programs To Assess Regulatory Compliance

Adopted December 6, 2012

Federal agencies in diverse areas have developed third-party programs to assess whether regulated entities are in compliance with regulatory standards and other requirements. Through these programs, third parties assess the safety of imported food, children's products, medical devices, cell phones and other telecommunications equipment, and electrical equipment used in workplaces. Third parties also ensure that products labeled as organic, energy-efficient, and water-efficient meet applicable federal standards. In these regulatory third-party programs, regulated entities generally contract with and pay third parties to carry out product testing, facility inspections, and other regulatory compliance assessment activities in the place of regulatory agencies. Regulatory agencies then adopt new roles in coordinating and overseeing these third-parties.[1]

In some areas of regulation, Congress has directed federal agencies to develop a third-party program; in others, regulatory agencies have developed programs under existing statutory authority. A third-party program is just one of many regulatory approaches that Congress and agencies may adopt.[2]

Regulatory objectives may, for example, be adequately met by requiring regulated entities to self-assess and report their compliance (sometimes referred to as ''first-party certification''). Also, statutory restrictions on information disclosure or other legal restrictions may preclude an agency from using third parties to conduct inspections and other compliance assessment activities. Some compliance assessment activities may be inherently governmental, and thus require performance by government personnel.[3]

Several broad reasons support the growing use of third-party programs in federal regulation. In many areas, federal regulatory agencies are faced with assuring the compliance of an increasing number of entities and products without a corresponding growth in agency resources. Third-party programs may leverage private resources and expertise in ways that make regulation more effective and less costly. In comparison with other regulatory approaches, third-party programs may also enable more frequent compliance assessment and more complete and reliable compliance data. Because agencies can authorize third parties located in other countries to undertake assessment activities, third-party programs may be particularly effective when regulated products or processes are international in scope.

Regulatory third-party programs raise a host of important questions. Because third-party programs represent a partial privatization of the public function of implementing and enforcing regulatory law, they are a form of ''public-private governance,'' in which private actors play roles that are traditionally viewed as governmental in nature.[4] While third-party programs may increase regulatory compliance or otherwise improve the performance of regulated entities and products, these programs also pose risks.[5] If they are not well-conceived and well-operated, they may both undermine the achievement of regulatory goals and impose unnecessary costs on agencies and regulated entities.

Frequently, regulatory third-party programs use the practices and terminology

Section 1500 so long as such repeal was ''accompanied by a provision for stay or transfer of duplicative claims.'' Judicial Conference of the United States, Report of the Proceedings of the Judicial Conference of the United States 83 (Sept. 19, 1995).

[19] Application of new procedural legislation to pending cases is not uncommon in the law. *Landgraf* v. *USI Film Prods.,* 511 U.S. 244, 274 (1994) (noting that the Court has ''regularly applied intervening statutes conferring or ousting jurisdiction, whether or not jurisdiction lay when the underlying conduct occurred or when the suit was filed.'')

[1] Agencies may use third parties in connection with regulatory, procurement, and federal assistance programs. This recommendation addresses use of third parties in regulatory programs.

[2] The Administrative Conference has addressed various approaches in prior recommendations. *See, e.g.,* Recommendation 94–1, The Use of Audited Self-Regulation as a Regulatory Technique, 59 FR 44,701 (Aug. 30, 1994); Recommendation 89–1, Peer Review and Sanctions in the Medicare Program, 54 FR 28,965 (Jul. 10, 1989); Recommendation 78–4, Federal Agency Interaction with Private Standard-Setting Organizations, 44 FR 1357 (Jan. 5, 1979).

[3] Office of Mgmt. & Budget, OMB Circular No. A–76 (Revised May 29, 2003).

[4] *See* William J. Novak, *Public-Private Governance: A Historical Introduction,* in Government by Contract: Outsourcing and American Democracy (Freeman and Minow, eds., Harvard University Press, 2009); Martha Minow, *Public and Private Partnerships: Accounting for the New Religion,* 116 Harv. L. Rev. 1229, 1230 (2002–2003); Jody Freeman, *Extending Public Law Norms through Privatization,* 116 Harv. L. Rev. 1285, 1286–87 (2002–2003); Jody Freeman, *Private Parties, Public Functions and the New Administrative Law, in Recrafting the Rule of Law: The Limits of Legal Order* 331 (David Dyzenhaus ed., Hart, 1999).

[5] *See* Lesley K. McAllister, *Regulation by Third-Party Verification,* 53 B.C. L. Rev. 1 (2012).

of a conformity assessment framework that has been developed by international private-sector standards organizations. ''Conformity assessment'' is defined in international standards as the ''demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled.''[6] International standards also set forth how the organizations that conduct conformity assessment—''conformity assessment bodies,'' which are usually private organizations—should operate. International standards have been developed for various types of conformity assessment bodies, including testing bodies, certification bodies, and inspection bodies.

Recognizing the assessment of regulatory compliance as a form of conformity assessment, many federal agencies that have established third-party programs have relied on conformity assessment standards and bodies. Agencies may require, for example, that third parties that certify conformity with regulatory requirements operate in accordance with the international standards for certification bodies. Federal agencies may also require that the third parties be accredited by accreditation bodies that operate in accordance with international accreditation standards. Accreditation bodies are established in many countries, and they may be either private or governmental.

Agencies that establish third-party programs generally cannot or do not delegate their regulatory authority to conformity assessment bodies. Rather, agencies authorize conformity assessment bodies to perform certain technical tasks to assess conformity, and regulatory agencies rely on these assessments in their own enforcement of regulatory requirements. The goal is to leverage private expertise and resources to serve regulatory objectives. Because the regulatory agency must remain ultimately responsible for achieving regulatory objectives, it is vital to provide public oversight of third-party assessment activities.

A key resource for agencies considering a regulatory third-party program is the National Institute of Standards and Technology (NIST), which has the responsibility under the National Technology Transfer and Advancement Act of 1995 to coordinate government conformity assessment activities with similar activities of private-sector entities, with the goal of avoiding unnecessary duplication and complexity. Following Office of Management and Budget (OMB) Circular A–119, NIST published guidance in 2000 for federal agencies on conformity assessment activities.[7] NIST: (1) provides advice, solutions, and program support for development of technical standards and conformity assessment programs to support agency missions; and (2) develops and conducts customized standards-related workshops and educational events for government.

Recognizing the growing use of third parties and the issues it raises, the Administrative Conference makes this recommendation to assist federal agencies in determining whether and how to establish third-party programs to assess regulatory compliance. The recommendation first suggests that, when considering a third-party program, agencies should consult relevant governmental and nongovernmental resources. Next, agencies should compare the advantages and disadvantages of a third-party approach to a more traditional approach of direct governmental compliance assessment. Also, if an agency is considering a program in which regulated entities could choose whether to contract with a third party for regulatory compliance assessment, it should first determine that regulated entities will have sufficient incentives to choose to contract with a third party.

The recommendation then sets forth considerations for agencies after they have decided to establish a third-party program. An agency should design conformity assessment programs to be proportional to the risks associated with regulatory noncompliance. When regulatory noncompliance implies serious risk to public health, safety, or other important values, third-party program rules should guarantee a high degree of rigor and independence. When possible, the agency should incorporate existing conformity assessment standards, which may avoid unnecessary duplication and create efficiencies for both agencies and regulated entities. The agency should also ensure appropriate government and public access to information about program operation. Finally, the agency should undertake appropriate oversight activities to ensure that the third-party program fulfills its regulatory purpose.

Recommendation

A. Considerations for a Federal Agency When Deciding Whether To Develop a Third-Party Program To Assess Regulatory Compliance

1. *Resources.* When considering whether to develop a third-party program to assess regulatory compliance, the agency should consult governmental and non-governmental resources relating to third-party conformity assessment, as appropriate. These include, but are not limited to, the National Institute of Standards and Technology (NIST); private conformity assessment standards, particularly the standards of the International Organization for Standardization (ISO); and conformity assessment bodies, for practical input on feasibility and the impacts on the regulated entities.

2. *Compare Regulatory Approaches.* The agency should compare a third-party approach with direct governmental assessment of compliance. In choosing between them, the agency should evaluate the advantages and disadvantages of these approaches, with consideration of:

(a) whether third-party conformity assessment is likely to be effective in practice and as a technical matter for the applicable regulatory standards and context;

(b) the costs and potential delay that may result from developing and establishing a third-party program;

(c) the capacity of the agency to perform effective oversight and its related costs;

(d) the potential for the agency to achieve efficiencies through reducing its direct compliance assessment costs and resource needs;

(e) the costs to regulated entities of paying third parties to perform conformity assessment activities, which are likely to be of particular concern to small businesses;

(f) the potential for development of a well-functioning market in third-party conformity assessment services; and

(g) the benefits that may accrue to regulated entities by, for example, receiving regulatory approval to market their products more quickly or simultaneously satisfying the regulatory requirements of other agencies to which they are subject, including state agencies or agencies in other countries. (*See* Administrative Conference of the United States, Recommendation 2011–6, International Regulatory Cooperation, 77 FR 2257, 2259 (Jan. 17, 2012); Exec. Order 13,609 (May 1, 2012); Exec. Order 13,563 (Jan. 18, 2011)).

3. *Evaluate Incentives.* If an agency is contemplating a third-party program in which regulated entities would have the choice of either contracting with third parties or being assessed directly by the agency, the agency should evaluate whether sufficient incentives exist or can be created to attract the participation of regulated entities in the third-party program. Incentives for regulated entities to utilize third parties may include:

(a) exemption from a governmental fee that would otherwise be applicable; or

(b) the ability to satisfy the regulatory requirements of multiple jurisdictions through a single third-party conformity assessment engagement.

B. Considerations for a Federal Agency When Establishing a Third-Party Program to Assess Regulatory Compliance

4. *Proportionality to the Risk.* An agency that has decided to establish a third-party program to assess regulatory compliance, or is directed by statute or other provision of law to do so, should design its conformity assessment program to be proportional to the risks associated with regulatory noncompliance. When the risks are high, a conformity assessment program should be characterized by high degrees of rigor and independence. When the risks associated with noncompliance are lower, the regulatory objective may be achievable with less rigor and independence. Types of rules that may be established by the agency to help ensure rigor and independence include:

(a) accreditation rules that set high standards of competence for the accreditation of third parties;

(b) selection rules that pertain to how regulated entities select third parties, requiring, for example, that third parties disclose conflicts of interests or that regulated entities contract with a different third party after a specified number of assessments;

[6] American National Standards Institute (ANSI), National Conformity Assessment Principles for the United States, 3, *available at http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/NCAP%20second%20edition.pdf.*

[7] OMB Circular A–119 Revised §§ 8, 13(e) (Feb. 10, 1998); NIST, Guidance on Federal Conformity Assessment Activities, 65 FR 48,894 (Aug. 10, 2000).

(c) performance rules that require third parties to perform a rigorous set of assessment activities; and

(d) reporting rules that require third parties to provide sufficient information to the agency and the public about the process and outcomes of assessment activities.

5. *Use of Existing Conformity Assessment Standards.* The agency should consider relying on existing conformity assessment standards, particularly international standards that set forth requirements for conformity assessment and accreditation bodies. Incorporating existing standards may reduce costs for the agency and for the regulated entities. To evaluate the suitability of using existing standards, the agency should take into account the following considerations:

(a) When an agency incorporates existing conformity assessment standards into its program requirements, important concerns may arise about the public availability of those standards due to the costs of obtaining copyrighted materials. When an agency considers incorporating copyrighted material by reference, the agency should be cognizant of issues relating to incorporation by reference. (*See* Administrative Conference of the United States, Recommendation 2011–5, Incorporation by Reference, 77 FR 2257 (Jan. 17, 2012));

(b) An agency that anticipates the use of conformity assessment bodies in other countries may particularly benefit by recognizing accreditation bodies that operate in accordance with international standards rather than the agency itself accrediting conformity assessment bodies;

(c) When an agency incorporates existing standards into its requirements for third parties, it can supplement those standards with program-specific rules. An agency may require, for example, that in addition to being accredited to an international standard, a conformity assessment body must satisfy accreditation rules specific to the third-party program; and

(d) Agencies should also be aware that existing conformity assessment standards may include confidentiality provisions that apply to information collected during the assessment. Agencies should consider when disclosure to agencies and/or the public is necessary and when confidentiality may be justified. Program-specific reporting rules, as discussed in section 6 below, may be necessary to enable appropriate governmental or public access to such information.

6. *Access to Information.* The agency should ensure that both the government and the public will have appropriate access to information about program operations. An agency's development of third-party program rules and guidance should include notice and an opportunity for public participation. Also, the agency should provide information to the public about the roles and identities of the third parties associated with a regulatory program. Finally, the agency should establish reporting rules that require third parties to provide information to the agency based on the following considerations:

(a) The reporting rules should facilitate transparency. Information about the compliance of regulated entities should be available from the agency to the public, comparable to what would be available in the absence of a third-party program. Agencies may also be able to provide additional compliance information to the public that was not available before the third-party program;

(b) The reporting rules should facilitate appropriate agency oversight. For example, conformity assessment bodies can be required to report to the agency potential conflicts of interest before performing a conformity assessment, or provide the dates of their assessment activities so that the agency can conduct site visits;

(c) In certain circumstances, the agency might have reporting rules that require conformity assessment bodies to send assessment results directly to the agency; and

(d) The agency might require conformity assessment bodies and/or regulated entities to report electronically, which may facilitate the provision of information to the public.

7. *Agency Oversight.* The agency has a duty to exercise oversight to ensure that the third-party program is fulfilling its regulatory purpose. An agency should generally set forth how it intends to conduct such oversight. For example, it may annually audit a certain number of accreditations or conformity assessments, or carry out a market surveillance program to test regulated products off-the-shelf. In exercising oversight, the agency should also take into account the following considerations:

(a) Beyond conducting direct oversight, an agency can require third parties to conduct additional assessment activities that provide further information to the agency about program operation. For example, an agency may require accreditation bodies annually to audit a certain number of conformity assessments, or it may require conformity assessment bodies to conduct particular types of surveillance on products they assess;

(b) The agency should establish procedures for receiving and responding to public complaints regarding potential noncompliance or other aspects of program operation. The agency could, for example, require a third party that has assessed the conformity of a regulated product or entity to investigate a complaint of noncompliance. In any event, the agency should ensure that complaints are resolved in an appropriate and timely manner; and

(c) The agency should make clear the possible adverse actions that it may take against third parties that do not comply with program rules. A key adverse action is removing third parties from the program. Third parties may be removed temporarily through a suspension of accreditation, or permanently through a withdrawal of accreditation.

Administrative Conference Recommendation 2012–8

Inflation Adjustment Act

Adopted December 7, 2012

Civil monetary penalties are used by the Congress and federal agencies to enforce and promote compliance with federal laws and regulations by deterring violations. These laws and regulations serve vital public purposes such as ensuring workplace or transportation safety, preserving the environment, and protecting consumers from dangerous products. As the then Deputy Director of the Office of Management and Budget testified to Congress regarding an earlier version of the Federal Civil Penalties Inflation Adjustment Act of 1990 (''the Act'' or ''the Inflation Adjustment Act''), civil monetary penalties ''do more than recover funds and sanction wrongdoers. They often serve as an effective alternative to court prosecutions and provide added deterrence to would be wrongdoers intending to defraud or abuse government programs.'' [1]

This Recommendation and the supporting Report build upon important earlier Administrative Conference works on agency authority to adjust and impose civil monetary penalties or on inflation adjustment. For example, in Recommendation 84–7, *Administrative Settlement of Tort and Other Monetary Claims Against the Government,* the Conference encouraged Congress to ''systematically raise ceilings on all agency authority to settle claims where inflation has rendered obsolete the present levels.'' [2] Recommendation 79–3, *Agency Assessment and Mitigation of Civil Money Penalties,* examined agency civil monetary penalty assessment and mitigation practices.[3]

Congress enacted the Federal Civil Penalties Inflation Adjustment Act of 1990 in recognition that ''the power of Federal agencies to impose civil monetary penalties for violations of Federal law and regulations plays an important role in deterring violations and furthering the policy goals embodied in such laws and regulations.'' [4] Congress sought to ''improve the collection by the Federal Government of civil monetary penalties'' given that ''inflation has weakened the deterrent effect of such penalties'' and that the government did not ''maintain comprehensive, detailed accounting of the efforts of Federal agencies to assess and collect civil monetary penalties.'' [5] The 1990 statute required the President to report annually to Congress on federal civil monetary penalties covered by the law, and to calculate a cost-of-living adjustment for those penalties.[6] At the time,

[1] *Federal Civil Penalties Inflation Adjustment Act of 1987: Hearing on S.1014 Before the Subcomm. on Oversight of Gov't Mgmt. of the S. Comm. on Gov't Affairs,* 101st Cong. 41 (1988) (statement of Joseph Wright Jr., Deputy Director of the Office of Management and Budget) [hereinafter 1988 Senate Hearing].

[2] ACUS, Recommendation 84–7, *Administrative Settlement of Tort and Other Monetary Claims Against the Government,* 49 FR 49840 (Dec. 24, 1984).

[3] ACUS, Recommendation 79–3, *Agency Assessment and Mitigation of Civil Money Penalties,* 44 FR 38824 (July 3, 1979).

[4] Public Law 101–410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note § 2(a)).

[5] *Id.* § 2(b). *See also* 1988 Senate Hearing, *supra* note 1, at 3 (statement of Senator Levin) (discussing the need to increase penalties to account for inflation and improve deterrence and noting that civil monetary penalties collected were over $400 million per year).

[6] *Id.* §§ 4–5.

agencies did not have legal authority to adjust civil monetary penalties directly. Any such modification had to be made by the passage of new legislation. Due to the slow pace of amendments of agency organic statutes in recent years, substantial periods of time could elapse between specific statutory adjustments of civil monetary penalty amounts, and the deterrent effect of the penalties could be diminished by the effects of inflation in the interim period. Accordingly, Congress considered adoption of a freestanding provision that would establish a procedure through which regulatory agencies could modify the amounts of the penalties they may assess without further legislative action.

In 1996, Congress amended the Federal Civil Penalties Inflation Adjustment Act to authorize and require the agencies, with limited exceptions for four statutory programs, to adjust their civil monetary penalties for inflation.[7] However, the implementation data demonstrate that under the mechanisms adopted by Congress, the adjustments regulatory agencies are authorized to make have not allowed the penalties to keep pace with the rate of inflation that has been experienced.[8] The existing pattern of adjustments has several anomalous features that may not have been apparent to the members of Congress when they adopted the 1996 legislation. These results raise two questions: whether the current pattern of penalty adjustments carries out the purposes of the statute, and whether Congress should adopt a modified adjustment procedure under which future changes in penalties would more closely track the actual rate of inflation.

Three statutory provisions account for why the adjustments lag behind the actual inflation rate. First, the Inflation Adjustment Act imposes a ten percent cap on initial penalty adjustments.[9] That cap creates an ''inflation gap'' which reflects the sometimes considerable difference between penalties, as adjusted under the Act, and the levels that such penalties would reach if the first adjustment had been based on changes in the cost of living that had actually occurred. This gap, once established in the first capped adjustment, grows over time as subsequent adjustments are made and can never be closed under the current statutory scheme.[10]

Second, the Act directs federal agencies to use Consumer Price Index (''CPI'') data in ways that are out of sync with inflation. Because of the Act's definition of ''cost-of-living adjustment,'' agencies must use CPI data that are at least seven months old, and sometimes as much as 18 months old in their adjustments, depending on when the agency chooses to update its penalties.[11] Adjustment of penalties using out-dated data creates a phenomenon known as ''CPI lag.'' The legislative history of the Act suggests that the ''CPI lag'' may have resulted from changes introduced during the iterative legislative drafting process, rather than by conscious design.[12] As with the ''inflation gap'' issue, CPI-based adjustments prescribed by the Act result in chronic underadjustment of civil monetary penalties relative to actual inflation.[13]

Third, the Act's elaborate rounding rules effectively prevent a second inflation adjustment for some penalties until inflation has increased by a total of at least 45 percent.[14] In an apparent scrivener's error, the Act ties the rounding of civil monetary penalty increases to the amount of the underlying civil penalty, rather than the base amount of the increase.[15] Over time, the rounding mechanism has the effect of deferring increases for certain penalties, only to unleash dramatic penalty increases after a long latency period (in some instances greater than the actual increase in inflation). For example, at an inflation rate of 2.5 percent, the rounding provisions, coupled with the 10 percent initial cap, could prevent an agency from adjusting its penalties for inflation for 15 years or more.[16] As with nonadjustment or under-adjustment, over-adjustment may also alter the intended effect of civil monetary penalties.

The Department of Homeland Security's 2011 adjustment of a host of penalties for violations of the Immigration and Nationality Act offers an excellent illustration of how the Inflation Adjustment Act works in action and why Congress should consider revisiting the operation of these procedures.[17] These penalties relate to a number of serious legal violations, including: failure to depart the U.S. voluntarily, failure to comply with removal orders or to remove alien stowaways, failure to report an illegal landing or desertion of an alien crewmen or passenger, or failure to prevent the unauthorized landing of aliens.[18] The following table, which is based on the Department's 2011 inflation adjustment, displays:

- The current penalty amount;
- The raw amount by which each penalty would be increased if adjusted for actual inflation;
- The effect of the Inflation Adjustment Act's constraint on inflation adjustment through, for example, capping the penalty adjustment at a maximum of a ten percent increase;
- The amount of the penalty increase prescribed the Act; and
- The distortion created by the variance between the raw adjusted penalty and the adjustment prescribed by the Act.

Although aggregate data are not available, the following example illustrates that the distortions created by the Act are considerable, particularly when considered in relation to the size of the unadjusted penalty.

DEPARTMENT OF HOMELAND SECURITY, IMMIGRATION AND NATIONALITY ACT CIVIL MONETARY PENALTIES INFLATION ADJUSTMENT (2011) [19]

[A] INA § Statute	[B] Current penalty	[C] Year last adjusted	[D] CPI factor (2011) (%)	[E] Raw increase (2011) [B × D]	[F] Rounder [Inflation Adjustment Act constraint]	[G] Rounded increase [Inflation Adjustment Act increase]	[H] Raw adjusted penalty* [B + E]	[I] Adjusted penalty [per IAA] [B + G]	[J] Inflation Adjustment Act distortion* [I–H]
INA § 231(g); 8 U.S.C. 1221(g).	$1,000.00	Enacted 2002 ..	21.16	$211.60	10% statutory cap ..	$100.00	$1,211.60	$1,100.00	−$111.60
INA § 234; 8 U.S.C. 1224.	$2,200.00	1999	31.15	$685.30	$1,000.00 [rounder]	$1,000.00	$2,885.30	$3,200.00	+$314.70
INA § 243(c)(1)(A); 8 U.S.C. 1253(c)(1)(A).	$2,000.00	Enacted 1996 ..	39.10	$782.00	10% statutory cap ..	$200.00	$2,782.00	$2,200.00	−$582.00

[7] Public Law 104–134, 110 Stat. 1321 (1996) (excluding penalties under the Internal Revenue Code, the Occupational Safety and Health Act, the Social Security Act, and the Tariff Act).

[8] James Ming Chen, *Inflation Based Adjustments in Federal Civil Monetary Penalties* (2012) (report to the Administrative Conference of the U.S.), *available* at *www.acus.gov* [hereinafter Chen Report]; *see also* United States General Accounting Office (GAO), GAO–03–409, Civil Penalties: Agencies Unable to Fully Adjust Penalties for Inflation Under Current Law (2003).

[9] Public Law 104–134, § 31001(s)(1), 110 Stat. 1321, 1373 (1996).

[10] Chen Report, *supra* at III.A.

[11] Inflation Adjustment Act, *supra* note 4, § 5.

[12] *See* Chen Report, *supra* note 8, at II (providing an extensive discussion of the legislative history and the evolution of the Act's cost-of-living adjustment methodology).

[13] *Id.* at III.B.

[14] Inflation Adjustment Act, *supra* note 4, § 5(a); Chen Report, *supra* note 8, at III.C.

[15] Chen Report, *supra* note 8, at III.C.

[16] *Id.*

[17] *See* Department of Homeland Security, *Civil Monetary Penalties Inflation Adjustment,* 76 FR 74625, 74,627–28 (Dec. 1, 2011). It is important to note, however, that several penalties adjusted in 2011 had not previously been adjusted or had not been adjusted for many years. As a result, the distortions caused by the Inflation Adjustment Act may have been magnified.

[18] *Id.*

DEPARTMENT OF HOMELAND SECURITY, IMMIGRATION AND NATIONALITY ACT CIVIL MONETARY PENALTIES INFLATION ADJUSTMENT (2011) [19]—Continued

[A] INA § Statute	[B] Current penalty	[C] Year last adjusted	[D] CPI factor (2011) (%)	[E] Raw increase (2011) [B × D]	[F] Rounder [Inflation Adjustment Act constraint]	[G] Rounded increase [Inflation Adjustment Act increase]	[H] Raw adjusted penalty* [B + E]	[I] Adjusted penalty [per IAA] [B + G]	[J] Inflation Adjustment Act distortion* [I–H]
INA § 243(c) (1)B); 8 U.S.C. 1253(c) (1)(B).	$5,000.00	Enacted 1996 ..	39.10	$1,955.00	10% statutory cap ..	$500.00	$6,955.00	$5,500.00	−$1,455.00

* * * * *

The issues with the Federal Civil Penalties Inflation Adjustment Act described above arise from its plain language, and federal regulatory agencies may not themselves adjust the penalty levels to track the inflation rate more closely. As the Government Accountability Office has found, some agencies have attempted to adjust civil monetary penalties in common-sense ways that better reflect the real economic impact of inflation.[20] However, these good faith efforts objectively did not comply with the plain language of the Inflation Adjustment Act. They also subjected agencies to the risk of legal challenges to penalty adjustments.

Review of **Federal Register** notices also shows that several agencies have failed to comply with the statutory requirement to review and, if necessary, adjust penalties at least once every four years.[21] Regular penalty adjustments ensure the continued deterrent effect of civil monetary penalties. This is especially important where maximum penalties are imposed by agencies to punish the worst offenders. It is essential to enforcement policy that the penalties have their intended deterrent effect and are not simply viewed as a cost of doing business.

The Administrative Conference therefore recommends that Congress reexamine the procedures set forth in the Inflation Adjustment Act and make such changes to the Act as are appropriate. The Recommendation also advises agencies to comply with the letter of the law, by applying the rounding adjustment based on the size of the penalty, rather than the size of the increase, and by making adjustments every four years. Agencies should be mindful of the financial or other adverse consequences of failing to adjust civil monetary penalties regularly, in compliance with the Inflation Adjustment Act, or of failing to comply with the adjustment provisions currently set forth in the Act.[22]

The current Recommendation is intentionally circumscribed in scope. The underlying research commissioned by the Conference examined only the existing statutory process for inflation adjustments under the Inflation Adjustment Act. The Recommendation does not address other potential issues involving the current process, including: The appropriateness of the Act's existing exemption for civil monetary penalties under four statutes or whether additional agency programs should be exempt; the effectiveness of self-enforcement by federal agencies; obligations for reporting compliance; the lack of a central authority for administering the Act; alternative metrics for measuring inflation; or alternative forms of civil monetary penalties (*e.g.,* percentages rather than fixed values). These important issues warrant thoughtful consideration and may lead to future Conference recommendations.

Recommendation

A. Recommendation to Congress

1. Congress should change the current statutory framework by which agencies must make periodic inflation adjustments to civil monetary penalties set forth in the Federal Civil Penalties Inflation Adjustment Act, codified as amended at 28 U.S.C. 2461 note (2012), as appropriate in light of the distortions resulting from:

(a) The ''inflation gap'' created by a ten percent cap on the initial penalty adjustment, which grows over time and can never be closed under the current statutory provision.

(b) The ''CPI lag'' that results from the statute's definition of the term ''cost-of-living adjustment,'' which directs agencies to base their adjustments on CPI data that are at least seven months old and may be as much as 18 months old, and thus lag behind the actual inflation rate.

(c) The rounding rules that tie rounding of increases to the size of the penalty, rather than the size of the increase, and that may result in significant periods of nonadjustment of civil monetary penalties followed by abrupt and substantial increases.

B. Recommendation to Agencies

2. Federal agencies subject to the Inflation Adjustment Act should review and, if necessary, adjust their civil monetary penalties for inflation at least once every four years, as required by the Act. Agencies should review their implementation procedures and practices to ensure that inflation adjustments comply with the plain language of the Act, and particularly its rounding provisions.

[FR Doc. 2013–00674 Filed 1–14–13; 8:45 am]

BILLING CODE 6110–01–P

[19] This table presents a subset of four penalties from the table of penalty adjustments contained in the 2011 **Federal Register** notice from the Department of Homeland Security, *id.,* together with two additional columns ([H] and [J], denoted by a *) from the Chen Report, *supra* note 8, at IV.C.

[20] *E.g.,* GAO, GAO–02–1084R, Compliance with the Inflation Adjustment Act (2002) (reporting that the Farm Credit Administration had rounded its penalty increase by the size of the increase rather than the penalty size); GAO, GAO–02–1085R, **DEPARTMENT OF COMMERCE: COMPLIANCE WITH THE INFLATION ADJUSTMENT ACT** (2002) (reporting that the Department of Commerce had rounded its penalty increase by the size of the increase rather than the penalty size).

[21] *E.g.,* Department of Agriculture, *Department of Agriculture Civil Monetary Penalties Adjustment,* 75 FR 17555 (Apr. 7, 2010) (remedying erroneous exclusion of some civil monetary penalties from earlier rounds of adjustments); Department of Transportation, *Civil Penalties,* 75 FR 5244 (Feb. 2, 2010) (reporting last inflation adjustment six years ago, rather than four years ago as the Act's quadrennial interval prescribes).

[22] *See supra* notes 20 and 21.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 9, 2013.

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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–

7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. 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.

Agricultural Research Service

Title: Electronic Mailing List Subscription Form—Nutrition and Food Safety.

OMB Control Number: 0518–0036.

Summary of Collection: The National Agricultural Library's Food and Nutrition Information Center (FNIC) currently maintains several on-line ''discussion groups.'' This voluntary ''Electronic Mailing List Subscription Form'' gives individuals working in the area of nutrition and food safety an opportunity to participate in these groups. Data collected using this form will help FNIC determine a person's eligibility to participate in these discussion groups. The authority for the National Agricultural Library (NAL) to collect this information is contained in the CFR, Title 7, Volume 1, Part 2, and Subpart K, Sec. 2.65 (92).

Need And Use Of The Information: FNIC will collect the name, email address, job title, employer, mailing address and telephone number in order to approve subscriptions for nutrition and food safety on-line discussion groups. Failure to collect this information would inhibit FNIC's ability to provide subscription services to these discussion groups.

Description of Respondents: Individuals or households; State, Local and Tribal Governments.

Number of Respondents: 1,000.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 17.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2013–00598 Filed 1–14–13; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Document Number AMS–FV–09–0028, FV–11–327]

United States Standards for Grades of Frozen Vegetables

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) proposes to revise eight United States Standards for Grades of Frozen Vegetables. AMS is proposing to replace the dual grade nomenclature with single letter grade designations. ''U.S. Grade A'' (or ''U.S. Fancy''), ''U.S. Grade B'' (or ''U.S. Extra Standard''), and ''U.S. Grade C'' (or ''U.S. Standard'') would become ''U.S. Grade A,'' ''U.S. Grade B,'' and ''U.S. Grade C,'' respectively. This would conform to recent changes in other grade standards. AMS is also proposing to provide updated contact information in order to obtain copies of the grade standards and color standards. These changes would bring these grade standards in line with the present quality levels being marketed today and would provide guidance in the effective utilization of these products. The grade standards covered by these proposed revisions are: frozen asparagus, frozen lima beans, frozen speckled butter beans, frozen cooked squash, frozen summer squash, frozen sweet potatoes, frozen turnip greens with turnips, and frozen mixed vegetables.

DATES: Comments must be submitted on or before March 18, 2013.

ADDRESSES: Written comments may be submitted via the Internet: *http://www.regulations.gov;* by email *brian.griffin@ams.usda.gov;* or by mail to Brian E. Griffin, Standardization Branch, Specialty Crops Inspection Division, Fruit and Vegetable Program, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Room 0709, South Building; STOP 0247, Washington, DC 20250; fax: (202) 690–1527. Copies of the proposed revised United States Standards for Grades are available at the addresses cited above and at the AMS Web site at: *http://www.ams.usda.gov/processedinspection.* All comments should reference the document number, date, and page number of this issue of the **Federal Register**. All comments will be posted without change, including any personal information provided. All comments submitted in response to this notice will be included in the public record and will be made available to the public on the Internet via *http://www.regulations.gov.* Comments will be made available for public inspection at the above address during regular business hours or can be viewed at: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Brian E. Griffin, at the address above, or phone (202) 720–5021; or fax (202) 690–1527.

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946, as amended, directs and authorizes the Secretary of Agriculture ''to develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.''

AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. Those United States Standards for Grades of Fruits and Vegetables no longer appear in the Code of Federal Regulations but are maintained by USDA, AMS, Fruit and Vegetable Program at the following Web site: *http://www.ams.usda.gov/processedinspection.* AMS is proposing revisions to these U.S. Standards for Grades using the procedures that appear in part 36 of Title 7 of the Code of Federal Regulations.

Background: AMS periodically reviews the processed fruit and vegetable grade standards for usefulness in serving the industry. AMS has identified eighteen grade standards covering various frozen vegetables for possible revision. More recently developed grade standards use a single term, such as ''U.S. Grade A'' or ''U.S. Grade B'' to describe each level of quality within a grade standard. Older standards used a dual system, such as ''U.S. Grade A'' and ''U.S. Fancy'' to describe the same level of quality within a grade standard. Prior to undertaking detailed work developing the proposed revisions to these grade standards, AMS published a notice in the **Federal Register** on July 23, 2010 [7 FR 43141] soliciting comments on the possible changes and any other comments regarding these grade standards to better serve the industry. A 60 day period was provided for interested persons to submit comments. In response to its request, AMS received one comment which was submitted by the American Frozen Food Institute (AFFI). AFFI is

the national trade association representing the interests of U.S. frozen food processors and their suppliers. AFFI's more than 500 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States. AFFI's comment was in support of the proposed revisions to the U.S. grade standards because its membership believes ''moving to a one-term system of grading (e.g., referring to ''Grade A'' solely, instead of allowing the use of ''Grade A'' and/or ''Extra Fancy'' to describe the same degree of quality) will help to improve consistency between new and old standards and minimize any confusion that might arise in the marketplace in interpreting or understanding the grading terminology used on packaging.''

This notice proposes to revise eight of the eighteen grade standards identified in the notice published July 23, 2010 [7 FR 43141]. The changes to each of the grade standards are as follows:

United States Standards for Grades of Frozen Asparagus

Update address for AMS. Change ''U.S. Grade A or U.S. Fancy'' to ''U.S. Grade A.'' Change ''U.S. Grade B or U.S. Extra Standard'' to ''U.S. Grade B.''

United States Standards for Grades of Frozen Cooked Squash

Update address for AMS. Change ''U.S. Grade A or U.S. Fancy'' to ''U.S. Grade A.'' Change ''U.S. Grade B or U.S. Extra Standard'' to ''U.S. Grade B.'' Correct typographical error to read: ''U.S. Grade B is the quality of frozen cooked squash * * * that possesses reasonably good flavor and odor.'' This would ensure that these requirements are consistent throughout the document.

United States Standards for Grades of Frozen Lima Beans

Update address for AMS. Change ''U.S. Grade A or U.S. Fancy'' to ''U.S. Grade A.'' Change ''U.S. Grade B or U.S. Extra Standard'' to ''U.S. Grade B.'' Change ''U.S. Grade C or U.S. Standard'' to ''U.S. Grade C.'' Update contact information to obtain color standards for frozen lima beans.

United States Standards for Grades of Frozen Mixed Vegetables

Update address for AMS. Change ''U.S. Grade A or U.S. Fancy'' to ''U.S. Grade A.'' Change ''U.S. Grade B or U.S. Extra Standard'' to ''U.S. Grade B.'' Change ''U.S. Grade C or U.S. Standard'' to ''U.S. Grade C.'' Update references to color standard and definitions to eliminate conflict with current U.S. Standards for Grades of Frozen Lima Beans (remove reference to Maerz and Paul's Dictionary of Color and replace with current USDA Color Standards for Frozen Lima Beans). Update definition for color to ''Green means that not less than 50 percent of the surface area of the individual lima bean possesses as much or more green color than U.S.D.A. lima bean green color standard for frozen lima beans.'' Update definition to ''White means that more than 50 percent of the surface area of the individual lima bean is lighter in color than U.S.D.A. lima bean white color standard for frozen lima beans.'' Add ''Information regarding these color standards may be obtained by contacting the Specialty Crops Inspection Division.'' These changes would eliminate the inconsistency in evaluating color of frozen lima beans when they are a component in frozen mixed vegetables.

United States Standards for Grades of Frozen Speckled Butter (Lima) Beans

Update address for AMS. Change ''U.S. Grade A or U.S. Fancy'' to ''U.S. Grade A.'' Change ''U.S. Grade B or U.S. Extra Standard'' to ''U.S. Grade B.''

United States Standards for Grades of Frozen Squash (Summer Type)

Update address for AMS. Change ''U.S. Grade A or U.S. Fancy'' to ''U.S. Grade A.'' Change ''U.S. Grade B or U.S. Extra Standard'' to ''U.S. Grade B.''

United States Standards for Grades of Frozen Sweet Potatoes

Update address for AMS. Change ''U.S. Grade A or U.S. Fancy'' to ''U.S. Grade A.'' Change ''U.S. Grade B or U.S. Extra Standard'' to ''U.S. Grade B.''

United States Standards for Grades of Frozen Turnip Greens With Turnips

Update address for AMS. Change ''U.S. Grade A or U.S. Fancy'' to ''U.S. Grade A.'' Change ''U.S. Grade B or U.S. Extra Standard'' to ''U.S. Grade B.'' Change references for ''flavor'' to ''flavor and odor'' to ensure that these requirements are consistent throughout the document.

The remaining grade standards identified in the **Federal Register** notice published July 23, 2010 [7 FR 43141), frozen carrots, frozen whole kernel corn, frozen corn on the cob, frozen breaded onion rings, frozen peas, frozen peas and carrots, frozen French fried potatoes, frozen sweet peppers, frozen succotash, and frozen tomato juice and tomato juice from concentrate will be revised at a later date. The Department has determined that these grade standards require additional revisions to take into account, i.e., U.S. Food and Drug Administration's Standards of Identity, new styles and pack types, and new commercial cultivated varieties (such as supersweet corn) which possess unique characteristics. AMS will seek additional guidance from the industry to update these grade standards so that they reflect current marketing practices and serve the needs of the industry.

The proposed revisions to these frozen vegetable grade standards would provide a common language for trade and better reflect the current marketing of frozen vegetables.

Authority: 7 U.S.C. 1621–1627.

Dated: January 9, 2013.

Rex A. Barnes,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2013–00600 Filed 1–14–13; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Manti-La Sal National Forest, Utah; Maverick Point Forest Health Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare environmental impact statement.

SUMMARY: The Forest Service will prepare an Environmental Impact Statement (EIS) to document the analysis and disclose the environmental impacts of the Maverick Point Forest Health Project. This project is designed to achieve goals of increasing aspen and ponderosa pine forest stand resilience and resistance to insects, disease, drought, and wildfire by altering stand density, species composition, and age class structure via use of timber harvesting and prescribed fire. Project activities also seek to maintain or improve the productivity and diversity of wildlife habitat and improve watershed health through restoring or protecting selected springs or active head cuts, closing unauthorized roads, and reclaiming abandoned uranium mine adits and waste rock. The project is also designed to provide for a sustainable and manageable system of roads and trails to meet public and administrative needs in the project area.

DATES: Comments concerning the scope of the analysis described in this notice must be received by February 14, 2013. The draft environmental impact statement is expected October 2013 and the date planned for release of the final EIS is March 2014.

ADDRESSES: Questions or written comments concerning the proposed

action or requests for copies of the proposal should be addressed to Michael Diem or Greg Montgomery at the following address: Moab/Monticello Ranger District, Manti-La Sal National Forest, P.O. Box 820, Monticello, Utah 84535, phone: 435–587–2041. Comments can also be hand delivered Monday through Friday 8 a.m. to 4:30 p.m. at the following physical address: 432 East Center St., Monticello, Utah. Comments may also be emailed to: *comments-intermtn-manti-lasal-moab-monticello@fs.fed.us* or submitted via facsimile to 435–587–2637.

FOR FURTHER INFORMATION CONTACT: A detailed description of the purpose and need and proposed action can be obtained from the Moab/Monticello Ranger District, Manti-La Sal National Forest. An Internet site is also available that provides detailed information. This information can be accessed on the Manti-La Sal National Forest Internet site: *http://www.fs.usda.gov/projects/mantilasal/landmanagement/projects.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Maverick Point Forest Health project area is an area with high resource and recreation values located about 14 air miles from Blanding, Utah and 14 air miles from Monticello, Utah. The project area is located within the Upper Colorado River Basin. Huc6 watersheds included are primarily the Upper North Cottonwood and Allen Canyon watersheds, but minor portions of the Cottonwood Creek and Stevens Canyon watersheds are included.

There is increasing evidence that ponderosa pine, aspen, and associated vegetation on the Manti-La Sal National Forest is being affected by climate change. Over the last 20 years drought conditions have increased; fire size, severity, and total acres burned have increased; and the health and vigor of aspen has declined as conifer encroachment increases, age, repeated drought, increasing temperatures, insects, and diseases affect many aspen clones. Ungulate grazing can also, and in areas, has had damaging effects on regenerating aspen.

National policy directs us to consider whether climate change is contributing to the health of the forest and watersheds, and where applicable, implement adaptation strategies to reduce the vulnerability of landscapes to expected climate change effects. This includes building resistance to climate-related stressors (drought, wildfire, insects, and disease) and increasing ecosystem resilience by minimizing the severity of climate change impacts, reducing vulnerability, and/or increasing the adaptive capacity of elements of the ecosystem.

The ponderosa pine vegetative community that dominates the upper mesa top and upper drainages of the project area was determined to be Condition Class 3 (FRCC–3). FRCC–3 is representative of conditions where the fire regimes have been significantly altered from their historical range. The risk of losing key ecosystem components is high. Fire frequencies have departed from historical frequencies by multiple return intervals. This results in dramatic changes to one or more of the following: fire size, intensity, severity, and landscape patterns. Vegetation attributes have been significantly altered from their historical range in the project area.

Purpose and Need for Action

The purposes of the project are:

(1) Increase resistance of ponderosa pine forest vegetation in the Maverick Point landscape and associated watersheds to climate related stressors (drought, wildfire, insects, and disease) and promote the growth and development of larger diameter trees and stands by:

- Encouraging a mosaic of vegetative conditions (species, age, and density);
- Restoration of fire occurrence to historic intervals, intensity, and severity; and
- Promoting improved health of forest stands.

(2) Increase the resistance and resilience of aspen vegetation in the Maverick Point landscape and *watersheds to climate related stressors (drought, temperature change, vegetative competition,* insects, and disease) and ungulate grazing pressure.

(3) Maintain or improve the productivity and diversity of wildlife habitat (Abert's squirrel, flammulated owl, turkey, northern goshawk, deer, and elk) in the project area.

(4) Maintain or improve watershed health by:

- Promoting a mosaic of vegetation ages, structures, and species (both herbaceous and woody) to buffer against large-scale fire, insect epidemics, and other disturbances;
- Moving the landscape towards historic fire regimes, thereby reducing the risk of stand-replacing fires that could damage soils and associated watershed conditions;
- Providing restoration and appropriate protection of selected springs and active head cuts in drainages;
- Closure of unauthorized roads currently in use in the project area that are not maintained and may contribute to watershed degradation; and
- Reclamation of abandoned uranium mine adits and waste rock that may be contributing contaminants downstream.

(5) Establish a ponderosa pine seed production area (SPA) for future collection of seed for reforestation on this and adjacent Forests within suitable seed transfer areas.

(6) Reduce the risk of stand-replacing fire and its negative consequences on soil, water, and vegetation resources and associated risk to life (fire fighters, recreationists, and permittees) within the area through reduction of fuels and fire hazard, restoration of Condition Class 1, and through clearing of Forest roads to provide safer ingress and egress for fire fighters and authorized public uses.

(7) Provide for a sustainable, manageable road and trail system to meet public and administrative needs within the project area.

Proposed Action

The Manti-La Sal National Forest proposes to:

(1) Implement thinning and selective harvest treatments of large (8 inches DBH [diameter at breast height] and larger) trees within stands totaling about 1,260 acres. About 660 acres would be thinned and about 600 acres would receive thinning and group selection regeneration treatments. About 5% of thin/group selection stands would be treated by clearcut or clearcut with reserve trees in openings less than two acres in size.

(2) Implement TSI (timber stand improvement) thinning treatments of small (less than 8 inches DBH) trees and deciduous shrubs (Gambel oak, manzanita, serviceberry, etc.) within stands totaling about 4,400 acres.

(3) Prescribed fire—Forested (ponderosa pine) stands and adjacent pinyon-juniper, manzanita, and Gambel oak stands would be prescribe burned with 40–80% effective burn, low intensity and severity surface fire on about 6,000 acres. About 400 acres of pinyon pine, juniper, and sagebrush burned at low to moderate intensity and severity to create a mosaic of habitat conditions for wildlife is included in the 6,000 acre prescribed burn area. In addition to initial fuel treatments, about 10 years following initial treatments, one maintenance ponderosa pine underburn is included in this proposed action on the 5600 acres prescribed burn

area (excludes the wildlife habitat burn area).

(4) Treatment (of 60 to 90 acres) in areas 0.2–15 acres in size to promote regeneration and retention of aspen implementing recommendations provided in Guidelines for Aspen Restoration on the National Forests in Utah (2011).

(5) Mechanized fuel reduction treatments (mastication or crushing) would occur on about 2,040 acres to reduce hazard fuels, provide conditions more suitable for prescribed and natural fire, and improve wildlife habitat. About 340 acres will be treated with a rollerchopper to diversify the age and structure of the sagebrush community, and about 1700 acres will be masticated to remove encroaching pinyon pine, juniper, manzanita, and Gambel oak to create openings for wildlife, reduce encroachment in sagebrush openings, reduce fire hazard through reduction of ladder fuels in forest and woodland areas, and create spacing between crowns of small trees and mountain shrub groups.

(6) About 10 miles of Forest System Road would receive mechanized treatments to create shaded fuel breaks (100 feet each side of the roads) and provide safer ingress egress for the public and firefighters.

(7) Authorize the following road and trail system for implementation of this project and future management of the area:

- Level 2 (open) road—31.5 miles
- Level 1 (administrative, closed to public motorized)—6.8 miles (about 3.2 miles dual designated as Motorized Trail)
- Temporary Road (used for project implementation, closed following project)—4.6 miles; this includes use and closure of 2.5 miles of unauthorized routes currently being used by the public.
- Road closed/obliterated—13.5 miles
- Non-motorized trail—0.1 miles
- Single track motorized (motorcycle) trail—6.3 miles
- ATV (motorized < 50'' width)—8.8 miles (about 2.4 miles dual designated as Level 1 road)
- Motorized Trail open to all vehicles—0.8 miles (dual designated as Level 1 road)
- Trail closed/obliterated—4.7 miles
- Total Motorized Trail—15.9 miles.

(8) Implement treatments and protection measures to protect/restore one headcut (erosion area) by Starvation Point (head of east fork of Vega Creek) and Sand Spring. Road and trail crossings of cuts/drainages will be hardened or culverts installed as determined necessary.

(9) Reclaim abandoned uranium mine adits and stabilize waste rock that may be contributing contaminants downstream.

- Adits that pose a threat to public safety will be closed by construction of a solid plug of rock and/or cement, or if utilized by bats, by installation of a lockable bat grate. Adits that are short in depth, have stable walls, have little to no water, and pose little threat to public safety will be left in their current condition (three adits).
- Adits(s) discharging water will have a small drain installed at the bottom of the wall to prevent water from accumulating behind the wall and creating a potentially hazardous condition.
- Soil and water samples are being taken to determine if uranium or other toxic heavy metals are being transported downstream from the mine adits and waste rock. If testing of soil and water determines that heavy metals and/or radionuclides are being transported downstream and it is expected these will degrade the stream water, a water filtration system will be designed and built according to Forest specifications.
- All access and exploration roads, with exception of Forest Service (FS) road 5067, will be decommissioned. The first 1,500 feet of FS road 5067 will remain as a Forest system road to provide Forest access to the public. Roads reopened temporarily to provide access for closure of adits or other associated rehabilitation work, following activities, would be ripped, have appropriate drainage installed, be seeded to minimize erosion, and be blocked to motorized access.

Possible Alternatives

Scoping comments will be used by the Forest Service to develop a range of alternatives in response to significant issues that are identified. A no-action alternative will be analyzed during the alternative process. No other tentative or preliminary alternatives have been identified at this time.

Nature of Decision To Be Made

The responsible official will decide where or not to implement the proposed action as described or to implement an alternative course of action, as expressed in alternatives to the proposed action.

This EIS will tier to the final EIS for the Manti-La Sal National Forest Land and Resource Management Plan (Forest Plan). The Manti-La Sal Forest Plan provides the overall guidance (Goals, Objectives, Standards, and Management Area Direction) to achieve the Desired Future Condition for the area being analyzed, and contains specific management area prescriptions for the entire Forest.

Responsible Official

The Responsible Official is the Acting Forest Supervisor, Allen Rowley.

Preliminary Issues

Tentative or preliminary issues that have been identified include: Unroaded character; and Management Indicator or Sensitive species.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement.

The Forest Service is seeking information and comments from Federal, State, and local agencies as well as individuals and organizations that may be interested in, or affected by the proposed action. The Forest Service invites written comments and suggestions on the issues related to the proposal and the area being analyzed. Information received will be used in preparation of the Draft EIS and Final EIS. For most effective use, comments should be submitted to the Forest Service within 30 days from the date of publication of this Notice in the **Federal Register**. Comments should include your name, address, telephone number, organization represented (if any), title of the proposal, and specific facts and supporting reasons for us to consider in the analysis. Names and comments received are public information and will be released to those who request them. This will include names, addresses, and any other personal information provided with the comments. Comments submitted anonymously will be accepted and considered; however, anonymous comments will not provide the Agency with the ability to provide the respondent with subsequent environmental documents.

The proposed management activities would be administered by the Moab/Monticello Ranger District, Manti-La Sal National Forest, San Juan County, Utah.

The Acting Forest Supervisor for the Manti-La Sal National Forest, who is the responsible official for the EIS, will then make a decision regarding this proposal, after considering the comments, responses, and environmental consequences discussed in the Final Environmental Impact Statement, and applicable laws, regulations, and policies. The reasons for the decision will be documented in a Record of Decision. The Forest Supervisor's office of the Manti-La Sal National Forest is located at 599 West Price River Drive,

Price, Utah 84501, phone: 435–637–2817.

Dated: January 9, 2013.

Allen Rowley,

Acting Forest Supervisor.

[FR Doc. 2013–00665 Filed 1–14–13; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Forestry Research Advisory Council

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Forestry Research Advisory Council will meet in Washington, DC February 7–8, 2013. The Council is required by Section 1441 of the Agriculture and Food Act of 1981 to provide advice to the Secretary of Agriculture on accomplishing efficiently the purposes of the Act of October 10, 1962 (16 U.S.C. 582a, *et seq.*), commonly known as the McIntire-Stennis Act of 1962. The Council also provides advice relative to the Forest Service research program, authorized by the Forest and Rangeland Renewable Resources Research Act of 1978 (Pub. L. 95–307, 92 Stat. 353, as amended; 16 U.S.C. 1600 (note)). The meeting is open to the public.

DATES: The meeting will be held February 7–8, 2013, from 8:30 a.m. to 5:00 p.m., Eastern Standard Time.

ADDRESSES: The meeting will be held at the Hamilton Crowne Plaza Hotel, 14th & K Streets NW., Washington, DC 20005. Written comments concering this meeting should be addressed to Daina Apple, Designated Federal Officer, Forestry Research Advisory Council, USDA Forest Service Research and Development, Mail Stop 1120, 1400 Independence Ave. SW., Washington DC 20250–1120, by January 31, 2013. Comments may also be sent via fascimile to 703–605–5133. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at 1620 North Kent Street, RPC–4th floor, Rosslyn, VA. Visitors are encouraged to call ahead at 202–205–1665 to facilitate entry into the USDA Forest Service Building.

FOR FURTHER INFORMATION CONTACT: Daina Apple, Forest Service Office of the Deputy Chief for Research and Development, 202–205–1665. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Council will be discussing current and emerging forestry and natural resource research issues, and discussion is limited to Forest Service, National Institute of Food and Agriculture staff and Council members; however, persons who wish to bring forestry research matters to the attention of the Council may file written statements with the Council staff before or after the meeting.

Meeting Accommodations: If you require sign language interpreting, assistive listening devices or other reasonable accommodation, please request this in advance of the meeting by contacting the person listed in the section titled for further information contact. All reasonable accommodations requests are managed on a case-by-case basis.

Dated: January 9, 2013.

Jimmy L. Reaves,

Deputy Chief, Research and Development.

[FR Doc. 2013–00725 Filed 1–14–13; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Opportunity To Comment on the Applicants for the Indianapolis, Indiana Area

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice and request for comments.

SUMMARY: GIPSA requests comments on the applicants for designation to provide official services in the Indianapolis, Indiana area.

DATES: Comments must be postmarked or electronically dated on or before February 14, 2013.

ADDRESSES: We invite you to submit comments on these applicants. You may submit comments by using any of the following methods:

- *Submit Comments Using the Internet:* Go to Regulations.gov (*http://www.regulations.gov*). Instructions for submitting and reading comments are detailed on the site.
- *Mail, Courier or Hand Delivery:* Eric J. Jabs, Chief, USDA, GIPSA, FGIS, QACD, QADB, 10383 North Ambassador Drive, Kansas City, MO 64153.
- *Fax:* Eric J. Jabs, 816–872–1257.
- *Email: Eric.J.Jabs@usda.gov.*

Read Applications and Comments: All applications and comments will be available for public inspection at the office above during regular business hours (7 CFR 1.27(c)).

FOR FURTHER INFORMATION CONTACT: Eric J. Jabs, 816–659–8408 or *Eric.J.Jabs@usda.gov.*

SUPPLEMENTARY INFORMATION: In the October 31, 2012, **Federal Register** (77 FR 65855), GIPSA asked persons interested in providing official services in the Indianapolis, Indiana area to submit an application for designation.

There were two applicants for the Indianapolis, Indiana area: Mid-Iowa Grain Inspection, Inc. (Mid-Iowa) and East Indiana Grain Inspection, Inc. (East Indiana). Both applicants are currently designated official agencies and applied for designation to provide official services the entire area formerly assigned to Indianapolis Grain Inspection and Weighing Service, Inc. The area, in the State of Indiana, includes Bartholomew; Brown; Hamilton, south of State Route 32; Hancock; Hendricks; Johnson; Madison, west of State Route 13 and south of State Route 132; Marion; Monroe; Morgan; and Shelby Counties.

GIPSA is publishing this notice to provide interested persons the opportunity to present comments concerning the applicants. Commenters are encouraged to submit reasons and pertinent data for support or objection to the designation of the applicants. All comments must be submitted to the Quality Assurance and Compliance Division at the above address. Comments and other available information will be considered in making a final decision. GIPSA will publish notice of the final decision in the **Federal Register**.

Authority: 7 U.S.C. 71–87k.

Larry Mitchell,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2013–00676 Filed 1–14–13; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Proposed Posting and Posting of Stockyards

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Grain Inspection, Packers and Stockyards Administration (GIPSA) is taking several actions to post and depost stockyards under the Packers and Stockyards Act (P&S Act). Specifically, we are proposing that sixteen stockyards now operating subject to the P&S Act be posted. We are also posting eight stockyards that were identified previously as operating subject to the P&S Act.

DATE: For the proposed posting of stockyards, we will consider comments that we receive by January 30, 2013.

ADDRESSES: We invite you to submit comments on this notice. You may submit comments by any of the following methods:

- Internet: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- Mail, hand deliver, or courier to Dexter Thomas, GIPSA, USDA, 1400 Independence Avenue SW., Room 2530–S, Washington, DC 20250–3604.
- Fax to (202) 690–2173.

Instructions: All comments should refer to the date and page number of this issue of the **Federal Register**. The comments and other documents relating to this action will be available for public inspection during regular business hours.

FOR FURTHER INFORMATION CONTACT: Catherine M. Grasso, Program Analyst, Policy and Litigation Division at (202) 720–7363 or *catherine.m.grasso@usda.gov.*

SUPPLEMENTARY INFORMATION: The Grain Inspection, Packers and Stockyards Administration (GIPSA) administers and enforces the P&S Act of 1921, (7 U.S.C. 181 *et seq.*). The P&S Act prohibits unfair, deceptive, and fraudulent practices by livestock market agencies, dealers, stockyard owners, meat packers, swine contractors, and live poultry dealers in the livestock, poultry, and meatpacking industries.

Section 302 of the P&S Act (7 U.S.C. 202) defines the term ''stockyard'' as follows:

''* * * any place, establishment, or facility commonly known as stockyards, conducted, operated, or managed for profit or nonprofit as a public market for livestock producers, feeders, market agencies, and buyers, consisting of pens, or other enclosures, and their appurtenances, in which live cattle, sheep, swine, horses, mules, or goats are received, held, or kept for sale or shipment in commerce.''

Section 302 (b) of the P&S Act requires the Secretary of Agriculture to determine which stockyards meet this definition, and to notify the owner of the stockyard and the public of that determination by posting a notice in each designated stockyard. Once the Secretary provides notice to the stockyard owner and the public, the stockyard is subject to the provisions of Title III of the P&S Act (7 U.S.C. 201–203 and 205–217a) until the Secretary deposts the stockyard by public notice. To post a stockyard, we assign the stockyard a facility number, notify the stockyard owner, and send an official posting notice to the stockyard owner to display in a public area of the stockyard. This process is referred to as ''posting.'' The date of posting is the date that the posting notices are physically displayed at the stockyard. A facility that does not meet the definition of a stockyard is not subject to the P&S Act, and therefore cannot be posted. A posted stockyard can be deposted, which occurs when the facility is no longer used as a stockyard.

We are hereby notifying stockyard owners and the public that the following sixteen stockyards meet the definition of a stockyard, and that we propose to designate these stockyards as posted stockyards.

Proposed facility No.	Stockyard name and location
GA–233 ...	Middle Georgia Goat & Chicken Auction, Cochran, Georgia.
GA–234 ...	Bent Staple Auctions, LLC., Ocilla, Georgia.
GA–235 ...	Dooly County Livestock, LLC., Unadilla, Georgia.
IN–170	Tri-State Livestock Auction, LLC., Angola, Indiana.
MS–177 ...	Clark's Livestock, Forest, Mississippi.
MT–124 ...	Headwaters Livestock Auction, Three Forks, Montana.
NY–178	Don Yahn Market, Cherry Creek, New York.
NY–179	HillTop Auction Company, Penn Yan, New York.
OK–217 ...	Cross Livestock Auction, LLC, Checotah, Oklahoma.
SC–164	H & S Stockyards, Ehrhardt, South Carolina.
TN–204	Heritage Horse Sales, LLC., Shelbyville, Tennessee.
TN–205	Bill Roark dba Roan Valley Auction Company and Livestock Market, Mountain City, Tennessee.
TN–206	The Sale of Champions, Shelbyville, Tennessee.
TN–207	Southern Saddlebred Sales, Inc., Murfreesboro, Tennessee.
TX–355	Sulphur Springs Horse Sales, Sulphur Springs, Texas.
TX–357	High Plains Livestock LLC., Hereford, Texas

We are also notifying the public that the stockyards listed in the following table meet the P& S Act's definition of a stockyard and that we have posted the stockyards. On January 26, 2010, we published a notice in the **Federal Register** (75 FR 4039–4040) of our proposal to post these eight stockyards. Since we received no comments to our proposal, we assigned the stockyards a facility number and notified the owner of the stockyard facilities. Posting notices were sent to the owner of the stockyard to display in public areas of the stockyard.

The table below reflects the date of posting for each stockyard.

Facility No.	Stockyard name and location	Date of posting
AZ–117	Robertson Horse Sales, Benson, Arizona	April 28, 2010.
CA–193	Westside Auction Yard, Newman, California	May 3, 2010.
IA–263	Clarke's Auctioneering, Chariton, Iowa	May 6, 2010.
KY–185	Bluegrass Sales Stables, LLC, Elkton, Kentucky	April 30, 2010.
ME–106	Clark's Auction Company, Skowhegan, Maine	May 4, 2010.
OK–216	Alva Livestock Market, Alva Oklahoma	May 6, 2010.
TX–356	Corsicana Livestock Auction, Inc., Corsicana, Texas	April 30, 2010.
WI–151	Turenne Livestock Market, Thorpe, Wisconsin	April 29, 2010.

Authority: 7 U.S.C. 202.

Larry Mitchell,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2013–00689 Filed 1–14–13; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–1–2013]

Foreign-Trade Zone 3—San Francisco, California; Application for Expansion and Expansion of Service Area Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the San Francisco Port Commission, grantee of Foreign-Trade Zone 3, requesting authority to expand its service area under the alternative site framework (ASF) adopted by the Board (15 CFR Sec. 400.2(c)), as well as to include an additional usage-driven site. The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u) and the regulations of the Board (15 CFR part 400). It was formally docketed on January 9, 2013.

FTZ 3 was approved by the Board on March 10, 1948 (Board Order 12, 13 FR 1459, 3/19/48) and the zone was reorganized under the ASF on October 7, 2010 (Board Order 1718, 75 FR 64708, 10/20/2010). The zone project currently has a service area that includes the City and County of San Francisco and San Mateo County, California.

The applicant is now requesting authority to expand the service area of the zone to include Contra Costa, Marin and Solano Counties, as well as portions of Napa and Sonoma Counties, California, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies' needs for FTZ designation. The proposed expanded service area is adjacent to the San Francisco U.S. Customs and Border Protection Port of Entry.

The applicant is also requesting authority to include an additional usage-driven site: Proposed Site 6 (15.5 acres)—Coda Automotive Company, 2050 Park Road, Benicia, California (Solano County).

In accordance with the Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is *March 18, 2013.* Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to *April 1, 2013.*

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.* For further information, contact Christopher Kemp at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: January 9, 2013.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2013–00727 Filed 1–14–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Renewable Energy and Energy Efficiency Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The Renewable Energy and Energy Efficiency Advisory Committee (RE&EEAC) will hold its inaugural meeting under its second charter. During the course of this charter term, which began in June 2012, the Committee is expected to develop recommendations on improving the competitiveness of U.S. renewable energy and energy efficiency exports. The meeting is open to the public and the room is disabled-accessible. Public seating is limited and available on a first-come, first-served basis.

DATES: February 20th, 2013, from 9:30 a.m. to 4:30 p.m. Eastern Standard Time (EST). Members of the public wishing to attend the meeting must notify Ryan Mulholland at the contact information below by 5:00 p.m. EST on Friday, February 15, in order to pre-register for clearance into the building. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting. Last minute requests will be accepted, but may be impossible to fill.

ADDRESSES: The meeting will be held at the U.S. Department of Commerce, Room 4830, 1401 Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Ryan Mulholland, Office of Energy and Environmental Industries (OEEI), International Trade Administration, U.S. Department of Commerce at (202) 482–4693; email: *ryan.mulholland@trade.gov.* This meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to OEEI at (202) 482–4693.

SUPPLEMENTARY INFORMATION:

Background: The Secretary of Commerce established the RE&EEAC pursuant to his discretionary authority and in accordance with the Federal Advisory Committee Act (5 U.S.C. App.) on July 14, 2010; and was re-chartered on June 18, 2012. The RE&EEAC provides the Secretary of Commerce with consensus advice from the private sector on the development and administration of programs and policies to enhance the international competitiveness of the U.S. renewable energy and energy efficiency industries. The RE&EEAC held its first meeting on December 7, 2010, and has held several subsequent meetings to date.

This inaugural meeting of the RE&EEAC will consist of introductions, the selection by the members of a potential Chair and Vice Chair, and a discussion of the creation of appropriate subcommittees to facilitate the development of recommendations. Additionally, the RE&EEAC will discuss ideas for improving the competitiveness of U.S. renewable energy and energy efficiency exporters in foreign markets.

A limited amount of time, from 3:00 p.m.–3:30 p.m., will be available for pertinent brief oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to five minutes per person. Individuals wishing to reserve speaking time during the meeting must contact Mr. Mulholland and submit a brief statement of the general nature of the comments and the name and address of the proposed participant by 5:00 p.m. EST on Friday,

February 15, 2013. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to bring at least 20 copies of their oral comments for distribution to the participants and public at the meeting.

Any member of the public may submit pertinent written comments concerning the RE&EEAC's affairs at any time before or after the meeting. Comments may be submitted to the Renewable Energy and Energy Efficiency Advisory Committee, Attention: Ryan Mulholland, Office of Energy and Environmental Technologies, U.S. Department of Commerce, Mail Stop: 4053, 1401 Constitution Avenue NW., Washington, DC 20230. To be considered during the meeting, written comments must be received no later than 5:00 p.m. EST on Friday, February 15, 2013, to ensure transmission to the Committee prior to the meeting. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of RE&EEAC meeting minutes will be available within 30 days of the meeting.

Dated: January 9, 2012.

Edward A. O'Malley,

Director, Office of Energy and Environmental Industries.

[FR Doc. 2013–00668 Filed 1–14–13; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No.: 120823388–2388–01]

National Cybersecurity Center of Excellence (NCCoE) Secure Exchange of Electronic Health Information Demonstration Project

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) invites organizations to provide products and technical expertise to support and demonstrate security platforms for exchange of electronic health care information by healthcare providers. This notice is the initial step for the National Cybersecurity Center of Excellence (NCCoE) in the Secure Exchange of Electronic Health Information project. Participation in the project is open to all interested organizations.

DATES: Interested parties must contact NIST to request a certification letter. Completed and signed certification letters must be received by NIST by 5:00 p.m. Eastern time on March 1, 2013.

ADDRESSES: The NCCoE is located at 9600 Gudelsky Drive Rockville, MD 20850. Certification letters must be submitted to Karen Waltermire via email at *NCCoE@nist.gov*; or via hardcopy to NCCoE, National Institute of Standards and Technology; 100 Bureau Drive; MS 2000 Gaithersburg, MD 20899.

FOR FURTHER INFORMATION CONTACT: Karen Waltermire via email at *NCCoE@nist.gov;* or telephone 301–975–4500; NCCoE, National Institute of Standards and Technology; 100 Bureau Drive; MS 2000; Gaithersburg, MD 20899. Additional details about the Secure Exchange of Electronic Health Information project will be available at: *http://nccoe.nist.gov/hit.*

SUPPLEMENTARY INFORMATION:

Background: The NCCoE, hosted by NIST, is a public-private collaboration for accelerating the widespread adoption of integrated cybersecurity tools and technologies. The NCCoE will bring together experts from industry, government, and academia under one roof to develop practical, interoperable cybersecurity approaches that address the real world needs of complex Information Technology (IT) systems. By accelerating dissemination and use of these integrated tools and technologies for protecting IT assets, the NCCoE will enhance trust in U.S. IT communications, data, and storage systems; lower risk for companies and individuals in the use of IT systems; and encourage development of innovative, job-creating cybersecurity products and services. The project is not restricted to organizations required to comply with the standards and implementation specifications promulgated under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 or to organizations using EHR technology that complies with the standards, implementation specifications, and certification criteria promulgated under the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009. NIST expects that participation in the project will help participating organizations gain knowledge that will help them comply with these requirements.

Process: NIST is soliciting responses from all sources of relevant security capabilities (e.g., vendors, academia, and integrators). Interested parties should contact NIST using the information provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Each interested party will be provided with a certification letter, which the party must complete and submit to NIST by the date provided in the **DATES** section of this notice. The certification letter must be completed and submitted to NIST by the responding organization. NIST will contact interested parties if there are questions regarding the responsiveness of the certification letters to the project objective or project requirements identified below. NIST will select participants who have submitted complete certification letters on a first come, first served basis within each category of product components or capabilities listed below up to the number of participants in each category necessary to carry out this project. Selected participants will be required to enter into a consortium Cooperative Research and Development Agreement (CRADA) with NIST. NIST published a notice in the **Federal Register** on October 19, 2012 (77 FR 64314) inviting U.S. companies to enter into ''National Cybersecurity Excellence Partnerships'' (NCEPs) in furtherance of the NCCoE. For this demonstration project NCEP partners will not be given priority for participation.

Project Objective: Healthcare providers increasingly need to securely exchange electronic health information with each other. The confidentiality, integrity, and availability of this information must be protected. Secure exchange of electronic health information is often particularly challenging for small healthcare providers, who may lack the security infrastructure or expertise that larger healthcare providers possess. Other challenges with secure electronic health information exchange include the variety of client devices (desktops, laptops, and mobile devices) and the range of healthcare data exchange standards.

Major security concerns for secure electronic health information exchange include, but are not limited to, the following categories:

- Lack of physical security controls (e.g., increased risk of loss or theft for mobile devices, public proximity to client devices)
- Use of untrusted client devices (lack of security features or circumvention of those features)
- Use of untrusted networks (e.g., broadband, WiFi, WiMAX, cellular networks)

• Interaction with other systems in terms of data synchronization and storage

Although a number of components are available to address some of these concerns in some healthcare environments, security platforms that are composed of available capabilities in a secure, usable, and affordable manner to provide comprehensive solutions are needed for the very large number of small healthcare providers. The goal for this project is to provide a security platform to enable small healthcare providers to exchange electronic health information in support of the U.S. federal government and the health IT community.

Requirements: Each organization must complete and execute the certification letter and certify that it is accurate and complete.

Each organization will be asked to identify which security platform components or capabilities it is offering. Product components or capabilities include one or more of the following:

1. Electronic health information entry and display devices,
2. Authentication and authorization mechanisms,
3. Data transfer/communications components,
4. Electronic health information storage and retrieval components,
5. Forms generation capabilities, and
6. Printer devices or interfaces.

Specific requirements of the Secure Exchange of Electronic Health Information demonstration project are as follows:

1. Compatibility with various electronic health record (EHR) systems in use by small healthcare providers;
2. Use of, or compatibility with, healthcare data exchange standards and implementation specifications (e.g., HL7, DICOM, IHE), including the transport standards adopted by the Department of Health and Human Services at 45 CFR 170.202;
3. Access by project staff to component interfaces and the organization's experts necessary to make functional connections among security platform components;
4. Enterprise security policy enforcement on the client devices through a hardware root of trust, such as implementing secure configuration baselines for operating systems and applications; automatically continuously monitoring, detecting, and reporting policy violations; and performing system health checks;
5. Support for standardized security automation technologies (e.g., SCAP);
6. Strong encryption of data communications and local storage;
7. User authentication, including support of directory services, multi-factor authentication, and key management;
8. Use of secure infrastructure components (e.g., DNSSEC, IPv4, and IPv6);
9. Development and demonstration of use cases in NCCoE facilities; and
10. Development and demonstration activities will be conducted in a manner consistent with Federal requirements (e.g., FIPS 200, FIPS 201, SP 800–53, and SP 800–63.

Additional details about the Secure Exchange of Electronic Health Information Use Case project will be available for organizations to look at specifics that are relevant to capability and component identification, at: *http://nccoe.nist.gov/hit.*

NIST cannot guarantee that all of the products proposed by respondents will be used in the demonstration. Each prospective participant will be expected to work collaboratively with NIST staff and other project participants under the terms of the consortium CRADA in the development of the Secure Exchange of Electronic Health Information capability. Prospective participants' contribution to the collaborative effort will include assistance in establishing the necessary interface functionality, connection and set-up capabilities and procedures, demonstration harnesses, environmental and safety conditions for use, integrated platform user instructions, and demonstration plans and scripts necessary to demonstrate the desired capabilities. Each prospective participant will train NIST personnel as necessary, to operate its product in capability demonstrations to the healthcare community. Following successful demonstrations, NIST will publish a description of the security platform and its performance characteristics sufficient to permit other organizations to develop and deploy security platforms that meet the security objectives of the Secure Exchange of Electronic Health Information Demonstration project. These descriptions will be public information.

Under the terms of the consortium CRADA, NIST will support development of interfaces among participants' products, including IT infrastructure, laboratory facilities, office facilities, collaboration facilities, and staff support to component composition, security platform documentation, and demonstration activities.

The dates of the demonstration of the Secure Exchange of Electronic Health Information capability to the healthcare community will be announced on the NCCoE Web site at least two weeks in advance at: *http://csrc.nist.gov/nccoe.* The expected outcome of the demonstration is to enable healthcare providers to exchange electronic health information. Participating organizations will gain from the knowledge that their products are interoperable with other participants' offerings.

For additional information on the NCCoE governance, business processes, and NCCoE operational structure, visit the NCCoE Web site *http://csrc.nist.gov/nccoe.*

Dated: January 10, 2013.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2013–00724 Filed 1–14–13; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC442

South Atlantic Fishery Management Council (Council)—Public Meetings

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

ACTION: Notice of public hearings and scoping meetings.

SUMMARY: The South Atlantic Fishery Management Council (SAFMC) will hold a series of scoping meetings and public hearings pertaining to Amendment 5 to the Dolphin Wahoo Fishery Management Plan (FMP) and Amendment 27 to the Snapper Grouper FMP.

DATES: The meetings will be held from January 22, 2013, through January 24, 2013 and from January 28, 2013, through January 30, 2013. All meetings will be held from 4 p.m. to 7 p.m.

ADDRESSES:

Meeting Addresses

1. January 22, 2013: Mighty Eighth Air Force Museum, 175 Bourne Avenue, Pooler, GA 31322; phone: 912/748–8888.
2. January 23, 2013: Hilton Garden Inn, 5265 International Blvd., N. Charleston, SC 29418; phone: 843/308–9330.
3. January 24, 2013: New Bern Riverfront Convention Center, 203 South Front Street, New Bern, NC 28563; phone: 252/637–1551.
4. January 28, 2013: Jacksonville Marriott, 4750 Salisbury Road, Jacksonville, FL 32256; phone: 904/296–2222.

5. January 29, 2013: Doubletree Cocoa Beach, 2080 North Atlantic Avenue, Cocoa Beach, FL 32931; phone: 321/783–9222.

6. January 30, 2013: Holiday Inn Key Largo, 99701 Overseas Hwy., Key Largo, FL 33037; phone: 305/451–2121.

Council Address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone 843/571–4366 or toll free 866/SAFMC–10; FAX 843/769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The items of discussion are as follows:

Scoping: Amendment 5 to the Dolphin Wahoo FMP

1. This amendment would revise: the Allowable Biological Catch (ABC); the Annual Catch Limit (ACL), including sector ACLs; sector allocations; and recreational Annual Catch Targets (ACT) for dolphin and wahoo based on Marine Recreational Information Program (MRIP) estimates.

2. Additionally, the amendment would: revise the accountability measures for dolphin and wahoo; modify the dolphin sector allocations; and revise the framework procedure in the Dolphin Wahoo FMP.

3. Written comments may be directed to Bob Mahood, Executive Director, SAFMC (see Council address) or via email to: *DWAmend5Scoping Comments@safmc.net.* Comments will be accepted until 5 p.m. on February 4, 2013.

Public Hearing: Amendment 27 to the Snapper Grouper FMP

1. This amendment would: extend management responsibility of Nassau grouper in Gulf of Mexico waters to the SAFMC; increase the number of allowable crew members on dual-permitted snapper grouper vessels; and address captain and crew bag limit retention of snapper grouper.

2. Additionally, the amendment would: modify snapper grouper framework procedures to allow ABC levels, ACLs and ACTs to be adjusted via **Federal Register** notice; and modify management measures for blue runner.

3. Written comments may be directed to Bob Mahood, Executive Director, SAFMC (see Council address) or via email to: *SGAmend27Comments@safmc.net.* Comments will be accepted until 5 p.m. on February 4, 2013.

Council staff will present an overview of the amendments and will be available for informal discussions and to answer questions. Members of the public will have an opportunity to go on record at any time during the meeting hours to record their comments on the public hearing and scoping topics for consideration by the Council. Local Council representatives will attend the meetings and listen to public comment. Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) three (3) days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: January 9, 2013.

Tracey L. Thompson,

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

[FR Doc. 2013–00601 Filed 1–14–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648- XX69

Marine Mammals; File Nos. 14451, 14353, and 13846

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

ACTION: Notice; receipt of applications for permit amendments.

SUMMARY: Notice is hereby given that Joseph Mobley, Jr., University of Hawaii at Manoa, 2528 McCarthy Mall, Honolulu, HI 96816; Ann Zoidis, Cetos Research Organization, 33 Echo Ave., Suite 5, Oakland, CA 94611; and Jim Darling, Ph.D., Whale Trust, P.O. Box 384, Tofino, BC V0R2Z0, Canada, have applied for amendments to Scientific Research Permit Nos. 14451, 14353, and 13846, respectively.

DATES: Written, telefaxed, or email comments must be received on or before February 14, 2013.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the *Features* box on the Applications and Permits for Protected Species home page, *https://apps.nmfs.noaa.gov,* and then selecting the appropriate File No. from the list of available applications.

These documents are also available upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Pacific Islands Region, NMFS, 1601 Kapiolani Blvd., Rm 1110, Honolulu, HI 96814–4700; phone (808) 944–2200; fax (808) 973–2941.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Kristy Beard or Carrie Hubard, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject amendments are requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226).

Permit No. 14451, issued on July 14, 2010 (75 FR 43151), authorizes the permit holder, Joseph Mobley, Jr., to study cetaceans off the east and west coast of the United States, Hawaii, Alaska, Guam, and the Mariana Islands. Researchers target numerous cetacean species including endangered blue whales (*Balaenoptera musculus*), fin whales (*B. physalus*), humpback whales (*Megaptera novaeangliae*), sei whales

(*B. borealis*), and sperm whales (*Physeter macrocephalus*), during aerial and vessel surveys for photo-identification, videography, and behavioral observations. The permit includes authorization under the MMPA to take 205 false killer whales (*Pseudorca crassidens*) in Pacific waters off of Hawaii. Insular Hawaiian false killer whales were listed as endangered under the ESA in November 2012; therefore, the permit holder now requires authorization under the ESA to take Insular Hawaiian false killer whales. The permit holder is requesting the permit be amended to allocate 180 of the false killer whale takes currently authorized under the MMPA to Insular Hawaiian false killer whales.

Permit No. 14353, issued on July 14, 2010 (75 FR 43151), authorizes the permit holder, Ann Zoidis, Cetos Research Organization, 33 Echo Ave., Suite 5, Oakland, CA 94611, to conduct scientific research on humpback and minke (*B. acutorostrata*) whales in Hawaiian waters. Research occurs annually from January through March. Humpback whale research is focused in the Au'au Channel near Maui. Research activities include photo-identification, behavioral observations, passive acoustic recording, and underwater photo/videography. Suction cup tags are deployed on humpback whales. Minke whales are approached for photo-identification anywhere within the main Hawaiian islands. The permit includes authorization under the MMPA for the incidental harassment of up to 1,000 false killer whales during activities in Pacific waters off of Hawaii. Insular Hawaiian false killer whales were listed as endangered under the ESA in November 2012; therefore, the permit holder now requires authorization under the ESA to take Insular Hawaiian false killer whales. The permit holder is requesting the permit be amended to include ESA authorization for the incidental harassment of Insular Hawaiian false killer whales and to expand the geographic area throughout the Hawaiian Islands, including the Northwestern Hawaiian Islands (NWHI) chain.

Permit No. 13846, issued on July 14, 2010 (75 FR 43151), authorizes the permit holder, Jim Darling, Ph.D., Whale Trust, P.O. Box 384, Tofino, BC V0R2Z0, Canada, to study humpback whales in Hawaii (primarily off west Maui) and humpback and Eastern gray (*Eschrichtius robustus*) whales along the coastlines of Washington and Alaska. Researchers may conduct photo-identification, passive acoustic recording, behavioral observation (by vessel, underwater and aerial), videorecording, collection of sloughed skin, photogrammetry, biopsy sampling, playback experiments, and/or suction cup and implant tagging of target whales. The permit includes authorization under the MMPA for the incidental harassment of up to 150 false killer whales during playback experiments in Pacific waters off Hawaii. Insular Hawaiian false killer whales were listed as endangered under the ESA in November 2012; therefore, the permit holder now requires authorization under the ESA to take Insular Hawaiian false killer whales. The permit holder is requesting the permit be amended to include ESA authorization for the incidental harassment of Insular Hawaiian false killer whales.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activities proposed are consistent with the Proposed Action Alternative in the Environmental Assessment for the Issuance of Scientific Research Permits for Research on Humpback Whales and Other Cetaceans (NMFS 2010). Based on the analyses in the EA, NMFS determined that issuance of the permits would not significantly impact the quality of the human environment and that preparation of an environmental impact statement was not required. That determination is documented in a Finding of No Significant Impact (FONSI), signed on July 14, 2010. The EA and FONSI are available upon request.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–00612 Filed 1–14–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC439

Marine Mammals; File No. 17005

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Peter Rogers, Ph.D., Georgia Institute of Technology, Woodruff School of Mechanical Engineering, Atlanta, GA 30332, has applied in due form for a permit to conduct research on cetacean species not listed under the Endangered Species Act (ESA).

DATES: Written, telefaxed, or email comments must be received on or before February 14, 2013.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the *Features* box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 17005 from the list of available applications.

These documents are also available upon written request or by appointment in the following offices: See **SUPPLEMENTARY INFORMATION.**

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman or Amy Sloan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Dr. Rogers proposes to conduct scientific research on cetacean species in Atlantic and Pacific coastal areas of the contiguous United States. In cooperation with local marine mammal stranding networks, researchers would use an ultrasound-based system for non-invasively determining the low frequency elastic properties of cetacean head tissues. The ultrasound system is intended to provide parameters needed to model the response of the head to sound, and may provide diagnostic capabilities for use by marine mammal stranding responders. Up to 10 individuals each of any non-ESA-listed cetacean species would be tested annually for five years. The research also would allow researchers to: (1) Determine any short term changes in soft tissue elasticity if an animal dies during the stranding response, and (2) assess differences between intact and

harvested tissues from deceased stranded animals.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Documents may be reviewed in the following locations:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376;

Northwest Region, NMFS, 7600 Sand Point Way NE., BIN C15700, Bldg. 1, Seattle, WA 98115–0700; phone (206) 526–6150; fax (206) 526–6426;

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562) 980–4001; fax (562) 980–4018;

Northeast Region, NMFS, 55 Great Republic Drive, Gloucester, MA 01930; phone (978) 281–9328; fax (978) 281 –9394; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–00611 Filed 1–14–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Flower Garden Banks National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The ONMS is seeking applications for the following vacant seats on the Flower Garden Banks National Marine Sanctuary Advisory Council: recreational fishing, research, education, and conservation. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen as members should expect to serve 3-year terms, pursuant to the council's charter.

DATES: Applications are due by February 18, 2013.

ADDRESSES: Application kits may be obtained from Jennifer Morgan, NOAA—Flower Garden Banks National Marine Sanctuary, 4700 Avenue U, Bldg. 216, Galveston, TX 77551 or downloaded from the sanctuary Web site *http://flowergarden.noaa.gov.* Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Jennifer Morgan, NOAA—Flower Garden Banks National Marine Sanctuary, 4700 Avenue U, Bldg. 216, Galveston, TX 77551, 409–621–5151 ext. 103, *Jennifer.Morgan@noaa.gov.*

SUPPLEMENTARY INFORMATION: Located in the northwestern Gulf of Mexico, the Flower Garden Banks National Marine Sanctuary includes three separate areas, known as East Flower Garden, West Flower Garden, and Stetson Banks. The Sanctuary was designated on January 17, 1992. Stetson Bank was added to the Sanctuary in 1996. The Sanctuary Advisory Council will consist of no more than 21 members; 16 non-governmental voting members and 5 governmental non-voting members. The Council may serve as a forum for consultation and deliberation among its members and as a source of advice to the Sanctuary superintendent regarding the management of the Flower Garden Banks National Marine Sanctuary.

Authority: 16 U.S.C. Sections 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: January 2, 2013.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2013–00536 Filed 1–14–13; 8:45 am]

BILLING CODE M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Applicability of Special Use Permit Requirements to Certain Categories of Activities Conducted Within the National Marine Sanctuary System

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice; request for public comments.

SUMMARY: In accordance with a requirement of Public Law 106–513 (16 U.S.C. 1441(b)), NOAA hereby gives public notice of the applicability of the special use permit requirements of Section 310 of the National Marine Sanctuaries Act to certain categories of activities conducted within the National Marine Sanctuary System. In addition, NOAA is seeking public comment on the subject of special use permits.

DATES: Comments must be received on or before March 18, 2013.

ADDRESSES: You may submit comments, identified by docket ID NOAA–NOS–2012–0162, by one of the following methods:

- *Electronic submissions:* Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov.* You may enter the following docket number to submit comments: NOAA–NOS–2012–0162.
- *Mail:* Submit all written comments to Vicki Wedell, Office of National Marine Sanctuaries, 1305 East West Highway (N/NMS2), 11th floor, Silver Spring, MD 20910.

Instructions: To submit electronic public comments through the Federal eRulemaking Portal, *http://www.regulations.gov,* select ''submit a comment'' under the heading ''Begin a search by choosing a task or entering a keyword,'' type docket number NOAA–NOS–2012–0162 under the heading ''Enter keyword or ID,'' and select ''Search'' to receive search results. Then follow online instructions for submitting your comments.

All comments received are a part of the public record and will be posted to *http://www.regulations.gov* 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. ONMS will accept anonymous

comments (for electronic comments submitted through the Federal eRulemaking Portal, enter N/A in the required fields if you wish to remain anonymous).

Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Vicki Wedell, Office of National Marine Sanctuaries, 1305 East West Highway (N/NMS2), Silver Spring, MD 20910, telephone (301) 713–3125, extension 237, email *Vicki.Wedell@noaa.gov.*

SUPPLEMENTARY INFORMATION: This **Federal Register** document is also accessible via the Internet at: *http://www.access.gpo.gov/.*

I. Background

Congress first granted NOAA the authority to issue special use permits for the conduct of specific activities in national marine sanctuaries in the 1988 Amendments to the National Marine Sanctuaries Act (16 U.S.C. 1431 *et seq.;* NMSA) (Pub. L. 100–627). The NMSA allows NOAA to issue special use permits to establish conditions of access to and use of any sanctuary resource or to promote public use and understanding of a sanctuary resource. Since 1988, special use permits have generally been issued to persons conducting commercial (and usually revenue-generating) operations in national marine sanctuaries. Section 310 of the NMSA allows NOAA to issue special use permits to authorize the conduct of specific activities and allows NOAA to assess fees for special use permits.

In the National Marine Sanctuaries Amendments Act of 2000 (Pub. L. 106–513), Congress added a requirement that prior to requiring a special use permit for any category of activity, NOAA shall give appropriate public notice. Subsection (b) of section 310 of the NMSA, as amended by Public Law 106–513, provides: ''[NOAA] shall provide appropriate public notice before identifying any category of activity subject to a special use permit under subsection (a).'' 16 U.S.C. 1441(b). In addition, Public Law 106–513 gives NOAA the authority to waive, reduce, or accept in-kind contributions in lieu of special use permit fees when the activity does not derive a profit from the access to or use of sanctuary resources. 16 U.S.C. 1441(d)(4).

On January 30, 2006, NOAA published a list of five categories for which the requirements of special use permits would be applicable (71 FR 4898):

1. The disposal of cremated human remains by a commercial operator in any national marine sanctuary;
2. The operation of aircraft below the minimum altitude in restricted zones of national marine sanctuaries;
3. The placement and subsequent recovery of objects associated with public events on non-living substrate of the seabed;
4. The deposit or placement and immediate recovery of objects related to special effects of motion pictures; and
5. The continued presence of commercial submarine cables beneath or on the seabed.

In publishing this list, NOAA clarified that simply being consistent with one of the categories would not guarantee approval of a special use permit for any given activity. Special use permit applications are reviewed for consistency with the relevant sanctuary's management plan and regulations, the NMSA, as well as the published description of the category. Individual special use permit applications are also reviewed with respect to all other pertinent regulations and statutes, including the National Environmental Policy Act. Special use permits are issued only for activities NOAA determines can be conducted in a manner that does not destroy, cause the loss of, or injure sanctuary resources.

II. Summary of Proposed Changes and Additions

NOAA proposes to revise three of the five existing categories of special use permits: (1) Disposal of cremated human remains in any national marine sanctuary; (2) the placement and recovery of objects associated with public or private events on nonliving substrate of the seabed; and (3) the placement and subsequent recovery of objects related to commercial filming. NOAA is also proposing to add two new categories of special use permits for: (1) Recreational diving near the USS MONITOR; and (2) fireworks displays. The remaining two special use permit categories would remain unchanged: (1) The operation of aircraft below the minimum altitude in restricted zones of national marine sanctuaries; and (2) the continued presence of commercial submarine cables beneath or on the seabed.

The Disposal of Cremated Human Remains in Any National Marine Sanctuary

NOAA is proposing to eliminate the requirement that the disposal of human cremains be performed by a ''commercial operator.'' Allowing both commercial operators and private individuals to discharge cremated human remains more adequately captures the full range of permit applicants for this activity. NOAA previously stated that when private individuals wish to scatter cremated human remains in a national marine sanctuary, they may request an authorization of the EPA's general permit from the appropriate sanctuary superintendent on a case-by-case basis pursuant to NOAA's authority under section 922.49. Because section 922.49 only applies to six sanctuaries individuals wishing to scatter cremated human remains in other sanctuaries may not be able to do so. NOAA has determined that this restriction is unnecessary and that the ability to permit this activity should apply to all sanctuaries.

The Placement and Recovery of Objects Associated With Public or Private Events on Non-Living Substrate of the Seabed

NOAA is proposing to expand the type of event associated with this category to include public and private events. As currently written, the category is specific to ''public'' events. NOAA believes that the previous **Federal Register** notice was not clear whether this term includes events that are not intended to be open to the public (i.e., private events or those run by commercial operators). NOAA has several examples of activities in Florida Keys National Marine Sanctuary that are not generally open to all members of the public, whether it is because the event is hosted by private industry or because participation requires an entry fee, etc. Specific examples of such events involve the promotion of SCUBA diving; an annual underwater pumpkin carving contest; and a contest to determine the world record for underwater ironing. NOAA believes that expanding the category to apply to events that are generally open to all members of the public and those that are limited to a restricted number of participants more accurately captures the types of events that can be conducted in a national marine sanctuary under the requirements of the special use permit.

The Placement and Recovery of Objects Related to Commercial Filming

NOAA is proposing to expand the category to include commercial filming, rather than just the special effects related to motion pictures. NOAA has found the terms ''special effects'' and ''motion picture'' to be too limiting and should be eliminated from the category

description in favor of the more broad term ''commercial filming'' which is intended to capture all aspects of motion pictures and other media productions.

Recreational Diving Near the USS MONITOR

NOAA is proposing to add a new category of special use permit for recreational diving near the USS MONITOR within Monitor National Marine Sanctuary. NOAA's management philosophy for Monitor National Marine Sanctuary and other maritime heritage resources favors in situ preservation over artifact recovery. As such, and to enhance public awareness and appreciation of the USS MONITOR, NOAA has determined that enhancing recreational diving access to the wreck is a priority. NOAA believes that recreational diving near the USS MONITOR can be conducted in a manner that does not injure maritime heritage resources of the sanctuary and therefore, it is an activity that should qualify for special use permits.

Fireworks Displays

NOAA is proposing to add a new category of special use permit for fireworks displays in sanctuaries. Fireworks are discharged from land or from a barge offshore (that is close enough for people to view). Permits are typically issued to individuals, pyrotechnics companies, or municipalities for special events. NOAA would evaluate each special use permit application for this category individually and against all applicable sanctuary regulations, laws, and policies. As with all other special use permits, permits would be issued under this category only if NOAA determines the activities can be conducted in a manner that does not destroy, cause the loss of, or injure sanctuary resources. For example, possible measures to mitigate adverse impacts to wildlife include changes to timing or location, and ensuring debris related to exploded fireworks are removed.

Summary

As proposed in this notice, the categories of activities that would be subject to the requirements of special use permits would be:

1. The disposal of cremated human remains in any national marine sanctuary;
2. The operation of aircraft below the minimum altitude in restricted zones of national marine sanctuaries;
3. The placement and recovery of objects associated with public or private events on non-living substrate of the seabed;
4. The placement and recovery of objects related to commercial filming;
5. The continued presence of commercial submarine cables beneath or on the seabed;
6. Recreational diving near the USS MONITOR;
7. Fireworks displays.

III. Request for Comments

NOAA is requesting comments on the modification of current categories of special use permits and the addition of new categories to the requirements of special use permits.

IV. Classification

A. National Environmental Policy Act

NOAA has concluded that this action will not have a significant effect, individually or cumulatively, on the human environment. This action is categorically excluded from the requirement to prepare an Environmental Assessment or Environmental Impact Statement in accordance with Section 6.03c3(i) of NOAA Administrative Order 216–6. Specifically, this action is a notice of an administrative and legal nature. Furthermore, individual permit actions by the ONMS will be subject to additional case-by-case analysis, as required under NEPA, which will be completed as new permit applications are submitted for specific projects and activities.

NOAA also expects that many of these individual actions will also meet the criteria of one or more of the categorical exclusions described in NOAA Administrative Order 216–6 because special use permits cannot be issued for activities that are expected to result in any destruction of, injury to, or loss of any sanctuary resource. However, the special use permit authority may at times be used to allow activities that may meet the Council on Environmental Quality's definition of the term ''significant'' despite the lack of apparent environmental impacts. In addition, NOAA may, in certain circumstances, combine its special use permit authority with other regulatory authorities to allow activities not described above that may result in environmental impacts and thus require the preparation of an Environmental Assessment or Environmental Impact Statement. In these situations NOAA will ensure that the appropriate NEPA documentation is prepared prior to taking final action on a permit or making any irretrievable or irreversible commitment of agency resources.

B. Paperwork Reduction Act

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number. Applications for the special use permits discussed in this notice involve a collection-of information requirement Subject to the requirements of the PRA. OMB has approved this collection-of-information requirement under OMB control number 0648–0141.

The collection-of-information requirement applies to persons seeking special use permits to conduct otherwise prohibited activities and is necessary to determine whether the proposed activities are consistent with the terms and conditions of special use permits prescribed by the NMSA. Public reporting burden for this collection of information is estimated to average twenty four (24) hours per response (application, annual report, and financial report), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This estimate also includes the significant time that may be required should the applicant choose to provide environmental information for preparing a draft of any documentation that may be required under the National Environmental Policy Act (NEPA), e.g., Environmental Impact Statement or Environmental Assessment. If the applicant chooses not to provide the information needed to prepare a draft of any NEPA documentation for the proposed activity, or if only minimal NEPA documentation is needed, the public reporting burden would be much less (approximately one hour for each response).

Dated: November 6, 2012.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries.

[FR Doc. 2013–00535 Filed 1–14–13; 8:45 am]

BILLING CODE 3510–NK–M

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO–P–2011–0046]

Request for Comments on Preparation of Patent Applications

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO) is seeking to improve the quality of issued patents. In this notice, the USPTO is focusing on potential practices that applicants can employ at the drafting stage of a patent application in order to facilitate examination and bring more certainty to the scope of issued patents. To that end, the USPTO is requesting input from interested members of the public on the specific practices set forth in the ''Topics for Public Comment'' section below. While this notice is directed to potential practices that applicants can employ, the USPTO also plans to issue a separate notice building on internal initiatives and further identifying potential practices the Office can employ to also facilitate examination and bring more certainty to the scope of issued patents. The USPTO intends to publish the separate notice subsequent to its review of comments received responsive to the present notice.

On January 3, 2013, the USPTO published a notice announcing the formation of a partnership with the software community to enhance the quality of software-related patents (Software Partnership). *See Request for Comments and Notice of Roundtable Events for Partnership for Enhancement of Quality of Software-Related Patents,* 78 FR 292 (Jan. 3, 2013). The Software Partnership notice seeks public comment on specific topics related to enhancing the quality of software-related patents, and announces two roundtable events, which will not only offer participants an opportunity to provide oral comments on the topics presented in the Software Partnership notice but also on the topics set forth in the present notice, to the extent they apply to software-related patents.

Comment Deadline: To be assured of consideration, written comments must be received on or before March 15, 2013. No public hearing will be held.

ADDRESSES: Written comments should be sent by electronic mail addressed to *QualityApplications_Comments@uspto.gov.* Comments may also be submitted by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, marked to the attention of Nicole D. Haines. Although comments may be submitted by mail, the USPTO prefers to receive comments via electronic mail.

The comments will be available for public inspection at the Office of the Commissioner for Patents, located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia, and will be available via the USPTO Internet Web site (address: *http://www.uspto.gov*). Because comments will be available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

Further Information: For further information about this request, contact Nicole D. Haines, Legal Advisor, at (571) 272–7717; Kathleen Kahler Fonda, Senior Legal Advisor, at (571) 272–7754; or Matthew J. Sked, Legal Advisor, at (571) 272–7627, of the Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy. General patent practice inquiries may be directed to the Office of Patent Legal Administration, by telephone at (571) 272–7701, or by electronic mail at *PatentPractice@uspto.gov.*

SUPPLEMENTARY INFORMATION: The USPTO is committed to enhancing the quality of issued patents and the efficiency of patent prosecution. To further this goal, the USPTO has undertaken a number of internal initiatives over the past several years. For example, the USPTO routinely provides its examiners with training on topics such as obviousness under 35 U.S.C. 103 and statutory subject matter under 35 U.S.C. 101 in order to provide clear guidance regarding the impact of significant new case law on the patent examination process. Patent examiners also receive training on 35 U.S.C. 112 to address concerns about the proper interpretation of claim language, the clarity of claim terms, and the adequacy of the specification to support functional claim limitations. Additionally, the USPTO has implemented a new quality measurement system that comprehensively evaluates examination quality. One component of this system is an external quality survey that obtains input from applicants and practitioners on the perceived quality of the patent examination process.

The USPTO has also undertaken initiatives that involve working with the public to enhance the examination process. For example, examiners participate in workshops focusing on compact prosecution and holding effective interviews with applicants. Also, the USPTO works with experts in industry to provide technical training for patent examiners and updates on developments and innovations in their field. This training initiative enhances examiners' insight in their fields, enabling them to better understand intended claim scope and make better informed patentability decisions.

I. Purpose of This Notice

This notice is directed to furthering the Office's dialog with the public about ways to enhance patent quality. Specifically, the topics set forth in the ''Topics for Public Comment'' section of this notice are potential practice changes that applicants can employ to augment the quality of issued patents. The public is invited to comment on whether these practices should be employed by applicants at the drafting stage of a patent application in order to facilitate examination and bring more certainty to the scope of issued patents.

II. Topics for Public Comment

The USPTO is seeking input on whether the following practices should be used by applicants during the preparation of an application to place the application in a better condition for examination. When patent applications are filed in the best possible condition for examination, examiners can better focus the examination on substantive patentability issues. Specifically, the USPTO is seeking input on whether adoption of the following practices by applicants early in the process would assist the public in determining the scope of claims as well as the meaning of claim terms in the specification after a patent is granted.

A. Clarifying the Scope of the Claims

The boundaries of patent protected subject matter should be clearly delineated and the scope of each claim made clear on filing of a patent application to facilitate examination and the publishing and patenting of claims that best serve the public notice function. In this regard, the USPTO is seeking public comment on advantages and disadvantages of applicants employing the following practices when preparing their patent applications:

1. Presenting claims in a multi-part format by way of a standardized template that places each claim component in separate, clearly marked, and designated fields. For instance, a template may facilitate drafting and review of claims by separately delineating each claim component into separate fields for the preamble,

transitional phrase, and each particular claim limitation.

2. Identifying corresponding support in the specification for each of the claim limitations utilizing, for example, a claim chart or the standardized template described above. This practice could be particularly beneficial where claims are amended or where a continuing application (continuation, divisional, continuation-in-part) is filed.

3. Indicating whether examples in the specification are intended to be limiting or merely illustrative.

4. Identifying whether the claim preamble is intended to be a limitation on claim scope.

5. Expressly identifying clauses within particular claim limitations for which the inventor intends to invoke 35 U.S.C. 112(f) and pointing out where in the specification corresponding structures, materials, or acts are disclosed that are linked to the identified 35 U.S.C. 112(f) claim limitations.[1]

6. Using textual and graphical notation systems known in the art to disclose algorithms in support of computer-implemented claim limitations, such as C-like pseudo-code or XML-like schemas for textual notation and Unified Modeling Language (UML) for graphical notation.

B. Clarifying the Meaning of Claim Terms in the Specification

The best source for determining the meaning of a claim term is the specification. *See Phillips* v. *AWH Corp.,* 415 F.3d 1303, 1315–16 (Fed. Cir. 2005). The specification should clearly define the claim language so that the scope of each claim can readily be determined, ensuring the public notice function of the patent claims is best served. In this regard, the USPTO is seeking public comments on advantages and disadvantages of applicants employing the following practices when preparing their patent applications:

1. Indicating whether terms of degree—such as substantially, approximately, about, essentially—have a lay or technical meaning and explaining the scope of such terms.

2. Including in the specification a glossary of potentially ambiguous, distinctive, and specialized terms used in the specification and/or claims, particularly for inventions related to certain technologies, such as software.

3. Designating, at the time of filing the application, a default dictionary or dictionaries (*e.g.,* a technical dictionary and a non-technical dictionary) to be used in ascertaining the meaning of the claim terms.

III. Guidelines for Written Comments

As discussed previously, the USPTO prefers to receive comments via electronic mail. Information provided in response to this request for comments will be made part of a public record and may be available via the Internet. In view of this, parties should not submit information that they do not wish to be publicly disclosed or made electronically accessible. Parties who would like to rely on confidential information to illustrate a point are requested to summarize or otherwise submit the information in a way that will permit its public disclosure.

Dated: January 10, 2013.

David J. Kappos,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2013–00690 Filed 1–14–13; 8:45 am]

BILLING CODE 3510–16–P

[1] 35 U.S.C. 112(f) replaces 35 U.S.C. 112, ¶ 6 as the section of the statute pertaining to means-plus-function limitations for applications filed on or after September 16, 2012. *See* Leahy-Smith America Invents Act, Pub. L. 112–29, § 4(c)(6), 125 Stat. 284, 296 (2011).

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting—Closed Meeting

The following notice of a closed meeting is published pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, 5 U.S.C. 552b.

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: January 14, 2013 at 10:00 a.m.

PLACE: Three Lafayette Center, 1155 21st St. NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Litigation Matters. In the event that the time or date of this meeting changes, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Stacy D. Yochum, Counsel to the Executive Director, 202–418–5157.

Stacy D. Yochum,

Counsel to the Executive Director.

[FR Doc. 2013–00787 Filed 1–11–13; 4:15 pm]

BILLING CODE 6351–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Proposed Collection; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau), 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 (PRA) of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau is soliciting comments concerning the information collection requirements relating to identifying strategies to help consumers make better-informed financial decisions.

DATES: Written comments are encouraged and must be received on or before March 18, 2013 to be assured of consideration.

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

- *Electronic: CFPB_Public_PRA@cfpb.gov.*
- *Mail/Hand Delivery/Courier:* Direct all written comments to Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552.

Instructions: Submissions should include agency name and Generic Clearance for Qualitative Consumer Education and Engagement Information Collections. Comments will be available for public inspection and copying at 1700 G Street NW., Washington, DC 20552 on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect comments by telephoning (202) 435–7275. All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. You should only submit information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the documents contained under this approval number should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington,

DC 20552, (202) 435–9011, or through the Internet at *CFPB_Public_PRA@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for Qualitative Consumer Education and Engagement Information Collections.

OMB Control Number: 3170–XXXX.

Abstract: Under the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, Section 1013(b), the Bureau is responsible for developing and implementing initiatives intended to educate and empower consumers to make better informed financial decisions. The collection will focus on identifying financial education and empowerment strategies, practices, and experiences that inform or improve consumer financial decision-making.

The Bureau expects to collect qualitative data on effective strategies from both financial education practitioners and consumers through a variety of methods, including in-person meetings, focus groups, qualitative surveys, online discussion forums, and other qualitative methods as necessary. The information collected through these processes will increase the Bureau's understanding of financial education and empowerment programs and practices that can improve financial decision-making skills and outcomes for consumers.

The core objective of the data collection is to develop a deeper understanding of effective financial education and empowerment strategies in order to help inform future work at the Bureau. This information collection will also provide useful information on financial education and empowerment practices that can be shared with providers and practitioners of financial education and empowerment programs, leading to better financial decision-making outcomes for adult consumers.

Below is an estimate of the aggregate burden hours for the activities anticipated under this information collection.

Type of Review: New Generic Collection.

Average Expected Annual Number of Activities: 15.

Affected Public: Individuals or Households, and Business or other for-profit, not-for-profit institutions, Farms, Federal government, State, Local or Tribal government.

Estimated Number of Annual Responses: 60,000 annual responses.

Estimated Time Per Respondent: Varies from 10 to 120 minutes.

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 15,000 hours.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and the 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.

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.

Dated: January 9, 2013.

Chris Willey,

Chief Information Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2013–00722 Filed 1–14–13; 8:45 am]

BILLING CODE 4810–AM–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Vol. 78, No. 7, Thursday, January 10, 2013, page 2257.

CHANGE IN ANNOUNCED TIME AND DATE OF OPEN MEETING: 10 a.m.–11 a.m., Wednesday January 16, 2013.

Changes To Open Meeting Agenda

MATTERS TO BE CONSIDERED: Decisional Matter: Fiscal Year 2013 Operating Plan.

ITEM REMOVED FROM THE AGENDA: Decisional Matter: Section 1110 Certification of Compliance—Notice of Proposed Rulemaking.

For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Todd A. Stevenson, Office of the Secretary, 4330 East West Highway, Bethesda, MD 20814 (301) 504–7923.

Dated: January 10, 2013.

Todd A. Stevenson,

Secretary.

[FR Doc. 2013–00762 Filed 1–11–13; 11:15 am]

BILLING CODE 6355–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Personnel Preparation in Special Education, Early Intervention, and Related Services

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information:

Personnel Development to Improve Services and Results for Children with Disabilities—Personnel Preparation in Special Education, Early Intervention, and Related Services Notice inviting applications for new awards for fiscal year (FY) 2013.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.325K.

DATES:

Applications Available: January 15, 2013.

Deadline for Transmittal of Applications: March 18, 2013.

Deadline for Intergovernmental Review: May 15, 2013.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of this program are to (1) help address State-identified needs for highly qualified personnel—in special education, early intervention, related services, and regular education—to work with children, including infants and toddlers, with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research and experience, to be successful in serving those children.

Priorities: In accordance with 34 CFR 75.105(b)(2)(iv), this priority is from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA)).

Absolute Priority: For FY 2013 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34

CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is: *Personnel Preparation in Special Education, Early Intervention, and Related Services.*

Background: The purpose of the Personnel Preparation in Special Education, Early Intervention, and Related Services priority is to improve the quality and increase the number of personnel who are fully credentialed to serve children, including infants and toddlers, with disabilities—especially in areas of chronic personnel shortage—by supporting projects that prepare special education, early intervention, and related services personnel at the baccalaureate, master's, and specialist levels.

State demand for fully credentialed special education, early intervention, and related services personnel to serve infants, toddlers, and children with disabilities exceeds the available supply (Bruder, 2004a; Bruder, 2004b; McLeskey & Billingsley, 2008; and McLeskey, Tyler & Flippin, 2004). These shortages of fully credentialed personnel can negatively affect the quality of services provided to infants, toddlers, and children with disabilities and their families (McLeskey *et al.,* 2004).

Personnel preparation programs that prepare personnel to enter the fields of special education, early intervention, and related services as fully credentialed personnel with the necessary competencies to use evidence-based practices are critical to overcome the personnel shortages in these fields. Federal support of these personnel preparation programs is needed to increase the supply of personnel with the necessary competencies to effectively serve infants, toddlers, and children with disabilities and their families.

Priority: Except as provided for Focus Area D projects, to be eligible under this priority, an applicant must propose a project associated with a pre-existing personnel preparation program that will prepare and support scholars [1] to complete, within the project period of the grant, a degree, State certification, professional license, or State endorsement in special education, early intervention, or a related services field. Projects also can be associated with personnel preparation programs that (a) prepare individuals to be assistants in related services professions (e.g., physical therapist assistants, occupational therapist assistants), or educational interpreters; or (b) provide an alternate route to certification or that support dual certification (special education and regular education) for teachers. For purposes of this priority, the term ''personnel preparation program'' refers to the program with which the applicant's proposed project is associated.

To be considered for funding under the Personnel Preparation in Special Education, Early Intervention, and Related Services absolute priority, applicants must meet the application requirements contained in the priority. All projects funded under this absolute priority also must meet the programmatic and administrative requirements specified in the priority. These requirements are as follows:

(a) Demonstrate, in the narrative section of the application under ''Significance of the Project,'' how the proposed project will—

(1) Address national, State, or regional shortages of personnel who are fully credentialed to serve children with disabilities, ages birth through 21, including high-need children with disabilities,[2] by preparing special education, early intervention, or related services personnel at the baccalaureate, master's, and specialist levels. To address this requirement, the applicant must present—

(i) Data that demonstrate a national, State, or regional need for the personnel the applicant proposes to prepare; and

(ii) Data that demonstrate the effectiveness of the applicant's personnel preparation program in preparing personnel in special education, early intervention, or related services.[3] These data could include the average amount of time it takes program participants to complete the program; the percentage of program graduates finding employment related to their preparation within one year of graduation; the effectiveness of program graduates in providing special education, early intervention, or related services, which could include data on the learning and developmental outcomes of children with disabilities they serve; or the percentage of program graduates who maintain employment for three or more years in the area for which they were prepared and who are fully qualified under IDEA. When providing the percentages in response to this paragraph, the applicant must also provide the denominator or total number of program participants or program graduates for each percentage.

(2) Increase the number of personnel who demonstrate the competencies needed to provide high-quality instruction, evidence-based interventions, and services for children with disabilities, ages birth through 21, including high-need children with disabilities, that result in improvements in learning and developmental outcomes (e.g., academic, social, emotional, behavioral); and college and career readiness. To address this requirement, the applicant must—

(i) Identify the competencies [4] that special education, early intervention, or related services personnel need in order to provide high-quality instruction, interventions, and services that will lead to improved learning and developmental outcomes; lead to college and career readiness of children with disabilities, ages birth through 21, including high-need children with disabilities; and maximize the use of effective technology to deliver instruction, interventions, and services; and

(ii) Provide the conceptual framework of the personnel preparation program, including any empirical support, that will promote the acquisition of the identified competencies (see paragraph (a)(2)(i) of this priority) needed by special education, early intervention, or related services personnel, and how these competencies relate to the proposed project.

(b) Demonstrate, in the narrative section of the application under ''Quality of Project Services,'' how the proposed project—

(1) Will use strategies to recruit and retain high-quality scholars and ensure equal access and treatment for eligible project participants who are members of groups who have traditionally been underrepresented based on race, color, national origin, gender, age, or

[1] For the purposes of this priority, the term ''scholar'' means an individual who is pursuing a degree, license, endorsement, or certification related to special education, related services, or early intervention services and who receives scholarship assistance under section 662 of IDEA (see 34 CFR 304.3(g)).

[2] For the purposes of this priority, ''high-need children with disabilities'' refers to children (ages birth through 21, depending on the State) who are eligible for services under IDEA, and who may be further disadvantaged and at risk of educational failure because they: (1) Are living in poverty, (2) are far below grade level, (3) are at risk of not graduating with a regular high school diploma on time, (4) are homeless, (5) are in foster care, (6) have been incarcerated, (7) are English learners, (8) are pregnant or parenting teenagers, (9) are new immigrants, (10) are migrant, or (11) are not on track to being college- or career-ready by graduation.

[3] Data provided in response to this requirement must be no older than five years from the start date of the project proposed in the application.

[4] For the purposes of this priority, the term ''competencies'' means what a person knows and can do: The knowledge, skills and dispositions necessary to effectively function in a role (National Professional Development Center on Inclusion, 2011).

disability. To meet this requirement, the applicant must describe—

(i) The selection criteria that it will use to identify high-quality applicants for enrollment in the proposed project;

(ii) The recruitment strategies that it will use to attract high-quality applicants, including any specific recruitment strategies targeting high-quality applicants from traditionally underrepresented groups, for enrollment in the proposed project; and

(iii) The approach, including mentoring and monitoring, that will be used to support scholars to complete the personnel preparation program.

(2) Reflects current research and evidence-based practices and is designed to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how the proposed project will—

(i) Incorporate current research and evidence-based practices that improve outcomes for children with disabilities (including relevant research citations) into the project's required coursework and clinical experiences; and

(ii) Use current research and evidence-based professional development practices for adult learners to instruct scholars.

(3) Is of sufficient quality, intensity, and duration to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how—

(i) The components of the proposed project (e.g., coursework, clinical experiences, or internships) will support scholars' acquisition and enhancement of the identified competencies;

(ii) The components of the proposed project (e.g., coursework, clinical experiences, internships) will be integrated to allow scholars to use their content knowledge in clinical practice, and how scholars will be provided with ongoing guidance and feedback;

(iii) The proposed project will provide ongoing induction opportunities and support to program graduates.

(4) Will collaborate with appropriate partners, including—

(i) High-need LEAs;[5] high-poverty schools;[6] low-performing schools including persistently lowest-achieving schools;[7] priority schools (in the case of States that have received the Department's approval of a request for Elementary and Secondary Education Act of 1965, as amended (ESEA) flexibility),[8] or publicly-funded preschool programs, including Head Start programs and programs serving children eligible for services under IDEA Part C and Part B Section 619, that are located within the geographic boundaries of a high-need LEA. The purpose of these partnerships is to provide clinical practice for scholars aimed at developing the identified competencies; and

(ii) Other programs on campus or at partnering universities for the purpose of sharing resources, supporting program development and delivery, and addressing personnel shortages.

(5) Will use technology, as appropriate, to promote scholar learning, enhance the efficiency of the project, collaborate with partners, and facilitate ongoing mentoring and support for scholars.

(c) Include, in the narrative section of the application under ''Quality of Project Evaluation,'' how—

(1) The proposed project will use comprehensive and appropriate methodologies to evaluate the effectiveness of the project, including the effectiveness of project processes and outcomes;

(2) The proposed project will collect and analyze data related to specific and measurable goals, objectives, and outcomes of the project. To address this requirement, the applicant must describe—

(i) How scholar competencies and other project processes and outcomes will be measured for formative evaluation purposes, including proposed instruments, data collection methods, and possible analyses; and

(ii) How data on the quality of services provided by proposed project graduates, including data on the learning and developmental outcomes (e.g., academic, social, emotional, behavioral), growth toward learning and developmental outcomes, and college and career readiness of the children with disabilities they serve, will be collected and analyzed;

Note: Following the completion of the project period, grantees are encouraged—but not required—to engage in ongoing data collection activities.

(3) The methods of evaluation will produce quantitative and qualitative data for objective performance measures that are related to the outcomes of the proposed project; and

(4) The methods of evaluation will provide performance feedback and allow for periodic assessment of progress towards meeting the project outcomes. To address this requirement, the applicant must describe how–

(i) Findings from the evaluation will be used as a basis for improving the proposed project to prepare special education, early intervention, or related services personnel to provide high-quality interventions and services to improve outcomes of children with disabilities; and

(ii) The proposed project will report evaluation results to the Office of Special Education Programs (OSEP) in the annual and final performance reports.

(d) Demonstrate, in the narrative under ''Project Assurances,'' or

[5] For the purposes of this priority, the term ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line.

[6] For the purposes of this priority, the term ''high-poverty school'' means a school in which at least 50 percent of students are eligible for free or reduced-price lunches under the Richard B. Russell National School Lunch Act or in which at least 50 percent of students are from low-income families as determined using one of the criteria specified under section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school under this definition is determined on the basis of the most currently available data (*www2.ed.gov/legislation/FedRegister/other/2010-4/121510b.html*).

[7] For the purposes of this priority, the term ''persistently lowest-achieving schools'' means, as determined by the State—

(a)(1) Any Title I school in improvement, corrective action, or restructuring that—

(i) Is among the lowest-achieving five percent of Title I schools in improvement, corrective action, or restructuring or the lowest-achieving five Title I schools in improvement, corrective action, or restructuring in the State, whichever number of schools is greater; or

(ii) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years; and

(2) Any secondary school that is eligible for, but does not receive, Title I funds that—

(i) Is among the lowest-achieving five percent of secondary schools or the lowest-achieving five secondary schools in the State that are eligible for, but do not receive, Title I funds, whichever number of schools is greater; or

(ii) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years.

(b) To identify the lowest-achieving schools, a State must take into account both—

(i) The academic achievement of the ''all students'' group in a school in terms of proficiency on the State's assessments under section 1111(b)(3) of the ESEA in reading/language arts and mathematics combined; and

(ii) The school's lack of progress on those assessments over a number of years in the ''all students'' group.

For the purposes of this priority, the Department considers schools that are identified as Tier I or Tier II schools under the School Improvement Grants Program (see 75 FR 66363) as part of a State's approved FY 2009, FY 2010, or FY 2011 application to be persistently lowest-achieving schools. A list of these Tier I and Tier II schools can be found on the Department's Web site at *http://www2.ed.gov/programs/sif/index.html.*

[8] For the purposes of this priority, the term ''priority school'' means a school that has been identified by the State as a priority school pursuant to the State's approved request for ESEA flexibility.

appendices, as applicable, that the following program requirements are met. The applicant must—

(1) Include, in the application appendix, syllabi for all required coursework of the proposed project, including syllabi for new or proposed courses.

(2) Ensure that all scholars who enroll in the proposed project can graduate by the end of the grant's project period.

(3) Ensure that the project will meet the statutory requirements in section 662(e) through 662(h) of IDEA.

(4) Ensure that at least 65 percent of the total requested budget over the five years will be used for scholar support.

(5) Ensure that the institution of higher education (IHE) will not require scholars to work (e.g., as graduate assistants) as a condition of receiving support (e.g., tuition, stipends, books) from the proposed project unless the work is specifically required to advance scholars' competencies or complete other requirements in their personnel preparation program. Please note that this prohibition on work as a condition of receiving support does not apply to the service obligation requirements in section 662(h) of IDEA.

(6) Ensure that the budget includes attendance of the project director at a three-day Project Directors' meeting in Washington, DC, during each year of the project.

(7) Ensure that if the proposed project maintains a Web site, relevant information and documents are in a format that meets government or industry-recognized standards for accessibility.

(8) Ensure that the Project Director will submit annual data on each scholar who receives grant support. Applicants are encouraged to visit the Personnel Development Program Scholar Data Report Web site at: *http://oseppdp.ed.gov* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590).

Focus Areas: Within this absolute priority, the Secretary intends to support projects under the following four focus areas: (A) Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities; (B) Preparing Personnel to Serve School-Age Children with Low-Incidence Disabilities; (C) Preparing Personnel to Provide Related Services to Children, Including Infants and Toddlers, with Disabilities; and (D) Preparing Personnel in Minority Institutions of Higher Education to Serve Children, Including Infants and Toddlers, with Disabilities. Interdisciplinary projects are encouraged to apply under Focus Area A, B, C, or D. Interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines.

Note: Applicants must identify the specific focus area (i.e., A, B, C, or D) under which they are applying as part of the competition title on the application cover sheet (SF form 424, line 4). Applicants may not submit the same proposal under more than one focus area.

Focus Area A: Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities. OSEP intends to fund nine awards under this focus area. For the purpose of Focus Area A, early intervention personnel are those who are prepared to provide services to infants and toddlers with disabilities ages birth to three, and early childhood personnel are those who are prepared to provide services to children with disabilities ages three through five (in States where the age range is other than ages three through five, we will defer to the State's certification for early childhood). In States where certification in early intervention is combined with certification in early childhood, applicants may propose a combined early intervention and early childhood personnel preparation project under this focus area. We encourage interdisciplinary projects under this focus area. For purposes of this focus area, interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines for early intervention providers or early childhood special educators, and related services personnel to serve infants, toddlers, and preschool-age children with disabilities. Projects preparing only related services personnel to serve infants, toddlers, and preschool-age children with disabilities are not eligible under this focus area (see Focus Area C).

Focus Area B: Preparing Personnel to Serve School-Age Children with Low-Incidence Disabilities. OSEP intends to fund 13 awards under this focus area. For the purpose of Focus Area B, personnel who serve children with low-incidence disabilities are special education personnel prepared to serve school-age children with low-incidence disabilities including visual impairments, hearing impairments, simultaneous visual and hearing impairments, significant intellectual disabilities, orthopedic impairments, autism, and traumatic brain injury. Programs preparing special education personnel to provide services to children with visual impairments or blindness that can be appropriately provided in braille must prepare those individuals to provide those services in braille. Projects preparing educational interpreters are eligible under this focus area. We encourage interdisciplinary projects under this focus area. For purposes of this focus area, interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines for low-incidence and related services personnel to serve school-aged children with low incidence disabilities. Projects preparing early intervention or preschool personnel are not eligible under this focus area (see Focus Area A).

Focus Area C: Preparing Personnel to Provide Related Services to Children, Including Infants and Toddlers, with Disabilities. OSEP intends to fund nine awards under this focus area. Programs preparing related services personnel to serve children, including infants and toddlers, with disabilities are eligible within Focus Area C. For the purpose of this focus area, related services include, but are not limited to, psychological services, physical therapy (including therapy provided by personnel prepared at the Doctor of Physical Therapy (DPT) level), adapted physical education, occupational therapy, therapeutic recreation, social work services, counseling services, audiology services (including services provided by personnel prepared at the Doctor of Audiology (AudD) level), and speech and language services. Preparation programs in States where personnel prepared to serve children with speech and language impairments are considered to be special educators are eligible under this focus area. We encourage interdisciplinary projects under this focus area. For purposes of this focus area, interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines for related services personnel who serve children, including infants and toddlers, with disabilities. Projects preparing educational interpreters are not eligible under this focus area (see Focus Area B).

Focus Area D: Preparing Personnel in Minority Institutions of Higher Education to Serve Children, Including Infants and Toddlers, with Disabilities.

OSEP intends to fund 12 awards under this focus area. Programs in minority institutions of higher education (IHEs) are eligible under Focus Area D if they prepare one of the following: (a) Personnel to serve infants, toddlers, and preschool-age children with disabilities; (b) personnel to serve school-age children with low-incidence disabilities; or (c) personnel to provide related services to children, including infants and toddlers, with disabilities. Minority IHEs include IHEs with a minority enrollment of 25 percent or more, which may include Historically Black Colleges and Universities, Tribal Colleges, and Predominantly Hispanic Serving Colleges and Universities. We encourage interdisciplinary projects under this focus area. For purposes of this focus area, interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines for: (a) Early intervention providers or early childhood special educators and related services personnel who serve infants, toddlers, and preschool-age children with disabilities; (b) low-incidence and related services personnel who serve school-age children with low-incidence disabilities; or (c) related services personnel who serve children, including infants and toddlers, with disabilities. Programs in minority IHEs preparing personnel in Focus Area A, B, or C are eligible within Focus Area D. Programs preparing high-incidence special education personnel are not eligible under this priority (for the purpose of this priority, ''high-incidence disabilities'' refers to learning disabilities, emotional disturbance, or intellectual disabilities).

Note: A project funded under Focus Area D may budget for less than 65 percent, the required percentage, for scholar support if the applicant can provide sufficient justification for any designation less than this required percentage. Sufficient justification for proposing less than 65 percent of the budget for scholar support would include support for activities such as program development, program expansion, or the addition of a new area of emphasis. Some examples of projects that may be eligible to designate less than 65 percent of their budget for scholar support include the following:

(1) A project that is proposing to develop and deliver a newly established personnel preparation program or add a new area of emphasis may request up to a year of funding for program development (e.g., hiring of a new faculty member or consultant to assist in course development, providing professional development and training for faculty). In the initial project year, scholar support would not be required. The project must demonstrate that the newly established program or area of emphasis is approved and ready for implementation in order to receive continuation funds in year two.

(2) A project that is proposing to expand or enhance an existing program may request funding for capacity building (e.g., hiring of a clinical practice supervisor, providing professional development and training for faculty), or purchasing needed resources (e.g., additional teaching supplies or specialized equipment to enhance instruction).

Note: Applicants proposing projects to develop, expand, or add a new area of emphasis to special education or related services programs must provide, in their applications, information on how these new areas will be sustained once Federal funding ends.

Competitive Preference Priority: Within this absolute priority, we give competitive preference to applications that meet the following priority. For FY 2013 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is a competitive preference priority.

Competitive Preference Priority 1: Under 34 CFR 75.105(c)(2)(i) we award 5 points to an application that meets this priority.

This priority is:

In Focus Area D, applicants that document that they are IHEs with minority enrollment of 50 percent or more.

References

Bruder, M.B. (December, 2004a). *The National Landscape of Early Intervention in Personnel Preparation Standards under Part C of the Individuals with Disabilities Education Act (IDEA).* A.J. Pappanikou Center for Excellence in Developmental Disabilities, Farmington, CT. Available at: *www.uconnucedd.org/projects/per_prep/resources.html.*

Bruder, M.B. (December, 2004b). *The National Landscape of Early Intervention and Early Childhood Special Education: 619 Data Report.* A.J. Pappanikou Center for Excellence in Developmental Disabilities, Farmington, CT. Available at: *www.uconnucedd.org/projects/per_prep/resources.html.*

McLeskey, J. & Billingsley, B. (2008). How does the quality and stability of the teaching force influence the research-to-practice gap? *Remedial and Special Education, 29*(5), 293–305.

McLeskey, J., Tyler, N., & Flippin, S.S. (2004). The supply and demand for special education teachers: A review of research regarding the chronic shortage of special education teachers. *Journal of Special Education, 38*(1), 5–21.

National Professional Development Center on Inclusion. (August, 2011). *Competencies for early childhood educators in the context of inclusion: Issues and guidance for states.* Chapel Hill, NC: The University of North Carolina, FPG Child Development Institute, Authors.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1462 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Education Department debarment and suspension regulations in 2 CFR part 3485. (c) The regulations for this program in 34 CFR part 304.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $85,799,000 for the Personnel Development to Improve Services and Results for Children with Disabilities program for FY 2013, of which we intend to use an estimated $10,750,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2014 from the list of unfunded applicants from this competition.

Estimated Range of Awards: See chart.

Estimated Average Size of Awards: See chart.

Maximum Award: See chart.

Estimated Number of Awards: See chart.

Project Period: See chart.

PERSONNEL DEVELOPMENT TO IMPROVE SERVICES AND RESULTS FOR CHILDREN WITH DISABILITIES (84.325K) APPLICATION NOTICE FOR FISCAL YEAR 2013

CFDA No. and name	Applications available	Deadline for transmittal of applications	Deadline for intergovernmental review	Estimated range of awards	Estimated average size of awards	Maximum award (budget period of 12 months)	Estimated number of awards	Project period	Contact person
84.325K Personnel Preparation in Special Education, Early Intervention, and Related Services.	January 15, 2013	March 18, 2013	May 15, 2013						
Focus Area A: Preparing Personnel to Serve Infants, Toddlers, and Preschool Age Children with Disabilities.				$225,000–$250,000	$237,500	*$250,000	9	Up to 60 mos.	Maryann McDermott, 202–245–7439, *maryann.mcdermott@ed.gov* PCP, Room 4062.
Focus Area B: Preparing Personnel to Serve School-Age Children with Low-Incidence Disabilities.				$225,000–$250,000	$237,500	*$250,000	13	Up to 60 mos.	Maryann McDermott, 202–245–7439, *maryann.mcdermott@ed.gov* PCP, Room 4062.
Focus Area C: Preparing Personnel to Provide Related Services to Children, Including Infants and Toddlers, with Disabilities.				$225,000–$250,000	$237,500	*$250,000	9	Up to 60 mos.	Sarah Allen, 202–245–7875, *sarah.allen@ed.gov,* PCP, Room 4105.
Focus Area D: Preparing Personnel in Minority Institutions of Higher Education to Serve Children, Including Infants and Toddlers, with Disabilities.				$225,000–$250,000	$237,500	*$250,000	12	Up to 60 mos.	Dawn Ellis, 202–245–6417, *dawn.ellis@ed.gov,* PCP, Room 4092.

*We will reject any application that proposes a budget exceeding the maximum award for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Note: The Department is not bound by any estimates in this notice.

III. Eligibility Information

1. *Eligible Applicants:* Institutions of higher education (IHEs) and private nonprofit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Other: General Requirements*—(a) The projects funded under this program must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Each applicant and grant recipient funded under this program must involve individuals with disabilities or parents of individuals with disabilities ages birth through 26 in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.325K.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to the equivalent of no more than 50 pages using the following standards:

• A ''page'' is 8.5″ × 11″, on one side only, with 1″ margins at the top, bottom, and both sides.

• Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.

• Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

• Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section [Part III].

We will reject your application if you exceed the page limit; or if you apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: January 15, 2013.

Deadline for Transmittal of Applications: March 18, 2013.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: May 15, 2013.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, Central Contractor Registry and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR)—and, after July 24, 2012, with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR or SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR or SAM registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days to complete. Information about SAM is available at SAM.gov.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/applicants/get_registered.jsp.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Personnel Preparation in Special Education, Early Intervention, and Related Services competition, CFDA number 84.325K, must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for Personnel Preparation in Special Education, Early Intervention, and Related Services at *www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.325, not 84.325K).

Please note the following:

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

• Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time

stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *http://www.G5.gov.*

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

• You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

• You must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material. Additional, detailed information on how to attach files is in the application instructions.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Grants.gov system; and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Maryann McDermott, U.S. Department of Education, 400 Maryland Avenue SW., room 4062, PCP, Washington, DC 20202–2600. FAX: (202) 245–7617.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.325K)
LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.325K)
550 12th Street, SW., Room 7041,
Potomac Center Plaza, Washington,
DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* (a) We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

(b) In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:*

In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The Standing Panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that, for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

4. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Personnel Development to Improve Services and Results for Children with Disabilities Program. These measures include: (1) The percentage of Special Education Personnel Development-projects that incorporate evidence-based practices into their curriculum; (2) the percentage of scholars completing Special Education Personnel Development-funded programs who are knowledgeable and skilled in evidence-based practices for infants, toddlers, children and youth with disabilities; (3) the percentage of Special Education Personnel Development-funded scholars

who exit preparation programs prior to completion due to poor academic performance; (4) the percentage of Special Education Personnel Development-funded degree/certification recipients who are working in the area(s) for which they were prepared upon program completion; (5) the percentage of Special Education Personnel Development-funded degree/certification recipients who are working in the area(s) for which they were prepared upon program completion and who are fully qualified under IDEA; (6) the percentage of Special Education Personnel Development degree/certification recipients who maintain employment in the area(s) for which they were prepared for three or more years and who are fully qualified under IDEA; and (7) the Federal cost per fully qualified degree/certification recipient.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made ''substantial progress toward meeting the objectives in its approved application.'' This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contacts

FOR FURTHER INFORMATION CONTACT: See chart in the *Award Information* section in this notice for the name, room number, telephone number, and email address of the contact person for each Focus Area of this competition. You can write to the Focus Area contact person at the following address: U.S. Department of Education, 400 Maryland Avenue SW., Potomac Center Plaza (PCP), Washington, DC 20202–2600.

If you use a TDD or a TTY, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 9, 2013.

Michael Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2013–00594 Filed 1–14–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information:

Personnel Development to Improve Services and Results for Children with Disabilities—Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel

Notice inviting applications for new awards for fiscal year (FY) 2013.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.325D.

DATES: *Applications Available:* January 15, 2013.

Deadline for Transmittal of Applications: March 1, 2013.

Deadline for Intergovernmental Review: April 30, 2013.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of this program are to (1) help address State-identified needs for highly qualified personnel in special education, related services, early intervention, and regular education to work with children, including infants and toddlers, with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research and experience, to be successful in serving those children.

Priorities: This competition has one absolute priority and one competitive preference priority. In accordance with 34 CFR 75.105(b)(2)(iv), the absolute priority is from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA)).

Absolute Priority: For FY 2013 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is: *Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel.*

Background: The purpose of the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel priority is to support programs that prepare special education, early intervention, and related services personnel at the graduate level who are well-qualified for, and can act effectively in, leadership positions in universities, State educational agencies (SEAs), lead agencies (LAs), local educational agencies (LEAs), early intervention services programs (EIS programs), or schools.

Over the last two decades, there has been a need for leadership personnel who are prepared at the doctoral and postdoctoral levels to fill faculty positions in special education, early intervention, and related services (Sindelar & Taylor, 1988; Smith & Lovett, 1987; Smith, Pion, & Tyler, 2004; Smith, Robb, West, & Tyler, 2010; Woods & Snyder, 2009). These leaders teach evidence-based practices to special education, early intervention, and related services professionals who

work in a variety of educational settings and provide services directly to children and youth with disabilities. They also conduct research to increase the knowledge of effective interventions and services for these children (Smith *et al.,* 2010).

State and local agencies also need leadership personnel who are prepared at the graduate level (i.e., master's, education specialist, and doctoral degrees, depending on State certification requirements) to fill special education and early intervention administrator positions. These administrators supervise and evaluate the implementation of evidence-based instructional programs to make sure that State or local agencies are meeting the needs of children with disabilities. Administrators also ensure that schools and programs meet Federal, State, and local requirements for special education, early intervention, and related services (Lashley & Boscardin, 2003).

Federal support can increase the supply of personnel who have the necessary knowledge and skills to assume leadership positions in special education, early intervention, and related services in universities, SEAs, LAs, LEAs, EIS programs, or schools. Critical competencies for special education, early intervention, and related services personnel vary depending on the type of personnel and the requirements of the preparation program but can include, for example, skills needed for postsecondary instruction, administration, policy development, professional practice, leadership, or research. However, all leadership personnel need to have current knowledge of effective interventions and services that improve outcomes for children with disabilities, including high-need children with disabilities.

Priority: The purpose of the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel priority is to support pre-existing degree programs that prepare special education, early intervention, and related services personnel at the graduate level who are well-qualified for, and can act effectively in, leadership positions in universities, SEAs, LAs, LEAs, EIS programs, or schools. This priority supports two types of programs:

Type A programs are designed to prepare special education, early intervention, or related services personnel to serve as higher education faculty. Type A programs culminate in a doctoral degree or provide postdoctoral learning opportunities.

Note: Preparation programs that lead to clinical doctoral degrees in related services (e.g., a Doctor of Audiology (AuD) degree or Doctor of Physical Therapy (DPT) degree) are not included in this priority. These types of preparation programs are eligible to apply for funding under the Personnel Preparation in Special Education, Early Intervention, and Related Services priority (CFDA 84.325K) that the Office of Special Education Programs (OSEP) intends to fund in FY 2013.

Type B programs are designed to prepare special education or early intervention administrators to work in SEAs, LAs, LEAs, EIS programs, or schools. Type B programs prepare personnel for positions such as SEA special education administrators, LEA or regional special education directors, school-based special education directors, preschool coordinators, and early intervention coordinators. Type B programs culminate in a master's, education specialist, or doctoral degree.

Note: OSEP intends to fund in FY 2013 at least three high-quality applications proposing Type B programs and may fund applications out of rank order.

Note: The preparation of school principals is not included in this priority.

Note: Applicants must identify the specific program type, A or B, for which they are applying for funding as part of the competition title on the application cover sheet (SF form 424, item 15). Applicants may not submit the same proposal for more than one program type.

To be considered for funding under the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel absolute priority, all program applicants must meet the application requirements contained in the priority. All projects funded under the absolute priority also must meet the programmatic and administrative requirements specified in the priority.

The requirements of this priority are as follows:

(a) Demonstrate, in the narrative section of the application, under ''Significance of the Project'' how—

(1) The project addresses national, State, or regional needs for leadership personnel to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes of children with disabilities, ages birth through 21, including high-need children with disabilities.[1] To address this requirement, the applicant must—

(i) Present appropriate and applicable national, State, or regional data demonstrating the need for the leadership personnel the applicant proposes to prepare; and

(ii) Present data on the effectiveness of the graduate program to date in areas such as: the effectiveness of program graduates as educators of teachers, service providers, or administrators, including any results from evaluating the impact of those teachers, service providers, or administrators on the outcomes of children with disabilities; the average amount of time it takes for program graduates to complete the program; the percentage of program graduates finding employment directly related to their preparation; and the professional accomplishments of program graduates (e.g., public service, honors, or publications) that demonstrate their leadership in special education, early intervention, or related services; and

Note: Data on the effectiveness of a graduate program should be no older than five years prior to the start date of the project proposed in the application. When reporting percentages, the denominator (i.e., the total number of students) must be provided.

(2) Scholar competencies to be acquired in the program relate to knowledge and skills needed by the leadership personnel the applicant proposes to prepare, including knowledge of technologies designed to provide instruction. To address this requirement, the applicant must—

(i) Identify the competencies needed by leadership personnel in postsecondary instruction, administration, policy development, professional practice, leadership, or research in order to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes of children with disabilities, ages birth through 21, including high-need children with disabilities; and

(ii) Provide the conceptual framework of the leadership preparation program, including any empirical support, that will promote the acquisition of the identified competencies needed by leadership personnel and, where applicable, how these competencies relate to the project's specialized preparation area.

[1] For purposes of this priority, ''high-need children with disabilities'' refers to children (ages birth through 21, depending on the State) who are eligible for services under IDEA, and who may be further disadvantaged and at risk of educational failure because they: (1) Are living in poverty, (2) are far below grade level, (3) are at risk of not graduating with a regular high school diploma on time, (4) are homeless, (5) are in foster care, (6) have been incarcerated, (7) are English learners, (8) are pregnant or parenting teenagers, (9) are new immigrants, (10) are migrant, or (11) are not on track to being college- or career-ready by graduation.

(b) Demonstrate, in the narrative section of the application, under ''Quality of the Project Services,'' how—

(1) The project will recruit and support high-quality scholars. The narrative must—

(i) Describe the selection criteria the applicant will use to identify high-quality applicants for admission in the program;

(ii) Describe the recruitment strategies the applicant will use to attract high-quality applicants and any specific recruitment strategies targeting high-quality applicants from traditionally underrepresented groups; and

(iii) Describe the approach the applicant will use to help scholars complete the program; and

(2) The project is designed to promote the acquisition of the competencies needed by leadership personnel to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes, including college and career readiness of children with disabilities. To address this requirement, the applicant must—

(i) Describe how the components of the project, such as coursework, internship or practicum experiences, research requirements, and other opportunities provided to scholars to analyze data, critique research and methodologies, and practice newly acquired knowledge and skills, will enable the scholars to acquire the competencies needed by leadership personnel for postsecondary instruction, administration, policy development, professional practice, leadership, or research in special education, early intervention, or related services;

(ii) Describe how the components of the project are integrated in order to support the acquisition and enhancement of the identified competencies needed by leadership personnel in special education, early intervention, or related services;

(iii) Describe how the components of the project prepare scholars to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes, including college and career readiness, of children with disabilities in a variety of settings, including in high-need LEAs,[2] high-poverty schools,[3] low-performing schools, including persistently lowest-achieving schools,[4] priority schools (in the case of States that have received the Department's approval of a request for ESEA flexibility),[5] and early childhood programs located within the geographical boundaries of a high-need LEA; and

(iv) Demonstrate, through a letter of support from the partnering agency, school, or program, a relationship with one or more high-need LEAs; publicly funded preschool programs, including Head Start programs, located within the geographic boundaries of a high-need LEA; or programs serving children eligible for services under Part C or Part B, section 619 of IDEA located within the geographic boundaries of a high-need LEA that it has agreed to provide scholars with a high-quality internship or practicum experience in a school in a high-need LEA, publicly funded preschool, or early intervention program.

(v) Describe the approach that faculty members will use to mentor scholars with the goal of helping them acquire competencies needed by leadership personnel and promote career goals in special education, early intervention, or related services.

(c) Demonstrate, in the narrative section of the application, under ''Quality of the Project Evaluation,'' how—

(1) The applicant will evaluate the effectiveness of the proposed leadership project. The applicant must describe the outcomes to be measured for both the project and the scholars, particularly the acquisition of scholar competencies and their impact on the services provided by future teachers, service providers, or administrators; the evaluation methodologies to be employed, including proposed instruments, data collection methods, and possible analyses; and the proposed standards or targets for determining effectiveness;

(2) The applicant will collect and use data on current scholars and scholars who graduate from the program to improve the proposed program on an ongoing basis; and

(3) The grantee will report the evaluation results to OSEP in its annual and final performance reports.

(d) Include, in the narrative under ''Required Project Assurances,'' or appendices as directed, that the following program requirements are met. The applicant must—

(1) Include in the application appendix—

(i) Course syllabi for all coursework in the major and any required coursework for a minor;

(ii) Course syllabi for all research methods, evaluation methods, or data analysis courses required by the degree program and elective research methods, evaluation methods, or data analysis courses that have been completed by more than one student enrolled in the program in the last five years; and

(iii) For new coursework, proposed syllabi;

(2) Ensure that all scholars recruited into the program can graduate from the program by the end of the grant's project period. The described scholar recruitment strategies, the program components and their sequence, and proposed budget must be consistent with this project requirement;

[2] For purposes of this priority, the term ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line.

[3] For purposes of this priority, the term ''high-poverty school'' means a school in which at least 50 percent of students are eligible for free or reduced-price lunches under the Richard B. Russell National School Lunch Act or in which at least 50 percent of students are from low-income families as determined using one of the criteria specified under section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school under this definition is determined on the basis of the most currently available data (*www2.ed.gov/legislation/FedRegister/other/2010-4/121510b.html*).

[4] For purposes of this priority, the term ''persistently lowest-achieving schools'' means, as determined by the State—

(a)(1) Any Title I school in improvement, corrective action, or restructuring that—

(i) Is among the lowest-achieving five percent of Title I schools in improvement, corrective action, or restructuring or the lowest-achieving five Title I schools in improvement, corrective action, or restructuring in the State, whichever number of schools is greater; or

(ii) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years; and

(2) Any secondary school that is eligible for, but does not receive, Title I funds that—

(i) Is among the lowest-achieving five percent of secondary schools or the lowest-achieving five secondary schools in the State that are eligible for, but do not receive, Title I funds, whichever number of schools is greater; or

(ii) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years.

(b) To identify the persistently lowest-achieving schools, a State must take into account both—

(i) The academic achievement of the ''all students'' group in a school in terms of proficiency on the State's assessments under section 1111(b)(3) of the ESEA in reading/language arts and mathematics combined; and

(ii) The school's lack of progress on those assessments over a number of years in the ''all students'' group.

For the purposes of this priority, the Department considers schools that are identified as Tier I or Tier II schools under the School Improvement Grants Program (see 75 FR 66363) as part of a State's approved FY 2009, FY 2010, or FY 2011 application to be persistently lowest-achieving schools. A list of these Tier I and Tier II schools can be found on the Department's Web site at *www2.ed.gov/programs/sif/index.html.*

[5] For purposes of this priority, the term ''priority school'' means a school that has been identified by the State as a priority school pursuant to the State's approved request for ESEA flexibility.

(3) Ensure that the project will meet the statutory requirements in section 662(e) through 662(h) of IDEA;

(4) Ensure that at least 65 percent of the total requested annual budget will be used for scholar support or provide justification in the application narrative for any designation less than 65 percent. Examples of sufficient justification for proposing less than 65 percent of the budget for scholar support include—

(i) A project servicing rural areas that provides long-distance coursework, and requires information technology personnel, adjunct professors, or site-based mentors to operate effectively; and

(ii) A project that expands or adds a new area of emphasis to special education, early intervention, or related services, and includes data on the need for the expansion and information on how these expanded or new areas will be sustained once Federal funding ends.

(5) Ensure that the institution will not require scholars enrolled in the program to work (e.g., as graduate assistants) as a condition of receiving a scholarship, unless the work is specifically related to the acquisition of scholars' competencies and the requirements for completion of their personnel preparation program. Please note that this prohibition on work as a condition of receiving a scholarship does not apply to the service obligation requirements in section 662(h) of IDEA;

(6) Ensure that the budget includes attendance of the project director at a three-day Project Directors' meeting in Washington, DC, during each year of the project. The budget may also provide for the attendance of scholars at the three-day Project Directors' meeting in Washington, DC;

(7) Ensure that if the project maintains a Web site, relevant information and documents are in a format that meets government or industry-recognized standards for accessibility; and

(8) Ensure that annual data will be submitted on each scholar who receives grant support. Applicants are encouraged to visit the Personnel Development Program Scholar Data Report Web site at: *http://oseppdp.ed.gov* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590).

Competitive Preference Priority: Within this absolute priority, we give competitive preference to applications that meet the following priority. For FY 2013 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award an additional 5 points to an application that meets this priority.

This priority is:

Applicants for Type B programs that provide a syllabus or syllabi for a new or existing course, or series of courses, that show(s) that the course or courses include or will include: (1) A discussion of applicable research and evaluation findings on the use of data on early learning outcomes, student achievement, or growth in student achievement in evaluating the effectiveness of early intervention providers, related services providers, teachers, or principals; (2) methodological and statistical considerations in conducting an evaluation of the effectiveness of these personnel using data on early learning outcomes, student achievement, or growth in student achievement; and (3) an opportunity for scholars to review, critique, and, as appropriate, participate in one or more evaluations of the effectiveness of early intervention providers, related services providers, teachers, or principals.

References

Lashley, C., & Boscardin, M. L. (2003). Special education administration at the crossroads: Availability, licensure, and preparation of special education administrators. Gainesville, FL: Center on Personnel Studies in Special Education, University of Florida. Retrieved from *www.coe.ufl.edu/copsse/docs/IB-8/1/IB-8.pdf.*

Sindelar, P. T., & Taylor, C. (1988). Supply and demand for doctoral personnel in special education and communication disorders. *Teacher Education and Special Education, 11,* 162–167.

Smith, D. D., & Lovett, D. (1987). The supply and demand of special education faculty members: Will the supply meet the demand? *Teacher Education and Special Education, 11,* 162–167.

Smith, D. D., Pion, G. M., & Tyler, N. C. (2004). Leadership personnel in special education: Can persistent shortages be resolved? In A. M. Sorells, H. J., Rieth & P. T. Sindelar (Eds.), *Critical Issues in Special Education: Access, Diversity, and Accountability* (pp. 258–276). New York: Pearson, Allyn & Bacon.

Smith, D. D., Robb, S. M., West, J., & Tyler, N. C. (2010). The changing education landscape: How special education leadership preparation can make a difference for teachers and their students with disabilities. *Teacher Education and Special Education, 33*(1), 25–43.

Woods, J., & Snyder, P. (2009). Interdisciplinary doctoral leadership training in early intervention. *Infants & Young Children, 22*(1), 32–34.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priorities in this notice.

Program Authority: 20 U.S.C. 1462 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 86, 97, 98, and 99. (b) The Education Department debarment and suspension regulations in 2 CFR part 3485. (c) The regulations for this program in 34 CFR part 304.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $85,799,000 for the Personnel Development to Improve Services and Results for Children with Disabilities program for FY 2013, of which we intend to use an estimated $4,250,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2014 from the list of unfunded applicants from this competition.

Estimated Range of Awards: $225,000–$250,000.

Estimated Average Size of Awards: $237,500.

Maximum Award: We will reject any application that proposes a budget exceeding $250,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 17.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* IHEs, private nonprofit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Other: General Requirements*—(a) The projects funded under this program must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Each applicant and grant recipient funded under this program must involve individuals with disabilities or parents of individuals with disabilities ages birth through 26 in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Address To Request Application Package:* You can obtain an application package via the Internet, from the Education Publications Center (ED Pubs), or from the program office. To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.325D.

To obtain a copy from the program office, contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to the equivalent of no more than 50 pages, using the following standards:

- A ''page'' is 8.5″ × 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

We will reject your application if you exceed the page limit; or if you apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: January 15, 2013.

Deadline for Transmittal of Applications: March 1, 2013.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: April 30, 2013.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, Central Contractor Registry, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR)—and, after July 24, 2012, with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR or SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR or SAM registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days to complete. Information about SAM is available at SAM.gov.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these

steps are outlined at the following Grants.gov Web page: *www.grants.gov/applicants/get_registered.jsp.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel competition, CFDA number 84.325D, must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel at *www.Grants.gov.* You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.325, not 84.325D).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *www.G5.gov.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material. Additional, detailed information on how to attach files is in the application instructions.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).
- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are

unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to Patricia Gonzalez: U.S. Department of Education, 400 Maryland Avenue SW., room 4082, Potomac Center Plaza (PCP), Washington, DC 20202–2600. Fax: (202) 202–245–7617.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 325D), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 325D), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The Standing Panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

4. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy

requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html*.

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Personnel Development to Improve Services and Results for Children with Disabilities Program. These measures include: (1) The percentage of projects that incorporate evidence-based practices into the curriculum; (2) the percentage of scholars completing Personnel Development to Improve Services and Results for Children with Disabilities-funded programs who are knowledgeable and skilled in evidence-based practices for children, including infants and toddlers, with disabilities; (3) the percentage of Personnel Development to Improve Services and Results for Children with Disabilities-funded scholars who exit preparation programs prior to completion due to poor academic performance; (4) the percentage of Personnel Development to Improve Services and Results for Children with Disabilities-funded degree/certification recipients who are working in the area(s) in which they were prepared upon program completion; (5) the percentage of Personnel Development to Improve Services and Results for Children with Disabilities-funded degree/certification recipients who are working in the area(s) for which they were prepared upon program completion and are fully qualified under IDEA; (6) the percentage of Personnel Development to Improve Services and Results for Children with Disabilities degree/certification recipients who maintain employment for three or more years in the area(s) for which they were prepared and who are fully qualified under IDEA; and (7) the Federal cost per fully qualified degree/certification recipient.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made ''substantial progress toward meeting the objectives in its approved application.'' This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Patricia Gonzalez, U.S. Department of Education, 400 Maryland Avenue SW., room 4082, PCP, Washington, DC 20202–2600. Telephone: (202) 245–7355.

If you use a TDD or a TTY, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys*. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 9, 2013.

Michael Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2013–00591 Filed 1–14–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3117–001.
Applicants: Lea Power Partners, LLC.
Description: Lea Power Partners, LLC's Updated Market Power Analysis and Order No. 697 Compliance Filing.
Filed Date: 1/7/13.
Accession Number: 20130107–5140.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER12–72–002.
Applicants: Public Service Company of New Mexico.
Description: Public Service Company of New Mexico submits tariff filing per 35: PNM Filing of Former NITSA and NOA with Navopache to be effective 4/14/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5116.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–717–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original Service Agreement No. 3476—Queue Position R11 to be effective 12/7/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5101.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–719–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii: 2509 Eva Wind, LLC GIA to be effective 12/6/2012.

Filed Date: 1/7/13.

Accession Number: 20130107–5142.

Comments Due: 5 p.m. ET 1/28/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 7, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00686 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2881–006; ER10–2882–006; ER10–2883–006; ER10–2884–006; ER10–2885–006; ER10–2641–006; ER10–2663–006; ER10–2886–006.

Applicants: Alabama Power Company, Southern Power Company, Georgia Power Company, Mississippi Power Company, Gulf Power Company, Oleander Power Project, Limited Partnership, Southern Company—Florida LLC, Southern Turner Cimarron I, LLC.

Description: Notice of Change in Status of Alabama Power Company, et al.

Filed Date: 1/7/13.

Accession Number: 20130107–5230.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER11–3551–000; ER11–3822–000; ER11–3553–000; ER11–3554–000; ER11–3824–000.

Applicants: Glacial Energy of New York, Glacial Energy of New England, Inc., Glacial Energy of New Jersey, Inc., Glacial Energy of California, Inc., Glacial Energy of Illinois, Inc.

Description: Revised Refund Report of Glacial Energy of New York, et al.

Filed Date: 1/7/13.

Accession Number: 20130107–5213.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–454–001.

Applicants: NDR Energy Group, LLC.

Description: Amendment Filing to be effective 1/7/2013.

Filed Date: 1/7/13.

Accession Number: 20130107–5183.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–720–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: 2013–01–07 SA 2078 NSP-Sibley G587 to be effective 1/8/2013.

Filed Date: 1/7/13.

Accession Number: 20130107–5200.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–721–000.

Applicants: Nevada Power Company.

Description: Rate Schedule No. 126 Nevada Cogeneration Associates #1 Contract LTPP From QF to be effective 3/8/2013.

Filed Date: 1/7/13.

Accession Number: 20130107–5206.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–722–000.

Applicants: Nevada Power Company.

Description: Rate Schedule No. 128 Nevada Cogeneration Associates #2 Contract LTPP From QF to be effective 3/8/2013.

Filed Date: 1/7/13.

Accession Number: 20130107–5207.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–723–000.

Applicants: Nevada Power Company.

Description: Rate Schedule No. 94 Amended & Restated McCullough Switchyard Agreement to be effective 3/8/2013.

Filed Date: 1/7/13.

Accession Number: 20130107–5208.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–724–000.

Applicants: Nevada Power Company.

Description: Rate Schedule No. 125 Saguaro Power Company Contract A LTPP from QF to be effective 3/8/2013.

Filed Date: 1/7/13.

Accession Number: 20130107–5209.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–725–000.

Applicants: Southwest Power Pool, Inc.

Description: 2220R1 Broken Bow Wind II, LLC to be effective 12/6/2012.

Filed Date: 1/7/13.

Accession Number: 20130107–5210.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–726–000.

Applicants: PJM Interconnection, L.L.C.

Description: Queue Position W3–066; Original Service Agreement Nos. 3473 & 3474 to be effective 12/6/2012.

Filed Date: 1/7/13.

Accession Number: 20130107–5211.

Comments Due: 5 p.m. ET 1/28/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 8, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00630 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC13–59–000.

Applicants: Brooklyn Navy Yard Cogeneration Partners, L.P.

Description: Application of Brooklyn Navy Yard Cogeneration Partners, L.P. for Authorization for Disposition of Jurisdictional Facilities and Request for Expedited Consideration.

Filed Date: 1/4/13.

Accession Number: 20130104–5163.

Comments Due: 5 p.m. ET 1/25/13.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–200–001.

Applicants: Woodland Biomass Power Ltd.
Description: MBR Deficiency Filing to be effective 10/29/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5026.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–204–001.
Applicants: DTE Stoneman, LLC.
Description: MBR Deficiency Filing to be effective 10/29/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5025.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–205–001.
Applicants: DTE Pontiac North, LLC.
Description: MBR Deficiency Filing to be effective 10/29/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5023.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–208–001.
Applicants: DTE Energy Supply, Inc.
Description: MBR Deficiency Filing to be effective 10/29/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5022.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–209–001.
Applicants: DTE River Rouge No. 1, LLC.
Description: MBR Deficiency Filing to be effective 10/29/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5024.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–210–001.
Applicants: DTE East China, LLC.
Description: MBR Deficiency Filing to be effective 10/29/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5018.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–212–001.
Applicants: DTE Calvert City, LLC.
Description: MBR Deficiency Filing to be effective 10/29/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5016.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–219–001.
Applicants: California Independent System Operator Corporation.
Description: 2013–01–04 Filing to Comply with December 20, 2012 Order in Docket No. ER13–219 to be effective 1/1/2013.
Filed Date: 1/4/13.
Accession Number: 20130104–5126.
Comments Due: 5 p.m. ET 1/25/13.

Docket Numbers: ER13–709–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: 2013–01–04 Scheds 10–16–17 to be effective 3/6/2013.
Filed Date: 1/4/13.
Accession Number: 20130104–5127.
Comments Due: 5 p.m. ET 1/25/13.

Docket Numbers: ER13–710–000.
Applicants: PJM Interconnection, L.L.C.
Description: Queue Position X1–068; Original Service Agreement No. 3471 to be effective 12/3/2012.
Filed Date: 1/4/13.
Accession Number: 20130104–5141.
Comments Due: 5 p.m. ET 1/25/13.

Docket Numbers: ER13–711–000.
Applicants: California Independent System Operator Corporation.
Description: 2013–01–04 CAISO DTBAOA with Public Service New Mexico to be effective 3/6/2013.
Filed Date: 1/4/13.
Accession Number: 20130104–5153.
Comments Due: 5 p.m. ET 1/25/13.

Docket Numbers: ER13–712–000.
Applicants: CPV Cimarron Renewable Energy Company, LLC.
Description: Cimarron Wind Energy, LLC Notice of Succession and Tariff Revisions to be effective 1/5/2013.
Filed Date: 1/4/13.
Accession Number: 20130104–5154.
Comments Due: 5 p.m. ET 1/25/13.

Docket Numbers: ER13–713–000.
Applicants: FirstEnergy Nuclear Generation Corp.
Description: Market-Based Rate Power Sales Tariff to be effective 1/4/2013.
Filed Date: 1/4/13.
Accession Number: 20130104–5155.
Comments Due: 5 p.m. ET 1/25/13.

Docket Numbers: ER13–714–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits Notice of Cancellation of service agreement No. 785.
Filed Date: 1/4/13.
Accession Number: 20130104–5162.
Comments Due: 5 p.m. ET 1/25/13.

Docket Numbers: ER13–715–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original Service Agreement No. 3451; Queue No. X3–079 to be effective 12/7/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5043.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: ER13–716–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2) (iii: Original Service Agreement No. 3446; Queue No. X1–116 to be effective 12/7/2012.
Filed Date: 1/7/13.
Accession Number: 20130107–5058.
Comments Due: 5 p.m. ET 1/28/13.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH13–7–000.
Applicants: Algonquin Power & Utilities Corp.
Description: Algonquin Power & Utilities Corp submits FERC–65–B Waiver Notification Withdrawal.
Filed Date: 1/4/13.
Accession Number: 20130104–5161.
Comments Due: 5 p.m. ET 1/25/13.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF13–218–000.
Applicants: Harbor Cogeneration Company, LLC.
Description: Form 556 of Harbor Cogeneration Company, LLC.
Filed Date: 12/27/12.
Accession Number: 20121227–5111.
Comments Due: None Applicable.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD13–3–000.
Applicants: North American Electric Reliability Corp.
Description: Errata to Petition of the North American Electric Reliability Corporation for Approval of Proposed Reliability Standard EOP–004–2—Event Reporting.
Filed Date: 2/4/13.
Accession Number: 20130104–5167.
Comments Due: 5 p.m. ET 2/4/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 7, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00685 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP13–380–000.
Applicants: El Paso Marketing Company, L.L.C.,Kinder Morgan Tejas Pipeline LLC.
Description: Withdrawal of the December 11, 2012 Joint Petition of El Paso Marketing Company, L.L.C. and Kinder Morgan Tejas Pipeline LLC for Temporary Waiver of Capacity Release Regulations and Policies.
Filed Date: 1/7/13.
Accession Number: 20130107–5223.
Comments Due: 5 p.m. ET 1/22/13.

Docket Numbers: RP13–437–000.
Applicants: East Tennessee Natural Gas, LLC.
Description: K410135 Release to K660958 to be effective 1/1/2013.
Filed Date: 1/4/13.
Accession Number: 20130104–5128.
Comments Due: 5 p.m. ET 1/16/13.

Docket Numbers: RP13–438–000.
Applicants: Saltville Gas Storage Company L.L.C.
Description: K00183S Release to K490041 to be effective 1/1/2013.
Filed Date: 1/4/13.
Accession Number: 20130104–5129.
Comments Due: 5 p.m. ET 1/16/13.

Docket Numbers: RP13–439–000.
Applicants: Northern Natural Gas Company.
Description: 20130107 Negotiated Rate to be effective 1/8/2013.
Filed Date: 1/7/13.
Accession Number: 20130107–5154.
Comments Due: 5 p.m. ET 1/22/13.

Docket Numbers: RP13–440–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Removing Expired Agreements to be effective 2/8/2013.
Filed Date: 1/8/13.
Accession Number: 20130108–5140.
Comments Due: 5 p.m. ET 1/22/01.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP13–294–001.
Applicants: Gulf South Pipeline Company, LP.
Description: Compliance Filing in Docket No. RP13–294 to be effective 1/1/2013.
Filed Date: 1/4/13.
Accession Number: 20130104–5030.
Comments Due: 5 p.m. ET 1/16/13.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated January 9, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00684 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–388–001.
Applicants: Sky River LLC.
Description: Sky River LLC Request to Defer Action on Shared Facilities Agreement to be effective 12/31/9998.
Filed Date: 1/8/13.
Accession Number: 20130108–5112.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: ER13–727–000.
Applicants: Southern California Edison Company.
Description: SGIA and Distribution Service Agmt Victor Mesa Linda A Project to be effective 1/9/2013.
Filed Date: 1/8/13.
Accession Number: 20130108–5064.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: ER13–728–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original Service Agreement No. 3456; Queue No. X1–032 to be effective 12/14/2012.
Filed Date: 1/8/13.
Accession Number: 20130108–5079
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: ER13–729–000.
Applicants: ISO New England Inc.
Description: ISO New England Inc. Resource Termination Filing—MATEP LLC.
Filed Date: 1/8/13.
Accession Number: 20130108–5107.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: ER13–730–000.
Applicants: Desert View Power, Inc.
Description: Amendment to Power Purchase Agreement to be effective 5/1/2012.
Filed Date: 1/8/13.
Accession Number: 20130108–5135.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: ER13–731–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original Service Agreement No. 3457; Queue No. X3–082 to be effective 12/11/2012.
Filed Date: 1/8/13.
Accession Number: 20130108–5139.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: ER13–732–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original Service Agreement No. 3458; Queue No. X3–083 to be effective 12/11/2012.
Filed Date: 1/8/13.
Accession Number: 20130108–5147.
Comments Due: 5 p.m. ET 1/29/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 8, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00631 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP12–471–000]

Northwest Pipeline GP; Notice of Availability of the Environmental Assessment for the Proposed South Seattle Delivery Lateral Expansion Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the South Seattle Delivery Lateral Expansion Project, proposed by Northwest Pipeline GP (Northwest) in the above-referenced docket. Northwest requests authorization to upgrade 4.0 miles of natural gas pipeline from 10- to 16-inch-diameter in King County, Washington, which would increase its natural gas transportation capacity by 74,850 dekatherms per day in the south Seattle market area.

The EA assesses the potential environmental effects of the construction and operation of the South Seattle Delivery Lateral Expansion Project in accordance with the requirements of the National Environmental Policy Act. The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The FERC staff mailed copies of the EA to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding.

In addition, the EA is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this project, it is important that we receive your comments in Washington, DC on or before February 8, 2013.

For your convenience, there are three methods you can use to file your comments to the Commission. In all instances, please reference the project docket number (CP12–471–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a project;

(2) You can also file your comments electronically using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.*'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search,'' and enter the docket number excluding the last three digits in the Docket Number field (i.e., CP12–471). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/esubscribenow.htm.*

Dated: January 9, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00645 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

[1] See the previous discussion on the methods for filing comments.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AC13–14–000]

Steuben Gas Storage Company (Steuben); Notice of Filing

Take notice that on October 19, 2012, Steuben Gas Storage Company (Steuben) submitted a request for a waiver of the reporting requirement to file the FERC Form 2–A for 2012.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies

of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC. 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: February 7, 2013.

Dated: January 8, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00640 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ13–7–000]

City of Azusa, CA; Notice of Filing

Take notice that on December 20, 2012, City of Azusa, California submitted its tariff filing per 35.28(e): Azusa 2013 TRBAA/ETC Update to be effective 1/1/2013.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on January 22, 2013.

Dated: January 8, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00639 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ13–6–000]

City of Pasadena, CA; Notice of Filing

Take notice that on December 19, 2012, City of Pasadena, California submitted its tariff filing per 35.28(e): Pasadena 2013 TRBAA Update to be effective 1/1/2013.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on January 22, 2013.

Dated: January 8, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00638 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–698–000]

Southard Energy Partners, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Southard Energy Partners, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is January 28, 2013.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 8, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00683 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–733–000]

Silver Bear Power, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Silver Bear Power, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is January 29, 2013.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 9, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00627 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–734–000]

Atlantic Coast Energy Corporation; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Atlantic Coast Energy Corporation's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is January 29, 2013.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 9, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00628 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3030–019]

Antrim County; Notice of Application Tendered for Filing With the Commission, Soliciting Additional Study Requests, and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed

with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent license.

b. *Project No.:* P–3030–019.

c. *Date filed:* December 21, 2012.

d. *Applicant:* Antrim County.

e. *Name of Project:* Elk Rapids Hydroelectric Project

f. *Location:* On the Elk River in the village of Elk Rapids in Antrim, Grand Traverse, and Kalkaskia counties, Michigan. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 USC 791 (a)–825(r).

h. *Applicant Contact:* William Stockhausen, Elk Rapids Hydroelectric Power, LLC, 218 West Dunlap Street, Northville, MI 48167; or at (248) 349–2833.

i. *FERC Contact:* Lee Emery at (202) 502–8379 or by email at *lee.emery@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: February 19, 2013.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

m. The application is not ready for environmental analysis at this time.

n. The existing Elk Rapids Hydroelectric Project is located on the Elk River in Antrim, Grand Traverse, and Kalkaskia counties, Michigan. The project consists of: (1) 2,560-acre Skegemog Lake; (2) 7,730-acre Elk Lake; (3) a 121-foot-long, 52-foot-high, 26-foot-wide existing powerhouse that spans the main channel of the Elk River, with an operating head of 10.5 feet, (4) four 22-foot-wide bays with a trash rack having a 1¾-inch clear bar spacing; (5) two turbine-generator units for a combined installed capacity of 0.700 megawatt; (6) two turbine gates used to spill excess water; (7) a 14-foot-wide overflow spillway equipped with stoplogs; (8) a 20-foot by 30-foot substation enclosure; (9) a 50-foot-long underground 12.5-kilovolt transmission line to connect the project substation to the local utility distribution lines; and (10) other appurtenant facilities.

The project operates in a run-of-river mode and the water surface elevation is maintained at 590.8 feet Elk Rapids dam gage datum from April 15 through November 1 and at 590.2 feet Elk Rapids dam gage datum from November 1 through April 15. The average annual generation is about 2,422 megawatt-hours.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. With this notice, we are initiating consultation with the Michigan State Historic Preservation Officer (SHPO), as required by section 106 of the National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. Procedural schedule and final amendments: The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Issue Notice of Acceptance—March 2013
Issue Scoping Document 1 for comments—April 2013
Comments due on Scoping Document 1—June 2013
Issue Scoping Document 2—June 2013
Issue notice of ready for environmental analysis—September 2013
Issue Environmental Assessment (EA)—March 2014
Comments on due on EA—April 2014

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: January 9, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00647 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5944–021]

Moretown Hydro Energy Company; Ampersand Moretown Hydro, LLC; Notice of Application for Transfer of License, and Soliciting Comments and Motions To Intervene

On September 25, 2012, Moretown Hydro Energy Company (transferor) and Ampersand Moretown Hydro, LLC (transferee) filed an application for transfer of license for the Moretown No. 8 Hydropower Project, No. 5944, located on the Mad River in Washington County, Vermont.

Applicants seek Commission approval to transfer the license for the Moretown No. 8 Hydropower Project from transferor to transferee.

Applicants' Contact: Transferor: Ms. Linda Bearisto, General Counsel, c/o Algonquin Power Fund (America) Inc., 2845 Bristol Circle, Oakville, Ontario, Canada L6H 7H7. For Transferee: Ms. Julie Perry, c/o Ampersand Hydro, LLC, 717 Atlantic Avenue, Suite 1A, Boston, MA 02111, telephone (617) 733–7202.

FERC Contact: Patricia W. Gillis (202) 502–8735.

Deadline for filing comments and motions to intervene: 15 days from the

issuance date of this notice. Comments and motions to intervene may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1) and the instructions on the Commission's Web site under *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original plus seven copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. More information about this project can be viewed or printed on the eLibrary link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–5944) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Dated: January 9, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00641 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12514–056]

Northern Indiana Public Service Company; Notice of Application for Temporary Variance of License Article 403 and Soliciting Comments, Motions to Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Extension of temporary variance of license article 403.

b. *Project No:* 12514–056.

c. *Date Filed:* November 28, 2012.

d. *Applicant:* Northern Indiana Public Service Company (licensee).

e. *Name of Project:* Norway-Oakdale Hydroelectric Project.

f. *Location:* The Norway-Oakdale Project is located on the Tippecanoe River near the town of Monticello, in Carroll and White counties, Indiana. The project consists of the upper Norway development and the lower Oakdale development each of which has a dam and powerhouse.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Justin Darling, Hydro Supervisor—Chemical and Environmental Compliance, Northern Indiana Public Service Company, 1414 W. Broadway, Monticello, IN 47960, 574–583–1154.

i. *FERC Contact:* Mr. Robert Ballantine at 202–502–6289, *robert.ballantine@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* February 8, 2013.

All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.gov/docs-filing/efiling.asp.* If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments.

Please include the project number (P–12514) on any comments, motions, or recommendations filed.

k. *Description of Request:* Northern Indiana Public Service Company, licensee for the Norway-Oakdale Hydroelectric Project, requests the Commission to grant an extension of time to a temporary variance of license Article 403 that was granted by the Commission on October 4, 2012, due to continued regional drought conditions. In that order, the Commission granted a temporary variance of license article 403 until December 31, 2012. Article 403, in part, requires the licensee to operate the project in a run-of-river manner where, project outflow is equal to project inflow and to maintain lake elevations of Lake Shafer within ±0.25 feet of elevation 647.47 feet National Geodetic Vertical Datum (NGVD) and Lake Freeman within ±0.25 feet of elevation 612.45 NGVD. The U.S. Fish and Wildlife Service and the Indiana Department of Natural Resources have requested that the licensee release a minimum flow of 200 cubic feet per second (cfs) from the Oakdale Dam for the preservation of federally endangered mussel species which inhabit the Tippecanoe River downstream of the project reservoirs. Due to the potential continuation of regional drought conditions affecting the project watershed, the release of 200 cfs downstream of the project, at times, may not be equal to project inflow and therefore may result in the lake elevations decreasing below 0.25 feet NGVD as permitted by Article 403 of the project license. The licensee is requesting that the temporary variance be extended to December 1, 2013.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling 202–502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call 202–502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) Bear in all capital letters the title ''COMMENTS''; ''PROTESTS'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the

requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: January 9, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00642 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission, DOE.

DATE AND TIME: January 17, 2013, 10:00 a.m.

PLACE: Room 2C, 888 First Street NE., Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda * **Note**—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400. For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's Web site at *http://www.ferc.gov* using the eLibrary link, or may be examined in the Commission's Public Reference Room.

989TH—MEETING, REGULAR MEETING, JANUARY 17, 2013, 10:00 A.M.

Item No	Docket No.	Company
	ADMINISTRATIVE	
A–1	AD02–1–000	Agency Business Matters.
A–2	AD02–7–000	Customer Matters, Reliability, Security and Market Operations.
	ELECTRIC	
E–1	RM13–2–000	Small Generator Interconnection Agreements and Procedures.
E–2	AD12–9–000	Allocation of Capacity on New Merchant Transmission Projects and New Cost-Based, Participant-Funded Transmission Projects.
	AD11–11–000	Priority Rights to New Participant-Funded Transmission.
E–3	EL11–46–000	NextEra Energy Resources, LLC; Peetz Logan Interconnect, LLC; and PWEC, LLC.
E–4	OMITTED	
E–5	ER11–2970–001	Peetz Logan Interconnect, LLC.
	ER11–2970–002	
E–6	EL12–11–000	*Rail Splitter Wind Farm, LLC* v. *Ameren Services Company and Midwest Independent Transmission System Operator, Inc.*
E–7	EL12–104–000	*Interstate Power and Light Company* v. *ITC Midwest, LLC.*
E–8	EL11–30–001	*E.ON Climate & Renewables North America, LLC* v. *Midwest Independent Transmission System Operator, Inc.*
	ER12–451–000	
E–9	OMITTED	
E–10	EL13–17–000	Blue Summit Wind, LLC.
E–11	EL13–18–000	Electric Transmission Texas, LLC
E–12	EL12–7–000	*Hess Corporation* v. *PJM Interconnection, LLC.*
E–13	EL13–10–000	*North American Natural Resources, Inc.* v. *PJM Interconnection, L.L.C., American Electric Power Service Corp., and Indiana Michigan Power Co.*
	GAS	
G–1	RP12–514–000	Tennessee Gas Pipeline Company, LLC.
	HYDRO	
H–1	RM11–6–000	Annual Charges for Use of Government Lands.
H–2	P–14404–001	Calleguas Municipal Water District.
	CERTIFICATES	
C–1	OMITTED	
C–2	CP12–498–000	The Gas Company, LLC.

Issued January 10, 2013.

Kimberly D. Bose,

Secretary.

A free webcast of this event is available through *www.ferc.gov.* Anyone with Internet access who desires to view this event can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the free webcasts. It also offers access to this event via television in the DC area and via phone bridge for a fee. If you have any questions, visit *www.CapitolConnection.org* or contact Danelle Springer or David Reininger at 703–993–3100.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters, but will not be telecast through the Capitol Connection service.

[FR Doc. 2013–00742 Filed 1–11–13; 11:15 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL13–38–000; QF87–120–012]

Badger Creek Limited; Notice of Petition for Declaratory Order

Take notice that on January 8, 2013, pursuant to section 292.205(c) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure implementing the Public Utility Regulatory Policies Act of 1978, as amended, 18 CFR 292.205(c) (2012), Badger Creek Limited filed a petition for declaratory order requesting a limited waiver, for calendar year 2012, of the qualifying facility operating and efficiency standards for its facility located in Bakersfield, California, as set forth in sections 292.205(c) of the Commission's regulations for the topping-cycle cogeneration facility.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on February 7, 2013.

Dated: January 9, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00626 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14478–000]

New England Hydropower Company, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On December 28, 2012, the New England Hydropower Company, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Eagleville Dam Hydroelectric Project (Eagleville Dam Project or project) to be located on the Willimantic River, in the towns of Coventry and Manchester, Tolland County, Connecticut. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) An existing 22-foot-high, 520-foot-long earth embankment dam with a 173-foot-long stone masonry spillway; (2) an existing 77-acre impoundment with an operating elevation of about 277.0 feet above mean sea level (msl); (3) an existing 12-foot-long, 16-foot-wide, 10-foot-deep head box and intake channel; (4) a new 10-foot-high, 16-foot-wide sluice gate equipped with two existing 10-foot-high, 7-foot-wide trashracks with 6-inch bar spacing; (5) a new 60-foot-long, 11.25-foot-wide Archimedes screw generator unit with an installed capacity of 133 kilowatts; (6) a new 10-foot-high, 19-foot-long, 22-foot-wide powerhouse containing a new gearbox and electrical controls; (7) a new above ground 215-foot-long, 13.8-kilovolt transmission line connecting the powerhouse to the Connecticut Light & Power's distribution system; and (8) appurtenant facilities. The estimated annual generation of the proposed Eagleville Dam Project would be about 630 megawatt-hours. The existing Eagleville Dam and appurtenant works, including a former penstock foundation and intake structures, are owned by the State of Connecticut and operated by the Connecticut Department of Energy and Environmental Protection.

Applicant Contact: Mr. Michael C. Kerr, New England Hydropower Company, LLC, P.O. Box 5524, Beverly Farms, Massachusetts 01915; phone: (978) 360–2547.

FERC Contact: John Ramer; phone: (202) 502–8969 or email: *john.ramer@ferc.gov.*

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll

free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14478) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: January 9, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00644 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14430–000]

Monroe Hydro LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On July 2, 2012, Monroe Hydro LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Monroe Water Project to be located on the North Unit Irrigation District's Main Canal, near Culver, Jefferson County, Oregon. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The North Unit Irrigation Project is operated by the U.S. Department of the Interior, Bureau of Reclamation for irrigation purposes. The proposed project would study the hydropower potential of the existing Monroe Drop on the Main Canal, which consists of a concrete, uncontrolled fixed crest dam about 15 feet long. The proposed project would consist of a new powerhouse and an associated intake channel and tailrace channel on the northwestern side of the canal. A concrete powerhouse would enclose a single turbine-generating unit with a capacity of 300 kilowatts. The estimated annual generation of the project would be 1.0 gigawatt-hour.

Applicant Contact: Ms. Gia Schneider, Natel Energy, 2175 Monarch Street, Alameda, California 94501; phone: (510) 342–5269.

FERC Contact: Mary Greene at *mary.greene@ferc.gov;* phone: (202)502–6095.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14430) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: January 7, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00636 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13346–002]

PayneBridge, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On November 1, 2012, PayneBridge, LLC filed an application for a successive preliminary permit under section 4(f) of the Federal Power Act proposing to study the feasibility of the proposed Williams Dam Water Power Project No. 13346–002, to be located at the existing Williams Dam on the East Fork of the White River, near the City of Bedford in Lawrence County, Indiana. The Williams Dam is owned by the State of Indiana.

The proposed project would consist of: (1) An existing 55-foot by 126-foot concrete powerhouse; (2) four new vertical Kaplan turbine having a total combined generating capacity of 4.0 megawatts (MW); (3) four new 1.0 MW three phase, 60-cycle generators; (4) a new 40-foot by 40-foot substation; (5) an existing 100-foot-wide by 21.5-foot-high by 80-foot-long intake structure; (6) a 100-foot-wide by 140-long tailrace area; (7) a new 265-foot-long, 69-kilovolt transmission line; and (8) appurtenant facilities. The project would have an estimated annual generation of 17,849 megawatt-hours.

Applicant Contact: Daniel Lissner, 239 Causeway Street, Suite 300, Boston, MA 02114; (978) 252–7111.

FERC Contact: Tyrone A. Williams, (202) 502–6331.

Deadline for filing comments, motions to intervene, and competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll

free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13346) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: January 8, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00648 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13563–002]

Juneau Hydropower, Inc.; Notice of Successive Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On December 3, 2012, Juneau Hydropower, Inc., filed an application for a successive preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Sweetheart Lake Project located on Lower Sweetheart Lake and Sweetheart Creek in Juneau, Alaska. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following facilities: (1) A new 275-foot-long, 105-foot-high concrete and rock face dam, including project intake facilities and a 125-foot-wide overflow spillway, constructed at the natural outlet of Lower Sweetheart Lake; (2) the existing Lower Sweetheart Lake, raised to a surface elevation of 628 feet above mean sea level, with a surface area of 1,701.5 acres and an active storage capacity of 94,069 acre-feet at the normal maximum water elevation; (3) a new 500-foot-long, 10-foot-diameter stream diversion tunnel that would be converted to reservoir outlet works after project construction; (4) a new 9,595-foot-long, 12-foot-diameter penstock diverting flow from the project intake to the powerhouse; (5) a new powerhouse containing three new 6.6-megawatt (MW), Francis generating units having a total installed capacity of 19.8 MW; (6) a tailrace consisting of a new 76-foot-wide to 22-foot-wide, 75-foot-long open afterbay; a new 225-foot-long, 12-foot-diameter tunnel extending from the afterbay to an outlet structure on a tributary to Sweetheart Creek; and an existing tributary stream channel, modified to a 100-foot-long, 35-foot-wide channel that will flow into Sweetheart Creek; (7) new marine access facilities, including a dual-height marine ramp, floating docks for seaplane and boat access, and a staging area adjacent to the docks; (8) a new switchyard adjacent to the powerhouse; (9) a new 8.69-mile-long, 138-kilovolt transmission line, consisting of buried, submarine, and overhead segments; (10) a new 4,400-foot-long access road; and (11) appurtenant facilities. The proposed Sweetheart Lake Project would have an average annual generation of 111 gigawatt-hours.

Applicant Contact: Duff Mitchell, Business Manager, Juneau Hydropower, Inc. P.O. Box 22775, Juneau, AK 99802; email: *duff.mitchell@juneauhydro.com;* phone: (907) 789–2775.

FERC Contact: Jennifer Harper; phone: (202) 502–6136.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13563) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: January 9, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00643 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP13–34–000]

Bear Creek Storage Company, L.L.C.; Notice of Request Under Blanket Authorization

Take notice that on December 21, 2012, Bear Creek Storage Company, L.L.C. (Bear Creek), 569 Brookwood Village, Suite 749, Birmingham, Alabama 35209, filed in Docket No. CP13–34–000, a prior notice request, pursuant to sections 157.205, 157.208, 157.213 and 157.216 of the Commission's Regulations under the Natural Gas Act, and Bear Creek's blanket certificate issued in Docket No. CP10–28–000 on January 12, 2010, for authorization to convert 1.2 billion cubic feet of cushion gas storage capacity and to make certain modifications at its Bear Creek Storage Field in order to access such converted capacity, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this Application should be directed to Tina Hardy, Regulatory Manager, Bear Creek Storage Company, L.L.C., 569 Brookwood Village, Suite 749, Birmingham, Alabama 35209, or call at (205) 325–3668 or *tina_hardy@kindermorgan.com.*

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenter's will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with he Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and ill not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a) (1) (iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the ''e-Filing'' link. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: January 8, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00637 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP13–33–000]

Southern Natural Gas Company, L.L.C.; Notice of Request Under Blanket Authorization

Take notice that on December 21, 2012, Southern Natural Gas Company, L.L.C. (Southern), P.O. Box 2563, Birmingham, AL 35202–2563, filed in Docket No. CP13–33–000, an application pursuant to sections 157.205, 157.208, 157.210 and 157.216 of the Commission's Regulations under the Natural Gas Act (NGA) as amended, to relocate one of its existing 10,350 horsepower compressor units from its Lacombe Compressor Station in St. Tammany Parish Louisiana downstream to its Enterprise Compressor Station in Clarke County Mississippi. In addition, Southern requests to perform other modifications to improve gas quality and increase the amount of available receipt point capacity and supply diversity on Southern's system, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Glenn A. Sheffield, Director, Rates & Regulatory Department, P.O. Box 2563, Birmingham, AL 35202–2563 at telephone (205) 325–3818 or email: *glenn_sheffield@kindermorgan.com,* Patricia S. Francis, Assistant General Counsel, P.O. Box 2563, Birmingham, AL 35202–2563 at telephone (205) 325–7696 or email: *patty_francis@kindermorgan.com* or Tina S. Hardy, Regulatory Manager, P.O. Box 2563, Birmingham, AL 35202–2563 at telephone (205) 325–3668 or email: *tina_hardy@kindermorgan.com.*

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the NGA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenter's will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: January 7, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00649 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP13–240–000]

Trailblazer Pipeline Company LLC; Notice of Technical Conference

The Commission's November 30, 2012 Order in the above-captioned proceeding [1] directed that a technical conference be held to address issues raised by Trailblazer Pipeline Company

[1] *Trailblazer Pipeline Company LLC,* 141 FERC ¶ 61,175 (2012).

LLC's proposal to establish a new Firm Transmission Balancing Service (FTB).

Take notice that a technical conference will be held on Thursday, January 31, 2013, at 10:00 a.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or 202–502–8659 (TTY), or send a fax to 202–208–2106 with the required accommodations.

All interested persons are permitted to attend. For further information please contact Andrew Knudsen at (202) 502–6527 or email *Andrew.Knudsen@ferc.gov.*

Dated: January 9, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00629 Filed 1–14–13; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2003–0073, FRL–9770–7]

Agency Information Collection Activities; Proposed Collection; Comment Request; Distribution of Offsite Consequence Analysis Information Under Section 112(r)(7)(H) of the Clean Air Act (CAA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an Information Collection Request (ICR), Distribution of Offsite Consequence Analysis Information under Section 112(r)(7)(H) of the Clean Air Act (CAA), (EPA ICR No. 1981.05, OMB Control No. 2050–0172) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through June 30, 2013. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before March 18, 2013.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2003–0073 online using *www.regulations.gov* (our preferred method), by email to *a-and-r-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Sicy Jacob, Office of Emergency Management, Mail Code 5104A, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–8019; fax number: (202) 564–2620; email address: *jacob.sicy@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: This ICR is the renewal of the ICR developed for the final rule, *Accidental Release Prevention Requirements; Risk Management Programs Under the Clean Air Act Section 112(r)(7); Distribution of Off-Site Consequence Analysis Information.* CAA section 112(r)(7) required EPA to promulgate reasonable regulations and appropriate guidance to provide for the prevention and detection of accidental releases and for responses to such releases. The regulations include requirements for submittal of a risk management plan (RMP) to EPA. The RMP includes information on offsite consequence analyses (OCA) as well as other elements of the risk management program.

On August 5, 1999, the President signed the Chemical Safety Information, Site Security, and Fuels Regulatory Relief Act (CSISSFRRA). The Act required the President to promulgate regulations on the distribution of OCA information (CAA section 112(r)(7)(H)(ii)). The President delegated to EPA and the Department of Justice (DOJ) the responsibility to promulgate regulations to govern the dissemination of OCA information to the public. The final rule was published on August 4, 2000 (65 FR 48108). The regulations imposed minimal requirements on the public, state and local agencies that request OCA data from EPA. The state and local agencies who decide to obtain OCA information must send a written request on their official letterhead to EPA certifying that they are covered persons under Public Law 106–40, and that they will use the information for official use only. EPA will then provide OCA data to those agencies as requested. The rule authorizes and encourages state and local agencies to set up reading rooms. The local reading rooms would provide read-only access to OCA information for all the sources in the LEPC's jurisdiction and for any source where the vulnerable zone extends into the LEPC's jurisdiction.

Members of the public requesting to view OCA information at federal reading rooms would be required to sign in and self certify. If asking for OCA information from federal reading rooms for the facilities in the area where they live or work, they would be required to provide proof that they live or work in that area. Members of the public are required to give their names, telephone number, and the names of the facilities for which OCA information is being

requested, when they contact the central office to schedule an appointment to view OCA information.

ICR number: EPA ICR No. 1981.05, OMB Control No. 2050–0172.

Respondents/affected entities: Entities potentially affected by this action are States, local agencies and members of the public.

Respondent's obligation to respond: Voluntary.

Estimated Number of Respondents: 3,915.

Frequency of Response: One.

Total Estimated Burden: 10,530 hours per year. Burden is defined in 5 CFR 1320.03(b).

Total Estimated Cost: $327,768 per year.

Change in Estimates: The burden and costs stated above are from the current approved ICR, 1981.04. EPA may adjust these estimates based on public comments received or other information gained by the Agency prior to submitting the ICR renewal package to OMB. EPA estimates a total of 5,430 hours (annually) for state and local agencies requesting OCA data from EPA and providing read-only access to the public. For the public to display photo identification, sign a sign-in sheet, certify that the individual has not received access to OCA information for more than 10 stationary sources for that calendar month, and to request information from the vulnerable zone indicator system (VZIS), EPA estimates a total of 5,100 hours annually. The total burden for the members of the public, state and local agencies is 10,530 hours and $327,768 annually (31,590 hours and $983,304 for three years). The labor and wage rates would also be adjusted based on the current rates available.

Dated: December 28, 2012.

Dana Stalcup,

Acting Director, Office of Emergency Management.

[FR Doc. 2013–00715 Filed 1–14–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9764–2]

Public Water System Supervision Program Approval for the State of Ohio

Correction

In notice document 2012–30953, appearing on pages 76034–76035 in the issue of Wednesday, December 26, 2012, make the following corrections:

On page 76035, in the first column, in the first full paragraph:

1. In lines three and four ''January 23, 2013'' should read ''January 25, 2013''.

2. In line ten ''January 23, 2013'' should read ''January 25, 2013''.

3. In line twenty ''January 23, 2013'' should read ''January 25, 2013''.

[FR Doc. C1–2012–30953 Filed 1–14–13; 8:45 am]

BILLING CODE 1505–01–D

FEDERAL COMMUNICATIONS COMMISSION

Information Collections Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: The Federal Communications Commission (FCC), as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act (PRA) of 1995. 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 March 18, 2013. 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 the Federal Communications Commission via email to *PRA@fcc.gov* and *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: 3060–0560.

Title: Section 76.911, Petition for Reconsideration of Certification.

Form Number: N/A.

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: 25 respondents; 30 responses.

Estimated Hours per Response: 10–12 hours.

Total Annual Burden: 220 hours.

Total Annual Costs: None.

Frequency of Response: On occasion and annual reporting requirements; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 4(i) and 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: 47 CFR 76.911(a) states a cable operator (or other interested party) may challenge a franchising authority's certification by filing a petition for reconsideration pursuant to § 1.106. The petition may allege either of the following: (1) The cable operator is not subject to rate regulation because effective competition exists as defined in § 76.905. Sections 76.907(b) and (c) apply to petitions filed under this section. (2) The franchising authority does not meet the certification standards set forth in 47 U.S.C. 543(a)(3). 47 CFR 76.911(b)(2) states a petitioner filing pursuant to paragraph (a)(2) of this section may request a stay of rate regulation.

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 is 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.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–00695 Filed 1–14–13; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden(s) and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). 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(s); 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 further ways to reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB Control Number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 18, 2013. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Nicholas A. Fraser, Office of Management and Budget (OMB), via fax at: (202) 395–5167 or via the Internet at *Nicholas_A._Fraser@omb.eop.gov* and to Leslie F. Smith, Office of Managing Director (OMD), Federal Communications Commission (FCC), via the Internet at *Leslie.Smith@fcc.gov.* To submit your PRA comments by email, send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Leslie F. Smith, Office of Managing Director (OMD), Federal Communications Commission (FCC), (202) 418–0217, or via the Internet at *Leslie.Smith@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0951.

Title: Sections 1.204(b) and 1.1206(a) Note 1, Service of Petitions for Preemption.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Businesses or other for-profit entities; individuals or households; not-for-profit institutions; and State, local, or Tribal Government.

Number of Respondents and Responses: 125 respondents; 125 responses.

Estimated Time per Response: 0.25 hours (15 minutes).

Frequency of Response: Occasion reporting requirements; Third party disclosure.

Obligation to Respond: Required to obtain or retain benefits; Statutory authority for this information collection is contained in 47 U.S.C. 151, 154, and 303.

Total Annual Burden: 35 hours.

Total Annual Costs: N/A.

Privacy Impact Assessment: Yes.

Nature and Extent of Confidentiality: The Commission is not requesting that respondents to submit confidential information to the Commission. If the Commission requests respondents to submit information which respondents believe is confidential, respondents may request confidential treatment of such information pursuant to section 0.459 of the Commission's rules, 47 CFR 0.459.

The FCC has a system of records, FCC/OGC–5, ''Pending Civil Cases,'' to cover the collection, purpose(s), storage, safeguards, and disposal of the personally identifiable information (PII) that individuals may submit with their petitions for preemption that they file with the Commission.

Needs and Uses: These provisions supplement the procedures for filing petitions seeking Commission preemption of state and local government regulation of telecommunications services. They require that such petitions, whether in the form of a petition for rulemaking or a petition for declaratory ruling, be served on all state and local governments. The actions for which are cited as a basis for requesting preemption. Thus, in accordance with these provisions, persons seeking preemption must serve their petitions not only on the state or local governments whose authority would be preempted, but also on other state or local governments whose actions are cited in the petition.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–693 Filed 1–14–13; 8:45 am]

BILLING CODE 6712–01–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 the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 10:00 a.m. on Tuesday, January 15, 2013, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous Board of Directors' Meetings.

Summary reports, status reports, reports of the Office of Inspector General, and reports of actions taken pursuant to authority delegated by the Board of Directors.

Memorandum and resolution re: Notice of Proposed Rulemaking Regarding the Retention of Records of an Insured Depository Institution in Receivership.

Memorandum and resolution re: Request for Authority to Publish a Privacy Act System of Records Notice in the **Federal Register**.

Discussion Agenda: Memorandum and resolution re: Final Rule: Higher-Risk Mortgage Appraisal Requirements.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC.

This Board meeting will be Webcast live via the Internet and subsequently made available on-demand approximately one week after the event. Visit *http://www.vodium.com/goto/fdic/boardmeetings.asp* to view the event. If you need any technical assistance, please visit our Video Help page at: *http://www.fdic.gov/video.html.*

The FDIC will provide attendees with auxiliary aids (e.g., sign language interpretation) required for this meeting. Those attendees needing such assistance should call 703–562–2404 (Voice) or 703–649–4354 (Video Phone) to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at 202–898–7043.

Dated: January 8, 2013.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2013–00821 Filed 1–11–13; 4:15 pm]

BILLING CODE P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS13–01]

Appraisal Subcommittee; Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council

ACTION: Notice of meeting.

Description: In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: OCC—400 7th Street SW., Washington, DC 20024.

Date: January 23, 2013.

Time: 10:30 a.m.

Status: Open.

Matters To Be Considered

Summary Agenda

December 12, 2012 Minutes—Open Session

(No substantive discussion of the above items is anticipated. These matters will be resolved with a single vote unless a member of the ASC requests that an item be moved to the discussion agenda.)

Discussion Agenda

Appraisal Complaint National Hotline Implementation Plan

FY 2013 Appraisal Foundation Grant

FY 2013 Revised ASC Budget

September 2012 Appraisal Foundation Grant Reimbursement Request

Massachusetts Compliance Review

Minnesota Compliance Review

Montana Compliance Review

How to Attend and Observe an ASC meeting: Email your name, organization and contact information to *meetings@asc.gov.* You may also send a written request via U.S. Mail, fax or commercial carrier to the Executive Director of the ASC, 1401 H Street NW., Ste 760, Washington, DC 20005. The fax number is 202–289–4101. Your request must be received no later than 4:30 p.m., ET, on the Monday prior to the meeting. If that Monday is a Federal holiday, then your request must be received by 4:30 p.m. ET on the previous Friday. Attendees must have a valid government-issued photo ID and must agree to submit to reasonable security measures. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

Dated: January 10, 2013.

James R. Park,

Executive Director.

[FR Doc. 2013–00698 Filed 1–14–13; 8:45 am]

BILLING CODE P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS13–02]

Appraisal Subcommittee; Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council, FFIEC.

ACTION: Notice of meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in closed session:

Location: OCC—400 7th Street SW., Washington, DC 20024.

Date: January 23, 2013.

Time: Immediately following the ASC open session.

Status: Closed.

Matters To Be Considered

December 12, 2012 minutes–Closed Session.

Preliminary discussion of State Compliance Reviews.

Dated:January 10, 2013.

James R. Park,

Executive Director.

[FR Doc. 2013–00697 Filed 1–14–13; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

Correction

This notice corrects a notice (FR Doc. 2013–00331) published on page 2273 of the issue for Thursday, January 10, 2013.

Under the Federal Reserve Bank of Kansas City heading, the entry for Whitewater Bancshares, Inc., Whitewater, Kansas, is revised to read as follows:

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *The Donald L. Patry Revocable Trust, Ellen M. Patry Revocable Trust, and Ellen Patry, trustee, all of Newton, Kansas; Corey and Cynthia Patry, Wichita, Kansas; Brandon Patry, and Katie Patry, both of Valley Center, Kansas,* as a group acting in concert, to retain control of Whitewater Bancshares, Inc., parent of Bank of Whitewater, both in Whitewater, Kansas.

Comments on this application must be received by January 25, 2013.

Dated: Board of Governors of the Federal Reserve System January 10, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–00664 Filed 1–14–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of December 11–12, 2012

In accordance with Section 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on December 11–12, 2012.[1]

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long-run objectives, the Committee seeks conditions in reserve markets consistent with federal funds trading in a range from 0 to ¼ percent. The Committee directs the Desk to complete the maturity extension program it announced in June to purchase Treasury securities with remaining maturities of 6 years to 30 years with a total face value of about $267 billion by the end of December 2012, and to sell or redeem Treasury securities with remaining maturities of approximately 3 years or less with a total face value of about $267 billion. Following the completion of this program, the Committee directs the Desk to resume its policy of rolling over maturing Treasury securities into new issues. From the beginning of January, the Desk is directed to purchase longer-term Treasury securities at a pace of about $45 billion per month. The Committee directs the Desk to maintain its existing policy of reinvesting principal payments on all agency debt and agency mortgage-backed securities in the System Open Market Account in agency mortgage-backed securities. The Desk is also directed to continue purchasing agency mortgage-backed securities at a pace of about $40 billion per month. The Committee directs the Desk to engage in dollar roll and coupon swap transactions as necessary to facilitate settlement of the Federal Reserve's agency MBS transactions. The System Open Market Account Manager and the Secretary will keep the Committee informed of ongoing developments regarding the System's balance sheet that could affect the attainment over time of the Committee's objectives of maximum employment and price stability.

[1] Copies of the Minutes of the Federal Open Market Committee at its meeting held on December 11–12, 2012, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, DC 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's Annual Report.

By order of the Federal Open Market Committee, January 8, 2013.

William B. English,

Secretary, Federal Open Market Committee.

[FR Doc. 2013–00716 Filed 1–14–13; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Community Preventive Services Task Force (Task Force)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces the next meeting of the Community Preventive Services Task Force (Task Force). The Task Force is independent and nonfederal. Its members are nationally known leaders in public health practice, policy, and research, and are appointed by the CDC Director. The Task Force was convened in 1996 by the Department of Health and Human Services (HHS) to assess the effectiveness of community, environmental, population, and healthcare system interventions in public health and health promotion. During this meeting, the Task Force will consider the findings of systematic reviews and issue findings and recommendations to help inform decision making about policy, practice, and research in a wide range of U.S. settings. The Task Force's recommendations, along with the systematic reviews of the scientific evidence on which they are based, are compiled in the *Guide to Community Preventive Services (Community Guide).*

DATES: The meeting will be held on Wednesday, February 20, 2013 from 8:30 a.m. to 5:30 p.m., EST and Thursday, February 21, 2013 from 8:30 a.m. to 1:00 p.m. EST.

Logistics: The Task Force Meeting will be held at the Emory Conference Center at 1615 Clifton Road, Atlanta, GA 30329. Information regarding logistics will be available Wednesday, January 23, 2013 on the Community Guide Web site (*www.thecommunityguide.org*).

FOR FURTHER INFORMATION CONTACT: Andrea Baeder, The Community Guide Branch, Epidemiology and Analysis Program Office, Office of Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road, MS–E–

69, Atlanta, Georgia 30333, phone: (404)498–6876, email: *CPSTF@cdc.gov.*

SUPPLEMENTARY INFORMATION: *Purpose:* The purpose of the meeting is for the Task Force to consider the findings of systematic reviews and issue findings and recommendations to help inform decision making about policy, practice, and research in a wide range of U.S. settings.

Matters to be discussed: Matters to be discussed: promoting health equity, improving oral health, cancer prevention and control—preventing skin cancer, cardiovascular disease prevention and control, reducing tobacco use and secondhand smoke exposure, and diabetes prevention and control.

Meeting Accessibility: This meeting is open to the public, limited only by space availability.

Dated: January 8, 2013.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2013–00666 Filed 1–14–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Comment Request: University Centers for Excellence in Developmental Disabilities Education, Research, and Service—Annual Report

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration on Intellectual and Developmental Disabilities (AIDD), Administration for Community Living (ACL) is announcing an opportunity to comment on the proposed collection of information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice collects comments on the information collection requirements relating to the continuation of an existing collection for University Centers for Excellence in Developmental Disabilities Education, Research, and Service.

DATES: Submit written comments on the collection of information by March 18, 2013.

ADDRESSES: To attain the revised set of the data collection tool and to submit written comments on the collection of information by email to *Suad.jama@acl.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Suad Jama, 202.690.6059.

SUPPLEMENTARY INFORMATION: Section 104 (42 U.S.C. 15004) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act of 2000) directs the Secretary of Health and Human Services to develop and implement a system of program accountability to monitor the grantees funded under the DD Act of 2000. The program accountability system shall include the National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service (UCEDDs) authorized under Part D of the DD Act of 2000. In addition to the accountability system, Section 154 (e) (42 U.S.C. 15064) of the DD Act of 2000 includes requirements for a UCEDD Annual Report.

ACL estimates the burden of this collection of information as follows:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Nuumber of responses per respondent	Average burden hours per response	Total burden hours
UCEDD Annual Report	67	1	1,412	94,604

Estimated Total Annual Burden Hours: 94,604.

Dated: January 9, 2013.

Kathy Greenlee,

Administrator.

[FR Doc. 2013–00657 Filed 1–14–13; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Intellectual and Developmental Disabilities (AIDD); Notice of Meeting via Conference Call

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID), HHS.

ACTION: Notice of Meeting via Conference Call.

DATES: Wednesday, February 27, 2013, from 1:30 p.m. to 3:00 p.m. EST. This meeting to be held via audio conference call, is open to the public.

Details for accessing the full Committee Conference Call, for the public, are cited below:

Toll Free Dial-In Number: 800–988–9688.

Pass Code: 2847971.

Individuals whose full participation in the conference call will require reasonable accommodations (e.g., sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Madjid Karimi, PCPID Program Analyst, via email at *MJ.Karimie@acl.hhs.gov,* or via telephone at 202–619–0634, no later than Wednesday, February 20, 2013. PCPID will attempt to meet requests for accommodations made after that date, but cannot guarantee ability to grant requests received after this deadline.

Agenda: Committee members will: (a) Finalize the submission process of the 2012 Report to the President; and (b) discuss plans for developing the PCPID 2013 Report to the President.

Additional Information: For further information, please contact Madjid Karimi, Program Analyst, President's Committee for People with Intellectual Disabilities, 200 Independence Avenue, SW., Room 637D, Washington, DC 20201. Telephone: 202–619–0634. Fax: 202–260–3053. Email: *MJ.Karimie@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services, through the Administration on Intellectual and Developmental Disabilities, on a broad range of topics relating to programs,

services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: January 9, 2013.

Kathy Greenlee,

Administrator.

[FR Doc. 2013–00661 Filed 1–14–13; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 030

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 030'' (Recognition List Number: 030), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of ''Modifications to the List of Recognized Standards, Recognition List Number: 030'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–847–8149. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by email: *standards@cdrh.fda.gov.* This document may also be accessed on FDA's Internet site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 030 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring, MD 20993, 301–796–6287.

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled ''Recognition and Use of Consensus Standards.'' The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, are identified in table 1 of this document.

TABLE 1—PREVIOUS PUBLICATIONS OF STANDARD RECOGNITION LISTS

February 25, 1998 (63 FR 9561)
October 16, 1998 (63 FR 55617)
July 12, 1999 (64 FR 37546)
November 15, 2000 (65 FR 69022)
May 7, 2001 (66 FR 23032)
January 14, 2002 (67 FR 1774)
October 2, 2002 (67 FR 61893)

TABLE 1—PREVIOUS PUBLICATIONS OF STANDARD RECOGNITION LISTS—Continued

April 28, 2003 (68 FR 22391)
March 8, 2004 (69 FR 10712)
June 18, 2004 (69 FR 34176)
October 4, 2004 (69 FR 59240)
May 27, 2005 (70 FR 30756)
November 8, 2005 (70 FR 67713)
March 31, 2006 (71 FR 16313)
June 23, 2006 (71 FR 36121)
November 3, 2006 (71 FR 64718).
May 21, 2007 (72 FR 28500).
September 12, 2007 (72 FR 52142).
December 19, 2007 (72 FR 71924).
September 9, 2008 (73 FR 52358).
March 18, 2009 (74 FR 11586).
September 8, 2009 (74 FR 46203).
May 5, 2010 (75 FR 24711).
June 10, 2010 (75 FR 32943).
October 4, 2010 (75 FR 61148).
March 14, 2011 (76 FR 13631).
August 2, 2011 (76 FR 46300).
March 16, 2012 (77 FR 15765).
August 20, 2012 (77 FR 50114).

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains ''hypertext markup language (HTML)'' and ''portable document format (PDF)'' versions of the list of ''FDA Recognized Consensus Standards.'' Both versions are publicly accessible at the Agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 030

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA will use the term ''Recognition List Number: 030'' to identify these current modifications.

In table 2 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the Agency is making

that involve the initial addition of standards not previously recognized by FDA.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Biocompatibility	
2–156		AAMI/ANSI/ISO 10993–1:2009 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.	Extent of recognition.
2–178	2–191	ISO 10993–12 Fourth edition 2012–07–01 Biological evaluation of medical devices—Part 12: Sample preparation and reference materials.	Withdrawn and replaced with newer version.
2–184	2–192	USP 35–NF30:2012<87> Biological Reactivity Test, In Vitro—Direct Contact Test.	Withdrawn and replaced with newer version.
2–185	2–193	USP 35–NF30:2012 Biological Tests <87> Biological Reactivity Test, In Vitro—Elution Test.	Withdrawn and replaced with newer version.
2–186	2–194	USP 35–NF30:2012 Biological Tests <88> Biological Reactivity Tests, In Vivo, Procedure Preparation of Sample.	Withdrawn and replaced with newer version.
2–187	2–195	USP 35–NF30:2012 Biological Tests <88> Biological Reactivity Test, In Vitro, Classification of Plastics—Intracutaneous Test.	Withdrawn and replaced with newer version.
2–188	2–196	USP 35–NF30:2012 Biological Tests <88> Biological Reactivity Tests, In Vivo, Classification of Plastics—Systemic Injection Test.	Withdrawn and replaced with newer version.
		B. Cardiovascular	
3–30	3–105	IEC 60601–2–25 Edition 2.0 2011–10 Medical electrical equipment—Part 2–25: Particular requirements for the basic safety and essential performance of electrocardiographs.	Withdrawn and replaced with newer version.
3–61		IEC 60601–2–27 Edition 3.0 2011–03 Medical electrical equipment—Part 2–27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.	Withdrawn, see 3–95.
3–101		ANSI/AAMI/ISO 60601–2–27 Edition 3.0 2011–03 Medical electrical equipment—Part 2–27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.	Withdrawn, see 3–100.
3–59		ISO 5841–3 Second edition 2000–10–15 Implants for surgery—Cardiac pacemakers—Part 3: Low-profile connectors [IS–1] for implantable pacemakers.	Title, processes impacted, related CFR citation(s) and procode(s), and relevant guidance.
		C. Dental/ENT	
4–43		ADA/ANSI Specification No. 5, Dental Casting Alloys: 1997	Withdrawn, see 4–146.
4–87	4–196	ANSI/ADA Specification No. 69, 2010 Dental Ceramic	Withdrawn and replaced with newer version.
4–94		Specification No.14, Dental Base Metal Casting Alloys: 1982 (Reaffirmed 1998).	Withdrawn, see 4–146.
4–96		ANSI/ADA Specification No. 30, Reaffirmed by ANSI October 2010 Dental Zinc Oxide-Eugenol and Zinc Oxide Non-Eugenol Cements.	Reaffirmation.
4–110		ADA/ANSI ADA Specification No. 11, Agar Impression Materials: 1997.	Withdrawn.
4–113		ADA/ANSI ADA Specification No. 20, Dental Duplicating Material; 1972 (Reaffirmed 1995).	Withdrawn.
4–131	4–198	ISO 3107 Fourth edition 2011–03 Dentistry—Zinc oxide/Eugenol cements and zinc oxide/non-eugenol cements.	Withdrawn and replaced with newer version.
4–133	4–199	ISO 6876 Third edition 2012–06–01 Dentistry—Root canal sealing materials.	Withdrawn and replaced with newer version.
4–147		ADA/ANSI Specification No. 27, Resin-Based Filling Materials: 2005	Withdrawn.
4–152	4–201	ISO 9693 Second edition 1999–12–15 Metal-ceramic dental restorative systems.	Withdrawn and replaced with newer version.
4–158		ISO 10139–1:2005, Dentistry—Soft lining materials for removable dentures—Part 1: Materials for short-term use Technical Corrigendum 1:2006.	Withdrawn—Duplicate, see 4–189.
4–192	4–202	ANSI/ADA Specification No. 58, 2010 Root Canal Files, Type H (Hedstrom).	Withdrawn and replaced with newer version.
		D. General	
5–56		ISO 15223–2 First edition 2010–01–15 Medical devices—Symbols to be used with medical devices labels, labelling, and information to be supplied—Part 2: Symbol development, selection and validation.	Withdrawn.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
5–68		AAMI/ANSI/ISO 15223–2, Medical devices—Symbols to be used with medical device labels, labellings, and information to be supplied—Part 2: Symbol development, selection and validation.	Withdrawn.
5–72	5–73	ISO 15223–1 Second Edition 2012–07–01 Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements.	Withdrawn and replaced with new version.
		E. General Hospital/General Plastic Surgery	
6–13		ISO 595–1 First edition 1986–12–15 Reusable all-glass or metal-and-glass syringes for medical use—Part 1: Dimensions.	Contact person and title.
6–14		ISO 595–2 First edition 1987–12–15 Reusable all-glass or metal-and-glass syringes for medical use—Part 2: Design, performance requirements and tests.	Contact person.
6–15		ISO 7864 Third edition 1993–05–15 Sterile hypodermic needles for single use.	Contact person.
6–107		ASTM F 882–84 (Reapproved 2002) Standard Performance and Safety Specification for Cryosurgical Medical Instruments.	Withdrawn.
6–122		ISO 8536–5 Second edition 2004–02–01 Infusion equipment for medical use—Part 5: Burette infusion sets for single use, gravity feed.	Contact person.
6–148		ISO 7886–3 First edition 2005–03–01 Sterile hypodermic syringes for single use—Part 3: Auto-disable syringes for fixed-dose immunization.	Contact person.
6–170		ISO 7886–1 First edition 1993–10–01 Sterile hypodermic syringes for single use—Part 1: Syringes for manual use.	Contact person and title.
6–203	6–282	ASTM D6499–12 Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products.	Withdrawn and replaced with newer version.
6–204		ISO 8537 Second edition 2007–10–01 Sterile single-use syringes, with or without needle, for insulin.	Contact person.
6–255	6–283	USP 35–NF30:2012 Sodium Chloride Irrigation	Withdrawn and replaced with newer version.
6–256	6–284	USP 35–NF30:2012 Sodium Chloride Injection	Withdrawn and replaced with newer version.
6–257	6–285	USP 35–NF30:2012 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version.
6–258	6–286	USP 35–NF30:2012 <881> Tensile Strength	Withdrawn and replaced with newer version.
6–259	6–287	USP 35–NF30:2012 <861> Sutures-Diameter	Withdrawn and replaced with newer version.
6–260	6–288	USP 35–NF30:2012 <871> Sutures-Needle Attachment	Withdrawn and replaced with newer version.
6–261	6–289	USP 35–NF30:2012 Sterile Water for Irrigation	Withdrawn and replaced with newer version.
6–262	6–290	USP 35–NF30:2012 Heparin Lock Flush Solution	Withdrawn and replaced with newer version.
6–623	6–291	USP 35–NF30:2012 Absorbable Surgical Suture	Withdrawn and replaced with newer version.
		F. In Vitro Diagnostics	
7–7		CLSI/NCCLS LA1–A2 1994 Assessing the Quality of Radioimmunoassay Systems—Second Edition; Approved Guideline.	Withdrawn.
7–124		CLSI/NCCLS I/LA24–A Fluorescence Calibration and Quantitative Measurement of Fluorescence Intensity; Approved Guideline.	Withdrawn.
7–99	7–232	CLSI MM05–A2 Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline—Second Edition.	Withdrawn and replaced with newer version.
7–194	7–233	CLSI EP17–A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition.	Withdrawn and replaced with newer version.
		G. Materials	
8–117	8–228	ASTM F86–12 Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants.	Withdrawn and replaced with a newer version.
8–124		ASTM F2052–06e1 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.	Relevant guidance.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
8–128		ASTM F2213–06 (Reapproved 2011) Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.	Relevant guidance.
8–153		ASTM F2119–07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.	Relevant guidance.
8–176		ASTM F2503–08 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	Relevant guidance.
8–227		ASTM F2182–11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.	Relevant guidance .
8–137	8–229	ASTM F75–12 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).	Withdrawn and replaced with a newer version.
8–142	8–330	ASTM F1978–12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser.	Withdrawn and replaced with a newer version.
8–155	8–331	ASTM F1580–12 Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.	Withdrawn and replaced with a newer version.
8–209	8–332	ASTM F899–12 Standard Specification for Wrought Stainless Steels for Surgical Instruments.	Withdrawn and replaced with a newer version.
		H. OB-GYN/Gastroenterology	
9–21		IS0 8600–4 First edition 1997–07–01 Optics and optical instruments—Medical endoscopes and certain accessories—Part 4: Determination of maximum width of insertion portion.	Contact person.
9–34		ISO 4074 First edition 2002–02–15 Corrected version 2002–12–01 Natural latex rubber condoms—Requirements and test methods.	Contact person.
9–36		ISO 8009 First edition 2004–10–01 Mechanical contraceptives—Reusable natural and silicone rubber contraceptive diaphragms—Requirements and tests.	Contact person.
9–37		ISO 8600–1 Second edition 2005–05–01 Optics and photonics—Medical endoscopes and endotherapy devices—Part 1: General requirements.	Contact person.
9–39		ISO 8600–5 First edition 2005–03–15 Optics and photonics—Medical endoscopes and endotherapy devices—Part 5: Determination of optical resolution of rigid endoscopes with optics.	Contact person.
9–40		ISO 8600–6 First edition 2005–03–15 Optics and photonics—Medical endoscopes and endotherapy devices—Part 6: Vocabulary.	Contact person.
9–43		ISO 16038 First edition 2005–11–01 Rubber condoms—Guidance on the use of ISO 4074 in the quality management of natural rubber latex condoms.	Contact person.
9–56		ASTM D 3492–08 Standard Specification for Rubber Contraceptives (Male Condoms).	Contact person.
9–61		IEC 60601–2–18 Edition 3.0 2009–08 Medical electrical equipment—Part 2–18: Particular requirements for the basic safety and essential performance of endoscopic equipment.	Contact person.
9–58		ASTM D6324–08 Standard Test Methods for Male Condoms Made from Polyurethane.	Withdrawn.
		I. Ophthalmic	
10–56		ANSI Z80.12–2007 (R2012) American National Standard for Ophthalmics—Multifocal Intraocular Lenses.	Reaffirmation.
10–57		ANSI Z80.13–2007 (R2012) American National Standard for Ophthalmics—Phakic Intraocular Lenses.	Reaffirmation.
		J. Orthopedics	
11–203		ASTM F1541–02 (Reapproved 2011) euroi;1 Standard Specification and Test Methods for External Skeletal Fixation Devices.	Title.
11–216		ASTM F1264–03 (Reapproved 2012) Standard Specification and Test Methods for Intramedullary Fixation Devices.	Reaffirmation.
11–229	11–244	ASTM F2083–11 Standard Specification for Total Knee Prosthesis ...	Withdrawn and replaced with newer version.
11–233	11–245	ASTM F384–12 Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices.	Withdrawn and replaced with newer version.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
11–236	11–246	ASTM F1717–12 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.	Withdrawn and replaced with newer version.
		K. Sterility	
14–64		ASTM F1929–98 (Reapproved 2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.	Relevant guidance.
14–169		ASTM F2391–05 (Reapproved 2011) Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas.	Relevant guidance.
14–197		ASTM F1608–00 (Reapproved 2009) Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method).	Relevant guidance.
14–211	14–362	AOAC 6.2.01:2012 Official Method 955.14 Testing Disinfectants against Salmonella enterica, Use-Dilution Method.	Withdrawn and replaced with newer version.
14–212		AOAC 6.2.02:2006 Official Method 991.47 Testing Disinfectants against Salmonella choleraesuis, Hard Surface Carrier Test Method.	Relevant guidance.
14–213		AOAC 6.2.03:2006 Official Method 991.48 Testing Disinfectants against Staphylococcus aureus, Hard Surface Carrier Test Method.	Relevant guidance.
14–215		AOAC 6.2.05:2006 Official Method 991.49 Testing Disinfectants against Pseudomonas aeruginosa, Hard Surface Carrier Test Method.	Relevant guidance.
14–216	14–363	AOAC 6.2.06:2012 Official Method 964.02 Testing Disinfectants against Pseudomonas aeruginosa, Use-Dilution Method.	Withdrawn and replaced with newer version.
14–217		AOAC 6.3.02:2006 Official Method 955.17 Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes.	Relevant guidance.
14–218		AOAC 6.3.05:2006 Official Method 966.04 Sporicidal Activity of Disinfectants Method I.	Relevant guidance.
14–225	14–364	ANSI/AAMI/ISO 11137–2:2012 Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.	Withdrawn and replaced with newer version.
14–229		ASTM F1980–07 (Reapproved 2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	Relevant guidance.
14–235		ASTM F1140–07 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.	Relevant guidance.
14–236		ASTM F2054–07 Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates.	Relevant guidance.
14–238		ANSI/AAMI/ISO 11140–5:2007/(R)2012 Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs.	Reaffirmation.
14–256		ASTM F2095–07e1 Standard Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates.	Relevant guidance and editorial change.
14–257		ASTM D3078–02 (Reapproved 2008)€ [1] Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission.	Relevant guidance and editorial change.
14–278		ANSI/AAMI/ISO 10993–7:2008(R)2012 Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals.	Reaffirmation.
14–282		ASTM F2338–09 Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method.	Relevant guidance.
14–283		ASTM F88/F88M–09 Standard Test Method for Seal Strength of Flexible Barrier Materials.	Relevant guidance.
14–288		ASTM F1886/F1886M–09 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.	Relevant guidance.
14–296		ANSI/AAMI/ISO 11138–1:2006/(R)2010 Sterilization of health care products—Biological indicators—Part 1: General requirements.	Relevant guidance, extent of recognition and title.
14–299		ASTM F2097–10 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products.	Relevant guidance.
14–300		ASTM D4169–09 Standard Practice for Performance Testing of Shipping Containers and Systems.	Relevant guidance.
14–313		ASTM F2475–11 Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials.	Relevant guidance.
14–315	14–366	USP 35–NF30:2012 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14–316	14–367	USP 35–NF30:2012 <71> Sterility Tests	Withdrawn and replaced with newer version.
14–317	14–368	USP 35–NF30:2012 <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version.
14–318	14–369	USP 35–NF30:2012 <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–319	14–370	USP 35–NF30:2012 <161> Transfusion and Infusion Assemblies and Similar Medical Devices.	Withdrawn and replaced with newer version
14–320	14–371	USP 35–NF30:2012 Biological Indicator for Steam Sterilization, Self-Contained.	Withdrawn and replaced with newer version.
14–321	14–372	USP 35–NF30:2012 Biological Indicator for Dry-Heat Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–322	14–373	USP 35–NF30:2012 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–323	14–374	USP 35–NF30:2012 Biological Indicator for Steam Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–324	14–375	USP 35–NF30:2012 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
14–329	14–365	ISO 11137–2 Second edition 2012–03–15 Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.	Withdrawn and replaced with newer version.
14–335		ISO 10993–7 Second edition 2008–10–15 Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals.	Extent of recognition and relevant guidance.
14–338		ISO 11138–1 Second edition 2006–07–01 Sterilization of health care products—Biological indicators—Part 1: General requirements.	Relevant guidance and extent of recognition.
14–345		ISO/ASTM 51261 First edition 2002–03–15 Guide for selection and calibration of dosimetry systems for radiation processing.	Relevant guidance.
14–359		ASTM F2096–11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test).	Relevant guidance.
14–360		ANSI/AAMI ST72:2011 Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing.	Relevant guidance.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

III. Listing of New Entries

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 030.

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
	A. Cardiovascular	
3–106	Medical electrical equipment—Part 2–25: Particular requirements for the basic safety and essential performance of electrocardiographs.	ANSI/AAMI/IEC 60601–2–25:2011.
3–107	Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.	IEC 80601–2–30 Edition 1.0 2009–01.
3–108	Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers CORRIGENDUM 1.	IEC 80601–2–30 (First edition—2009).
3–109	Active implantable medical devices—Four-pole connector system for implantable cardiac rhythm management devices—Dimensional and test requirements.	ANSI/AAMI/ISO 27186:2010.
3–110	Active implantable medical devices—Guidance for designation of left ventricle and implantable cardioverter defibrillator lead connectors and pulse generator connector cavities for implantable pacemakers and implantable cardioverter defibrillators.	AAMI TIR41:2011.
3–111	Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters	ANSI/AAMI/ISO 25539–3: 2011.
3–112	Cardiovascular implants and artificial organs—Blood-gas exchangers (oxygenators)	ANSI/AAMI/ISO 7199: 2009.
3–113	Cardiovascular implants and artificial organs—Blood-gas exchangers (oxygenators)	ISO 7199 Second edition 2009–04–15.
	B. Dental/ENT	
4–200	Dentistry—Mercury and alloys for dental amalgam AMENDMENT 1: Requirements for marking and manufacturer's instructions concerning mercury.	ISO 24234 First edition 2004–10–15 AMENDMENT 1 2011–08–15.
	C. General	
5–74	Medical electrical equipment—Part 1: General requirements for basic safety and essential performance, Amendment 1.	ANSI/AAMI ES60601–1:2005/C1:2009/(R)2012.
	D. General Hospital/General Plastic Surgery	
6–292	Sterile hypodermic syringes for single use—Part 1: Syringes for manual use	ISO 7886–1:1993 TECHNICAL CORRIGENDUM 1 Published 1995–11–01.

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
6–293	Sharps injury protection—Requirements and test methods—Sharps containers	ISO 23907 First edition 2012–09–01.
	E. In Vitro Diagnostics	
7–234	Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline—Second Edition.	CLSI EP24–A2.
7–235	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline	CLSI EP25–A.
7–236	Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas; Approved Guideline.	CLSI M43–A.
7–237	Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline—Third Edition.	CLSI MM01–A3.
7–238	Quantitative Molecular Methods for Infectious Diseases; Approved Guideline—Second Edition.	CLSI MM06–A2.
7–239	Metrological Traceability and Its Implementation; A Report	CLSI X5–R.
	F. Materials	
8–333	Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications.	ASTM F2393–12.
8–334	Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis.	ASTM F2459–12.
	G. OB–GYN/Gastroenterology	
9–79	Water treatment equipment for haemodialysis applications and related therapies	ISO 26722 First edition 2009–04–15.
9–80	Medical electrical equipment—Part 2–16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment.	IEC 60601–2–16 Edition 4.0 2012–03.
9–81	Mechanical contraceptives—Reusable natural and silicone rubber contraceptive diaphragms—Requirements and tests.	ISO 8009 First edition 2004–10–01 ISO 8009: 2004/Amd. 1: 2012 (E) AMENDMENT 1 2012–02–15
	H. Ophthalmic	
10–75	Ophthalmic implants—Intraocular lenses—Part 7: Clinical investigations AMENDMENT 1.	ISO 11979–7 Second edition 2006–05–01 AMENDMENT 1 2012–01–15.
10–76	Ophthalmic implants—Intraocular lenses—Part 8: Fundamental requirements AMENDMENT 1.	ISO 11979–8 Second edition 2006–07–01 AMENDMENT 1 2011–05–15.
	I. Orthopedic	
11–247	Standard Guide for Mechanical and Functional Characterization of Nucleus Devices	ASTM F2789–10.
11–250	Implants for surgery—Wear of total hip joint prostheses—Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test.	ISO 14242–3 First edition 2009–03–15.
11–249	Implants for surgery—Wear of total hip joint prostheses—Part 2: Methods of measurement.	ISO 14242–2 First edition 2000–09–15.
11–248	Implants for surgery—Wear of total hip joint prostheses—Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test.	ISO 14242–1 Second edition 2012–01–15.
11–251	Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems.	ASTM F2554–10.
	J. Radiology	
12–250	Medical electrical equipment—Part 2–44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography CORRIGENDUM 1.	IEC 60601–2–44 (Third edition-2009).
12–251	Medical electrical equipment—Part 2–44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography.	IEC 60601–2–44 Edition 3.0 2012–08 Amendment 1.
	K. Software/Informatics	
13–33	Validation of software for regulated processes	AAMI TIR362007.
13–34	Medical device software—Part 1: Guidance on the application of ISO 14971 to medical device software.	IEC/TR 80002–1 Edition 1.0 2009–09.
13–35	Application of quality management system concepts to medical device data systems.	ANSI/AAMI SW87 2012.
13–36	Guidance on the use of AGILE practices in the development of medical device software.	AAMI TIR45 2012.

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
	L. Sterility	
14–376	Sterilization of health care products—Moist heat—Part 2: Guidance on the application of ANSI/AAMI/ISO 17665–1.	ANSI/AAMI/ISO TIR 17665–2:2009.
14–377	Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier.	ASTM F2638–12.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register,** this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to the contact person (See **FOR FURTHER INFORMATION CONTACT**). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the **Federal Register,** this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 030'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/MedicalDevices.*

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 030. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: January 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00605 Filed 1–14–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1248]

Creating an Alternative Approval Pathway for Certain Drugs Intended to Address Unmet Medical Need; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain input on a potential new pathway to expedite the development of drugs, including biological products, for serious or life-threatening conditions that would address an unmet medical need. The drug's safety and effectiveness would be studied in a smaller subpopulation of patients with more serious manifestations of a condition. Such a pathway could involve smaller and more rapid clinical trials than would occur if the drug were studied in a broader group of patients with a wide range of clinical manifestations. The labeling of drugs approved using this pathway would make clear that the drug is narrowly indicated for use in limited, well-defined subpopulations in which the drug's benefits have been shown to outweigh its risks. The purpose of the public hearing is to obtain information and comments from the public on the need for and feasibility of this pathway and its potential advantages and disadvantages.

DATES: *Dates and Time:* The public hearing will be held on February 4 and 5, 2013, from 9 a.m. to 4 p.m. The public hearing may be extended or may end early depending on the level of public participation.

Attendance, Presentations, and Comments: Individuals who wish to attend or present at the public hearing must register on or before 5 p.m. e.s.t. on January 22, 2013. To register for the

public hearing, email your registration information to *ExpeditedPathwayPublicMtg@fda.hhs.gov.* Section IV of this document provides attendance and registration information. Either electronic or written comments will be accepted after the hearing until March 1, 2013.

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD, 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Jonas Santiago, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5346, Fax: 301–847–3529, email: *ExpeditedPathwayPublicMtg@fda.hhs.gov;*

or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is announcing a public hearing to obtain input on a potential new pathway for approving drugs, including biological products, targeted at serious or life-threatening conditions and intended to address an unmet medical need. The drug's safety and effectiveness would be studied in a smaller subpopulation of patients with more serious manifestations of a condition. Such a pathway could involve smaller and more rapid clinical trials than would occur if the drug were studied in a broader group of patients with a wide range of clinical manifestations. The labeling of drugs approved using this pathway would make clear that the drug is narrowly indicated for use in limited, well-defined subpopulations in which the drug's benefits have been shown to outweigh the risks.

I. Background

In the last two decades, major advances in molecular and cellular biology have greatly expanded our understanding of a broad range of complex disease processes and have led to major advances in the treatment of conditions such as cystic fibrosis, HIV, hepatitis C, and multiple sclerosis. In some cases, however, the resource-intensive programs needed for approval of drugs to treat a broad condition with a wide range of clinical manifestations require very large study populations and can hinder the ability to make promising new drugs available in a timely manner to subpopulations of patients with important unmet medical needs. FDA recognizes its role in fostering the application of scientific advances to the treatment of disease through drug development, including the use of novel approaches that can facilitate development of treatment for unmet needs.

Traditional drug development programs are designed to evaluate the benefits and risks of treatment with a high degree of precision for the range of manifestations of a disease or condition. Often this will involve studies that expose a large number of patients to the drug, normally for an extended period of time. In some cases, such as when safety issues have arisen with prior drugs in a class, additional trials are needed to help identify serious but infrequent risks. Typically, these studies are needed when there is an expectation that the drug will be used broadly in patients with less severe manifestations of the condition.

Existing processes to expedite drug development and review of important new therapies have worked effectively in many circumstances. For example, more than 100 new therapies and indications have been approved under the accelerated approval process (21 CFR part 314, subpart H; 21 CFR part 601, subpart E).[1] In addition, FDA's existing flexibility in applying the statutory requirements for approval has effectively facilitated development of drugs for conditions where the entire intended patient population has serious unmet medical needs. However, FDA believes that it is important to explore the need for and feasibility of a new process focused on developing drugs for subpopulations of patients with serious or life-threatening conditions, including patients with serious or life-threatening infections caused by antibiotic-resistant bacteria.

[1] See a list of Center for Drug Evaluation and Research Drug and Biologic Accelerated Approvals as of September 30, 2011, available at *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/UCM278506.pdf.*

II. New Pathway

FDA is seeking input on a potential new pathway to approve drugs for use in limited, well-defined subpopulations of patients with serious or life-threatening conditions for whom the benefits of the drug have been shown to outweigh the risks. The pathway could include product labeling with a specific designation to make clear that the drug indication is limited to the narrow subpopulation and the rationale for limiting use to that population. The pathway also might provide for the designation and an appropriate logo to appear on a drug's container label.

This designation could be designed to inform the health care community, including practitioners, payers, and patients, of compelling reasons to carefully manage use of such drugs, limiting use to appropriate patients, as the benefit-risk profile only warrants use in the identified subpopulation. In addition, the potential new pathway could be used to help reduce the development of resistance to important antibacterial drugs by limiting their use to those patients in whom use is appropriate and necessary.

This approval of a narrow indication could be broadened if additional data become available which demonstrate the safety and effectiveness of the drug in treating a broader condition or patient population. For example, a drug could be initially approved using this pathway for a narrow subpopulation of patients because of uncertainty about a cardiovascular risk that would not be acceptable in a broad population. If a long-term study subsequently demonstrates that the benefit-risk profile makes the drug appropriate for broader use, the designation could be removed. Alternatively, there may be drugs for which we would not anticipate the possibility of approval in the broader population, such as when there is a known toxicity that, while acceptable in patients with serious manifestations of a condition, would not be appropriate for use in patients with milder manifestations of the condition.

The proposed pathway was recommended by the President's Council of Advisors on Science and Technology (PCAST) in their September 2012 ''Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation,'' as a way to improve drug evaluation. The PCAST recommendations support the goal of increasing the output of innovative, new medicines for patients with important unmet medical needs, while increasing drug efficacy and safety, through

industry, academia, and government working together to decrease clinical failure, clinical trial costs, time to market, and regulatory uncertainty.[2]

III. Scope of the Public Hearing and Discussion Questions

FDA is holding this public hearing to seek input from interested members of the public including patients and consumers, practitioners and other members of the medical community, regulated industry, insurers, and managed care organizations on a potential new pathway to approve drugs shown to be safe and effective in a subpopulation of patients with serious or life-threatening conditions in which an unmet medical need exists. FDA is interested in obtaining information and public comment on the following issues:

1. Considering existing processes to expedite drug development and review of important new therapies (i.e., accelerated approval, fast-track designation), would this new pathway increase the therapeutic options for serious or life-threatening conditions for which an unmet medical need exists? If not, what might be some alternative approaches?

2. Can you identify specific serious or life-threatening conditions for which an unmet medical need exists and for which this approval pathway may benefit subpopulations of patients?

3. What approaches could be undertaken (by FDA or by people or organizations other than FDA) to monitor use of drugs approved under this pathway to determine whether they are being used inconsistent with the terms of approval? What approaches could be undertaken to prevent, manage, or monitor use in a broader population where safety and efficacy has not been demonstrated? For example, if this pathway were adopted to approve new antibacterial drugs when limited use was needed (e.g., to prevent the emergence of further antimicrobial resistance), what other measures (by FDA or by people or organizations other than FDA) might ensure that these products are used appropriately only in the indicated subpopulations?

4. Would this pathway help to address some of the current challenges in antibacterial drug development, particularly for serious or life-threatening infections for which there is an unmet medical need?

5. This potential pathway could be used to approve drugs for a limited subpopulation based upon smaller clinical trials, when benefit-risk is appropriate for the limited population but safety and efficacy have not been demonstrated for use in a broader population of patients or patients with less severe manifestations of the condition. For the serious or life-threatening conditions you identified in question 2, what benefit-risk considerations need to be taken into account before and after marketing and how should they be addressed?

6. Would the use of a formal designation and logo to reflect approval under this pathway, with clear labeling of clinical information that only supports use in the indicated subpopulation, but without other constraints from FDA be effective in limiting use to the indicated subpopulation? Why or why not?

IV. Attendance, Registration, and Requests for Oral Presentations

The public hearing is free and seating will be on a first-come, first-served basis. Attendees, including those not presenting, need to register for the public hearing.

If you wish to attend or make an oral presentation during the hearing, you must register by submitting either an electronic or written request received on or before January 22, 2013. (See **FOR FURTHER INFORMATION CONTACT**.) You must provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, email address, and type of organization you represent (e.g., industry, consumer organization). If requesting to present, you also should submit a brief summary of the presentation, including the discussion question(s) that will be addressed and the approximate time requested for your presentation. FDA has included discussion questions in section III of this document. You should identify the question(s) and the number of each question you wish to address in your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted for each oral presentation, and the approximate time that each oral presentation is scheduled to begin. Persons registered to make an oral presentation should submit to FDA an electronic copy of their presentation and an abstract to *ExpeditedPathwayPublicMtg@fda.hhs.gov* on or before January 30, 2013.

If you need special accommodations because of a disability, please contact Jonas Santiago (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

V. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VII of this document).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

VI. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as discussed in section III of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

[2] For more information on the PCAST Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation, see *http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-fda-final.pdf.*

VII. Transcripts

Transcripts of the public hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.regulations.gov* approximately 30 days after the public hearing. A transcript will also be made available in either hard copy or on CD–ROM, upon submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: January 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00607 Filed 1–14–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Organ Donation/Transplant Life Stories (OMB No. 0915–xxxx)—[New]

Abstract

HRSA's Division of Transplantation (DoT) is the primary entity in the Department of Health and Human Services (HHS) responsible for the Organ Transplant Program established under the National Organ Transplant Act (Pub. L. 98–507, codified at sections 371–377D of the Public Health Service (PHS) Act). Section 377A of the PHS Act authorizes the Secretary of HHS to establish a public education program to increase awareness about organ donation and the need to provide for an adequate rate of such donations. In brief, DoT's responsibilities are two-fold: (1) to provide oversight and guidance to the national organ transplant system in the U.S. including monitoring the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients, and (2) to implement a program of public and professional education and outreach aimed at increasing the number of organ donors in this country. Many preventable deaths occur each year because of a staggering imbalance between the supply and demand for donor organs. As of November 2012, the national transplant waiting list exceeded 116,000. In 2011, the total number of deceased and living organ donors was only 14,145. These donors enabled 28,538 patients to receive a transplant while 6,693 died waiting. Without successful interventions to increase donation, the disparity between need and supply is likely to be substantially exacerbated, resulting in even more unnecessary deaths.

Organdonor.gov is DoT's primary mechanism for providing the public with information about organ donation. Among the most visited pages on organdonor.gov are the donor and recipient life stories, which in a recent evaluation study were shown to raise interest on the topic, and, more importantly, persuade people to register as organ donors. To expand this component of organdonor.gov, DoT proposes to develop an application to give organ recipients and donor families the opportunity to voluntarily submit their stories to DoT via a standardized online form. The online form will be posted on organdonor.gov and will collect demographic and contact information, the individual's donation/transplant story up to 500 words, a high-resolution photo, and a signed authorization. The standardized, electronic form will increase HRSA staff's ability to process those stories more efficiently. In addition to enabling story submission, the online application process will make the donor and recipient life stories posted on the site searchable by the public to enhance public viewing and understanding of the organ donation process. Submission of a story and completion of the form is voluntary. Overall, this application has the potential to strengthen DoT's outreach efforts and increase organ donation registration in the United States.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Donation/Transplantation Life Story Submission Form	100	1	100	0.25	25
Total	100	1	100	0.25	25

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: January 9, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–00673 Filed 1–14–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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 Dental and Craniofacial Research Special Emphasis Panel.

Date: January 31, 2013.

Time: 10:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, DEA/SRB/NIDCR, 6701 Democracy Blvd., Room 668, Bethesda, MD 20892–4878, 301–451–2405, *henriquv@nidcr.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. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: January 8, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00619 Filed 1–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: February 5, 2013.

Time: 10:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Louis A. Rosenthal, Ph.D., Scientific Review Officer, Scientific Review Program, DHHS/NIH/NIAID/DEA, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892, 301–402–8399, *rosenthalla@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: February 6, 2013.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Louis A. Rosenthal, Ph.D., Scientific Review Officer, Scientific Review Program, DHHS/NIH/NIAID/DEA, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892, 301–402–8399, *rosenthalla@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 8, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00616 Filed 1–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 BTRC Review.

Date: February 13–15, 2013.

Time: 6:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Los Angeles Downtown Hotel, 711 Hope Street, Los Angeles, CA.

Contact Person: Manana Sukhareva, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301–451–3397, *sukharem@mail.nih.gov.*

Dated: January 8, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00618 Filed 1–14–13; 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 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: Center for Scientific Review Special Emphasis Panel; Xenopus Genetics and Genomics.
Date: February 1, 2013.
Time: 1:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Richard Panniers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Enhancing Developmental Biology AREA Review.
Date: February 6–7, 2013.
Time: 8:00 a.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Wallace Ip, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, 301–435–1191, *ipws@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Behavioral Neuroscience.
Date: February 6, 2013.
Time: 1:00 p.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.
Contact Person: Christine L Melchior, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435–1713, *melchioc@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function D Study Section.
Date: February 7, 2013.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.
Contact Person: James W Mack, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435–2037, *mackj2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.
Date: February 7, 2013.
Time: 1:00 p.m. to 3:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Lynn E Luethke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 806–3323, *luethkel@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Program Project Review.
Date: February 7, 2013.
Time: 1:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.
Contact Person: Nicholas Gaiano, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5178, MSC 7844, Bethesda, MD 20892–7844, 301–435–1033, *gaianonr@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Molecular Neuropharmacology and Signaling Study Section.
Date: February 12–13, 2013.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.
Contact Person: Deborah L Lewis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301–408–9129, *lewisdeb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Brain Injury.
Date: February 12, 2013.
Time: 2:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, *bhagavas@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR11–257: Systems Developmental Biology for Understanding Embryonic Development and the Ontogeny of Structural Birth Defects.
Date: February 13, 2013.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To provide concept review of proposed grant applications.
Place: Renaissance Harborplace Hotel, 202 East Pratt Street, Baltimore, MD 21202.
Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301–435–2406, *ariasj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nursing and Related Clinical Sciences Overflow.
Date: February 13, 2013.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.
Contact Person: Martha L Hare, Ph.D., RN, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 451–8504, *harem@mail.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.
Date: February 13–14, 2013.
Time: 8:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Marina del Rey Hotel, 13534 Bali Way, Marina Del Rey, CA 90292.
Contact Person: Kathryn Kalasinsky, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7806, Bethesda, MD 20892, 301–402–1074, *kalasinskyks@mail.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Xenobiotic and Nutrient Disposition and Action Study Section.
Date: February 13, 2013.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.
Contact Person; Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2172, MSC 7818, Bethesda, MD 20892, 301–435–1169, *greenwep@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative and Clinical Endocrinology and Reproduction Study Section.
Date: February 13, 2013.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hotel Monaco Baltimore, 2 North Charles Street, Baltimore, MD 21201.
Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biodata Management and Analysis Study Section.

Date: February 13–14, 2013.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Torrance Marriott South Bay, 3635 Fashion Way, Torrance, CA 90503.

Contact Person: Mark Caprara, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, *capraramg@mail.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Cardiovascular and Sleep Epidemiology Study Section.

Date: February 13, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: Julia Krushkal, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, 301–435–1782, *krushkalj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Integrative Functional and Cognitive Neurobiology.

Date: February 13–14, 2013.

Time: 9:00 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: Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181 MSC 7846, Bethesda, MD 20892–7846, 301–435–1236, *zhaow@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Surgical Sciences and Bioengineering.

Date: February 13, 2013.

Time: 12:00 p.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: Malgorzata Klosek, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7849, Bethesda, MD 20892, (301) 435–2211, *klosekm@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 9, 2012

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00623 Filed 1–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed 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: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases Research Committee.

Date: February 5–6, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant. applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michelle M. Timmerman, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 2217, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892–7616, 301–451–4573, *timmermanm@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 8, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00617 Filed 1–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; 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: Office of Research Infrastructure Programs Special Emphasis Panel; Comparative Medicine Review: Training.

Date: February 6–7, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health/NCATS, Democracy 1, Room 1082, 6701 Democracy Blvd., Bethesda, MD, (Virtual Meeting).

Contact Person: Sheri A. Hild, Ph.D., Scientific Review Officer, Office of Grants Management & Scientific Review, National Center For Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Dem. 1, Room 1082, Bethesda, MD 20892–4874, 301–435–0811, *hildsa@mail.nih.gov.*

Name of Committee: Office of Research Infrastructure Programs Special Emphasis Panel; Comparative Medicine Review: Resources.

Date: February 13–14, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health/NCATS, Democracy 1, Room 1082, 6701 Democracy Blvd., Bethesda, MD, (Virtual Meeting).

Contact Person: Sheri A. Hild, Ph.D., Scientific Review Officer, Office Of Grants Management & Scientific Review, National Center For Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Dem. 1, Room 1082, Bethesda, MD 20892–4874, 301–435–0811, *hildsa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research

Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: January 8, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00622 Filed 1–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Digestive Diseases and Nutrition.

Date: February 14, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street NW., Washington, DC 20037.

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; DDK–C Conflicts.

Date: February 14, 2013.

Time: 4:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street NW., Washington, DC 20037.

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference.

Date: February 21, 2013.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: D.G. Patel, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7682, *pateldg@niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR12–265: NIDDK-Ancillary Studies to Major Ongoing Clinical Studies on LIFE-Moms (R01).

Date: February 25, 2013.

Time: 1:00 p.m. to 3:00 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: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@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: January 8, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00621 Filed 1–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Translational Research.

Date: January 17, 2013.

Time: 10:00 a.m. to 3:00 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: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.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.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK–KUH Fellowship Application Review.

Date: January 25, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20014.

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*.

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.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity Policy and Program Evaluation.

Date: January 28, 2013.

Time: 10:00 a.m. to 12:00 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: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.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. 93.847, 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: January 8, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00620 Filed 1–14–13; 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: Neurodevelopment and Neuroplasticity.

Date: January 28, 2013.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Toby Behar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435–4433, *behart@csr.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: January 9, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00615 Filed 1–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; 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.

Proposed Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR Part 8 (OMB No. 0930–0206) and Opioid Treatment Programs (OTPs)—Revision

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. ''Certification'' is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA–162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA–163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA–168), which may be used on a voluntary basis by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA–168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: A patient's medical examination when admitted to treatment, A patient's history, a treatment plan, any prenatal support provided the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic attendance, and documentation of physiologic dependence.

The rule also includes requirements that OTPs and accreditation organizations disclose information. For example, 42 CFR 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered to be consistent with the common medical practice and is not considered an additional burden. Further, the rule requires, under Sec. 8.4(i)(1) that accreditation organizations shall make public their fee structure; this type of disclosure is standard business practice and is not considered a burden.

There are no changes being made to the forms. The reason for the reduction in burden hours is due to more respondents submitting information through an online function. The forms are available online with a unique feature for both the SMA–162 and SMA–168 that pre-populates certain information within the form. This in turn reduces the program's time spent

filling out the forms as well as the staff time spent on processing it. Also, a final rule effective January 7, 2013, (77 FR 72752, **Federal Register** December 6, 2012) eliminated dispensing restrictions for buprenorphine products used in OTPs. As a result there OTPs will complete and submit fewer SMA–168 forms, therefore reducing burden hours.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.3(b)(1–11)	Initial approval (SMA–163)	1	1	1	6.0	6
8.3(c)	Renewal of approval (SMA–163)	2	1	2	1.0	2
8.3(e)	Relinquishment notification	1	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTPs.	1	90	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs.	2	2	4	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance.	2	10	20	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request.	6	5	30	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request.	6	75	450	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request.	6	6	36	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA.	6	5	30	0.5	15
8.4(d)(5)	Summaries of Inspections	6	50	300	0.5	150
8.4(e)	Notifications of Complaints	12	6	72	0.5	36
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs.	1	185	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA.	1	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status.	1	185	185	0.3	55.0
Sub Total	54		1,407		394.20	

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of espondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.11(b)	Renewal of approval (SMA–162)	386	1	386	0.15	57.9
8.11(b)	Relocation of Program (SMA–162)	35	1	35	1.17	40.95
8.11(e)(1)	Application for provisional certification.	42	1	42	1	42.00
8.11(e)(2)	Application for extension of provisional certification.	30	1	30	0.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA–162).	60	1	60	0.1	6.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance.	1	1	1	1	1.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12 (including SMA–168).	1,200	20	24,000	0.07	1680
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA–162).	10	1	10	0.25	2.5
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	20	20	0.33	6.6
8.24	Contents of Appellant Request for Review of Suspension.	2	1	2	0.25	.50
8.25(a)	Informal Review Request	2	1	2	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement.	2	1	2	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review.	2	1	2	1.00	2.00
8.28(c)	Appellant Review File and Written Statement.	2	1	2	5.00	10.00
Sub Total		1,775		24,594		1868.95

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS—Continued

42 CFR citation	Purpose	Number of espondents	Responses/ respondent	Total responses	Hours/ response	Total hours
Total		1,829		26,001		2,263.15

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 or email her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received by March 18, 2013.

Summer King,

Statistician.

[FR Doc. 2013–00585 Filed 1–14–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2012–0034]

Privacy Act of 1974; U.S. Customs and Border Protection; DHS/CBP–004–Intellectual Property Rights e-Recordation and Search Systems, System of Records

AGENCY: Department of Homeland Security, Privacy Office.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security, U.S. Customs and Border Protection proposes to establish a new system of records titled, ''U.S. Customs and Border Protection, DHS/CBP–004–Intellectual Property Rights e-Recordation and Search Systems System of Records.'' This system of records allows the Department and CBP to collect and maintain records on copyrights, trademarks, and trade names that the respective owners have applied to have recorded with CBP. In addition, the Department is issuing a Notice of Proposed Rulemaking elsewhere in the **Federal Register** to exempt this system of records from certain provisions of the Privacy Act. This newly established system will be included in the Department's inventory of record systems.

DATES: Submit comments on or before February 14, 2013. This new system will be effective February 14, 2013.

ADDRESSES: You may submit comments, identified by docket number DHS–2012–034 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Laurence E. Castelli, 202–325–0280, CBP Privacy Officer, Office of International Trade/Regulations and Rulings, U.S. Customs and Border Protection, Mint Annex, 799 9th Street NW., Washington, DC 20229–1177. For privacy issues, please contact: Jonathan R. Cantor, 202–343–1717, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS), U.S. Customs and Border Protection (CBP) proposes to establish a new DHS system of records titled, ''DHS/CBP–004–Intellectual Property Rights e-Recordation and Search Systems System of Records.''

The Intellectual Property Rights e-Recordation and Search Systems (IPRRSS) collect, use, and maintain records related to intellectual property rights recordations and their owners. The purpose of IPRRSS is to aid in the enforcement of intellectual property rights by making intellectual property recordations available to the public and to CBP officials.

IPRRSS collectively encompasses three separate systems. The first system is the online Intellectual Property Rights e-Recordation (IPRR) system, which allows intellectual property owners to submit applications for trademark and copyright recordations. The IPRR system shares information with the public Intellectual Property Rights Search (IPRS) system and the CBP Intellectual Property Rights Internal Search (IPRiS) system. Because CBP may collect personally identifiable information (PII) about intellectual property rights holders, their agents, or their licensees in IPRR, IPRS, and IPRiS (collectively IPRRSS), CBP is providing the public notice about how CBP collects, uses, and maintains records related to intellectual property rights recordations.

The authority for this system derives from Section 42 of the Lanham Act (Trademark Act of 1946), as amended, 15 U.S.C. 1124; Sections 101 and 602 through 603 of the Copyright Act of 1976, as amended, 17 U.S.C. 101, 602–603; and Sections 526, 595a, and 624 of the Tariff Act of 1930, as amended, 19 U.S.C. 1526, 1595a, and 1624. The cited sections provide that intellectual property rights owners may submit information to CBP to enable CBP officials to identify infringing articles at the borders and prevent the importation of counterfeit or pirated merchandise. Owners seeking to have merchandise excluded from entry must provide proof to CBP of the validity of the intellectual property rights they seek to protect.

Pursuant to the Independent Offices Appropriations Act of 1952, 31 U.S.C. 9701, and regulations at 19 CFR 133.3, 133.13, and 133.33, intellectual property rights owners or their agents must pay a fee when they apply for the recordation with CBP of their trademark, trade name, or copyright. Through IPRR's web-based interface, the user will be prompted through several steps that capture the user's required application information. Once the applicant has entered all required application information, IPRR will guide the applicant through a series of prompts seeking his/her billing name, billing address, and credit card information. IPRR forwards this payment information to Pay.gov for payment processing, and the applicant name and an IPRR tracking number to the DHS/CBP–003 Credit/Debit Card Data System (CDCDS) System of Records for payment reconciliation. Pay.gov sends a nightly activity file, including the last four digits of the credit card, authorization number, billing name, billing address, IPRR

tracking number, and Pay.gov tracking numbers to CDCDS. Pay.gov also sends a daily batch file with the necessary payment information to a commercial bank for settlement processing. After processing, the commercial bank sends a settlement file, including the full credit card number, authorization number, card type, transaction date, amount, and IPRR tracking number to CDCDS. Once IPRR receives confirmation from Pay.gov that the payment has been processed successfully, IPRR will retain the Pay.gov tracking number for payment reconciliation purposes in accordance with the CDCDS system of records retention schedule.

When an applicant enters the registration number of a copyright or trademark he or she would like to record with CBP, the IPRR system must receive a positive match response from the U.S. Patent and Trademark Office (USPTO) and U.S. Copyright Office Web sites in order for the application to proceed. Only the registration number is shared with the USPTO and U.S. Copyright Office Web sites. If the registration number entered in IPRR does not match an entry in either of these Web sites, the applicant cannot record their trademark or copyright with CBP. Once a positive match response is received from these systems, certain fields in the application are automatically populated with public data taken directly from the U.S. Copyright Office or USPTO Web sites. All of the information copied from the U.S. Copyright Office or U.S. Patent and Trademark Office Web sites is publicly available at *www.uspto.gov* and *www.copyright.gov.*

The public may search for trademark, trade name, and copyright information in IPRS, the public facing portion of this system of records. The IPRS database collects and retains only a portion of the information entered by the right holder in IPRR, such as the name, address, and phone number of the right holder or representative, along with a text description of the recorded trademark or copyright. This information allows retailers, consumers, and other businesses to contact the right owner to ensure that they are not obtaining goods that infringe on the owner's intellectual property rights.

CBP and U.S. Immigration and Customs Enforcement (ICE) officials have access to IPRiS to assist in the enforcement of intellectual property rights. IPRiS provides a central searchable database of all trademark, trade name, and copyright recordation information. IPRiS contains the same information as IPRS, but with additional fields containing confidential information submitted by the right holder, including the names of entities who have used the trademark or copyright, the country of manufacture of merchandise, images of the recorded trademark or copyright, lists of licensees, and any additional information relating to enforcement of the intellectual property right. Only CBP and ICE officials may search IPRiS.

Only a few users within CBP have access to an administrative interface to process IPRR recordations. Those authorized CBP users with administrative access process the renewals of existing trademark and copyright recordations, trade name recordations, and information about ownership changes or cancellations.

Consistent with DHS' information-sharing mission, information stored in the DHS/CBP–004–Intellectual Property Rights e-Recordation and Intellectual Property Rights Search Systems may be shared with other DHS components with a need to know the information. In addition these records may be shared with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies so long as the recipient has a need to know the information to carry out functions consistent with the routine uses set forth in this system of records notice (SORN).

In addition, DHS is issuing a Notice of Proposed Rulemaking elsewhere in the **Federal Register** to exempt certain portions of this system of records from specific provisions of the Privacy Act. DHS is not exempting any data in IPRRSS regarding an individual's application for recordation of his or her trademark, trade name, or copyright. This system of records may contain records or information pertaining to the accounting of disclosures made from IPRRSS to other national security, law enforcement, or intelligence agencies (federal, state, local, foreign, international or tribal) in accordance with the published routine uses or statutory basis for disclosure under 5 U.S.C. 552a(b). For the accounting of these disclosures only, in accordance with 5 U.S.C. 552a(j)(2), DHS will claim exemptions for these records or information. In addition, the system may contain records or information pertaining to individuals who may have used an intellectual property right without the owner's authorization. For information or records pertaining to the unauthorized use of intellectual property rights, in accordance with 5 U.S.C. 552a(k)(2), DHS will claim exemptions for these records or information.

This newly established system of records will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which the federal government collects, maintains, uses, and disseminates personally identifiable information. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all persons, regardless of citizenship, where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/CBP–004–Intellectual Property Rights e-Recordation and Search Systems, System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM OF RECORDS:

DHS/CBP–004

SYSTEM NAME:

U.S. Customs and Border Protection, Intellectual Property Rights e-Recordation and Search Systems (IPRRSS).

SECURITY CLASSIFICATION:

Unclassified, sensitive.

SYSTEM LOCATION:

Records are maintained at the U.S. Customs and Border Protection Headquarters in Washington, DC and field offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The individuals included in the system include the owners of the trademark, trade name, or copyright; former owners of the trademark, trade name, or copyright; agents or representatives applying on behalf of the intellectual property right owners; contact persons; individuals authorized to use the trademark, trade name, or copyright; and other individuals who

are alleged to have infringed on the trademark, trade name, or copyright. For trade names, the system may include individuals who are not associated with or related to the trade name applicant, but who have actual knowledge and state that the applicant used the trade name, that the applicant is the only one who may use the trade name, and that the trade name is not identical or confusingly similar to another trademark or trade name used in connection with the same class or kind of merchandise. *See* 19 CFR 133.13. For copyrights, the names of the performers in the copyrighted work may be included. The photographs may include an individual modeling the trademark or copyrighted work, or an individual depicted in the copyrighted work.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in the system include, but are not limited to:

- Full name (first, middle, and last).
- Address (country, city, state and zip code).
- Telephone number.
- Fax number.
- Email address.
- Citizenship.
- Relationship to trademark, copyright, or trade name owner.
- USPTO or U.S. Copyright Office registration number.
- Description of registered trademark or registered copyright.
- Date of issuance of trademark or copyright registration.
- Country of manufacture of goods bearing the genuine trademark, or genuine copies or phonorecords of the protected work.
- Names of all parties authorized to use the trademark, trade name, or copyright, and the nature of the relationship to the owner.
- Names of any parties, foreign or domestic, who use or claim the trademark, trade name, or copyright, and a description of those uses or claims.
- Filing date of trademark registration.
- If the trademark being registered is a standard character mark.
- Date of expiration of the USPTO registration.
- Supplemental information concerning the trademark (e.g., type of mark or design code category).
- International class of goods covered by the USPTO registration and the specific products entitled to protection.
- Title of copyrighted work.
- Foreign title of the copyrighted work.
- IPRR tracking number.
- Pay.gov payment tracking number.
- Up to five digital images of the protected mark or copyrighted work.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for this system derives from section 42 of the Lanham Act (Trademark Act of 1946), as amended, 15 U.S.C. 1124; sections 101 and 602 through 603 of the Copyright Act of 1976, as amended, 17 U.S.C. 101, 602–603; and sections 526, 595a, and 624 of the Tariff Act of 1930, as amended, 19 U.S.C. 1526, 1595a, and 1624; the Independent Offices Appropriations Act, 1952, 31 U.S.C. 9701; and regulations at 19 CFR 133.3, 133.13, and 133.33.

PURPOSE(S):

The purpose of this system is to collect and maintain information on valid trademarks, trade names, and copyrights, to enable CBP officials to identify at the border merchandise that infringes on registered trademarks, registered copyrights, or trade names. IPRRSS collection encompasses three separate systems. The Intellectual Property Rights e-Recordation (IPRR) system allows intellectual property owners to submit applications for trademark and copyright recordations. The IPRR system shares information with two other CBP intellectual property search systems: The public Intellectual Property Rights Search (IPRS) system, and the Intellectual Property Rights Internal Search (IPRiS) system. IPRS provides a web-based search engine for the public to research trademark, trade name, and copyright recordations. IPRiS is used to assist CBP and Immigration and Customs Enforcement (ICE) in enforcing copyrights, trademarks, and trade names.

The Pay.gov tracking number (associated with the payment information provided to Pay.gov and stored in DHS/CBP–003 Credit/Debit Card Data System (CDCDS)) will be used to process application fees and to reconcile issues regarding payment between CDCDS and Pay.gov. Payment information, such as credit card numbers or account information, will not be used for determining recordation in IPRS or IPRiS, and is stored in a separate system (CDCDS) from the IPRR application data.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including U.S. Attorney Offices, or other federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is necessary or relevant to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;
2. Any employee of DHS in his/her official capacity;
3. Any employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or
4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made pursuant to a written Privacy Act waiver at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;
2. DHS has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) or harm to the individuals that rely upon the compromised information; and
3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided

information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To appropriate federal, state, tribal, local, or foreign governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where CBP believes the information would assist enforcement of applicable civil or criminal laws.

H. To the U.S. Copyright Office or U.S. Patent and Trademark Office, to confirm that the applicant has a registered copyright or a registered trademark.

I. To Pay.gov, for payment processing and payment reconciliation purposes.

J. To members of the public, through IPRS, a portion of the intellectual property rights information, such as the name, address, and phone number of the intellectual property right owner and the owner's representative; and a description of the recorded trademark, trade name, or copyright. The intellectual property right owner consents to disclosing this portion of information in IPRS upon application for recordation, and the public information in IPRS does not include trade secrets, business proprietary information, or information about enforcement.

K. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

Authorized CBP officials may retrieve information in IPRiS by the data elements supplied by the applicant. The public may search the non-confidential records in IPRS by keyword and Boolean operators, and may limit the search by title, product, description, owner, contact name, firm name, recordation number, or agency registration number; the public may also filter the search by trademarks, copyrights, trade names, exclusion orders, or whether the recordation has expired.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

CBP will retain expired recordations, which have not been renewed, for seven years after the date of expiration. NARA guidelines for retention and archiving of data will apply to IPRR, IPRS, and IPRiS; CBP is in negotiation with NARA for approval of the IPRRSS data retention and archiving plan.

Payment information is not stored in IPRR, IPRiS or IPRS, but is forwarded to Pay.gov and stored in CBP's financial processing system, CDCDS, pursuant to the DHS/CBP–003, CDCDS system of records notice.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Automated Systems, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Washington, DC 20229.

NOTIFICATION PROCEDURE:

The Secretary of Homeland Security has exempted portions of this system of records from the notification, access, and amendment procedures of the Privacy Act because the records may be used for law enforcement purposes. No exemption shall be asserted with respect to information maintained in the systems as it relates to data submitted by or on behalf of the owner of the trademark, trade name, or copyright, except with respect to information about individuals who are alleged to have infringed on the trademark, trade name, or copyright. DHS/CBP will consider individual requests to determine whether or not information may be released. Thus, individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the CBP FOIA Officer whose contact information can be found at *http://www.dhs.gov/foia* under ''contacts.'' If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov* or 1–866–431–0486. In addition you should:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If your request seeks records pertaining to another living individual, you must also include a statement from that individual certifying his/her agreement for you to access his/her records. Without the information specified above, the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records are obtained primarily from the individual submitting the application for recordation of the trademark, trade name, or copyright. If the applicant provides a registered trademark number, the USPTO Web site will provide automatically supplemental information concerning the trademark, the USPTO registration number, the international class of goods covered by the registration and the specific products entitled to protection, the date the owner filed the registration application, and the date it issued the trademark registration. If the applicant provides a registered copyright, the U.S. Copyright Office Web site will provide automatically the title of the copyrighted work, the U.S. Copyright Office registration number, the date it issued the copyright registration, and the name of the copyright owner.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

CBP will not assert any exemptions with respect to information in the systems submitted by the intellectual property right owner or the owner's representative, except with respect to information about individuals who are alleged to have infringed on the trademark, trade name, or copyright. Information in the system pertaining to persons alleged to have infringed on an intellectual property right may be shared with national security, law enforcement, or intelligence agencies pursuant to the above routine uses. The Privacy Act requires DHS to maintain an accounting of the disclosures made pursuant to all routines uses. Disclosing the fact that national security, law enforcement or intelligence agencies have sought particular records may affect ongoing national security, law enforcement, or intelligence activity. As such, pursuant to 5 U.S.C. 552a(j)(2), DHS will claim exemption from subsections (c)(3), (e)(8), and (g) of the Privacy Act of 1974, as amended, as necessary and appropriate to protect this information. In addition, because the system may contain information or records about the unauthorized use of intellectual property rights and disclosure of that information could impede law enforcement investigations, DHS will claim, pursuant to 5 U.S.C. 552a(k)(2), exemption from subsections (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f) of the Privacy Act of 1974, as necessary and appropriate to protect this information.

Dated: December 12, 2012.

Jonathan R. Cantor,

Acting Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2013–00603 Filed 1–14–13; 8:45 am]

BILLING CODE 9110–06–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2012–0025]

Privacy Act of 1974; Science & Technology Directorate–001 Research, Development, Test, and Evaluation Records System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update and reissue a current Department of Homeland Security system of records titled, ''Department of Homeland Security/Science and Technology Directorate–001 Research, Development, Test, and Evaluation System of Records.'' This system of records allows the Department of Homeland Security/Science and Technology Directorate to collect and maintain records collected in support of, or during the conduct of, Science & Technology-funded research, development, test, and evaluation activities. As a result of the biennial review of this system, routine uses have been updated. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before February 14, 2013. This updated system will be effective February 14, 2013.

ADDRESSES: You may submit comments, identified by docket number DHS–2012–0025 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change and may be read at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Christopher Lee, *STPrivacy@hq.dhs.gov,* the Science & Technology Directorate's Privacy Office, Mail Stop: 0205, Department of Homeland Security, 245 Murray Lane SW., Washington, DC 20528. For privacy issues, please contact: Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) Science and Technology Directorate (S&T) proposes to update and reissue a current DHS system of records titled, ''DHS/S&T–001 Research, Development, Test, and Evaluation System of Records.''

An integral part of the Department of Homeland Security (DHS) Science & Technology Directorate's (S&T) mission is to conduct research, development, testing, and evaluation (RDT&E activities) on topics and technologies related to improving homeland security and combating terrorism. Some RDT&E activities involve the collection of personally identifiable information. This system of records notice covers records collected in support of, or during the conduct of, DHS/S&T-funded RDT&E activities, when those records are retrieved by personal identifier.

As a general rule, the information collected will be used by DHS/S&T solely for the purposes of supporting RDT&E activities (e.g., testing and evaluating a screening technology or obtaining feedback on a technology from volunteer participants). S&T will not use the information collected for law enforcement, intelligence, or any purpose other than RDT&E. This system of records notice only covers the collection and use of information for the purpose of RDT&E activities. In situations when DHS/S&T-funded RDT&E activities directly involve law enforcement, intelligence personnel, and/or other operational entities, a separate SORN is required to address any activities from which information collected would be used in operations, to support operational decisions, or any purpose other than RDT&E activities. An exception to the above general rule limiting the use of collected information

to RTD&E activities is if, during a human subject testing activity, the individual provides information that indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations. Only in that limited situation, the information collected may be referred to federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, pursuant to Routine Use G, below.

The Routine Uses have been updated to include Routine Use ''H,'' disclosure to the news media and the public. Additionally, this notice includes non-substantive changes to simplify and clarify the formatting and text of the previously published notice. The updates do not have a significant impact on individual privacy. All current privacy protections and considerations remain intact ensuring individual privacy is protected during S&T RDT&E activities, including conducting a Privacy Impact Assessment (PIA) and using technical safeguards and access controls to protect data from unauthorized use. The updates specify that any law enforcement, intelligence personnel, or operational partners collaborating with S&T may make operational decisions based on information collected during S&T RDT&E activities, if they have appropriate legal authority and an appropriate SORN is in place.

This updated system will be included in DHS' inventory of record systems.

II. The Privacy Act

The Privacy Act embodies fair information principles in a statutory framework governing the means by which federal government agencies collect, maintain, use and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other particular assigned to an individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and legal permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is a description of the DHS/S&T–001 Research, Development, Test, and Evaluation Records System of records.

In accordance with 5 U.S.C. 552a(r), a report on this system has been sent to Congress and to the Office of Management and Budget.

SYSTEM OF RECORDS:

Department of Homeland Security/S&T–001

SYSTEM NAME:

DHS/S&T–001 Research, Development, Test, and Evaluation Records

SECURITY CLASSIFICATION:

Unclassified

SYSTEM LOCATION:

Records are maintained at the S&T Headquarters in Washington, DC, in S&T field offices, and at public or private institutions, including the National Labs, conducting research funded by S&T.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this notice include voluntary participants in S&T-funded research (**note:** all S&T-funded research that involves human subjects research is conducted in accordance with 45 CFR part 46 and is reviewed by a certified Institutional Review Board); individuals whose names may appear in publicly available documents (e.g., newspapers and academic articles) about terrorism, terrorist events, violent groups, or other topics related to terrorism research; individuals whose personally identifiable information may be collected through DHS operations and maintained by other DHS components; individuals whose images, biometrics, physiological features, or other information may be intentionally (with notice to and consent by the individual) or incidentally captured during testing of S&T technologies; subject matter experts who publish articles related to terrorism or biomedical and life sciences research; and subject matter experts who voluntarily consent to be included in a database of experts.

CATEGORIES OF RECORDS IN THE SYSTEM:

S&T RDT&E Records will vary according to the specific project. The information may include, but is not limited to, an individual's:

- Name;
- Age;
- Gender;
- Contact information;
- Birthplace;
- Ethnicity;
- Level of education;
- Occupation;
- Institutional or organizational affiliation;
- Publication record, such as article and publication titles, dates and sources;
- Medical history;
- Lifestyle information (e.g., caffeine or tobacco use);
- Publicly available reports of criminal history;
- Video or still images;
- Other images (e.g., infrared thermography, terahertz, millimeter wave);
- Audio recordings;
- Fingerprints, iris images, DNA or other biometric information; and
- Physiological measurements collected using sensors (e.g., heart rate, breathing pattern, and electrodermal activity).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Homeland Security Act of 2002, Public Law 1007–296, § 302(4) (codified at 6 U.S.C. 182(b)), authorizes the Science and Technology Directorate to conduct ''basic and applied research, development, demonstration, testing, and evaluation activities that are relevant to any or all elements of the Department, through both intramural and extramural programs.'' In exercising its responsibility under the Homeland Security Act, S&T is authorized to collect information, as appropriate, to support research and development related to improving the security of the homeland. When research includes human subjects, S&T complies with the provisions of DHS Management Directive 026–04, ''Protection of Human Subjects'', which adopts the regulations set forth in 45 CFR part 46 and establishes Departmental policy for the protection of human subjects in research.

PURPOSE(S):

Records are collected for the purpose of furthering S&T's mission to push innovation and development, and the use of high technology in support of homeland security. The purposes of the records are to:

- Understand the motivations and behaviors of terrorists, individuals that engage in violent or criminal activities, terrorist groups, and groups that engage in violent or criminal activities.
- Understand terrorist incidents and the phenomenon of terrorism and identify trends and patterns in terrorist activities.
- Collect and maintain searchable records of individuals (such as subject matter experts on chemical weapons)

and/or their characteristics and professional accomplishments, organized according to categories useful for the purpose of collaboration or conduct of research, including research to determine the efficacy and utility of new or enhanced technologies intended for eventual transition to and use by S&T's customers.

• Evaluate the performance and utility to the future customer of an experimental homeland security or first responder technology or product in a laboratory or ''real-world'' setting.

• Test the accuracy of a research hypothesis. (For example, S&T might hypothesize that an individual's behavior changes in a detectable manner when he or she is being deceitful, and then design a research experiment to test that hypothesis.)

• Answer a research question. (For example, ''Can an experimental screening technology distinguish between threat objects and non-threat objects?'').

• Conduct testing and evaluation of an experimental technology at the request of or on behalf of a customer.

• Conduct research and development to solve a technical problem for a customer.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3):

A. To the Department of Justice (DOJ), including U.S. Attorney Offices, or other federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. any employee of former employee of DHS in his/her official capacity;

3. any employee or former employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or

4. the United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS' officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

RDT&E records maintained in hard copy are stored in a locked file cabinet or safe. Electronic records are stored in computer files that require a password for access and are protected by a firewall. Data and systems are encrypted as necessary, pursuant to DHS guidelines.

RETRIEVABILITY:

In most cases, S&T RDT&E is focused on evaluating the performance of a given experimental technology or system. Thus, only the aggregated performance data (e.g., the technology has a 5% false positive rate, or the technology is accurate 92% of the time) is important and relevant to S&T. For this reason, S&T RDT&E records are not as a matter of course retrieved by name or other identifier assigned to the individual. However, S&T may need to access RDT&E records by name or other identifier in order to make corrections to an individual's record, resolve an anomaly related to a specific individual's record, and/or link disparate pieces of information related to an individual. For example, if an individual informed a researcher that he or she had inadvertently provided incorrect information regarding his or her medical history, the researcher would retrieve that individual's record using the research identifier in order to correct the erroneous data.

SAFEGUARDS:

All RDT&E records are protected by employing a multi-layer security approach to prevent unauthorized access to sensitive or personal data through appropriate administrative, physical, and technical safeguards. Protective strategies such as implementing physical access controls at DHS facilities; ensuring confidentiality of communications using tools such as encryption, authentication of sending parties, and compartmentalizing databases; and employing auditing software and personnel screening to ensure that all personnel with access to data are

screened through background investigations commensurate with the level of access required to perform their duties.

S&T RDT&E records are also monitored for changes to the source data. The program manager has the capability to maintain system back-ups for the purpose of supporting continuity of operations and the discrete need to isolate and copy specific data transactions for the purpose of conducting privacy or security incident investigations. S&T RDT&E records are secured in full compliance with the requirements of DHS IT Security Program Handbook. This handbook establishes a comprehensive information security program.

RETENTION AND DISPOSAL:

All records will be maintained in accordance with the NARA-approved retention schedule. All existing S&T RDT&E records fall under General Records System 20, which covers the disposition of electronic files or records created solely to test system performance, as well as hard-copy printouts and related documentation for the electronic files/records. According to General Records System 20, records should be ''delete[d]/destroy[ed] when the agency determines that they are no longer needed for administrative, legal, audit, or other operational purposes.'' Electronic records will be deleted from all computers, storage devices, and networks, and paper records will be shredded. Oftentimes, PII collected during the project is retained for the duration of the project; at the conclusion of the project, PII is destroyed. However, researchers may retain aggregated research data (without PII) indefinitely, as it may help inform future RDT&E efforts.

SYSTEM MANAGER(S) AND ADDRESS:

S&T Privacy Office, Mail Stop: 0205, Department of Homeland Security, 245 Murray Lane, SW., Washington, DC 20528.

NOTIFICATION PROCEDURE:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to S&T FOIA Officer, Mail Stop: 0205 Department of Homeland Security, 245 Murray Lane SW., Washington, DC 20528, specific FOIA contact information can be found at *http://www.dhs.gov/foia* under ''contacts.''

When seeking records about yourself from this system of records or any other S&T system of records your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from Director, Disclosure and FOIA, *http://www.dhs.gov* or 1–866–431–0486. In addition you should provide the following:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records; and

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without the above information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

S&T RDT&E records include (1) Records collected directly from the individual; (2) publicly available documents (e.g., articles from newspapers and academic journals); (3) records collected from the individual using sensors (e.g., a heart rate monitor) or technologies (e.g., cameras, audio recorders, infrared thermography or other images, or biometric devices).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Jonathan R. Cantor,

Acting Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2013–00602 Filed 1–14–13; 8:45 am]

BILLING CODE 9110–9F–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4092–DR; Docket ID FEMA–2013–0001]

Virginia; Amendment No. 1 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 Commonwealth of Virginia (FEMA–4092–DR), dated November 26, 2012, and related determinations.

DATES: *Effective Date:* January 2, 2013.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Virginia is hereby amended to include Disaster Unemployment Assistance for 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 November 26, 2012.

Accomack County for Disaster Unemployment 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. 2013–00720 Filed 1–14–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4092–DR; Docket ID FEMA–2013–0001]

Virginia; Amendment No. 2 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 Commonwealth of Virginia (FEMA–4092–DR), dated November 26, 2012, and related determinations.

DATES: *Effective Date:* January 3, 2013.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Virginia 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 November 26, 2012.

New Kent County for Public Assistance, including direct federal 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. 2013–00717 Filed 1–14–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4091–DR; Docket ID FEMA–2013–0001]

Maryland; 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 Maryland (FEMA–4091–DR), dated November 20, 2012, and related determinations.

DATES: *Effective Date:* January 3, 2013.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Maryland 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 November 20, 2012.

Baltimore County for Public 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. 2013–00718 Filed 1–14–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–NWRS–2012–0092; FXRS 84510900000–134–FF09R20000]

RIN 1018–AY36

Draft Policy on Donations, Fundraising, and Solicitation

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comment.

SUMMARY: The U.S. Fish and Wildlife Service (Service) proposes to establish a policy that covers Service procedures for accepting, using, and recognizing donations. This draft donations policy is an extension of the Department of the Interior's guidance on donations, found in the Departmental Manual (DM) at 374 DM 6. It focuses on the ethical considerations of all types of donations, as opposed to our Fish and Wildlife Service Manual (FW) guidance, 342 FW 5, Non-Purchase Acquisition, which covers the acquisition of real property rights by methods other than purchase, including donation.

If finalized, this draft policy would establish procedures for reviewing and evaluating potential donors and donations. It lists delegations of authority for accepting donations and the roles and responsibilities of the Service's Donations Senior Manager and employees authorized to accept donations. It provides guidance on soliciting donations, where appropriate, and provides general guidance on fundraising by non-Federal entities on the Service's behalf. It also covers recognition of donors.

We propose to incorporate this draft policy as 212 FW 8 in the Fish and Wildlife Service Manual (*http://www.fws.gov/policy/manuals/*).

DATES: To ensure consideration, please send your written comments by February 14, 2013.

ADDRESSES: You may submit comments on this draft policy by any of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* Search for FWS–HQ–NWRS–2012–0092, which is the docket number for this notice. You may submit a comment by clicking on ''Comment Now!''
- *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–HQ–NWRS–2012–0092; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2024–PDM; Arlington, VA 22203.

We will not accept email or faxes. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see *Request for Public Comments* under **SUPPLEMENTARY INFORMATION** for more information).

FOR FURTHER INFORMATION CONTACT: Janet Bruner, 703–358–1713.

SUPPLEMENTARY INFORMATION: The draft guidance document that is the subject of this notice is available at *www.fws.gov/refuges/donations.*

Background

The Department of the Interior issued ''ETHICS AND CONDUCT, Employee Responsibilities and Conduct, Donations'' (374 DM 6), in 2007. This guidance requires all Interior bureaus to develop their own policy on donations.

Several authorities allow various types of donations, including real and personal property, services, and money. These include the Fish and Wildlife Coordination Act (16 U.S.C. 661 et seq.), which allows acceptance of funds or lands, pending State approval. A later amendment to the Fish and Wildlife Act of 1956 (16 U.S.C. 742f) allows the Service to accept real and personal property donations. Other authorities cited in this draft donations policy include the Partnerships for Wildlife Act (16 U.S.C. 3741); Alaska National Interest Lands Conservation Act (16 U.S.C. 3101); Migratory Bird Conservation Act, as amended (16 U.S.C. 715–715r); National Wildlife Refuge System Volunteer and Community Partnership Enhancement Act of 1998, as amended (16 U.S.C. 742f); Great Lakes Fisheries Act of 1956 (16 U.S.C 932); and the National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd(b)(2)).

In addition to those broader authorities, individual units of the National Wildlife Refuge System or the National Fish Hatchery System may have specific legislative authority to accept donations. This draft donations policy is in keeping with statutory requirements as well as with the aforementioned Departmental guidance, 374 DM 6.

Draft Policy

We recognize the value of donations, but also the potential problems with accepting them. This draft policy covers the ethical considerations for donations, fundraising, and solicitation. While donations can be a means to further our mission, not all donations are appropriate. This draft policy provides consistent procedures for evaluating potential donors and donations to determine if acceptance is appropriate. The policy also helps the reader determine who has authority to accept appropriate donations. That authority depends on the type (real property or non-real property) and the monetary value of the donation.

This draft policy also covers soliciting donations and fundraising. Those activities are primarily done by Friends groups, groups of volunteers who support specific refuges. Requirements for solicitation of donations by Friends groups are covered in existing Service Manual chapters 150 FW 1–3. The draft donations policy we are putting out for comment now will list the limited circumstances when Service employees may solicit donations. It will describe inappropriate fundraising activities and also mention grant applications and acceptance.

Recognizing donors is very important. This draft policy also contains information on that, including a template for a thank-you letter.

Request for Public Comments

You may submit comment and materials on this notice by any of the methods listed in the **ADDRESSES** section. We will not accept comments sent by email or fax or to an address not listed in the **ADDRESSES** section. We will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in the **DATES** section.

We will post your entire comment on *http://www.regulations.gov.* Before including personal identifying information in your comment, you should be aware that we may make your entire comment—including your personal identifying information—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. We will post all hardcopy comments on *http://www.regulations.gov.*

Dated: December 21, 2012.

Daniel M. Ashe,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2013–00654 Filed 1–14–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–R–2012–N296; FXRS12650400000S3–123–FF04R02000]

Sam D. Hamilton Noxubee National Wildlife Refuge, MS; Intent To Prepare a Comprehensive Conservation Plan and Environmental Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent.

SUMMARY: We, the Fish and Wildlife Service (Service), intend to prepare a comprehensive conservation plan (CCP) and associated National Environmental Policy Act (NEPA) documents for Sam D. Hamilton Noxubee National Wildlife Refuge (NWR) in Noxubee, Oktibbeha, and Winston Counties, Mississippi. We provide this notice in compliance with our CCP policy to advise other Federal and State agencies, Native-American tribes, and the public of our intentions, and to obtain suggestions and information on the scope of issues to consider in the planning process.

DATES: To ensure consideration, we must receive your written comments by February 14, 2013.

ADDRESSES: You may send comments, questions, and requests for information to: Mr. Steve Reagan, Project Leader, Sam D. Hamilton Noxubee NWR, 2970 Bluff Lake Road, Brooksville, MS 39739; or *steve_reagan@fws.gov* (email).

FOR FURTHER INFORMATION CONTACT: Ms. Michelle Paduani, Natural Resource Planner, at 662–323–5548 (telephone); or *michelle_paduani@fws.gov* (email); or Mr. Steve Reagan at 662–323–5548 (telephone).

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we initiate our process for developing a CCP for Sam D. Hamilton Noxubee NWR in Mississippi. This notice complies with our CCP policy to: (1) Advise other Federal and State agencies, Native-American tribes, and the public of our intention to conduct detailed planning on this refuge; and (2) obtain suggestions and information on the scope of issues to consider in the environmental document and during development of the CCP.

Background

The CCP Process

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Administration Act), as amended by the National Wildlife

Refuge System Improvement Act of 1997, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System (Refuge System), consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Administration Act.

Each unit of the Refuge System was established for specific purposes. We use these purposes as the foundation for developing and prioritizing the management goals and objectives for each refuge within the Refuge System mission, and to determine how the public can use each refuge. The planning process is a way for us and the public to evaluate management goals and objectives for the best possible conservation approach to this important wildlife habitat, while providing for wildlife-dependent recreation opportunities that are compatible with the refuge's establishing purposes and the mission of the Refuge System.

Our CCP process provides participation opportunities for Tribal, State, and local governments; agencies; organizations; and the public. We encourage input in the form of issues, concerns, ideas, and suggestions for the future management of Sam D. Hamilton Noxubee NWR.

We will conduct the environmental review of this project in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C. 4321 *et seq.*); NEPA regulations (40 CFR parts 1500–1508); other appropriate Federal laws and regulations; and our policies and procedures for compliance with those laws and regulations.

The Noxubee NWR was established on June 14, 1940, by Executive Order 8444, under the authority of 16 U.S.C. 715 (Migratory Bird Conservation Act). It was renamed the Sam D. Hamilton Noxubee National Wildlife Refuge on June 22, 2012. The refuge's stated purpose is ''for use as a Refuge and breeding ground for migratory birds and other wildlife.'' In conjunction with the primary establishing purposes, the refuge provides an area for the ''conservation, management, and restoration of the fish, wildlife, and plant resources and their habitats for the benefit of present and future generations of Americans'' 16 U.S.C. 668dd(a)(2) (National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997), as well as ''for the development, advancement, management, conservation, and protection of fish and wildlife resources'' 16 U.S.C. 742(a)(4) (Fish and Wildlife Act of 1956). Subsequently, a small amount of land was purchased with Migratory Bird Conservation Stamp monies ''for use as an inviolate sanctuary, or for any other management purpose, for migratory birds'' 16 U.S.C. 715d (Migratory Bird Conservation Act).

Public Availability and Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

This notice is published under the authority of the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd *et seq.*).

Dated: December 20, 2012.

Mark J. Musaus,

Acting Regional Director.

[FR Doc. 2013–00652 Filed 1–14–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–R–2012–N218; FXRS12650400000S3–123–FF04R02000]

St. Vincent National Wildlife Refuge, FL; Final Comprehensive Conservation Plan and Finding of No Significant Impact for the Environmental Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the Fish and Wildlife Service (Service), announce the availability of the final comprehensive conservation plan (CCP) and finding of no significant impact for the environmental assessment for St. Vincent National Wildlife Refuge (NWR) in Franklin and Gulf Counties, Florida. In the final CCP, we describe how we will manage this refuge for the next 15 years.

ADDRESSES: You may obtain a copy of the CCP by writing to Ms. Shelley Stiaes via U.S. mail at St. Vincent National Wildlife Refuge, P.O. Box 447, Apalachicola, FL 32329. Alternatively, you may download the document from our Internet site, *http://southeast.fws.gov/planning,* under ''Final Documents.''

FOR FURTHER INFORMATION CONTACT: Ms. Shelley Stiaes, at 850–653–8808 (telephone) or *shelley_stiaes@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we finalize the CCP process for St. Vincent NWR. We started the process through a notice in the **Federal Register** on April 8, 2009 (74 FR 16002). For more about the process, see that notice.

St. Vincent NWR is located in Franklin and Gulf Counties along the Gulf Coast of northwest Florida, approximately 60 miles from Panama City and 80 miles from Tallahassee. St. Vincent NWR's approved acquisition boundary is approximately 13,736 acres, with a current management boundary of approximately 12,490 acres. The staff oversees 21 Farm Service Agency easements, totaling 1,625 acres in six counties. The 12,490-acre refuge boundary includes two islands—St. Vincent (12,358 acres) and Pig (46 acres). It also includes a mainland tract—14 Mile Tract (86 acres).

Background

The CCP Process

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including

opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Administration Act.

Comments

We made copies of the Draft Comprehensive Conservation Plan and Environmental Assessment (Draft CCP/EA) available for a 30-day public review and comment period via a **Federal Register** notice on May 2, 2012 (77 FR 26035). We provided more than 125 copies of the Draft CCP/EA to those individuals or organizations requesting a copy. A total of 12 individuals, organizations, and government agencies provided comments by U.S. mail or email. Comments were received from many organizations, including the Florida Fish and Wildlife Commission; University of South Florida; Florida State University; Florida Department of Environmental Protection; Florida Natural Areas Inventory; Choctaw Nation of Oklahoma; Jena Band of Choctaw Indians; and Florida Department of State, Division of Historical Resources; and several members of the public.

CCP Alternatives, Including our Preferred Alternative

We developed three alternatives for managing the refuge (Alternatives A, B, and C), with Alternative C selected for implementation. This alternative will focus on a greater effort to manage and protect the refuge's native and imperiled species. We will continue to survey and monitor species of federal responsibility, such as threatened and endangered species, migratory birds, and key native species, but will also gain a better understanding of native species on the refuge. Additional efforts will be made to protect and support nesting for key species, as well as gain a better understanding of population dynamics of some species. We will conduct evaluations to determine if it is suitable to reestablish populations of the eastern indigo snake, gopher tortoise, and eastern wild turkey on the refuge.

We will continue to manage lakes 1, 2, and 3 by seasonal draw-downs to support the needs of shorebirds and wading birds. Lakes 4 and 5 will continue to support deep water for a freshwater fisheries program, with an occasional draw-down to manage vegetation within the system. Since the purchase of the refuge, there has been minimal emphasis on timber condition, so a forest habitat assessment will be conducted. The management of exotic, invasive, and nuisance animals and plants will be a focus, with emphasis on aggressively eradicating feral hogs.

Wildlife-dependent recreational uses of the refuge will be expanded. We will allow hunting of white-tailed deer, sambar deer, and raccoon. Fishing will consist of saltwater and freshwater opportunities. Wildlife observation, wildlife photography, and environmental education and interpretation will be enhanced to focus on imperiled species, the unique barrier island history and ecosystem as they relate to the coastal environment, and management style incorporating climate change effects. We will enhance the environmental education program to incorporate Florida Sunshine Standards, while establishing guidelines for public programs. Vehicle tours that meet management objectives will continue as long as we have sufficient staff to support the program. In addition to the current staff, the following positions will be added: assistant refuge manager, wildlife biologist, maintenance worker, wildlife officer, visitor services specialist, and boat operator. We will also add a wildlife biologist under the Student Conservation Employment Program, continue our participation in the Youth Conservation Corps, and explore Student Conservation Association and AmeriCorps program opportunities.

We will continue to use volunteers and strive to build stronger relationships with the Friends group and our partners to manage the resources, support the Strategic Habitat Conservation initiative, and the Landscape Conservation Cooperative. As climate change affects the refuge, we will increase research of species and habitat changes to support the best management decisions through adaptive management.

We have included compatibility determinations in the final CCP for the following: (1) Hunting (Big Game); (2) Recreational Fishing; (3) Environmental Education and Interpretation; (4) Wildlife Observation and Photography; (5) Hiking, Jogging, Walking, and Bicycling; (6) Boating (canoeing and kayaking); (7) Camping (associated with hunting); (8) Firewood Gathering (associated with hunting); (9) General Research and Scientific Collecting; and (10) Beach Use and Shelling.

Authority

This notice is published under the authority of the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd *et seq.*).

Dated: November 2, 2012.

Mark J. Musaus,

Acting Regional Director.

[FR Doc. 2013–00653 Filed 1–14–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–R–2012–N232; FF06R06000–FXRS1265066CCP0S2–123]

Establishment of Swan Valley Conservation Area, Montana

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: This notice advises the public that the U.S. Fish and Wildlife Service (Service) has established the Swan Valley Conservation Area as a unit of the National Wildlife Refuge System. The Service established the Swan Valley Conservation Area on August 6, 2012, with the donation of an 80-acre conservation easement in Missoula County, Montana.

ADDRESSES: A map depicting the approved Refuge boundary and other information regarding the Refuge is available on the Internet at *http://www.fws.gov/mountain-prairie/planning/.*

FOR FURTHER INFORMATION CONTACT: Toni Griffin, Planning Team Leader, Division of Refuge Planning, USFWS, P.O. Box 25486, DFC, Denver, CO 80225. *http://www.fws.gov/mountain-prairie/planning/.*

SUPPLEMENTARY INFORMATION: The Service has established the Swan Valley Conservation Area in western Montana, including portions of Lake and Missoula Counties. The Service will conserve wildlife resources in the conservation area, primarily through the purchase of perpetual easements and a limited amount of fee-title from willing sellers. These easements will connect and expand existing lands under conservation protection. Fee-title purchases will be restricted to lands immediately adjacent to Swan River National Wildlife Refuge.

The project will help ensure the perpetual conservation of one of the last undeveloped, low-elevation coniferous forest ecosystems in western Montana, in the greater Crown of the Continent ecosystem. Based on anticipated levels of landowner participation, objectives for the conservation area are to protect 10,000 acres of wildlife habitat through conservation easements and another 1,000 acres through fee-title around the

existing Swan River National Wildlife Refuge. The conservation area is a component of the broader landscape-scale Crown of the Continent initiative to ensure the continued function of one of the only ecosystems in the United States which still contains essentially the full suite of species that were present during the Lewis and Clark expedition. The prioritization for land protection will incorporate the elements of strategic habitat conservation (SHC) to ensure effective conservation. SHC entails strategic biological planning and conservation design, integrated conservation delivery, monitoring, and research at ecoregional scales.

This conservation area allows the Service to purchase conservation easements using the acquisition authority of the Fish and Wildlife Act of 1956 (16 U.S.C. 742a–j) and the Migratory Bird Conservation Act of 1929 (16 U.S.C. 715–715d, 715e, 715f–r). The Federal money used to acquire conservation easements is from the Land and Water Conservation Fund Act of 1965, as amended (16 U.S.C. 460l–4 through 11; funds received under this act are derived primarily from oil and gas leases on the Outer Continental Shelf, motorboat fuel taxes, and the sale of surplus Federal property), and the sale of Federal Duck Stamps [Migratory Bird Hunting and Conservation Stamp Act (16 U.S.C. 718–718j, 48 Stat. 452)]. Additional funding to acquire lands, water, or interests for fish and wildlife conservation purposes could be identified by Congress or donated by nonprofit organizations. The purchase of easements or fee title from willing sellers will be subject to available money.

The Service has involved the public, agencies, partners, and legislators throughout the planning process for the easement program. At the beginning of the planning process, the Service initiated public involvement for the proposal to protect habitats primarily through acquisition of wetland and grassland conservation easements for management as part of the Refuge System. The Service spent time discussing the proposed project with landowners; conservation organizations; Federal, State, and county governments; tribes; and other interested groups and individuals. Open house meetings were held on May 18 and June 2, 2010, in Condon, Montana. These meetings were announced in local and regional media.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321), the Service prepared an environmental assessment (EA) that evaluated two alternatives and their potential impacts on the project area. The Service released the draft environmental assessment (EA) and LPP on July 26, 2010, for a 30-day public review period. The draft documents were made available to Federal elected officials and agencies, State elected officials and agencies, Native American tribes with aboriginal or tribal interests, local media, and other members of the public that were identified during the scoping process. The Service received six written comments from agencies, organizations, and members of the public. After all comments were received, they were reviewed, added to the administrative record, and, if substantial, incorporated into the environmental assessment (EA).

Based on the documentation contained in the environmental assessment (EA), a Finding of No Significant Impact was signed on September 24, 2010, for the authorization of the Swan Valley Conservation Area.

Dated: August 24, 2012.

Steve Guertin,

Regional Director, Mountain-Prairie Region, U.S. Fish and Wildlife Service.

[FR Doc. 2013–00658 Filed 1–14–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZC03000.L51050000.EA0000 LVRCA13SA040.241A, AZ–SRP–030–10–04 and AZ–SRP–030–10–05]

Notice of Temporary Closures of Public Lands in La Paz County, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) Lake Havasu Field Office will close certain public lands during the Best in the Desert (BITD) Racing Association ''BITD PARKER 250'' and ''BITD 425'' events.

DATES: These closures will be in effect from 2 p.m., January 11, 2013, through 6 p.m., January 12, 2013, and 2 p.m., February 1, 2013, through 11:59 p.m., February 2, 2013, Mountain Standard Time.

FOR FURTHER INFORMATION CONTACT: Michael Dodson, Field Staff Ranger, BLM Lake Havasu Field Office, 2610 Sweetwater Avenue, Lake Havasu City, AZ 86406, 928–505–1200. 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. FIRS is available 24 hours a day, 7 days a week, to leave a message or question for the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The closures affect public lands administered by the Lake Havasu Field Office in La Paz County, Arizona. This action is being taken to help ensure public safety, prevent unnecessary environmental degradation, and to protect natural and cultural resources adjacent to the event site during the Best in the Desert (BITD) Racing Association ''BITD Parker 250'' and ''BITD 425'' official permitted off-highway vehicle (OHV) events.

The closure orders are issued under the authority of 43 CFR 8340 subpart 8341; 43 CFR 8360, subpart 8364.1; and 43 CFR 2932 which allow the BLM to establish closures for the protection of persons, property, and public lands and resources. Violation of any of the terms, conditions, or restrictions contained within this closure order may subject the violator to citation or arrest with a penalty or fine or imprisonment or both as specified by law.

Penalties: Violation of any regulations in this part by a member of the public is punishable by a fine not to exceed $1,000 and/or imprisonment not to exceed 12 months.

Description of Race Course Closed Area: Beginning at the eastern boundary of the Colorado River Indian Tribe (CRIT) Reservation, the closed area runs east along Shea Road, then east into Osborne Wash on the Parker-Swansea Road to the Central Arizona Project (CAP) Canal, then north on the west side of the CAP Canal, crossing the canal on the county-maintained road, running northeast into Mineral Wash Canyon, then southeast on the county-maintained road, through the four-corners intersection to the Midway (Pit) intersection, then east on Transmission Pass Road, through State Trust Land located in Butler Valley, turning north into Cunningham Wash to North Tank; continuing south to Transmission Pass Road and east (reentering public land) within 2 miles of Alamo Dam Road. The course turns south and west onto the wooden power line road, onto the State Trust Land in Butler Valley, turning southwest into Cunningham Wash to the Graham Well, intersecting Butler Valley Road, then north and west on the county-maintained road to the ''Bouse Y'' intersection, 2 miles north of Bouse, Arizona. The course proceeds north, paralleling the Bouse-Swansea Road to the Midway (Pit) intersection, then west

along the north boundary (power line) road of the East Cactus Plain Wilderness Area to Parker-Swansea Road. The course turns west into Osborne Wash crossing the CAP Canal, along the north boundary of the Cactus Plain Wilderness Study Area; it continues west staying in Osborne Wash and crossing Shea Road along the southern boundary of Gibraltar Wilderness, rejoining Osborne Wash at the CRIT Reservation boundary.

Closure Restrictions: The following acts are prohibited during the temporary land closures:

1. Being present on, or driving on, the designated race course or the adjacent lands described above. Spectators must stay within the designated spectator areas. The spectator areas have protective fencing and barriers. This does not apply to race participants, race officials, nor emergency vehicles authorized or operated by local, State, or Federal government agencies. Emergency medical response shall only be conducted by personnel and vehicles operating under the guidance of the La Paz County Emergency Medical Services and Fire, the Arizona Department of Public Safety, or the Bureau of Land Management.

2. Vehicle parking or stopping in areas affected by the closures, except where such is specifically allowed (designated spectator areas).

3. Camping in the closed area described above, except in the designated spectator areas.

4. Discharge of firearms.

5. Possession or use of any fireworks.

6. Cutting or collecting firewood of any kind, including dead and down wood or other vegetative material.

7. Operating any vehicle (except registered race vehicles), including off-highway vehicles, not registered and equipped for street and highway operation.

8. Operating any vehicle in the area of the closure or on roads within the event area at a speed of more than 35 mph. This does not apply to registered race vehicles during the race, while on the designated race course.

9. Failure to obey any official sign posted by the BLM, La Paz County, or the race promoter.

10. Parking any vehicle in a manner that obstructs or impedes normal traffic movement.

11. Failure to obey any person authorized to direct traffic or control access to event area including law enforcement officers, BLM officials, and designated race officials.

12. Failure to observe Spectator Area quiet hours of 10 p.m. to 6 a.m.

13. Failure to keep campsite or race viewing site free of trash and litter.

14. Allowing any pet or other animal to be unrestrained. All pets must be restrained by a leash of not more than 6 feet in length.

Exceptions to Closure: The restrictions do not apply to emergency or law enforcement vehicles owned by the United States, the State of Arizona, or La Paz County, and designated race officials, participants, pit crews, or persons operating on their behalf. Persons who violate these closure orders are subject to arrest and may be taken before a United States Magistrate and upon conviction, may be fined not more than $1,000 and/or imprisoned for not more than 12 months. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

Authority: 43 CFR 8364.1.

Kimber Liebhauser,

Field Manager.

[FR Doc. 2013–00542 Filed 1–14–13; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SERO–BLRI–11177; 2031–A048–409]

Final Environmental Impact Statement for General Management Plan, Blue Ridge Parkway, Virginia and North Carolina

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service (NPS) announces the availability of the Final Environmental Impact Statement (FEIS) for the General Management Plan (GMP) for Blue Ridge Parkway (parkway). Consistent with NPS laws, regulations, and policies and the purpose of the parkway, the FEIS/GMP will guide the management of the parkway over the next 20+ years.

DATES: The NPS will execute a Record of Decision (ROD) no sooner than 30 days following publication of the Environmental Protection Agency of its Notice of Availability of the FEIS/GMP in the **Federal Register**.

ADDRESSES: Electronic copies of the FEIS/GMP will be available online at *http://parkplanning.nps.gov/BLRI.* To request a copy, contact Superintendent Phil Francis, Blue Ridge Parkway, 199 Hemphill Knob Road, Asheville, NC 28803.

A limited number of compact disks and printed copies of the FEIS/GMP will be made available at Blue Ridge Parkway Headquarters, 199 Hemphill Knob Road, Asheville, NC 28803.

FOR FURTHER INFORMATION CONTACT: Superintendent Phil Francis, Blue Ridge Parkway, 199 Hemphill Knob Road, Asheville, NC 28803; telephone (828) 271–4779.

SUPPLEMENTARY INFORMATION: The FEIS/GMP responds to, and incorporates, agency and public comments received on the draft plan/EIS, which was available for public review from October 7, 2011, through December 16, 2011. Four public meetings were held from November 2, 2011, through November 10, 2011, to gather input on the draft plan/EIS. There were 3,360 pieces of correspondence received during the public review period. The NPS responses to substantive agency and public comments are provided in Chapter 5, Consultation and Coordination section, of the FEIS/GMP.

The FEIS/GMP evaluates three alternatives for managing use and development of the parkway. The NPS preferred alternative is Alternative B, which emphasizes the original parkway design and traditional driving experience, while enhancing outdoor recreation opportunities and regional natural resource connectivity, and providing modest improvements to visitor services. In essence, it seeks to reinvest in the parkway's aging infrastructure, update inadequate visitor services and facilities and protect a natural environment that is only surpassed in biologically diversity by two other units in the national park system. When approved, the plan will guide the management of the parkway over the next 20+ years.

The responsible official for this FEIS/GMP is the Regional Director, NPS Southeast Region, 100 Alabama Street SW., 1924 Building, Atlanta, Georgia 30303.

Dated: January 9, 2013.

Shawn T. Benge,

Acting Regional Director, Southeast Region.

[FR Doc. 2013–00691 Filed 1–14–13; 8:45 am]

BILLING CODE 4310–3P–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Amended Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act and Proposed Stipulation, Settlement Agreement and Order Under the Federal Debt Collection Procedure Act and the Federal Priority Act

On January 9, 2013, the Department of Justice lodged a proposed Amended Consent Decree in *United States* v. *the Atlas-Lederer Company, et al.,* Civil Action No. C–3–91–309 and a proposed Amended Stipulation, Settlement Agreement and Order in *United States* v. *Larry Katz, et al.,* Civil Action No. 3:05–cv–0058, with the United States District Court for the Southern District of Ohio.

In *Atlas-Lederer,* the United States sought reimbursement of response costs in connection with the United Scrap Lead Superfund Site in Troy, Miami County, Ohio (''the Site''). The proposed Amended Consent Decree resolves the United States claims against a defunct scrap metal company, Senser Metal Company, and its deceased owner and operator, Saul Senser, under Section 107(a) of the Comprehensive Environmental Response, Compensation and Liability Act (''CERCLA''), 42 U.S.C. 9607(a), and also resolves the United States' claim against Mr. Senser and his estate under Ohio ''veil piercing'' law.

This is an ''ability-to-pay'' settlement based on financial analyses conducted by the Department's Antitrust Corporate Finance Unit. Senser Metal and Mr. Senser's Estate (represented by Kenneth Senser as the Executor the Estate of Saul Senser) will pay the United States $243,250.00 within 30 days of entry of the Consent Decree, and within 24 days thereafter will pay the United States any amount remaining in the estate following payment to the United States in the *Katz* case and the payment of certain documented attorneys' fees and expenses.

The Amended Consent Decree also resolves the United Scrap Lead Respondent Group's (''Respondent Group'') CERCLA claims against Senser Metal Company for response costs incurred by the Respondent Group in cleaning up the Site under an earlier Consent Decree. The settling Senser defendants will pay the Respondent Group $21,500 within 30 days of entry of the Consent Decree.

In *Katz,* the United States filed suit against Mr. Senser and other defendants seeking to recover funds under the Federal Debt Collection Procedures Act and the Federal Priority Act. In its complaint, the United States alleged, among other things, that Mr. Senser liquidated the assets of Senser Metal Company and fraudulently diverted a portion of the proceeds to himself. To resolve this claim, the Estate of Saul Senser, together with Kenneth Senser in his capacity as Executor of the Estate, shall pay the United States $243,250.00 within 30 days of entry of the Amended Stipulation, Settlement Agreement and Order.

While a prior Consent Decree and Stipulation of Settlement were lodged in these cases in March of 2012, it was subsequently determined that certain tax consequences attendant upon the liquidation of a pension plan in the estate meant that there were insufficient assets available to settle the United States' claims on the original basis and also provide for the widow of Mr. Senser and the expenses of his estate. The revised settlements in the two cases will recover at least $486,500 in response costs incurred by EPA at the Site. This is approximately $73,000 less than the settlement amount originally agreed to in the March 2012 Consent Decree and Stipulation, but will allow the Estate to pay certain previously incurred expenses and purchase an annuity to secure a lifetime monthly stipend for Mr. Senser's widow.

The publication of this notice opens a period for public comment on the proposed Amended Consent Decree and the proposed Amended Stipulation, Settlement Agreement and Order. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *the Atlas-Lederer Company, et al.,* D.J. Ref. 90–11–3–279B and *United States* v. *Larry Katz, et al.,* D.J. Ref. 90–11–3–279/4. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the proposed Amended Consent Decree and the proposed Amended Stipulation, Settlement Agreement and Order may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* The Amended Stipulation is included as Appendix D to the Amended Consent Decree. We will provide a paper copy of the proposed Amended Consent Decree (including the Stipulation as an Appendix) upon written request and payment of reproduction costs. Please mail your request and payment to:

Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $10.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2013–00596 Filed 1–14–13; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Comment Request for Information Collection for the Trade Activity Participant Report (TAPR); Extension Without Revisions

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (Department), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the 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 [44 U.S.C. 3506(c)(2)(A)]. This program helps ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, ETA is soliciting comments concerning the collection of data about The Trade Activity Participant Report (OMB No. 1205–0392), which provides information on participant activities and performance outcomes for those served under the Trade Adjustment Assistance Program, as authorized under the Trade Act of 1974, as amended.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before March 18, 2013.

ADDRESSES: Submit written comments to Susan Worden, Office of Trade Adjustment Assistance Room N–5428, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Telephone number: 202–693–3517 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD). Fax: 202–693–3585 Email: *worden.susan@dol.gov.* A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed above.

SUPPLEMENTARY INFORMATION:

I. Background

The Department uses information from the TAPR Form completed by the states to establish state funding needs and evaluate the effectiveness of state administration of the Trade Adjustment Assistance program under the Trade Act. The Department is requesting a three year extension of the currently approved collection in order to continue to meet reporting requirements in Sections 239 and 249B of the Trade Act, as amended.

II. Review Focus

The Department is particularly interested in comments which:

- 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 submissions of responses.

III. Current Actions

Type of Review: extension without changes.

Title: Trade Activity Participant Report.

OMB Number: 1205–0392.

Affected Public: State, Local or Tribal Governments.

Form(s): Trade Activity Participant Report.

Total Annual Respondents: 50.

Annual Frequency: Quarterly.

Total Annual Responses: 200.

Average Time per Response: 47.5 hours.

Estimated Total Annual Burden Hours: 9,500.

Total Annual Burden Cost for Respondents: $0.

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval of the ICR; they will also become a matter of public record.

Jane Oates,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2013–00635 Filed 1–14–13; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–80,490]

Novartis Pharmaceuticals Corporation, Primary Care Business Unit (Sales) Division, East Operating Unit, North Operating Unit and South Operating Unit, Formerly Known as Southeast Operating Unit, Southwest Operating Unit, Northwest Operating Unit and Northeast Operating Unit, Including On-Site Leased Workers From Inventiv Health, Ashfield Healthcare, and Pro Unlimited, East Hanover, NJ and Off-Site Workers of Novartis Pharmaceuticals Corporation, Primary Care Business Unit (Sales) Division, East Operating Unit in Illinois Who Report to East Hanover, NJ; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 6, 2012, applicable to workers of Novartis Pharmaceuticals Corporation, Primary Care Business Unit (Sales) Division, East Hanover, New Jersey. The Department's notice of determination was published in the **Federal Register** on January 24, 2012 (77 FR 3501). The notice was amended on May 4, 2012 and October 17, 2012 to include workers under the control of the subject firm working off-site in Illinois and to include the primary Care Business Unit Division that is part of the East Operating Unit. The amended notices were published in the **Federal Register** on May 16, 2012 (77 FR 28901) and October 29, 2012 (77 FR 65581) respectively.

At the request of a company official, the Department reviewed the certification for workers of the subject firm.

New information shows that following a company merger, the East Operating Unit, North Operating Unit and South Operating Unit, formerly known as Southeast Operating Unit, Southwest Operating Unit, Northwest Operating Unit and Northeast Operating Unit of the Primary Care Business Unit (Sales) Division of the subject firm operate in the same capacity, together are part of a continuous operation and all experienced worker separations due to increased aggregate imports of pharmaceuticals.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased aggregate imports. The amended notice applicable to TA–W–80,490 is hereby issued as follows:

''All workers of Novartis Pharmaceuticals Corporation, Primary Care Business Unit (Sales) Division, East Operating Unit, North Operating Unit and South Operating Unit, formerly known as Southeast Operating Unit, Southwest operating Unit, Northwest Operating Unit and Northeast Operating Unit, including on-site leased workers from Inventiv Health, Ashfield Healthcare, and Pro Unlimited, East Hanover, New Jersey, and off-site workers of Novartis Pharmaceuticals Corporation, Primary Care Business Unit (Sales) Division, East Operating Unit in Illinois who report to East Hanover, New Jersey, who became totally or partially separated from employment on or after October 3, 2010, through January 6, 2014, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.''

Signed in Washington, DC, this 19th day of December, 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2013–00687 Filed 1–14–13; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,739; TA–W–81,739A; TA–W–81,739B]

Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

TA–W–81,739, HEWLETT–PACKARD COMPANY, PERSONAL PRINTING SYSTEMS (PPS), FORMERLY KNOWN AS DESIGN DELIVERY ORGANIZATION (DDO), INCLUDING ON–SITE LEASED WORKERS FROM, MANPOWER, SYNOVA, INC., AND PINNACLE TECHNICAL RESOURCES, CORVALLIS, OR;

TA–W–81,739A, HEWLETT–PACKARD COMPANY, PERSONAL PRINTING SYSTEMS (PPS), INK JET & WEB SERVICES (IWS), WORLD WIDE DESIGN GROUP, VANCOUVER, WA;

TA–W–81,739B, HEWLETT–PACKARD COMPANY, PERSONAL PRINTING SYSTEMS (PPS), SUPPLY CHAIN OPERATIONS (FORMERLY KNOWN AS IWS), VANCOUVER, WA.

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on September 18, 2012, applicable to workers of Hewlett-Packard Company (H–P), Design Delivery Organization (DDO), Corvallis, Oregon. The Department's Notice of determination was published in the **Federal Register** on October 5, 2012 (77 FR 194). Workers are engaged in activities related to the supply of new product introduction, development, and support.

New information obtained by the Department revealed that H–P experienced a re-organization, effective July 1, 2012, which placed several Corvallis, Oregon business units under its Personal Printing Systems Organization (PPS) unit, formerly referred to as DDO. The reorganization switched DDO with PPS as the largest business unit. PSS and all the sub-units within PPS continue to be managed by the same H–P company official, and PSS includes not only the unit DDO but also all units that were formerly within DDO. In addition, the reorganization placed under PPS, Vancouver, Washington, the Ink Jet and Web Services (IWS) and Supply Chain Operations (formerly known as IWS) units. The workers within PPS (both Corvallis, Oregon and Vancouver, Washington locations) supply research & development technology services, as well as analytical and reporting support services.

The intent of the Department's certification is to include all workers at H–P, PPS, Corvallis, Oregon (TA–W–81,739), and H–P, PPS, IWS, World Wide Design Group, Vancouver, Washington (TA–W–81,739A), and H–P, PPS, Supply Chain Operations, Vancouver, Washington, (TA–W–81,739B) who were all adversely affected by a shift of services abroad.

This amendment includes workers covered by TA–W–81,739A so that those workers who constitute the World Wide Design Group whose wages are reported under PPS (instead of IWS) are able to apply for Trade Adjustment Assistance.

The amended notice applicable to TA–W–81,739 is hereby issued as follows:

''All workers of Hewlett-Packard Company, Personal Printing Systems (PPS), formerly known as Design Delivery Organization (DDO), including on-site leased workers from Manpower, Synova, Inc., and Pinnacle Technical Resources, Corvallis, Oregon (TA–W–81,739); Hewlett-Packard Company, Personal Printing Systems (PPS), Ink Jet & Web Services (IWS), World Wide Design Group, Vancouver, Washington (TA–W–81,739A); and Hewlett-Packard Company, Printing & Personal Systems (PPS), Supply Chain Operations (formerly known as IWS), Vancouver, Washington, (TA–W–81,739B), who became totally or partially separated from employment on or after June 20, 2011 through September 18, 2014, and all workers in the groups threatened with total or partial separation from employment on September 18, 2012 through September 18, 2014, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1074, as amended.''

Signed at Washington, DC this 7th day of December, 2012

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2013–00688 Filed 1–14–13; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Investment Act; Native American Employment and Training Council

AGENCY: Employment and Training Administration, U. S. Department of Labor.

ACTION: Notice of Teleconference Meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, and Section 166(h)(4) of the Workforce Investment Act (WIA) [29 U.S.C. 2911(h)(4)], notice is hereby given of the next teleconference meeting of the Native American Employment and Training Council (Council), as constituted under WIA.

DATES: The teleconference meeting will begin at 2:00 p.m. (Eastern Time) on Thursday, January 31, 2013, and continue until 4:00 p.m. that day. The call in number is (888) 316–9414. Council members must enter the participants pass code number 4738145#. Members of the public can access the teleconference via listening mode by calling (800) 779–2568 and entering pass code 9921457#.

ADDRESSES: On January 31, 2013, the teleconference is being held at the U.S. Department of Labor, Francis Perkins Building, 200 Constitution Avenue, Northwest, Room S–2320, Washington, DC 20210.

SUPPLEMENTARY INFORMATION: The teleconference is open to the public. Members of the public not participating on the teleconference call may submit a written statement on or before January 16, 2013, to be included in the record of the meeting. Submit written statements to Mrs. Evangeline M. Campbell, Designated Federal Official (DFO), U.S. Department of Labor, 200 Constitution Avenue, Northwest, Room S–4209, Washington, DC 20210. The formal agenda will focus on the following topics: (1) Two Page White Paper on Statement of Urgency Section 166 Indian and Native American Programs; (2) DOL, Division of Indian and Native American Program Update on the Education (Credential) Measure; and (3) Council Update and Recommendations. Persons who need special accommodations (TTY), or members of the public who would like a copy of the formal agenda, should contact Mr. Craig Lewis at (202) 693–3384, at least two business days before the meeting.

FOR FURTHER INFORMATION CONTACT: Mrs. Evangeline M. Campbell, DFO, Division of Indian and Native American Programs, Employment and Training Administration, U.S. Department of Labor, Room S–4209, 200 Constitution Avenue, Northwest, Washington, DC 20210. Telephone number (202) 693–3737 (VOICE) (this is not a toll-free number).

Signed at Washington, DC, this 8th day of January, 2013.

Jane Oates,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2013–00651 Filed 1–14–13; 8:45 am]

BILLING CODE 4501–FR–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and 30 CFR Part 44 govern the application, processing, and disposition of petitions for modification. This notice is a summary of petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below to modify the application of existing mandatory safety standards codified in Title 30 of the Code of Federal Regulations.

DATES: All comments on the petitions must be received by the Office of Standards, Regulations and Variances on or before February 14, 2013.

ADDRESSES: You may submit your comments, identified by ''docket number'' on the subject line, by any of the following methods:

1. *Electronic Mail: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.
2. *Facsimile:* 202–693–9441.
3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939, Attention: George F. Triebsch, Director, Office of Standards, Regulations and Variances. Persons delivering documents are required to check in at the receptionist's desk on the 21st floor. Individuals may inspect copies of the petitions and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Barbara Barron, Office of Standards, Regulations and Variances at 202–693–9447 (Voice), *barron.barbara@dol.gov* (Email), or 202–693–9441 (Facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION:

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

(1) An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

(2) That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petitions for Modification

Docket No: M–2012–170–C.

Petitioner: Prairie State Generating Company, LLC, Three Gateway Center, Suite 1340, 401 Liberty Avenue, Pittsburgh, Pennsylvania 15222–1000.

Mine: Lively Grove Mine, MSHA I.D. No. 11–03193, located in Washington County, Illinois.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to permit the use of battery-powered nonpermissible surveying equipment in or in by the last open crosscut, including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers. The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200, use of the most practical and accurate surveying equipment is necessary.

(2) Application of the existing standard would result in a diminution of safety to the miners. Underground mining by its nature and size, and the complexity of mine plans, requires that accurate and precise measurements be completed in a prompt and efficient manner. The petitioner proposes the following as an alternative to the existing standard:

(a) Nonpermissible electronic surveying equipment will be used when equivalent permissible electronic surveying equipment is not available. Such nonpermissible surveying equipment includes portable battery-operated total station surveying equipment, mine transits, distance meters, and data loggers.

(b) All nonpermissible electronic surveying equipment to be used in or in by the last open crosscut will be examined by surveying personnel prior to use to ensure the equipment is being maintained in a safe operating condition. These examinations will include the following steps:

(i) Checking the instrument for any physical damage and the integrity of the case.

(ii) Removing the battery and inspecting for corrosion.

(iii) Inspecting the contact points to ensure a secure connection to the battery.

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections.

(v) Checking the battery compartment cover to ensure that it is securely fastened.

(c) The results of such examinations will be recorded and retained for one year and made available to MSHA on request.

(d) A qualified person as defined in 30 CFR 75.151 will continuously monitor for methane immediately before and during the use of nonpermissible surveying equipment in or inby the last open crosscut.

(e) Nonpermissible surveying equipment will not be used if methane is detected in concentrations at or above one percent for the area being surveyed. When methane is detected at such levels while the nonpermissible surveying equipment is being used, the equipment will be deenergized immediately and the nonpermissible electronic equipment withdrawn outby the last open crosscut.

(f) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition as defined in 30 CFR 75.320.

(g) Batteries in the surveying equipment will be changed out or charged in fresh air outby the last open crosscut.

(h) Qualified personnel who use surveying equipment will be properly trained to recognize the hazards associated with the use of nonpermissible surveying equipment in areas where methane could be present.

(i) The nonpermissible surveying equipment will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions in this petition.

Within 60 days after the Proposed Decision and Order becomes final, the petitioner will submit proposed revisions for its approved 30 CFR part 48 training plan to the District Manager. The revisions will specify initial and refresher training regarding the terms and conditions in the Proposed Decision and Order.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection as that afforded by the existing standard.

Docket Number: M–2012–171–C.

Petitioner: Prairie State Generating Company, LLC, Three Gateway Center, Suite 1340, 401 Liberty Avenue, Pittsburgh, Pennsylvania 15222–1000.

Mine: Lively Grove Mine, MSHA I.D. No. 11–03193, located in Washington County, Illinois.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to permit the use of battery-powered nonpermissible surveying equipment in return airways, including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers. The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200, use of the most practical and accurate surveying equipment is necessary.

(2) Application of the existing standard would result in a diminution of safety to the miners. Underground mining by its nature and size, and the complexity of mine plans, requires that accurate and precise measurements be completed in a prompt and efficient manner. The petitioner proposes the following as an alternative to the existing standard:

(a) Nonpermissible electronic surveying equipment will be used when equivalent permissible electronic surveying equipment is not available. Such nonpermissible surveying equipment includes portable battery-operated total station surveying equipment, mine transits, distance meters, and data loggers.

(b) All nonpermissible electronic surveying equipment to be used in return airways will be examined by surveying personnel prior to use to ensure the equipment is being maintained in a safe operating condition. These examinations will include the following steps:

(i) Checking the instrument for any physical damage and the integrity of the case.

(ii) Removing the battery and inspecting for corrosion.

(iii) Inspecting the contact points to ensure a secure connection to the battery.

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections.

(v) Checking the battery compartment cover to ensure that it is securely fastened.

(c) The results of such examinations will be recorded and retained for one year and made available to MSHA on request.

(d) A qualified person as defined in 30 CFR 75.151 will continuously monitor for methane immediately before and during the use of nonpermissible surveying equipment in return airways.

(e) Nonpermissible surveying equipment will not be used if methane is detected in concentrations at or above one percent for the area being surveyed. When methane is detected at such levels while the nonpermissible surveying equipment is being used, the equipment will be deenergized immediately and the nonpermissible electronic equipment withdrawn out of the return airways.

(f) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition as defined in 30 CFR 75.320.

(g) Batteries in the surveying equipment will be changed out or charged in fresh air out of the return.

(h) Qualified personnel who use surveying equipment will be properly trained to recognize the hazards associated with the use of nonpermissible surveying equipment in areas where methane could be present.

(i) The nonpermissible surveying equipment will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions in this petition.

Within 60 days after the Proposed Decision and Order becomes final, the petitioner will submit proposed revisions for its approved 30 CFR part 48 training plan to the District Manager. The revisions will specify initial and refresher training regarding the terms and conditions in the Proposed Decision and Order.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection as that afforded by the existing standard.

Docket Number: M–2012–172–C.

Petitioner: South Central Coal Company, Inc., P.O. Box 6, Spiro, Oklahoma 74959.

Mine: P8 North Mine, MSHA I.D. No. 34–02080, located in Le Flore County, Oklahoma.

Regulation Affected: 30 CFR 75.1700 (Oil and gas wells).

Modification Request: The petitioner requests a modification of the existing standard to mine through certain active or abandoned plugged wells which may lie in the engineered path of the proposed mining activity. The petitioner further requests that two previously granted petitions for modification, M–2008–053–C and M–95–151–C, be included in the evaluation of this petition regarding the P8 North Mine. The petitioner states that:

(1) The petitions granted for modification (M–2008–053–C and M–95–151–C) relate to the same reserve block referenced in this petition for the P8 North Mine.

(2) The primary reasons for not deviating from the P8 North Mine plan and adhering to the proposed mine plans include:

(a) Due to mining through a rock zone to reach coal-bearing strata, the petitioner cannot deviate from the mine plan without exceeding the permit boundary, thus requiring mining through plugged well 29–1H or the required barrier zone.

(b) Maintaining proper ventilation systems without complications.

(c) Maintaining easy to explain and easy to maintain emergency escape routes for mine personnel.

(d) Maintaining a straight-forward, uncomplicated system of ingress, egress and coal removal (belt layout).

(e) Maintaining an uncomplicated system of removing any water that may be encountered during mining.

(3) The petitioner further states that the procedures to be used when plugging or replugging and mining through hydrocarbon dry holes, gas wells, or oil wells within the mining operations include:

(a) All available data has been acquired to identify any hydrocarbon wells within the Department of Interior, Bureau of Land Management coal lease that is proposed for mining (Lease OKNM 91190 near the town of Spiro, Le Flore County, Oklahoma).

(b) Oklahoma Corporation Commission 1002 A forms (well completion records) and 1003 forms (plugging records) have been obtained for the wells within the proposed mine area. These records indicate details of the wells' completion and plugging procedures.

(c) The research well data in conjunction with coal geology information indicates well locations and confirmation of replugging procedures.

The petitioner asserts that the proposed alternative method will guarantee no less than the same measure of protection as that afforded by the existing standard.

Dated: January 10, 2013.

George F. Triebsch,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 2013–00624 Filed 1–14–13; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL COUNCIL ON DISABILITY

Sunshine Act Meetings

TIME AND DATES: The Members of the National Council on Disability (NCD) will hold a special meeting of the Council on Friday, January 11, 2013, 12:00 p.m.–1:00 p.m. (ET).

PLACE: The meeting will occur by teleconference. Interested parties may join the meeting by phone in a listening-only capacity using the following call-in number: 1–877–446–3914; passcode 4121872.

MATTERS TO BE CONSIDERED: The Council will meet to review, discuss, and vote on a letter of policy recommendations and concerns to the interagency taskforce created in the wake of the Newtown tragedy.

CONTACT PERSON FOR MORE INFORMATION: Anne Sommers, NCD, 1331 F Street NW., Suite 850, Washington, DC 20004; 202–272–2004 (V), 202–272–2074 (TTY).

ACCOMMODATIONS: Those who plan to participate by phone and require accommodations should notify NCD as soon as possible to allow time to make arrangements.

Dated: January 11, 2013.

Aaron Bishop,

Executive Director.

[FR Doc. 2013–00805 Filed 1–11–13; 4:15 pm]

BILLING CODE 6820–MA–P

NATIONAL COUNCIL ON DISABILITY

Sunshine Act Meetings Notice

TIME AND DATES: The Members of the National Council on Disability (NCD) will hold a quarterly meeting on Tuesday, January 29, 2013, 9:00 a.m.–5:00 p.m. (ET).

PLACE: The meeting will occur at the Access Board Conference Room, 1331 F Street, NW., Suite 800, Washington, DC. Interested parties may join the meeting in person or may join by phone in a listening-only capacity (with the exception of the public comment period) using the following call-in number: 1–888–523–1228; passcode 3484831. If asked, the conference call host's name is Jonathan Young.

MATTERS TO BE CONSIDERED: The Council will receive updates from the Council's standing committees, will discuss and vote on two Medicaid reports (one on self-direction and one on block-granting), will discuss the agency's 2013 progress report, will receive a briefing from Administrator Craig Fugate of the Federal Emergency Management Agency (FEMA) regarding the response to Hurricane Sandy, as it pertains to people with disabilities, and will receive public comment. The times provided below are approximations for when each agenda item is anticipated to be discussed (all times Eastern):

9:00–9:30 a.m. Chairman's Report, Executive Director's Report

9:30–10:30 a.m. Audit and Finance Committee report, Governance Committee report

10:30 a.m.–12:00 p.m. Policy and Program Evaluation Committee Report (including discussion and votes on Medicaid reports)

1:15–2:15 p.m. NCD Progress Report Discussion

2:15–3:15 p.m. Agency briefing with FEMA Administrator Craig Fugate

3:30–4:00 p.m. Public comment period

Any individuals interested in providing public comment will be asked to provide their names and their organizational affiliations, if applicable, and to limit their comments to three minutes. Individuals may also provide public comment by sending their comments in writing to Lawrence Carter-Long, Public Affairs Specialist, at *lcarterlong@ncd.gov,* using the subject line of ''Public Comment.''

CONTACT PERSON FOR MORE INFORMATION: Anne Sommers, NCD, 1331 F Street NW., Suite 850, Washington, DC 20004; 202–272–2004 (V), 202–272–2074 (TTY).

ACCOMMODATIONS: Those who plan to attend and require accommodations should notify NCD as soon as possible to allow time to make arrangements. Please note: To help reduce exposure to fragrances for those with multiple chemical sensitivities, NCD requests that all those attending the meeting in person please refrain from wearing scented personal care products such as perfumes, hairsprays, colognes, and deodorants.

Dated: January 10, 2013.

Aaron Bishop,

Executive Director.

[FR Doc. 2013–00779 Filed 1–11–13; 11:47 am]

BILLING CODE 6820–MA–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting; Agenda

TIME AND DATE: 9:30 a.m., Tuesday, January 29, 2013.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

STATUS: The one item is open to the public.

MATTER TO BE CONSIDERED:

8371A Aircraft Accident Report—Loss of Control, Sundance Helicopters, Inc., Eurocopter AS350–B2, N37SH, Near Las Vegas, Nevada, December 7, 2011.

NEWS MEDIA CONTACT: Telephone: (202) 314–6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle Hall at (202) 314–6305 or by email at *Rochelle.Hall@ntsb.gov* by Friday, January 25, 2013.

The public may view the meeting via a live or archived webcast by accessing a link under ''News & Events'' on the NTSB home page at *www.ntsb.gov.*

Schedule updates including weather-related cancellations are also available at *www.ntsb.gov*.

FOR MORE INFORMATION CONTACT: Candi Bing, (202) 314–6403 or by email at *bingc@ntsb.gov*.

FOR MEDIA INFORMATION CONTACT: Peter Knudson (202) 314–6219 or by email at *peter.knudson@ntsb.gov*.

Dated: January 11, 2013.

Candi R. Bing,

Federal Register Liaison Officer.

[FR Doc. 2013–00822 Filed 1–11–13; 4:15 pm]

BILLING CODE 7533–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–348 and 50–364; NRC–2012–0309]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, opportunity to

request a hearing and to petition for leave to intervene; order.

DATES: Comments must be filed by February 14, 2013. Requests for a hearing or leave to intervene must be filed by March 18, 2013. Any potential party as defined in § 2.4 of Title 10 of the *Code of Federal Regulations* (10 CFR) who believes access to Sensitive Unclassified Non-Safeguards Information is necessary to respond to this notice must request document access by January 22, 2013.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and is publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2012–0309. You may submit comments by any one of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0309. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov*.
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2012–0309 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, by any one of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0309.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2012–0309 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* and enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing sensitive unclassified non-safeguards information (SUNSI).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request follows.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the

subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC regulations are accessible electronically from the NRC Library on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be issued in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital information (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of

a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email at *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the following three factors in 10 CFR 2.309(c)(1): (i) The information upon which the filing is based was not previously available; (ii) the information upon which the filing is based is materially different from information previously available; and (iii) the filing has been submitted in a timely fashion based on the availability of the subsequent information.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Date of amendment request: August 20, 2012, as supplemented by letters dated October 25 and November 8, 2012.

Description of amendment request: This license amendment request contains Sensitive Unclassified Non-Safeguards Information (SUNSI). The proposed amendments would revise the Technical Specification (TS) surveillance requirement (SR) 3.7.6.1 required water volume for condensate storage tank (CST) operability from 150,000 to 164,000 gallons.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change would revise TS 3.7.6, ''Condensate Storage Tank (CST),'' to revise the CST level requirements specified in Surveillance Requirement (SR) 3.7.6.1. The proposed change administratively increases the volume margin of the CST.

The CST is not an accident initiator and is credited to mitigate accidents and events. These changes have no impact on the method by which the CST performs its functions. With these changes, a sufficient quantity of water will continue to be supplied by the CST to the Auxiliary Feedwater (AFW) pumps to remove heat from the Reactor Coolant System (RCS) during a plant event.

With this change, the overall quantity of water required to meet operability requirements of SR 3.7.6.1 is increased. This increase is acceptable, providing increased CST volume margin and is based on plant specific CST minimum storage volume calculations.

This change does not impact any accident initiators or analyzed events. It does not impact any assumed mitigation capability for any accident or transient event. The change does not involve the addition or removal of any equipment; however, a design change to the low level alarm setpoint will be required. Therefore, operation of the facility in accordance with the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The CST is not an accident initiator and is credited to mitigate accidents and events. These changes have no impact on the method by which the CST performs its functions. This change does not involve any physical modifications to plant structures, systems, or components (SSCs), or the manner in which SSCs are maintained, modified, tested, or inspected. In addition, there is no change in the types or increases in the amounts of effluents that may be released offsite, and there is no increase in individual or cumulative occupational radiation exposure. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The accident analyses credit CST inventory to meet RCS design pressure, containment design pressure, 10 CFR 100 dose limits, and 10 CFR 50.36 peak cladding temperature limits. The increase in SR 3.7.6.1 CST required minimum volume increases the CST volume margin. The CST volume for the natural circulation cooldown event is greater than that required to mitigate accidents. The CST will continue to provide the entire required source of usable volume of safety grade water to the AFW System pumps to remove decay and sensible heat from the RCS. This change does not involve any

physical modifications to SSCs or the manner in which SSCs are maintained, modified, tested, or inspected. However, a design change to the low level alarm setpoint will be required. The change does not alter the manner in which safety limits, limiting safety system settings, or limiting conditions for operation are determined. The setpoints at which protective actions are initiated are not altered by the change. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based on the above, SNC concludes that the proposed amendment does not involve a significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and, accordingly, a finding of ''no significant hazards consideration'' is justified.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: M. Stanford Blanton, Esq., Balch and Bingham, Post Office Box 306, 1710 Sixth Avenue North, Birmingham, Alabama 35201.

NRC Branch Chief: Robert J. Pascarelli.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI).

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requestor may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

H. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It Is So Ordered.

Dated at Rockville, Maryland, this 7th day of January 2013.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—General Target Schedule for Processing and Resolving Requests for Access to Sensitive Unclassified Non-Safeguards Information in This Proceeding

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 requestor/petitioner reply).
20	Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for requestor/petitioner to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2013–00424 Filed 1–10–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0261]

Japan Lessons-Learned Project Directorate Interim Staff Guidance JLD–ISG–2012–06; Performing a Tsunami, Surge, or Seiche Hazard Assessment

AGENCY: Nuclear Regulatory Commission.

ACTION: Japan Lessons-Learned Project Directorate Interim Staff Guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing the Final Japan Lessons-Learned Project Directorate Interim Staff Guidance (JLD–ISG), JLD–ISG–2012–06, ''Performing a Tsunami, Surge, or Seiche Hazard Assessment'' (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12314A412). This JLD–ISG provides guidance and clarification to assist nuclear power reactors applicants and licensees with the flooding hazard reassessment in response to Enclosure 2 of the NRC staff's request for information, ''Request for Information Pursuant to section 50.54(f) of Title 10 of the *Code of Federal Regulations* (10 CFR), Regarding Recommendations 2.1, 2.3, and 9.3 of the Near-Term Task Force Review of Insights from the Fukushima Dai-ichi Accident,'' dated March 12, 2012 (ADAMS Accession No. ML12053A340).

ADDRESSES: Please refer to Docket ID NRC–2012–0261 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and are publicly-available, using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0261. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The JLD–ISG–2012–06 is available under ADAMS Accession No. ML12314A412.
- *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, MD 20852.
- *NRC's Interim Staff Guidance Web Site:* Go to *http://www.nrc.gov/reading-rm/doc-collections/isg/japan-lessons-*

learned.html and refer to JLD–ISG–2012–06.

FOR FURTHER INFORMATION CONTACT: Mr. G. Edward Miller, Japan Lessons-Learned Project Directorate, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2481; email: *ed.miller@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Background Information

The NRC staff developed JLD–ISG–2012–06 to provide guidance and clarification to assist nuclear power reactor licensees, applicants for power reactor licenses, and holders of construction permits in active or deferred status with the performance of a tsunami, surge, or seiche hazard assessment.

On March 11, 2011, a magnitude 9.0 earthquake struck off the coast of the Japanese island of Honshu. The earthquake resulted in a large tsunami, estimated to have exceeded 14 meters (45 feet) in height, that inundated the Fukushima Dai-ichi nuclear power plant site. The earthquake and tsunami produced widespread devastation across northeastern Japan and significantly affected the infrastructure and industry in the northeastern coastal areas of Japan. When the earthquake occurred, Fukushima Dai-ichi Units 1, 2, and 3 were in operation and Units 4, 5, and 6 were shut down for routine refueling and maintenance activities. The Unit 4 reactor fuel was offloaded to the Unit 4 spent fuel pool. Following the earthquake, the three operating units automatically shut down and offsite power was lost to the entire facility. The emergency diesel generators (EDG) started at all six units providing alternating current (ac) electrical power to critical systems at each unit. The facility response to the earthquake appears to have been normal. Approximately 40 minutes following the earthquake and shutdown of the operating units, however, the first large tsunami wave inundated the site, followed by additional waves. The tsunami caused extensive damage to site facilities and resulted in a complete loss of all ac electrical power at Units 1 through 5, a condition known as station blackout. In addition, all direct current electrical power was lost early in the event on Units 1 and 2, and after some period of time at the other units. Unit 6 retained the function of one air-cooled EDG. Despite their actions, the operators lost the ability to cool the fuel in the Unit 1 reactor after several hours, in the Unit 2 reactor after about 70 hours, and in the Unit 3 reactor after about 36 hours, resulting in damage to the nuclear fuel shortly after the loss of cooling capabilities.

Following the events at the Fukushima Dai-ichi nuclear power plant, the NRC established a senior-level agency task force referred to as the Near-Term Task Force (NTTF). The NTTF was tasked with conducting a systematic and methodical review of the NRC's regulations and processes, and determining if the agency should make additional improvements to these programs in light of the events at Fukushima Dai-ichi. As a result of this review, the NTTF developed a comprehensive set of recommendations, documented in SECY–11–0093, ''Near-Term Report and Recommendations for Agency Actions Following the Events in Japan,'' dated July 12, 2011 (ADAMS Accession No. ML11186A950). These recommendations were enhanced by the NRC staff following interactions with stakeholders. Documentation of the staff's efforts is contained in SECY–11–0124, ''Recommended Actions to be Taken Without Delay from the Near-Term Task Force Report,'' dated September 9, 2011 (ADAMS Accession No. ML11245A158), and SECY–11–0137, ''Prioritization of Recommended Actions to be Taken in Response to Fukushima Lessons Learned,'' dated October 3, 2011 (ADAMS Accession No. ML11272A111).

As directed by the Commission's staff requirements memorandum (SRM) for SECY–11–0093, dated August 19, 2011 (ADAMS Accession No. ML112310021), the NRC staff reviewed the NTTF recommendations within the context of the NRC's existing regulatory framework and considered the various regulatory vehicles available to the NRC to implement the recommendations. SECY–11–0124 and SECY–11–0137 established the staff's prioritization of the recommendations based upon the potential for each recommendation to enhance safety.

As part of the SRM for SECY–11–0124, dated October 18, 2011, the Commission approved the staff's proposed actions, including the development of three information requests under 10 CFR 50.54(f). The information collected would be used to support the NRC staff's evaluation of whether further regulatory action was needed in the areas of seismic and flooding design and emergency preparedness.

In addition to Commission direction, the Consolidated Appropriations Act, Public Law 112–074, was signed into law on December 23, 2011. Section 402 of the law directs the NRC to require licensees to reevaluate their design basis for external hazards.

In response to the aforementioned Commission and Congressional direction, the NRC issued a request for information to all power reactor licensees and holders of construction permits under 10 CFR Part 50 on March 12, 2012. The letter dated March 12, 2012, includes a request that licensees reevaluate flooding hazards at nuclear power plant sites using updated flooding hazard information and present-day regulatory guidance and methodologies. The letter also requests the comparison of the reevaluated hazard to the current design basis at the site for each potential flood mechanism. If the reevaluated flood hazard at a site is not bounded by the current design basis, licensees are requested to perform an integrated assessment. The integrated assessment will evaluate the total plant response to the flood hazard, considering multiple and diverse capabilities such as physical barriers, temporary protective measures, and operational procedures. The NRC staff will review the licensees' responses to this request for information and determine whether regulatory actions are necessary to provide additional protection against flooding.

Numerous public meetings were held to receive stakeholder input on the proposed guidance prior to its issuance formally for public comment. On October 26, 2012 (77 FR 65417), the NRC requested public comments on draft JLD–ISG–2012–06. The staff received thirty-eight (38) comments from four (4) stakeholders. Comments were received related to the following topical areas: (1) General comments; (2) comments specific to the storm surge evaluation; and (3) comments specific to the tsunami evaluation. In public meetings on October 24–25, 2012, and November 14, 2012, the NRC staff interacted extensively with external stakeholders to discuss, understand, and resolve public comments. Modifications were made to the text of the ISG in response to the public comments and the outcomes of the public meetings. Full detail of the comments, staff responses, and the staff's bases for changes to the ISG are contained in ''NRC Response to Public Comments'' to JLD–ISG–2012–06, which can be found under ADAMS Accession No. ML12314A414.

Backfitting and Issue Finality

This ISG does not constitute backfitting as defined in 10 CFR 50.109 (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.'' This ISG provides guidance on an acceptable method for implementing the March 12, 2012, request for information. Neither the information request nor the ISG require the modification or addition to systems, structures, or components, or design of a facility. Applicants and licensees may voluntarily use the guidance in JLD–ISG–2012–06 to comply with the request for information. The information received by this request may, at a later date, be used in the basis for imposing a backfit. The appropriate backfit review process would be followed at that time.

Congressional Review Act

This interim staff guidance is a rule as designated in the Congressional Review Act (5 U.S.C. 801–808). OMB has found that this is not a major rule in accordance with the Congressional Review Act.

Dated at Rockville, Maryland, this 4th day of January 2013.

For the Nuclear Regulatory Commission.

Matthew A. Mitchell,

Acting Director, Japan Lessons-Learned Project Directorate, Office of Nuclear Reactor Regulation.

[FR Doc. 2013–00671 Filed 1–14–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0001]

Notice of Sunshine Act Meetings

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATE: Weeks of January 14, 21, 28, February 4, 11, 18, 2013.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of January 14, 2013

There are no meetings scheduled for the week of January 14, 2013.

Week of January 21, 2013—Tentative

There are no meetings scheduled for the week of January 21, 2013.

Week of January 28, 2013—Tentative

Thursday, January 31, 2013

9:00 a.m.

Briefing on Public Participation in NRC Regulatory Decision-Making (Public Meeting) (Contact: Lance Rakovan, 301–415–2589).

This meeting will be webcast live at the Web address—*www.nrc.gov*.

Friday, February 1, 2013

9:30 a.m.

Briefing on Equal Employment Opportunity (EEO) and Small Business Programs (Public Meeting) (Contact: Sandra Talley, 301–415–8059)

This meeting will be webcast live at the Web address—*www.nrc.gov*.

Week of February 4, 2013—Tentative

Thursday, February 7, 2013

1:00 p.m.

Briefing on Steam Generator Tube Degradation (Public Meeting) (Contact: Ken Karwoski, 301–415–2752)

This meeting will be webcast live at the Web address—*www.nrc.gov*.

Week of February 11, 2013—Tentative

There are no meetings scheduled for the week of February 11, 2013.

Week of February 18, 2013—Tentative

Wednesday, February 20, 2013

1:00 p.m.

Briefing on Uranium Recovery (Public Meeting) (Contact: Bill von Till, 301–415–0598)

This meeting will be webcast live at the Web address—*www.nrc.gov*.

Thursday, February 21, 2013

9:30 a.m.

Briefing on the Threat Environment Assessment (Closed—Ex. 1)

* * * * *

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—301–415–1292. Contact person for more information: Rochelle Bavol, 301–415–1651.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html*.

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0727, or by email at *kimberly.meyer-chambers@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed electronically to subscribers. If you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an email to *darlene.wright@nrc.gov*.

Dated: January 10, 2013.

Rochelle C. Bavol,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2013–00794 Filed 1–11–13; 4:15 pm]

BILLING CODE 7590–01–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

SUMMARY: In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and purpose of information collection: Evidence of Marital Relationship, Living with Requirements; OMB 3220–0021.

To support an application for a spouse or widow(er)'s annuity under Sections 2(c) or 2(d) of the Railroad Retirement Act, an applicant must submit proof of a valid marriage to a railroad employee. In some cases, the existence of a marital relationship is not formalized by a civil or religious ceremony. In other cases, questions may arise about the legal termination of a prior marriage of the employee, spouse, or widow(er). In these instances, the RRB must secure additional information to resolve questionable marital relationships. The circumstances requiring an applicant to submit documentary evidence of marriage are prescribed in 20 CFR 219.30.

In the absence of documentary evidence, the RRB needs to determine if a valid marriage existed between a spouse or widow(er) annuity applicant and a railroad employee. The RRB

utilizes Forms G–124, Individual Statement of Marital Relationship; G–124a, Certification of Marriage Information; G–237, Statement Regarding Marital Status; G–238, Statement of Residence; and G–238a, Statement Regarding Divorce or Annulment, to secure the needed information. One response is requested of each respondent. Completion is required to obtain benefits. The RRB proposes minor non-burden impacting changes to the forms in the collection.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

[The estimated annual respondent burden is as follows]

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–124 (in person)	125	15	31
G–124 (by mail)	75	20	25
G–124a	300	10	50
G–237 (in person)	75	15	19
G–237 (by mail)	75	20	25
G–238 (in person)	150	3	8
G–238 (by mail)	150	5	13
G–238a	150	10	25
Total	1,100		196

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.* Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or emailed to *Charles.Mierzwa@RRB.GOV.* Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2013–00613 Filed 1–14–13; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–30347; 812–14094]

J.P. Morgan Securities LLC, et al.; Notice of Application and Temporary Order

January 9, 2013.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Temporary order and notice of application for a permanent order under section 9(c) of the Investment Company Act of 1940 (''Act'').

SUMMARY OF APPLICATION: Applicants have received a temporary order exempting them from section 9(a) of the Act, with respect to an injunction entered against J.P. Morgan Securities LLC (''JPMS''), EMC Mortgage, LLC (''EMC''), Bear Stearns Asset Backed Securities I, LLC (''BSABS''), Structured Asset Mortgage Investments II, Inc. (''SAMI''), SACO I Inc. (''SACO'') and J.P. Morgan Acceptance Corporation I (''JPMAC'') (together, the ''Defendants'') on January 8, 2013, by the United States District Court for the District of Columbia (''Injunction'') until the Commission takes final action on an application for a permanent order. Applicants also have applied for a permanent order.

APPLICANTS: JPMS, EMC, BSABS, SAMI, SACO, JPMAC, Bear Stearns Asset Management Inc. (''BSAM''), Bear Stearns Health Innoventures Management, L.L.C. (''BSHIM''), BSCGP Inc. (''BSGCP''), Constellation Growth Capital LLC (''Constellation''), Constellation Ventures Management II, LLC (''Constellation II''), Highbridge Capital Management, LLC (''Highbridge''), JF International Management Inc. (''JFIMI''), JPMorgan Distribution Services, Inc. (''JPMDS''), J.P. Morgan Institutional Investments, Inc. (''JPMII''), J.P. Morgan Investment Management Inc. (''JPMIM''), J.P. Morgan Partners, LLC (''JPMP''), J.P. Morgan Private Investments Inc. (''JPMPI''), OEP Co-Investors Management II, Ltd. (''OEP II''), OEP Co-Investors Management III, Ltd. (''OEP III,'' and together with OEP II, the ''OEP Entities''), Security Capital Research & Management Incorporated (''Security Capital''), Sixty Wall Street GP Corporation (''Sixty Wall GP'') and Sixty Wall Street Management Company, LLC (''Sixty Wall Management'') (each an ''Applicant'' and collectively, the ''Applicants'').[1]

FILING DATE: The application was filed on November 16, 2012, and amended on January 8, 2013.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 4, 2013, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Elizabeth M. Murphy, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: JPMS, BSABS, SAMI, SACO and JPMAC, 383 Madison Avenue, New York, NY 10179; EMC, 2780 Lake Vista Drive, Lewisville, TX 75067; BSAM, BSHIM, BSCGP, Constellation II, JPMII, JPMIM, JPMP, JPMPI, Sixty Wall GP and Sixty Wall Management, 270 Park Avenue, New York, NY 10017; Constellation and Highbridge, 40 West 57th Street, 32nd Floor, New York, NY 10019; JFIMI, 21st Floor, Chater House, 8 Connaught Road Central, Hong Kong; JPMDS, 1111 Polaris Parkway, Columbus, OH 43240; OEP Entities, 320 Park Avenue, 18th Floor, New York, NY

[1] Applicants request that any relief granted pursuant to the application also apply to any other company of which any Defendant is or may become an affiliated person within the meaning of section 2(a)(3) of the Act (together with the Applicants, the ''Covered Persons'').

10022; and Security Capital, 10 South Dearborn Street, Suite 1400, Chicago, IL 60603.

FOR FURTHER INFORMATION CONTACT: Jaea F. Hahn, Senior Counsel, at 202–551–6870 or Janet M. Grossnickle, Assistant Director, at 202–551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a temporary order and summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm,* or by calling (202) 551–8090.

Applicants' Representations

1. JPMS, a limited liability company organized under the laws of Delaware, is registered as a broker-dealer under the Securities Exchange Act of 1934, as amended (the ''Exchange Act'') and is registered as an investment adviser under the Investment Advisers Act of 1940, as amended (the ''Advisers Act''). EMC and BSABS are each Delaware limited liability companies; neither is registered as a broker-dealer under the Exchange Act or as an investment adviser under the Advisers Act. SAMI, SACO and JPMAC are each Delaware corporations, none of which is registered as a broker-dealer under the Exchange Act or as an investment adviser under the Advisers Act. The Defendants do not currently serve as investment adviser, sub-adviser, or depositor of any registered investment company, or principal underwriter for any registered open-end investment company, registered unit investment trust (''UIT'') or registered face amount certificate company, or investment adviser of any employees' securities company, as defined in section 2(a)(13) of the Act (''ESC'') (''Fund Service Activities,'' and the Applicants that do serve in such capacities, ''Fund Servicing Applicants''). ''Funds'' refers to the registered investment companies or ESCs for which a Covered Person provides Fund Service Activities.

2. The ultimate parent of each Defendant is J.P. Morgan Chase & Co. (''JPMC''). JPMC is a financial services holding company whose businesses provide a broad range of financial services to consumer and corporate customers. JPMC is also the ultimate parent of each of the Fund Servicing Applicants, who, as majority-owned and wholly-owned subsidiaries of the same ultimate parent, are under common control with the Defendants.

3. BSAM is registered as an investment adviser under the Advisers Act and serves as investment adviser or sub-adviser to various Funds, including as a general partner that provides investment advisory services to various ESCs, which provide investment opportunities for highly compensated key employees, officer, directors and current consultants of JPMC and its affiliates.[2] BSHIM, BSCGP, Constellation II and the OEP Entities also serve as general partners that provide investment advisory services to various ESCs. Constellation serves as a sub-adviser to various ESCs. Highbridge, JFIMI, JPMIM, JPMPI, and Security Capital are registered as investment advisers under the Advisers Act and serve as investment advisers or sub-advisers to various Funds. JPMP, Sixty Wall GP, Sixty Wall Management are registered as investment advisers under the Advisers Act and serve as investment advisers or sub-advisers to ESCs. JPMDS is registered as a broker-dealer under the Exchange Act and serves as principal underwriter to various Funds. JPMII is registered as a broker-dealer under the Exchange Act and serves as placement agent to various Funds.[3]

4. On January 8, 2013, the United States District Court for the District of Columbia entered a judgment, which included the Injunction, against the Defendants (''Judgment'') in a matter brought by the Commission.[4] The Commission alleged in the complaint (''Complaint'') that the Defendants violated Sections 17(a)(2) and (3) of the Securities Act of 1933 in connection with alleged false and misleading disclosures involving offerings of certain residential mortgage-backed securities (''RMBS''). Without admitting or denying any of the allegations in the Complaint (other than those relating to the jurisdiction of the District Court over it and the subject matter, solely for purposes of this action), the Defendants consented to the entry of the Injunction and other relief, including disgorgement, prejudgment interest, and civil monetary penalties.

Applicants' Legal Analysis

1. Section 9(a)(2) of the Act, in relevant part, prohibits a person who has been enjoined from engaging in or continuing any conduct or practice in connection with the purchase or sale of a security, or in connection with activities as an underwriter, broker or dealer, from acting, among other things, as an investment adviser or depositor of any registered investment company or a principal underwriter for any registered open-end investment company, registered UIT, or registered face-amount certificate company or as investment adviser of an ESC. Section 9(a)(3) of the Act makes the prohibition in section 9(a)(2) applicable to a company, any affiliated person of which has been disqualified under the provisions of section 9(a)(2). Section 2(a)(3) of the Act defines ''affiliated person'' to include, among others, any person directly or indirectly controlling, controlled by, or under common control, with the other person. Applicants state that the Defendants are affiliated persons of each of the other Applicants within the meaning of section 2(a)(3) of the Act. Applicants state that, as a result of the Injunction, they would be subject to the prohibitions of section 9(a) of the Act.

2. Section 9(c) of the Act provides that the Commission shall grant an application for exemption from the disqualification provisions of section 9(a) of the Act if it is established that these provisions, as applied to the Applicants, are unduly or disproportionately severe or that the conduct of the Applicants has been such as not to make it against the public interest or the protection of investors to grant the exemption. Applicants have filed an application pursuant to section 9(c) seeking a temporary and permanent order exempting them and other Covered Persons from the disqualification provisions of section 9(a).

3. Applicants believe they meet the standard for exemption specified in section 9(c). Applicants state that the prohibitions of section 9(a) as applied to them would be unduly and disproportionately severe and that the conduct of the Applicants has been such as not to make it against the public interest or the protection of investors to grant the exemption from section 9(a).

4. Applicants state that the alleged conduct giving rise to the Injunction did not involve any of the Applicants

[2] Every Applicant that is a general partner that provides investment advisory services to one or more ESCs believes, for purposes of the application, that it is performing a function that falls within the definition of ''investment adviser'' in section 2(a)(20) of the Act.

[3] JPMII serves as placement agent to JPMorgan Institutional Trust (''Trust'') with respect to three of its series. The Trust is an open-end investment company registered under the Act, but its shares are not registered under the Securities Act of 1933, as amended. JPMII believes, for purposes of the application, that it is performing a function that falls within the definition of principal underwriter in section 2(a)(29) of the Act.

[4] *U.S. Securities and Exchange Commission* v. *J.P. Morgan Securities LLC, EMC Mortgage, LLC, Bear Stearns Asset Backed Securities I, LLC, Structured Asset Mortgage Investments II, Inc., SACO I Inc., and J.P. Morgan Acceptance Corporation I,* Case No. 1:12–cv–01862–RLW (D.D.C. Jan. 8, 2013).

engaging in Fund Service Activities. Applicants also state to the best of their knowledge (i) none of the current directors, officers, or employees of the Applicants (other than the Defendants) that are involved in providing Fund Service Activities (or any other persons in such roles during the time period covered by the Complaint) participated in the conduct alleged in the Complaint to have constituted the violations that provide a basis for the Injunction; and (ii) the personnel at the Defendants who participated in the conduct alleged in the Complaint to have constituted the violations that provide a basis for the Injunction have had no, and will not have any, involvement in providing Fund Service Activities to the Funds on behalf of the Applicants or other Covered Persons.

5. Applicants state that the inability of the Applicants to engage in Fund Service Activities would result in potentially severe financial hardships for the Funds they serve and the Funds' shareholders or unitholders. Applicants state that they will distribute written materials, including an offer to meet in person to discuss the materials, to the boards of directors of the Funds (excluding for this purpose the ESCs) (the ''Boards''), including the directors who are not ''interested persons,'' as defined in section 2(a)(19) of the Act, of such Funds, and their independent legal counsel as defined in rule 0–1(a)(6) under the Act, if any, describing the circumstances that led to the Injunction, any impact on the Funds,[5] and the application. Applicants state that they will provide the Boards with the information concerning the Injunction and the application that is necessary for the Funds to fulfill their disclosure and other obligations under the federal securities laws.

6. Applicants also state that, if they were barred from providing Fund Service Activities to registered investment companies and ESCs, the effect on their businesses and employees would be severe. Applicants state that they have committed substantial resources to establish an expertise in providing Fund Service Activities. Applicants further state that prohibiting them from providing Fund Service Activities would not only adversely affect their businesses, but would also adversely affect approximately 940 employees that are involved in those activities. Applicants also state that disqualifying certain Applicants from continuing to provide investment advisory services to ESCs is not in the public interest or in furtherance of the protection of investors. Because the ESCs have been formed for the benefit of key employees, officers and directors of JPMC and its affiliates, it would not be consistent with the purposes of the ESC provisions of the Act or the terms and conditions of the ESC orders to require another entity not affiliated with JPMC to manage the ESCs. In addition, participating employees of JPMC and its affiliates likely subscribed for interests in the ESCs with the expectation that the ESCs would be managed by an affiliate of JPMC.

7. Applicants state that Applicants and certain other affiliated persons of the Applicants have previously received orders under section 9(c) of the Act, as the result of conduct that triggered section 9(a), as described in greater detail in the application.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Any temporary exemption granted pursuant to the application shall be without prejudice to, and shall not limit the Commission's rights in any manner with respect to, any Commission investigation of, or administrative proceedings involving or against, Covered Persons, including without limitation, the consideration by the Commission of a permanent exemption from section 9(a) of the Act requested pursuant to the application or the revocation or removal of any temporary exemptions granted under the Act in connection with the application.

Temporary Order

The Commission has considered the matter and finds that the Applicants have made the necessary showing to justify granting a temporary exemption.

Accordingly,

It is hereby ordered, pursuant to section 9(c) of the Act, that Applicants and any other Covered Persons are granted a temporary exemption from the provisions of section 9(a), solely with respect to the Injunction, subject to the condition in the application, from January 8, 2013, until the Commission takes final action on their application for a permanent order.

By the Commission.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00660 Filed 1–14–13; 8:45 am]

BILLING CODE 8011–01–P

[5] Applicants state that several Funds may have owned certain series of the RMBS which are the subject of the Injunction. Applicants further state that these RMBS were acquired from unaffiliated parties, generally in secondary market transactions. To the extent that any of these Funds suffered losses from their investment in the RMBS, the Funds will be able to participate in the Fair Fund to the extent available to any other investor.

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30346; 812–13486]

Exchange Traded Spreads Trust, et al.; Notice of Application

January 9, 2013.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and (B) of the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (2) of the Act.

Applicants: ETSpreads, LLC (''Adviser''), Exchange Traded Spreads Trust (''Trust''), and ALPS Distributors, Inc. (''Distributor'').

SUMMARY: *Summary of Application:* Applicants request an order that permits: (a) Actively-managed series of the Trust to issue shares (''Shares'') redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Shares to occur at negotiated market prices; (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days after the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; and (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares.

DATES: *Filing Dates:* The application was filed on January 30, 2008, and amended on July 30, 2008, April 28, 2011, December 18, 2012, and January 9, 2013.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission

by 5:30 p.m. on February 4, 2013, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. Applicants, Stephen C. Rogers, ETSpreads, LLC, 44 Montgomery Street, Suite 2100, San Francisco, CA 94104.

FOR FURTHER INFORMATION CONTACT: David J. Marcinkus, Attorney-Advisor, at (202) 551–6882 or David P. Bartels, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is registered as an open-end management investment company under the Act and is organized as a Delaware statutory trust. The Trust will initially offer four series, ETSpreads High Yield Tighten Fund, ETSpreads High Yield Widen Fund, ETSpreads High Yield Investment Grade Tighten Fund, and ETSpreads High Yield Investment Grade Widen Fund (together, the ''Initial Funds''). The investment objective of each Initial Fund will be to seek capital appreciation.

2. The Adviser, a California limited liability company, is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''), and will serve as investment adviser to the Initial Funds. A Fund may engage one or more sub-advisers (''Sub-Advisers'') to manage specific strategies suited to their expertise. Any Sub-Adviser will be registered, or not subject to registration, under the Advisers Act. The Distributor, a Delaware corporation, is registered as a broker-dealer (''Broker) under the Securities Exchange Act of 1934 (''Exchange Act'') and will serve as the principal underwriter and distributor for each of the Funds.

3. Applicants request that the order apply to the Initial Funds, any future series of the Trust and to any other open-end investment company or series thereof that is an actively managed exchange-traded fund (''ETF'') and (a) is advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser [1] and (b) complies with the terms and conditions of the application (collectively, ''Future Funds,'' and together with the Initial Funds, the ''Funds'').[2] The Funds may invest in equity securities (''Equity Funds'') or fixed income securities (''Fixed Income Funds'') traded in the U.S. or non-U.S. markets. The Equity Funds that invest in equity securities traded in the U.S. market (''Domestic Equity Funds''), Fixed Income Funds that invest in fixed income securities traded in the U.S. market (''Domestic Fixed Income Funds'') and Funds that invest in equity and fixed income securities traded in the U.S. market (''Domestic Blend Funds'') together are ''Domestic Funds.'' Funds that invest in foreign and domestic equity securities are ''Global Equity Funds.'' Funds that invest in foreign and domestic fixed income securities are ''Global Fixed Income Funds.'' Funds that invest in equity securities and fixed income securities traded in the U.S. or non-U.S. markets are ''Global Blend Funds'' (and collectively with the Global Equity Funds and Global Fixed Income Funds, ''Global Funds''). Funds that invest solely in foreign equity securities are ''Foreign Equity Funds'', Funds that invest solely in foreign fixed income securities are ''Foreign Fixed Income Funds'' and Funds that invest solely in foreign equity and foreign fixed income securities are ''Foreign Blend Funds'' (and collectively with Foreign Equity Funds and Foreign Fixed Income Funds, ''Foreign Funds''). The Funds may also invest in ''Depositary Receipts.'' [3] If a Fund invests in derivatives, then (a) the Fund's board of directors or trustees (''Board'') will periodically review and approve the Fund's use of derivatives and how the Adviser assesses and manages risk with respect to the Fund's use of derivatives and (b) the Fund's disclosure of its use of derivatives in its offering documents and periodic reports will be consistent with relevant Commission and staff guidance. Each Fund will consist of a portfolio of securities (including equity and fixed income securities), currencies traded in the U.S. or in non-U.S. markets, derivatives, other assets and other investment positions (''Portfolio Instruments'').

4. Applicants also request that any exemption under section 12(d)(1)(J) of the Act from sections 12(d)(1)(A) and (B) apply to: (i) Any Fund that is currently or subsequently part of the same ''group of investment companies'' as an Initial Fund within the meaning of section 12(d)(1)(G)(ii) of the Act; (ii) any principal underwriter for the Fund; (iii) any Brokers selling Shares of a Fund to an Investing Fund (defined below); and (iv) each management investment company or unit investment trust registered under the Act that is not part of the same ''group of investment companies'' as the Fund within the meaning of section 12(d)(1)(G)(ii) of the Act and that enters into a FOF Participation Agreement (defined below) with the Fund (such management investment companies, ''Investing Management Companies,'' such unit investment trusts, ''Investing Trusts,'' and Investing Management Companies and Investing Trusts together are ''Investing Funds''). Investing Funds do not include the Funds.[4]

5. Applicants anticipate that a Creation Unit will consist of at least 25,000 Shares and that the trading price of a Share will range from $20 to $200. All orders to purchase Creation Units must be placed with the Distributor by or through an ''Authorized Participant,'' which is either (a) a Broker or other participant in the Continuous Net Settlement System of the National Securities Clearing Corporation (''NSCC'', and such process the ''NSCC Process''), or (b) a participant in the Depository Trust Company (''DTC,'' such participant ''DTC Participant'' and such process the ''DTC Process''), which, in either case, has executed an agreement with the Distributor with respect to the purchase and redemption of Creation Units

6. Shares will be purchased and redeemed in Creation Units. The Initial Funds will generally sell Creation Units

[1] Any such advisory entity will be registered as an investment adviser under the Advisers Act.

[2] All entities that currently intend to rely on the order are named as applicants. Any entity that relies on the order in the future will comply with the terms and conditions of the application.

[3] Depositary Receipts are typically issued by a financial institution (a ''Depositary'') and evidence ownership in a security or pool of securities that have been deposited by the Depositary. A Fund will not invest in any Depositary Receipts that the Adviser deems to be illiquid or for which pricing information is not readily available. No affiliated persons of applicants or any Sub-Adviser will serve as the Depositary for any Depositary Receipts held by a Fund.

[4] An Investing Fund may rely on the order only to invest in a Fund and not in any other registered investment company.

entirely for cash to the extent permissible under the procedures described below and will generally redeem Creation Units in-kind. In the case of in-kind purchases and redemptions of Creation Units, purchasers will be required to purchase Creation Units by making an in-kind deposit of specified instruments (''Deposit Instruments''), and shareholders redeeming their Shares will receive an in-kind transfer of specified instruments (''Redemption Instruments'').[5] On any given Business Day[6] the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will be identical, and these instruments may be referred to, in the case of either a purchase or a redemption, as the ''Creation Basket.'' In addition, the Creation Basket will correspond pro rata to the positions in a Fund's portfolio (including cash positions)[7], except: (a) In the case of bonds, for minor differences when it is impossible to break up bonds beyond certain minimum sizes needed for transfer and settlement; (b) for minor differences when rounding is necessary to eliminate fractional shares or lots that are not tradeable round lots;[8] or (c) TBA Transactions[9] and other positions that cannot be transferred in kind[10] will be excluded from the Creation Basket.[11] If there is a difference between the net asset value (''NAV'') attributable to a Creation Unit and the aggregate market value of the Creation Basket exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the ''Cash Amount'').

7. Purchases and redemptions of Creation Units may be made in whole or in part on a cash basis, rather than in kind, solely under the following circumstances: (a) To the extent there is a Cash Amount, as described above; (b) if, on a given Business Day, a Fund announces before the open of trading that all purchases, all redemptions or all purchases and redemptions on that day will be made entirely in cash; (c) if, upon receiving a purchase or redemption order from an Authorized Participant, a Fund determines to require the purchase or redemption, as applicable, to be made entirely in cash; (d) if, on a given Business Day, a Fund requires all Authorized Participants purchasing or redeeming Shares on that day to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) such instruments are not eligible for transfer through either the NSCC Process or DTC Process; or (ii) in the case of Global Funds and Foreign Funds, such instruments are not eligible for trading due to local trading restrictions, local restrictions on securities transfers or other similar circumstances; or (e) if a Fund permits an Authorized Participant to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are, in the case of the purchase of a Creation Unit, not available in sufficient quantity; (ii) such instruments are not eligible for trading by an Authorized Participant or the investor on whose behalf the Authorized Participant is acting; or (iii) a holder of Shares of a Global Fund or Foreign Fund would be subject to unfavorable income tax treatment if the holder receives redemption proceeds in kind.[12]

8. Each Business Day, before the open of trading on a national securities exchange, as defined in section 2(a)(26) of the Act (''Listing Market''), on which Shares are listed and traded, each Fund will cause to be published through the NSCC the names and quantities of the instruments comprising the Creation Basket, as well as the estimated Cash Amount (if any), for that day. The published Creation Basket will apply until a new Creation Basket is announced on the following Business Day, and there will be no intra-day changes to the Creation Basket except to correct errors in the published Creation Basket. A Listing Market will disseminate every 15 seconds throughout the trading day an amount representing, on a per Share basis, the sum of the current value of the Deposit Instruments and the estimated Cash Amount.

9. An investor purchasing or redeeming a Creation Unit from a Fund will be charged a fee (''Transaction Fee'') to prevent the dilution of the interests of the remaining shareholders resulting from costs in connection with the purchase or sale of Creation Units.[13] All orders to purchase Creation Units must be placed with the Distributor by or through an Authorized Participant and the Distributor will transmit such orders to the Funds. The Distributor will be responsible for maintaining records of both the orders placed with it and the confirmations of acceptance furnished by it.

10. Purchasers of Shares in Creation Units may hold such Shares or may sell such Shares into the secondary market. Shares will be listed and traded at negotiated prices on a Listing Market. The principal secondary market for Shares will be the Listing Market on which the Shares are listed and traded (the ''Primary Listing Exchange''). When the NYSE Arca, Inc. (''NYSE Arca'') is the Primary Listing Exchange, it is expected that one or more NYSE Arca member firms will be designated by the Listing Market to act as a market maker (a ''Market Maker'').[14] The price of Shares trading on a Listing Market will be based on a current bid-offer in the secondary market. Purchases and sales of Shares in the secondary market will

[5] The Funds must comply with the federal securities laws in accepting Deposit Instruments and satisfying redemptions with Redemption Instruments, including that the Deposit Instruments and Redemption Instruments are sold in transactions that would be exempt from registration under the Securities Act of 1933 (''Securities Act''). In accepting Deposit Instruments and satisfying redemptions with Redemption Instruments that are restricted securities eligible for resale pursuant to Rule 144A under the Securities Act, the Funds will comply with the conditions of Rule 144A.

[6] Each Fund will sell and redeem Creation Units on any day the Fund is open, including as required by section 22(e) of the Act (each, a ''Business Day'').

[7] The portfolio used for this purpose will be the same portfolio used to calculate the Fund's NAV for that Business Day.

[8] A tradeable round lot for a security will be the standard unit of trading in that particular type of security in its primary market.

[9] A TBA Transaction is a method of trading mortgage-backed securities. In a TBA Transaction, the buyer and seller agree on general trade parameters such as agency, settlement date, par amount and price.

[10] This includes instruments that can be transferred in kind only with the consent of the original counterparty to the extent the Fund does not intend to seek such consents.

[11] Because these instruments will be excluded from the Creation Basket, their value will be reflected in the determination of the Cash Amount (defined below).

[12] A ''custom order'' is any purchase or redemption of Shares made in whole or in part on a cash basis in reliance on clause (e)(i) or (e)(ii).

[13] Cash purchases and redemptions of Shares may involve a higher Transaction Fee to cover the costs of purchasing and selling the applicable Deposit and Redemption Instruments. In all cases, the Transaction Fee will be limited in accordance with requirements of the Commission applicable to management investment companies offering redeemable securities.

[14] If Shares are listed on The NASDAQ Stock Market LLC (''Nasdaq'') or a similar electronic Listing Market (including NYSE Arca), one or more member firms of that Listing Market will act as Market Maker and maintain a market for Shares trading on that Listing Market. On Nasdaq, no particular Market Maker would be contractually obligated to make a market in Shares. However, the listing requirements on Nasdaq stipulate that at least two Market Makers must be registered in Shares to maintain a listing. Registered Market Makers are required to make a continuous two-sided market or subject themselves to regulatory sanctions. No Market Maker will be an affiliated person, or an affiliated person of an affiliated person, of the Funds, except within the meaning of section 2(a)(3)(A) or (C) of the Act due solely to ownership of Shares.

not involve a Fund and will be subject to customary brokerage commissions and charges.

11. Applicants expect that purchasers of Creation Units will include institutional investors and arbitrageurs. Market Makers, in providing a fair and orderly secondary market for Shares, also may purchase Creation Units for use in their own market making activities. Applicants expect that secondary market purchasers of Shares will include both institutional and retail investors.[15] Applicants believe that the structure and operation of the Funds will be designed to enable efficient arbitrage and, thereby, minimize the probability that Shares will trade at a material premium or discount to a Fund's NAV.

12. Shares will not be individually redeemable and owners of Shares may acquire those Shares from a Fund, or tender such shares for redemption to the Fund, in Creation Units only. To redeem, an investor must accumulate enough Shares to constitute a Creation Unit. Redemption requests must be placed by or through an Authorized Participant. As discussed above, redemptions of Creation Units will generally be made on an in-kind basis, subject to certain specified exceptions under which redemptions may be made in whole or in part on a cash basis, and will be subject to a Transaction Fee.[16]

13. Neither the Trust nor any Fund will be advertised or marketed or otherwise held out as a traditional open-end investment company or mutual fund. Instead, each Fund will be marketed as an ''actively managed exchange-traded fund.'' All marketing materials that describe the features or method of obtaining, buying, or selling Creation Units, or Shares traded on a Listing Market, or refer to redeemability, will prominently disclose that Shares are not individually redeemable and that the owners of Shares may acquire those Shares from a Fund or tender those Shares for redemption to the Fund in Creation Units only.

14. The Trust's Web site (''Web site''), which will be publicly available prior to the public offering of Shares, will include each Fund's prospectus (''Prospectus'') and/or Summary Prospectus, and Statement of Additional Information (''SAI''). The Web site will contain, on a per Share basis for each Fund, the prior Business Day's NAV and the market closing price or mid-point of the bid/ask spread at the time of calculation of such NAV (''Bid/Ask Price''), and a calculation of the premium or discount of the market closing price or the Bid/Ask Price against such NAV. On each Business Day, prior to the commencement of trading in Shares on a Listing Market, the Adviser shall post on the Web site the identities and quantities of the Portfolio Instruments held by each Fund that will form the basis for the calculation of the NAV at the end of that Business Day.[17]

Applicants' Legal Analysis

1. Applicants request an order under section 6(c) of the Act granting an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act; and under sections 6(c) and 17(b) of the Act granting an exemption from sections 17(a)(1) and (2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and (B) of the Act.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an ''open-end company'' as a management investment company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the holder, upon its presentation to the issuer, is entitled to receive approximately a proportionate share of the issuer's current net assets, or the cash equivalent. Because Shares will not be individually redeemable, applicants request an order that would permit the Trust and each Fund to redeem Shares in Creation Units only. Applicants state that investors may purchase Shares in Creation Units from each Fund and that Creation Units will always be redeemable in accordance with the provisions of the Act. Applicants further state that because the market price of Shares will be disciplined by arbitrage opportunities, investors should be able to sell Shares in the secondary market at prices that do not vary substantially from their NAV.

Section 22(d) of the Act and Rule 22c–1 under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security that is currently being offered to the public by or through a principal underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming, or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in Shares will take place at negotiated prices, not at a current offering price described in the Prospectus, and not at a price based on NAV. Thus, purchases and sales of Shares in the secondary market will not comply with section 22(d) of the Act and rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.

5. Applicants assert that the concerns sought to be addressed by section 22(d) of the Act and rule 22c–1 under the Act with respect to pricing are equally satisfied by the proposed method of pricing Shares. Applicants maintain that, while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been designed to (a) prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers resulting from sales at different prices, and (c) assure an orderly distribution of

[15] Shares will be registered in book-entry form only. DTC or its nominee will be the registered owner of all outstanding Shares. Beneficial ownership of Shares will be shown on the records of DTC or DTC Participants.

[16] *See* supra note 11.

[17] Under accounting procedures followed by each Fund, trades made on the prior Business Day (''T'') will be booked and reflected in NAV on the current Business Day (T + 1). Accordingly, the Funds will be able to disclose at the beginning of the Business Day the portfolio that will form the basis for the NAV calculation at the end of the Business Day.

investment company shares by eliminating price competition from brokers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

6. Applicants believe that none of these purposes will be thwarted by permitting Shares to trade in the secondary market at negotiated prices. Applicants state that (a) secondary market trading in Shares does not involve the Funds as parties and cannot result in dilution of an investment in Shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in Shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants contend that the proposed distribution system will be orderly because arbitrage activity will ensure that the difference between the market price of Shares and their NAV remains narrow.

Section 22(e) of the Act

7. Section 22(e) generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants observe that the settlement of redemptions of Creation Units of the Foreign and Global Funds is contingent not only on the settlement cycle of the U.S. securities markets but also on the delivery cycles present in foreign markets for underlying foreign Portfolio Instruments in which those Funds invest. Applicants have been advised that, under certain circumstances, the delivery cycles for transferring Portfolio Instruments to redeeming investors, coupled with local market holiday schedules, will require a delivery process of up to fourteen (14) calendar days. Applicants therefore request relief from section 22(e) in order to provide payment or satisfaction of redemptions within a longer number of calendar days as required for such payment or satisfaction in the principal local markets where transactions in the Portfolio Instruments of each Foreign and Global Fund customarily clear and settle, but in all cases no later than fourteen (14) days following the tender of a Creation Unit.[18]

8. Applicants state that section 22(e) was designed to prevent unreasonable, undisclosed and unforeseen delays in the actual payment of redemption proceeds. Applicants assert that the requested relief will not lead to the problems that section 22(e) was designed to prevent. Applicants state that the Prospectus and/or SAI will identify those instances in a given year where, due to local holidays, more than seven calendar days, up to a maximum of fourteen calendar days, will be needed to deliver redemption proceeds and will list such holidays. Applicants are not seeking relief from section 22(e) for Foreign and Global Funds that do not effect redemptions of Creation Units in-kind.

Section 12(d)(1) of the Act

9. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring shares of an investment company if the securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter, or any other broker or dealer from selling its shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by investment companies generally.

10. Applicants request relief to permit Investing Funds to acquire Shares in excess of the limits in section 12(d)(1)(A) of the Act and to permit the Funds, their principal underwriters and any Broker to sell Shares to Investing Funds in excess of the limits in section 12(d)(l)(B) of the Act.

11. Applicants assert that the proposed transactions will not lead to any of the abuses that section 12(d)(1) was designed to prevent. Applicants submit that the proposed conditions to the requested relief address the concerns underlying the limits in section 12(d)(1), which include concerns about undue influence, excessive layering of fees and overly complex structures.

12. Applicants submit that their proposed conditions address any concerns regarding the potential for undue influence. To limit the control that an Investing Fund may have over a Fund, applicants propose a condition prohibiting the adviser of an Investing Management Company (''Investing Fund Adviser''), sponsor of an Investing Trust (''Sponsor''), any person controlling, controlled by, or under common control with the Investing Fund Adviser or Sponsor, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by the Investing Fund Adviser, the Sponsor, or any person controlling, controlled by, or under common control with the Investing Fund Adviser or Sponsor (''Investing Fund's Advisory Group'') from controlling (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any sub-adviser to an Investing Fund (''Investing Fund Sub-Adviser''), any person controlling, controlled by or under common control with the Investing Fund Sub-Adviser, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Investing Fund Sub-Adviser or any person controlling, controlled by or under common control with the Investing Fund Sub-Adviser (''Investing Fund's Sub-Advisory Group'').

13. Applicants propose a condition to ensure that no Investing Fund or Investing Fund Affiliate[19] (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in an offering of securities during the existence of an underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate (''Affiliated Underwriting''). An ''Underwriting Affiliate'' is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Investing Fund Adviser, Investing Fund Sub-Adviser, employee or Sponsor of the Investing Fund, or a person of which any such officer, director, member of an advisory board, Investing Fund Adviser, Investing Fund Sub-Adviser, employee

[18] Rule 15c6–1 under the Exchange Act requires that most securities transactions be settled within three business days of the trade. Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations applicants may have under rule 15c6–1.

[19] An ''Investing Fund Affiliate'' is any Investing Fund Adviser, Investing Fund Sub-Adviser, Sponsor, promoter and principal underwriter of an Investing Fund, and any person controlling, controlled by or under common control with any of these entities. ''Fund Affiliate'' is an investment adviser, promoter, or principal underwriter of a Fund or any person controlling, controlled by or under common control with any of these entities.

or Sponsor is an affiliated person (except any person whose relationship to the Fund is covered by section 10(f) of the Act is not an Underwriting Affiliate).

14. Applicants propose several conditions to address the potential for layering of fees. Applicants note that the Board of any Investing Management Company, including a majority of the directors or trustees who are not ''interested persons'' within the meaning of section 2(a)(19) of the Act (''disinterested directors or trustees''), will be required to find that the advisory fees charged under the contract are based on services provided that will be in addition to, rather than duplicative of, services provided under the advisory contract of any Fund in which the Investing Management Company may invest. Applicants also state that any sales charges and/or service fees charged with respect to shares of an Investing Fund will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.[20]

15. Applicants submit that the proposed arrangement will not create an overly complex fund structure. Applicants note that a Fund will be prohibited from acquiring securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Fund to purchase shares of other investment companies for short-term cash management purposes.

16. To ensure that an Investing Fund is aware of the terms and conditions of the requested order, the Investing Funds must enter into an agreement with the respective Funds (''FOF Participation Agreement''). The FOF Participation Agreement will include an acknowledgement from the Investing Fund that it may rely on the order only to invest in a Fund and not in any other investment company.

Section 17(a) of the Act

17. Section 17(a) of the Act generally prohibits an affiliated person of a registered investment company, or an affiliated person of such person (''Second Tier Affiliates''), from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines ''affiliated person'' to include any person directly or indirectly owning, controlling, or holding with power to vote 5% or more of the outstanding voting securities of the other person and any person directly or indirectly controlling, controlled by, or under common control with, the other person. Section 2(a)(9) of the Act provides that a control relationship will be presumed where one person owns more than 25% of another person's voting securities. The Funds may be deemed to be controlled by the Adviser or an entity controlling, controlled by or under common control with the Adviser and hence affiliated persons of each other. In addition, the Funds may be deemed to be under common control with any other registered investment company (or series thereof) advised by the Adviser or an entity controlling, controlled by or under common control with the Adviser (an ''Affiliated Fund'').

18. Applicants request an exemption under sections 6(c) and 17(b) of the Act from sections 17(a)(1) and 17(a)(2) of the Act to permit in-kind purchases and redemptions of Creation Units from the Funds by persons that are affiliated persons or Second Tier Affiliates of the Funds solely by virtue of one or more of the following: (a) Holding 5% or more, or more than 25%, of the Shares of the Trust of one or more Funds; (b) having an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25%, of the shares of one or more Affiliated Funds. Applicants also request an exemption in order to permit each Fund to sell Shares to and redeem Shares from, and engage in the transactions that would accompany such sales and redemptions with, any Investing Fund of which the Fund is an affiliated person or Second-Tier Affiliate.[21]

19. Applicants contend that no useful purpose would be served by prohibiting such affiliated persons or Second Tier Affiliates from acquiring or redeeming Creation Units through in-kind transactions. Both the deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions will be the same for all purchases and redemptions. Deposit Instruments and Redemptions Instruments will be valued in the same manner as the Portfolio Instruments held by the relevant Fund. Applicants thus believe that in-kind purchases and redemptions will not result in self-dealing or overreaching of the Fund.

20. Applicants also submit that the sale of Shares to and redemption of Shares from an Investing Fund satisfies the standards for relief under sections 17(b) and 6(c) of the Act. Applicants note that any consideration paid for the purchase or redemption of Creation Units directly from a Fund will be based on the NAV of the Fund.[22] The FOF Participation Agreement will require any Investing Fund that purchases Creation Units directly from a Fund to represent that the purchase will be in compliance with its investment restrictions and consistent with the investment policies set forth in its registration statement. Applicants also state that the proposed transactions are consistent with the general purposes of the Act and appropriate in the public interest.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

A. Actively Managed Exchange-Traded Fund Relief

1. As long as a Fund operates in reliance on the requested Order, the Shares of the Fund will be listed on a Listing Market.

2. Neither the Trust nor any Fund will be advertised or marketed as an open-end investment company or a mutual fund. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that Shares are not individually redeemable and that owners of the Shares may acquire Shares from a Fund and tender Shares for redemption to the Fund in Creation Units only.

[20] Any reference to NASD Conduct Rule 2830 includes any successor or replacement rule that may be adopted by the Financial Industry Regulatory Authority.

[21] Applicants anticipate that most Investing Funds will purchase Shares in the secondary market and will not purchase or redeem Creation Units directly from a Fund. Relief from section 17(a) is not required when an Investing Fund that is an affiliate or Second Tier Affiliate of a Fund purchases or sells Shares in the secondary market as such transactions are not principal transactions with the Fund. However, the requested relief would apply to direct sales of Shares in Creation Units by a Fund to an Investing Fund and redemptions of those Shares in Creation Units. The requested relief is intended to cover transactions that would accompany such sales and redemptions. Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an affiliated person, or an affiliated person of an affiliated person of an Investing Fund because the Adviser or an entity controlling, controlled by or under common control with the Adviser is also an investment adviser to that Investing Fund.

[22] Applicants acknowledge that the receipt of compensation by (a) an affiliated person of an Investing Fund, or an affiliated person of such person, for the purchase by the Investing Fund of Shares of a Fund or (b) an affiliated person of a Fund, or an affiliated person of such person, for the sale by the Fund of its Shares to an Investing Fund, may be prohibited by section 17(e)(1) of the Act. The FOF Participation Agreement also will include this acknowledgment.

3. The Web site, which is and will be publicly accessible at no charge, will contain, on a per Share basis for each Fund, the prior Business Day's NAV, the market closing price or the Bid/Ask Price, and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV.

4. On each Business Day, before commencement of trading in Shares on a Listing Market, each Fund will disclose on the Web site the identities and quantities of the Portfolio Instruments held by the Fund that will form the basis for the Fund's calculation of NAV at the end of that Business Day.

5. No Adviser or any Sub-Adviser, directly or indirectly, will cause any Authorized Participant (or any investor on whose behalf an Authorized Participant may transact with the Fund) to acquire any Deposit Instrument for a Fund through a transaction in which the Fund could not engage directly.

6. The requested order will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of actively managed ETFs.

B. Section 12(d)(1) Relief

1. The members of the Investing Fund's Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The members of the Investing Fund's Sub-Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding voting securities of a Fund, the Investing Fund's Advisory Group or the Investing Fund's Sub-Advisory Group, each in the aggregate, becomes a holder of more than 25 percent of the outstanding voting securities of a Fund, it will vote its Shares in the same proportion as the vote of all other holders of the Fund's Shares. This condition does not apply to the Investing Fund's Sub-Advisory Group with respect to a Fund for which the Investing Fund Sub-Adviser or a person controlling, controlled by or under common control with the Investing Fund Sub-Adviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

2. No Investing Fund or Investing Fund Affiliate will cause any existing or potential investment by the Investing Fund in a Fund to influence the terms of any services or transactions between the Investing Fund or an Investing Fund Affiliate and the Fund or a Fund Affiliate.

3. The Board of an Investing Management Company, including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to ensure that the Investing Fund Adviser and any Investing Fund Sub-Adviser are conducting the investment program of the Investing Management Company without taking into account any consideration received by the Investing Management Company or an Investing Fund Affiliate from a Fund or a Fund Affiliate in connection with any services or transactions.

4. Once an investment by an Investing Fund in the Shares of a Fund exceeds the limit in section l2(d)(1)(A)(i) of the Act, the board, including a majority of the disinterested board members, will determine that any consideration paid by the Fund to the Investing Fund or an Investing Fund Affiliate in connection with any services or transactions: (i) Is fair and reasonable in relation to the nature and quality of the services and benefits received by the Fund; (ii) is within the range of consideration that the Fund would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (iii) does not involve overreaching on the part of any person concerned. This condition does not apply with respect to any services or transactions between a Fund and its investment adviser(s), or any person controlling, controlled by or under common control with such investment adviser(s).

5. The Investing Fund Adviser, trustee or Sponsor, as applicable, will waive fees otherwise payable to it by the Investing Fund in an amount at least equal to any compensation (including fees received pursuant to any plan adopted under rule 12b–l under the Act) received from a Fund by the Investing Fund Adviser, trustee or Sponsor, or an affiliated person of the Investing Fund Adviser, trustee or Sponsor, other than any advisory fees paid to the Investing Fund Adviser, trustee or Sponsor, or its affiliated person by the Fund, in connection with the investment by the Investing Fund in the Fund. Any Investing Fund Sub-Adviser will waive fees otherwise payable to the Investing Fund Sub-Adviser, directly or indirectly, by the Investing Fund in an amount at least equal to any compensation received from a Fund by the Investing Fund Sub-Adviser, or an affiliated person of the Investing Fund Sub-Adviser, other than any advisory fees paid to the Investing Fund Sub-Adviser or its affiliated person by the Fund, in connection with any investment by the Investing Fund in the Fund made at the direction of the Investing Fund Sub-Adviser. In the event that the Investing Fund Sub-Adviser waives fees, the benefit of the waiver will be passed through to the Investing Fund.

6. No Investing Fund or Investing Fund Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in any Affiliated Underwriting.

7. The Board, including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to monitor any purchases of securities by a Fund in an Affiliated Underwriting, once an investment by an Investing Fund in the Shares of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment by the Investing Fund in the Fund. The Board will consider, among other things: (i) Whether the purchases were consistent with the investment objectives and policies of the Fund; (ii) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (iii) whether the amount of securities purchased by the Fund in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to assure that purchases of securities in Affiliated Underwritings are in the best interest of shareholders of a Fund.

8. Each Fund will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings once an investment by an Investing Fund in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate's members, the

terms of the purchase, and the information or materials upon which the determinations of the Board were made.

9. Before investing in Shares in excess of the limits in section 12(d)(1)(A), each Investing Fund and a Fund will execute a FOF Participation Agreement stating, without limitation, that their boards of directors or trustees and their investment adviser(s), their Sponsors or trustees, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in Shares in excess of the limit in section 12(d)(1)(A)(i), an Investing Fund will notify the Fund of the investment. At such time, the Investing Fund will also transmit to the Fund a list of each Investing Fund Affiliate and Underwriting Affiliate. The Investing Fund will notify the Fund of any changes to the list of names as soon as reasonably practicable after a change occurs. The Fund and the Investing Fund will maintain and preserve a copy of the order, the FOF Participation Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

10. Before approving any advisory contract under section 15 of the Act, the Board of each Investing Management Company, including a majority of the disinterested directors or trustees, will find that the advisory fees charged under such advisory contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract(s) of any Fund in which the Investing Management Company may invest. These findings and their basis will be recorded fully in the minute books of the appropriate Investing Management Company.

11. Any sales charges and/or service fees charged with respect to shares of an Investing Fund will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

12. No Fund will acquire securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Fund to purchase shares of other investment companies for short-term cash management purposes.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00681 Filed 1–14–13; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68602; File No. SR–OCC–2012–22]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Approving Proposed Rule Change To Clarify the Use of Certain Amounts Credited to the Liquidating Settlement Account To Settle Mark-to-Market Payments Arising From Stock Loan and Borrow Positions Carried in the Customers' Account

January 9, 2013.

I. Introduction

On November 13, 2012, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change SR–OCC–2012–22 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder.[2] The proposed rule change was published for comment in the **Federal Register** on November 30, 2012.[3] The Commission received no comment letters. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The purpose of the proposed rule changes is to eliminate potential ambiguity as to OCC's right to use margin and other amounts credited to the Liquidating Settlement Account pursuant to OCC Rule 1104 to settle mark-to-market payments arising from stock loan and borrow positions carried in the clearing member's customers' account even though such payments are required by OCC's Rules to be settled in the clearing member's firm account or its combined market makers' account. In addition, a proposed amendment to Rule 1104 provides that any proceeds from stock loan and borrow positions carried in the customers' account could be applied only to obligations arising in such account as is the case with margin assets deposited in respect of that account.

Background

OCC's By-Laws currently provide that stock loan and borrow positions (collectively, ''Stock Loan Positions'') may be carried at OCC in any eligible account of a clearing member, including the firm, market-maker, and customers' accounts. More specifically, under Section 5 of Articles XXI and XXIA of the OCC By-Laws, and notwithstanding the provisions of Section 3 of Article VI of the OCC By-Laws (requiring separation of firm and customer positions), clearing members have discretion as to which Stock Loan Positions may be carried in which eligible accounts, subject only to the clearing member's general representations under OCC Rules 2202(e) and 2202A(f) that the clearing member's participation in the lending and borrowing activity is in compliance with all applicable laws and regulations. However, Rules 2201(a) and 2201A(a) provide that a clearing member must designate either its firm account or its combined market-makers' account as the account to or from which all stock loan mark-to-market payments are to be made, regardless of the account in which particular Stock Loan Positions may be held.

OCC Rule 1104 generally provides that, upon suspension of a clearing member, OCC shall promptly liquidate, in the most orderly manner practicable, all margins deposited with OCC by such clearing member in all accounts (excluding securities held in a specific deposit or escrow deposit) and all of such clearing member's contributions to the clearing fund, subject to certain conditions. Under Rule 1104, in general, these and all other funds of the suspended clearing member subject to the control of OCC (except proceeds of segregated long positions, funds disposed of pursuant to Rules 1105 through 1107, and funds held in or payable to a segregated futures account) shall be credited by OCC to a special account, to be known as the Liquidating Settlement Account, in the name of the suspended clearing member, for the purposes specified in Chapter 11.

Under Rule 1104, therefore, in general, proceeds of all margin (other than margin held in segregated futures accounts) including margin in a clearing member's securities customers' account, are credited to the Liquidating Settlement Account. However, for purposes of administration of the liquidation, the margin does not lose its identity as being derived from the customers' account. Rules 2210 and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 68288 (November 26, 2012), 77 FR 71466 (November 30, 2012).

2210A (relating to the Stock Loan/Hedge Program and Market Loan Program, respectively) provide that net proceeds from, or amounts due in respect of, the termination of Stock Loan Positions shall be credited to or withdrawn from the Liquidating Settlement Account. The Liquidating Settlement Account will include any mark-to-market payments received that day. In addition, Rule 1104 provides that the proceeds from the liquidation of securities, or from drawing on letters of credit, held as margin in a restricted lien account (such as the customers' account) may be withdrawn and applied to the closing out of pending transactions, open positions, and exercised or matured contracts in such accounts pursuant to Rules 1105, 1106, and 1107, respectively.[4] To the extent that the proceeds derived from assets maintained in accounts subject to OCC's restricted lien exceed the proceeds used from such accounts for that purpose, such proceeds must be remitted by the Corporation to the suspended clearing member or its representative for distribution to the persons entitled thereto in accordance with applicable law.

Description of Rule Change

For the avoidance of doubt, OCC proposes to insert an interpretation indicating that when mark-to-market payments are owed with respect to Stock Loan Positions maintained in a clearing member's customers' account, proceeds of margin and unsegregated long positions, and all other amounts credited to the Liquidating Settlement Account in respect of the customers' account, may be used to satisfy the mark-to-market obligations arising from the Stock Loan Positions in such customers' account, even though such mark-to-market payments may settle in the clearing member's firm account or its combined market makers' account.

OCC's By-Laws clearly provide that Stock Loan Positions may be included in the customers' account and that such positions will be margined in that account along with positions in options and other cleared contracts in the account. It would therefore be inconsistent to conclude that margin required under OCC's Rules to be deposited in the customers' account to margin Stock Loan Positions cannot be used to settle mark-to-market payments in respect of those positions if the clearing member is suspended. OCC intends that the proposed rule changes are to eliminate any doubt in this regard.

In addition, as noted above, the liquidation rules for Stock Loan Positions in Rules 2210 and 2210A provide that any net proceeds of closing out Stock Loan Positions shall be credited to the Liquidating Settlement Account and that any net amounts payable in respect of such close-outs may be withdrawn from such account. However, Rule 1104 as currently drafted does not limit the use of proceeds of Stock Loan Positions carried in a restricted lien account to obligations arising from that restricted lien account as it does in the case of proceeds from a restricted lien account that are credited pursuant to Rules 1105 through 1107. While such a restriction might be implied from the fact that the Stock Loan Positions themselves are subject to a restricted lien and not a general lien pursuant to Section 3(e) of Article VI of the By-Laws, OCC believes that Rule 1104 should be amended to make this restriction explicit. Because margin and other proceeds from a restricted lien account that are credited to the Liquidating Settlement Account may be applied to mark-to-market payments owed in respect of Stock Loan Positions in the restricted lien account, any proceeds of such positions should be subject to the same restriction applicable to proceeds from other positions in the restricted lien account that are credited to the Liquidating Settlement Account. They should be applied only to obligations arising from that restricted lien account. OCC therefore also proposes to amend Rule 1104 to include references to Rules 2210 and 2210A to clearly provide that margin and other proceeds from the customers' account that are credited to the Liquidating Settlement Account may be applied to amounts payable with respect to Stock Loan Positions in the customers' account and that proceeds from Stock Loan Positions in such customers' account may be applied *only* to obligations arising in that account.

III. Discussion

Section 17A(b)(3)(F) of the Act[5] requires that, among other things, that the rules of a clearing agency are designed to safeguard securities and funds in its custody or control or for which it is responsible and to protect investors and the public interest. The proposed rule change will further these ends by clarifying OCC's use collateral held. Specially the proposal clarifies that OCC may, in connection a clearing member's suspension, use the collateral that it holds in a clearing member's customers' account to settle mark-to-market payments arising from Stock Loan Positions carried in the clearing member's customers' account (notwithstanding that such payments are required by OCC's Rules to be settled in the clearing member's firm account or its combined market makers' account requiring a minimum clearing fund size that is designed to enable OCC to draw in full on its committed credit facilities that are secured by the clearing fund).

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act[6] and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[7] that the proposed rule change (File No. SR–OCC–2012–22) be and hereby is *approved.*[8]

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00609 Filed 1–14–13; 8:45 am]

BILLING CODE 8011–01–P

[4] The term ''restricted lien account'' is defined in Article I, Section 1 of OCC's By-Laws as follows: ''Any account of a Clearing Member with the Corporation over which the Corporation has a restricted lien with respect to specified assets (including any proceeds thereof) in such account.'' The term ''restricted lien'' is defined in Article I, Section 1 of OCC's By-Laws as follows: ''A security interest of the Corporation in specified assets (including any proceeds thereof) in an account of a Clearing Member with the Corporation as security for the Clearing Member's obligations to the Corporation arising from such account or, to the extent so provided in the By-Laws or Rules, a specified group of accounts that includes such account including, without limitation, obligations in respect of all Exchange transactions effected through such account or group of accounts, short positions maintained in such account or group of accounts, and exercise notices assigned to such account or group of accounts.''

[5] 15 U.S.C. 78q–1(b)(3) (F).

[6] 15 U.S.C. 78q–1.

[7] 15 U.S.C. 78s(b)(2).

[8] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68608; File No. SR–BX–2013–002]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating To Routing Fee

January 9, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 2, 2013, 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 amend Chapter XV, Section 2 entitled ''BX Options Market—Fees and Rebates'' to amend various fees for routing options to away markets.

The text of the proposed rule change is provided in *Exhibit 5.* The text of the proposed rule change is also 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to recoup costs that the Exchange incurs for routing and executing certain orders in equity options to away markets. The Exchange proposes to amend Routing Fees for the following away markets: BATS Exchange, Inc. (''BATS''), BOX Options Exchange LLC (''BOX''), the Chicago Board Exchange Incorporated (''CBOE''), the International Securities Exchange LLC (''ISE''), the NASDAQ Options Market LLC (''NOM''), NYSE ARCA, Inc. (''NYSE Arca'') and NASDAQ OMX PHLX LLC (''Phlx''). These away markets amended their transaction fees and the Exchange desires to amend its Routing Fees to reflect the amended transaction cost for routing to these away markets. In addition, the Exchange proposes to adopt Routing Fees when routing orders to Miami International Securities Exchange, LLC (''MIAX'').

BX Options Rules at Chapter XV, Section 2(4) included the following fees for routing Customer, Firm, Market Maker, Broker-Dealer and Professional orders:

Exchange	Customer	Firm/Market maker/Broker-dealer	Professional
BATS (Penny Pilot)	$0.55	$0.55	$0.55
BOX	$0.11	$0.55	$0.11
CBOE	$0.11	$0.55	$0.31
CBOE orders greater than 99 contracts in ETFs, ETNs and HOLDRS)	$0.29	N/A	$0.31
C2	$0.55	$0.55	$0.55
ISE (Standard)	$0.11	$0.55	$0.29
ISE (Select Symbols)	$0.35	$0.55	$0.39
NOM	$0.55	$0.55	$0.55
NYSE Arca (Penny Pilot)	$0.55	$0.55	$0.55
NYSE Amex	$0.11	$0.55	$0.31
PHLX (for all options other than PHLX Select Symbols)	$0.11	$0.55	$0.36
PHLX Select Symbols	$0.50	$0.55	$0.55

BX currently recoups clearing and transaction charges incurred by the Exchange as well as certain other costs incurred by the Exchange when routing to away markets, such as administrative and technical costs associated with operating the order router, membership fees at away markets, and technical costs associated with routing.[3] For example, BX incurs costs related to the Nasdaq Options Services LLC (''NOS''), a member of the Exchange and the Exchange's exclusive order router.[4] Each time NOS routes an order to an away market, NOS is charged a clearing fee[5] and, in the case of certain exchanges, a transaction fee is also charged in certain symbols, which fees are passed through to the Exchange. The Exchange proposes to recoup a portion of the above costs along with the away market's routing fee when routing to an away market. The Exchange is proposing to amend various away market fees to account for amendments to fees to remove liquidity at those markets. The Exchange currently assesses an $0.11 per contract fixed routing fee in addition to the away market's transaction fee.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In addition to membership fees and transaction fees, the Exchange also incurs an Options Regulatory Fee (''ORF'') when it routes to an away market that assesses an ORF.

[4] *See* BX Rules at Chapter VI, Section 11(e) (Order Routing).

[5] The Options Clearing Corporation (''OCC'') assesses $0.01 per contract side.

BATS assesses the following fees for removing liquidity from the BATS Options order book in all other securities, or Non-Penny Pilot Securities: $0.84 per contract for a Professional, Firm or Market Maker order and $0.75 per contract for a Customer order.[6] The Exchange is proposing to adopt a new category of Routing Fees entitled ''BATS (Non-Penny Pilot)'' and assess the following Routing Fees: $0.94 per contract for a Firm/Market Maker/Broker-Dealer and $0.86 per contract for a Customer.[7]

BOX amended its Professional fees to assess a Professional non-auction transaction fee of $0.20 per contact.[8] The Exchange is proposing to increase the BOX Professional Routing Fee from $0.11 to $0.31 per contract.[9]

CBOE amended its fees in Select Symbols to assess a Professional transaction fee of $0.30 per contract.[10] The Exchange is proposing to increase the CBOE Professional Routing Fee from $0.31 to $0.41 per contract.[11] In addition, the Exchange is proposing to amend the Professional Routing Fee for CBOE orders greater than 99 contracts in ETFs, ETNs and HOLDRs of $0.31 per contract to ''N/A.'' The Exchange noted a $0.31 per contract fee, which is the same fee for the Professional CBOE Routing Fee, at the time that the Exchange created the CBOE orders greater than 99 contracts Routing Fee category. This was an error because the Routing Fees for CBOE orders greater than 99 contracts only apply to Customer orders and not Professional orders. The Exchange has never assessed the Professional Routing Fee for CBOE orders greater than 99 contracts on a Professional because it was only able to route Customer orders over 99 contracts to CBOE in this category. The Exchange proposes to amend the fee rate to display ''N/A'' because a Professional would not qualify for this category. Additionally, the Exchange proposes to update the title of the Routing Fee to ''CBOE orders greater than 99 contracts in ETFs and ETNs'' to remove the HOLDRs product, which is no longer listed on CBOE.

ISE amended its Professional Customer Non-Select Symbols or ''Standard'' fee to $0.20 per contract.[12] The Exchange is proposing to increase the ISE (Standard) Professional Routing Fee from $0.29 to $0.31 per contract.[13] Additionally, ISE amended its Professional Customer taker fee in Select Symbols to $0.33 per contract.[14] The Exchange is proposing to increase the ISE (Select Symbols) Professional Routing Fee from $0.39 to $0.44 per contract.[15]

The Exchange proposes to rename the ''NOM'' Routing Fees as ''NOM (Penny Pilot)'' and adopt a new category of NOM Routing Fees entitled ''NOM (Non-Penny Pilot).'' NOM assesses the following Non-Penny Pilot Fees for Removing Liquidity: $0.82 per contract for a Customer and NOM Market Maker and $0.89 per contract for a Professional, Firm and Non-NOM Market Maker.[16] The Exchange is proposing to adopt NOM Non-Penny Pilot Routing Fees as follows: $0.93 per contract for a Customer and $0.94 per contract for a Firm/Market Maker/Broker-Dealer and Professional.[17]

NYSE Arca assesses the following take liquidity fees: $0.79 per contact for a Customer and $0.85 per contract for a Firm and Broker-Dealer.[18] The Exchange is proposing to adopt new Routing Fees for NYSE Arca entitled ''NYSE Arca (Non-Penny Pilot)'' Routing Fees as follows: $0.90 per contract for a Customer and Professional and $0.94 for a Firm/Market Maker/Broker-Dealer Routing Fees.[19]

Phlx recently amended its fees in Select Symbols to assess no Customer Fee to Remove Liquidity.[20] The Exchange is proposing to decrease the Phlx Select Symbols Customer Routing Fee from $0.50 to $0.11 per contract.[21]

MIAX recently filed to adopt transaction fees, which included the following fees applicable to all classes of options: $0.00 for a Priority Customer, $0.45 for a Non-MIAX Market Maker, $0.45 for a Broker-Dealer and $0.25 per contract for a Public Customer other than a Priority Customer.[22] The Exchange is proposing to adopt MIAX Routing Fees, entitled ''MIAX,'' as follows: $0.11 per contract for a Customer and $0.36 for a Professional and $0.55 per contract for a Firm/Market Maker/Broker-Dealer.[23]

The Exchange is not proposing to otherwise amend other Routing Fees not specifically mentioned. As with all fees, the Exchange may adjust these Routing Fees in response to competitive conditions by filing a new proposed rule change.

2. Statutory Basis

BX believes that the proposed rule changes are consistent with the provisions of Section 6 of the Act,[24] in general, and with Section 6(b)(4) of the Act,[25] in particular, in that they provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which BX operates or controls.

The Exchange's amendments to the BATS, BOX, CBOE, ISE, NOM, NYSE Arca and Phlx Routing fees as well as the adoption of MIAX Routing Fees are reasonable because these fees are designed to recoup costs that are incurred by the Exchange when routing certain orders to these away markets on behalf of members. Each destination market's transaction charge varies and

[6] *See* BATS BZX Exchange Fee Schedule.

[7] The Exchange computed the BATS Non-Penny Pilot Routing Fees by adding an $0.11 per contract fixed fee to the away market's transaction fee. The Exchange proposes to cap the Firm/Market Maker/Broker-Dealer and Professional BATS Routing Fees at $0.94 per contract similar to NYSE Arca and BX Options Routing Fees.

[8] *See* BOX Options Exchange Fee Schedule.

[9] The Exchange computed the BOX Professional Routing Fee by adding an $0.11 per contract fixed fee to the away market's transaction fee.

[10] *See* CBOE's Fees Schedule.

[11] The Exchange computed the CBOE Professional Routing Fee by adding an $0.11 per contract fixed fee to the away market's transaction fee.

[12] *See* ISE's Fee Schedule.

[13] The Exchange computed the ISE (Standard) Professional Routing Fee by adding an $0.11 per contract fixed fee to the away market's transaction fee.

[14] *See* ISE's Fee Schedule.

[15] The Exchange computed the ISE (Select Symbols) Professional Routing Fee by adding an $0.11 per contract fixed fee to the away market's transaction fee.

[16] *See* NASDAQ Stock Market LLC Rules at Chapter XV, Section 2.

[17] The Exchange computed the NOM Non-Penny Pilot Customer Routing Fee by adding an $0.11 per contract fixed fee to the away market's transaction fee. With respect to the Firm/Market Maker/Broker-Dealer and Professional Routing Fees, the Exchange determined to cap the fees at $0.94 per contract. The Exchange similarly capped Routing Fees for BATS and NYSE Arca.

[18] *See* NYSE ARCA General Options and Trading Permit (OTP) Fees.

[19] The Exchange computed the NYSE Arca Non-Penny Pilot Customer and Professional Routing Fees by adding an $0.11 per contract fixed fee to the away market's transaction fee. Because NYSE Arca does not have a Professional category, Professional orders would be routed as Customer to NYSE Arca. In light of this, the Professional Routing Fee was computed the same as the Customer Routing Fee. With respect to the Firm/Market Maker/Broker-Dealer Routing Fees, the Exchange added an $0.11 per contract fixed fee to the away market's transaction fee and determined to cap the Routing Fees at $0.94 per contract similar to BATS and BX Options.

[20] *See* SR–Phlx–2013–01 (not yet published). Phlx lists its Select Symbols in Section I of its Pricing Schedule.

[21] The Exchange is proposing to assess the $0.11 per contract fixed fee as there is no transaction fee when routing a Customer order to Phlx in Select Symbols.

[22] *See* MIAX's Fee Schedule.

[23] The Exchange computed the MIAX Customer and Professional Routing Fees by adding an $0.11 per contract fixed fee to the away market's transaction fee. With respect to the Firm, Market Maker and Broker-Dealer Routing Fees, the Exchange determined to cap the fees at $0.55 per contract similar to other Routing Fees.

[24] 15 U.S.C. 78f.

[25] 15 U.S.C. 78f(b)(4).

there is a standard clearing charge for each transaction incurred by the Exchange along with other administrative and technical costs [26] that are incurred by the Exchange. The Exchange believes that the proposed Routing Fees would enable the Exchange to recover the respective remove fee assessed to each market participant by the away market, plus clearing and other administrative and technical fees for the execution of orders routed to BX and executed on these away markets.

The Exchange also believes that the amended Routing Fees are equitable and not unfairly discriminatory because these fees would be uniformly applied to all market participant orders that are routed to the respective away market to cover the cost to route the order. The Exchange applied a similar methodology in calculating the routing fees for each market participant by adding not more than a $0.11 per contract fee to the away market's remove fee to determine the NOM Routing Fees.[27]

The Exchange believes that the technical amendments to the titles of the Routing Fees are reasonable, equitable and not unfairly discriminatory as the amendments add clarity to the fee categories.

B. Self-Regulatory Organization's Statement on Burden on Competition

BX does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the rule change would allow the Exchange to recoup its costs when routing orders designated as available for routing by the market participant. Today, other options exchanges also assess similar fees to recoup costs incurred by the Exchange to route orders to away markets. Further, a BX Options Participant may designate an order as not available for routing to avoid Routing Fees.[28] For these reasons, the Exchange does not believe that the proposed fees impose a burden on competition.

[26] The Exchange utilizes the NOS a member of the Exchange and the Exchange's exclusive order router to route orders in options listed and open for trading on the BX to destination markets. *See* Securities Exchange Act Release No. 67256 (June 26, 2012) 77 FR 39277 (July 2, 2012) (SR–BX–2012–030).

[27] *See* NASDAQ Stock Market LLC Rules at Chapter XV, Section 2(4).

[28] *See* BX Rules at Chapter VI, Section 11(e).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[29] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2013–002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2013–002. 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 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2013–002, and should be submitted on or before February 5, 2013.

[29] 15 U.S.C. 78s(b)(3)(A)(ii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00662 Filed 1–14–13; 8:45 am]

BILLING CODE 8011–01–P

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68609; File No. SR–NASDAQ–2013–001]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Routing Fees

January 9, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 2, 2013, The NASDAQ Stock Market LLC (''NASDAQ'' 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 NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes to modify Chapter XV, Section 2, entitled ''NASDAQ

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Options Market—Fees and Rebates,'' which govern pricing for NASDAQ members using the NASDAQ Options Market (''NOM''), NASDAQ's facility for executing and routing standardized equity and index options, to amend Routing Fees.

The text of the proposed rule change is provided in *Exhibit 5.* The text of the proposed rule change is also available on the Exchange's Web site at *http://www.nasdaq.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. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to recoup costs that the Exchange incurs for routing and executing certain orders in equity options to away markets. The Exchange proposes to amend Routing Fees for the following away markets: BATS Exchange, Inc. (''BATS''), BOX Options Exchange LLC (''BOX''), NASDAQ OMX BX, Inc. (''BX Options''), the Chicago Board Exchange Incorporated (''CBOE''), the International Securities Exchange LLC (''ISE''), NYSE ARCA, Inc. (''NYSE Arca'') and NASDAQ OMX PHLX LLC (''Phlx''). These away markets amended their transaction fees and the Exchange desires to amend its Routing Fees to reflect the amended transaction cost for routing to these away markets. In addition, the Exchange proposes to adopt Routing Fees when routing orders to Miami International Securities Exchange, LLC (''MIAX'').

Today, the Exchange's Rules at Chapter XV, Section 2(4) include the following fees for routing Customer, Firm, Market Maker and Professional orders:

Exchange	Customer	Firm	MM	Professional
BATS Penny	$0.55	$0.55	$0.55	$0.55
BATS non-Penny	0.86	0.91	0.91	0.91
BOX	0.11	0.55	0.55	0.11
BX Options	0.11	0.54	0.54	0.54
CBOE	0.11	0.55	0.55	0.31
CBOE orders greater than 99 contracts in NDX, MNX ETFs, ETNs & HOLDRs	0.29	0.55	0.55	0.31
C2	0.55	0.55	0.55	0.55
ISE	0.11	0.55	0.55	0.29
ISE Select Symbols	0.35	0.55	0.55	0.39
NYSE Arca Penny Pilot	0.55	0.55	0.55	0.55
NYSE Arca Non Penny Pilot	0.11	0.55	0.55	0.11
NYSE AMEX	0.11	0.55	0.55	0.31
PHLX (for all options other than PHLX Select Symbols)	0.11	0.55	0.55	0.31
PHLX Select Symbols	0.50	0.55	0.55	0.51

NASDAQ currently recoups clearing and transaction charges incurred by the Exchange as well as certain other costs incurred by the Exchange when routing to away markets, such as administrative and technical costs associated with operating the order router, membership fees at away markets, and technical costs associated with routing.[3] For example, the Exchange incurs costs related to the Nasdaq Options Services LLC (''NOS''), a member of the Exchange and the Exchange's exclusive order router.[4] Each time NOS routes an order to an away market, NOS is charged a clearing fee [5] and, in the case of certain exchanges, a transaction fee is also charged in certain symbols, which fees are passed through to the Exchange. The Exchange proposes to recoup a portion of the above costs along with the away market's routing fee when routing to an away market. The Exchange is proposing to amend various away market fees to account for amendments to fees to remove liquidity at those markets. The Exchange currently assesses an $0.11 per contract fixed routing fee in addition to the away market's transaction fee.

BATS assesses the following fees for removing liquidity from the BATS Options order book in all other securities, or Non-Penny Pilot Securities, as follows: $0.84 per contract for a Professional, Firm or Market Maker order and $0.75 per contract for a Customer order.[6] The Exchange is proposing to amend the BATS Non-Penny Pilot Routing Fees by increasing the Firm, Market Maker and Professional Routing Fees from $0.91 to $0.94 per contract.[7] The Exchange proposes to make a technical amendment for consistency to the ''BATS non-Penny'' category to rename it ''BATS Non-Penny Pilot.'' The Exchange also proposes to rename the ''BATS Penny'' Routing Fees as the ''BATS Penny Pilot'' Routing Fees for consistency in the Routing Fees.

BOX amended its Professional fees to assess a Professional non-auction transaction fee of $0.20 per contact.[8] The Exchange is proposing to increase the BOX Professional Routing Fee from $0.11 to $0.31 per contract.[9]

BX Options recently adopted Non-Penny Pilot Pricing.[10] The Exchange is

[3] In addition to membership fees and transaction fees, the Exchange also incurs an Options Regulatory Fee (''ORF'') when it routes to an away market that assesses an ORF.

[4] *See* Exchange Rules at Chapter VI, Section 11(e) (Order Routing).

[5] The Options Clearing Corporation (''OCC'') assesses $0.01 per contract side.

[6] *See* BATS BZX Exchange Fee Schedule.

[7] The Exchange computed the BATS Non-Penny Pilot Routing Fees by adding an $0.11 per contract fixed fee to the away market's transaction fee. The Exchange proposes to cap the Firm, Market Maker and Professional BATS Non-Penny Pilot Routing Fees at $0.94 per contract similar to NYSE Arca and BX Options Routing Fees. The Exchange is not proposing to amend the Customer Routing Fee in BATS Non-Penny Pilot Options.

[8] *See* BOX Options Exchange Fee Schedule.

[9] The Exchange computed the BOX Professional Routing Fee by adding an $0.11 per contract fixed fee to the away market's transaction fee.

[10] *See* SR–BX–2012–074 (not yet published). BX Options Non-Penny Pilot Fees to Remove Liquidity are as follows: Customer is not assessed a fee, a BX Options Market Maker and Non-Customer are assessed an $0.88 per contract fee. A Non-Customer

proposing to amend the title of the current BX Options Routing Fees from ''BX Options'' to ''BX Options Penny Pilot'' and create a new category of Routing Fees entitled ''BX Options Non-Penny Pilot.'' The Exchange is proposing to adopt the following BX Options Non-Penny Pilot Routing Fees: $0.11 per contract for a Customer and $0.94 per contract for a Firm, Market Maker and Professional.[11]

CBOE amended its fees in Select Symbols to assess a Professional transaction fee of $0.30 per contract.[12] The Exchange is proposing to increase the CBOE Professional Routing Fee from $0.31 to $0.41 per contract.[13] In addition, the Exchange is proposing to amend the Professional Routing Fee for CBOE orders greater than 99 contracts in ETFs, ETNs and HOLDRs of $0.31 per contract to ''N/A.'' The Exchange noted a $0.31 per contract fee, which is the same fee for the Professional CBOE Routing Fee, at the time that the Exchange created the CBOE orders greater than 99 contracts Routing Fee category. This was an error because the Routing Fees for CBOE orders greater than 99 contracts only apply to Customer orders and not Professional orders. The Exchange has never assessed the Professional Routing Fee for CBOE orders greater than 99 contracts on a Professional because it was only able to route Customer orders over 99 contracts to CBOE in this category. The Exchange proposes to amend the fee rate to display ''N/A'' because a Professional would not qualify for this category. Additionally, the Exchange proposes to update the title of the Routing Fee to ''CBOE orders greater than 99 contracts in ETFs and ETNs'' to remove the HOLDRs product, which is no longer listed on CBOE.

The Exchange is proposing to rename the ''ISE'' Routing Fees as the ''ISE (Standard)'' Routing Fees to further distinguish this fee from the ISE Select Symbols Routing Fees. ISE amended its Professional Customer Non-Select Symbols or ''Standard'' fee to $0.20 per contract.[14] The Exchange is proposing to increase the newly named ISE (Standard) Professional Routing Fee from $0.29 to $0.31 per contract.[15] Additionally, ISE amended its Professional Customer taker fee in Select Symbols to $0.33 per contract.[16] The Exchange is proposing to increase the ISE (Select Symbols) Professional Routing Fee from $0.39 to $0.44 per contract.[17]

NYSE Arca assesses the following take liquidity fees: $0.79 per contact for a Customer and $0.85 per contract for a Firm and Broker-Dealer.[18] The Exchange is proposing to amend the NYSE Arca Non-Penny Pilot Routing Fees as follows: the Customer and Professional Routing Fees will increase from $0.11 to $0.90 per contract, and the Firm and Market Maker Routing Fees will increase from $0.55 to $0.94 per contract.[19]

Phlx recently amended its fees in Select Symbols to assess no Customer Fee to Remove Liquidity and to decrease the Professional Fee for Removing Liquidity in Select Symbols from $0.45 to $0.44 per contract.[20] The Exchange is proposing to decrease the Phlx Select Symbols Customer Routing Fee from $0.50 to $0.11 per contract and increase the Professional Routing Fee from $0.51 to $0.55 per contract.[21]

MIAX recently filed to adopt transaction fees, which included the following fees applicable to all classes of options: $0.00 for a Priority Customer, $0.45 for a Non-MIAX Market Maker, $0.45 for a Broker-Dealer and $0.25 per contract for a Public Customer other than a Priority Customer.[22] The Exchange is proposing to adopt MIAX Routing Fees as follows: $0.11 per contract for a Customer, $0.36 per contract for a Professional and $0.55 per contract for a Firm and Market Maker.[23]

The Exchange is not proposing to otherwise amend other Routing Fees not specifically mentioned. As with all fees, the Exchange may adjust these Routing Fees in response to competitive conditions by filing a new proposed rule change.

2. Statutory Basis

NASDAQ believes that its proposal to amend its rules is consistent with Section 6(b) of the Act[24] in general, and furthers the objectives of Section 6(b)(4) of the Act[25] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

The Exchange's amendments to the BATS, BOX, BX Options, CBOE, ISE, NYSE Arca and Phlx Routing fees as well as the adoption of MIAX Routing Fees are reasonable because these fees are designed to recoup costs that are incurred by the Exchange when routing certain orders to these away markets on behalf of members. Each destination market's transaction charge varies and there is a standard clearing charge for each transaction incurred by the Exchange along with other administrative and technical costs[26] that are incurred by the Exchange. The Exchange believes that the proposed Routing Fees would enable the Exchange to recover the respective remove fee assessed to each market participant by the away market, plus clearing and other administrative and technical fees for the execution of orders routed to NOM and executed on these away markets.

The Exchange also believes that the amended Routing Fees are equitable and not unfairly discriminatory because these fees would be uniformly applied to all market participant orders that are routed to the respective away market to cover the cost to route the order. The

includes a Professional, Firm, Broker-Dealer and Non-BX Options Market Maker.

[11] The Exchange computed the BX Options Customer Non-Penny Pilot Routing Fee by assessing only the $0.11 per contract fixed fee. The Exchange computed the Firm, Market Maker and Professional Routing Fees by adding $0.11 per contract to the away market's transaction fee. The Exchange determined to cap the Firm, Market Maker and Professional Routing Fees at $0.94 per contract similar to BATS and NYSE Arca Routing Fees.

[12] *See* CBOE's Fees Schedule.

[13] The Exchange computed the CBOE Professional Routing Fee by adding an $0.11 per contract fixed fee to the away market's transaction fee.

[14] *See* ISE's Fee Schedule.

[15] The Exchange computed the ISE (Standard) Professional Routing Fee by adding an $0.11 per contract fixed fee to the away market's transaction fee.

[16] *See* ISE's Fee Schedule.

[17] The Exchange computed the ISE (Select Symbols) Professional Routing Fee by adding an $0.11 per contract fixed fee to the away market's transaction fee.

[18] *See* NYSE ARCA General Options and Trading Permit (OTP) Fees.

[19] The Exchange computed the NYSE Arca Non-Penny Pilot Customer and Routing Fees by adding an $0.11 per contract fixed fee to the away market's transaction fee. Because NYSE Arca does not have a Professional category, Professional orders would be routed as Customer to NYSE Arca. In light of this, the Professional Routing Fee was computed the same as the Customer Routing Fee. With respect to the Firm and Market Maker Routing Fees, the Exchange added an $0.11 per contract fixed fee to the away market's transaction fee and determined to cap the Routing Fees at $0.94 per contract similar to BATS and BX Options.

[20] *See* SR–Phlx–2013–01 (not yet published). Phlx lists its Select Symbols in Section I of its Pricing Schedule.

[21] The Exchange is proposing to assess a Customer the $0.11 per contract fixed fee as there is no transaction fee when routing a Customer order to Phlx in Select Symbols. The Exchange is also proposing to add the $0.11 per contract fixed fee to the away market's transaction fee to compute the Professional Routing Fee in Select Symbols. The Exchange proposes to cap the fee at $0.55 per contract similar to the Firm and Market Maker Routing Fee in PHLX Select Symbols.

[22] *See* MIAX's Fee Schedule.

[23] The Exchange computed the MIAX Routing Fees by adding an $0.11 per contract fixed fee to the away market's transaction fee. With respect to the Firm and Market Maker Routing Fees, the Exchange determined to cap the fees at $0.55 per contract similar to other Routing Fees.

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(4).

[26] The Exchange utilizes the NOS a member of the Exchange and the Exchange's exclusive order router to route orders in options listed and open for trading on NOM to destination markets.

Exchange applied a similar methodology in calculating the routing fees for each market participant by adding not more than a $0.11 per contract fee to the away market's remove fee to determine the BX Options Routing Fees.[27]

The Exchange believes that the technical amendments to the titles of the Routing Fees are reasonable, equitable and not unfairly discriminatory as the amendments add clarity to the fee categories.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the rule change would allow the Exchange to recoup its costs when routing orders designated as available for routing by the market participant. Today, other options exchanges also assess similar fees to recoup costs incurred by the Exchange to route orders to away markets. Further, a NOM Participant may designate an order as not available for routing to avoid Routing Fees.[28] For these reasons, the Exchange does not believe that that the proposed fees impose a burden on 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.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[29] 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.

[27] *See* BX Rules at Chapter XV, Section 2(4).

[28] *See* NOM Rules at Chapter VI, Section 11.

[29] 15 U.S.C. 78s(b)(3)(A)(ii).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2013–001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2013–001. 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 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2013–001, and should be submitted on or before February 5, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00633 Filed 1–14–13; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68612; File No. SR–NSX–2012–27]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend its Fee and Rebate Schedule

January 9, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 27, 2012, National Stock Exchange, Inc. (''NSX®'' 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 comment on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend to amend its Fee and Rebate Schedule (the ''Fee Schedule'') issued pursuant to Exchange Rule 16.1(a) to modify the Order Delivery Notification Fee charged for each Order Delivery Notification[3] transmitted by the Exchange to an Equity Trading Permit (''ETP'')[4] Holder using the Exchange's Order Delivery mode (''Order Delivery Mode'').

The text of the proposed rule change is available on the Exchange's Web site at *www.nsx.com,* at the Exchange's principal office, and at the Commission's public reference room.

[30] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] An ''Order Delivery Notification'' refers to a message sent by the Exchange to the Order Delivery participant communicating the details of the full or partial quantity of an inbound contra-side order that potentially may be matched within the System for execution against an Order Delivery Order.

[4] Exchange Rule 1.5 defines the term ''ETP'' as an Equity Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's Trading Facilities.

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 its Fee Schedule issued pursuant to Exchange Rule 16.1(a) to increase the Order Delivery Notification Fee charged for each Order Delivery Notification transmitted by the Exchange to an ETP Holder using the Exchange's Order Delivery Mode from $0.29 to $0.35.

The Exchange's Order Delivery Mode provides Electronic Communication Networks (''ECNs'') with an electronic trading platform to interact with the National Market System. Order Delivery Mode provides ECNs with the ability to (i) Publish quotations into the consolidated quotation system, (ii) receive ''protected quotation'' status under Rule 611 of Regulation NMS,[5] (iii) receive an Order Delivery Notification when there is a potential match against a published quotation, and (iv) distribute attributed quotations through the Exchange's Depth-of-Book market data product.[6]

On December 3, 2012, the Exchange amended Section IV of its Fee Schedule to adopt an Order Delivery Notification Fee for Order Delivery participants.[7] The Exchange adopted the Order Delivery Notification Fee as a means of recouping the development and ongoing operational costs, excluding the costs of regulation, of Order Delivery Mode. The Order Delivery Notification Fee is currently $0.29 for each Order Delivery Notification sent by the Exchange to an Order Delivery participant, which is capped at 1.5 million Order Delivery Notifications per month.

The Exchange now proposes to increase the Order Delivery Notification Fee from $0.29 to $0.35. The Order Delivery Notification Fee cap will remain unchanged. The Exchange believes the modified fee is better designed to recover the development and ongoing operational costs, excluding the costs of regulation, of Order Delivery Mode.

The Exchange believes that this approach equitably allocates fees among its ETP Holders and is not unfairly discriminatory because Order Delivery Mode provides ECNs with advertising through attributed quotations which facilitates an increasing rate of executions away from the Exchange. This disproportionate trade-to-quote ratio in Order Delivery Mode is a result of ECNs successfully leveraging the Exchange's infrastructure to develop their businesses away from the Exchange, even as the majority of the Exchange's operational costs are fixed. Consequently, the Exchange strongly believes that relying on transaction-based revenues to support Order Delivery Mode is not feasible. The Exchange believes that it is equitable and not unfairly discriminatory to charge for the services provided to Order Delivery Participants as a means to recover the development and ongoing operational costs, excluding the costs of regulation, of Order Delivery Mode.

Operative Date and Notice

The Exchange will make the proposed modifications, which are effective on filing of this proposed rule, operative as of commencement of trading on January 2, 2013.[8] Pursuant to Exchange Rule 16.1(c), the Exchange will ''provide ETP Holders with notice of all relevant dues, fees, assessments and charges of the Exchange'' through the issuance of an Information Circular of the changes to the Fee Schedule and will post a copy of the rule filing on the Exchange's Web site (*www.nsx.com*).

2. Statutory Basis

The Exchange believes that the amended Order Delivery Notification Fee for Order Delivery participants is consistent with the provisions of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[9] in general, and furthers the objectives of Section 6(b)(4) of the Act,[10] in particular, because it provides for the equitable allocation of reasonable dues, fees and other charges among its ETP Holders and other persons using the facilities of the Exchange.

The Exchange believes the amended Order Delivery Notification Fee is reasonable because Order Delivery Mode imposes on the Exchange greater operational costs than should the Exchange offer only automatic execution mode of interaction (''Auto-Ex Mode''),[11] because Order Delivery Mode is a model that utilizes a substantial portion of the Exchange's infrastructure, operational and processing resources. Order Delivery Participants are eligible to submit (or not submit) liquidity adding quotes, and may do so at their discretion in the daily volumes they choose during any given trading day. As stated earlier, due to the low level of executions resulting from the quotation activity, the Exchange does not believe that a transaction-based fee is a reasonable means for the Exchange to recover the development and the ongoing operational costs of the Order Delivery program. Therefore, the Exchange believes that it is reasonable to charge an Order Delivery Participant the amended fee which covers the proportionate cost of their participation in, and services provided by, the Exchange's Order Delivery Mode.

Furthermore, the Exchange believes that the amended Order Delivery Fee is consistent with the provisions of Section 6(b)(5) of the Act,[12] because it is equitable and not unfairly discriminatory. As stated above, Order Delivery participants utilize a substantial portion of the Exchange's infrastructure, operational and processing resources. The Order Delivery Notification Fee is a mechanism under which the Exchange can recoup the costs associated with Order Delivery Mode. The Exchange believes that it is equitable and not unfairly discriminatory to charge an Order Delivery Participant a fee which covers the proportionate cost of a unique technology that offers Order Delivery Mode.

The Exchange will evaluate the Order Delivery Notification Fee on an ongoing

[5] 17 CFR 611.

[6] ECNs can also use Order Delivery Mode to fulfill certain regulatory obligations such as qualifying as an ECN Display Alternative (17 CFR 242.602(b)(5)(i)) or publishing quotations in the consolidated quotation system when the five (5) percent order display requirement is triggered (17 CFR 242.301(b)(3)(B)).

[7] *See* Securities Exchange Act Release No. 68391 (December 10, 2012), 77 FR 74536 (December 14, 2012) (SR–NSX–2012–25).

[8] While the Exchange proposes to amend the date of its Fee Schedule to January 1, 2013, it will not implement the proposed fee changes until Wednesday, January 2, 2013, the first day of trading. The Exchange proposes to amend the Fee Schedule's date to January 1, 2013 as it contains non-transaction based fees that are charged on a monthly basis.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] Under Auto-Ex Mode, the Exchange matches and executes like-priced orders (including against Order Delivery orders resting on the NSX book). Auto-Ex orders resting in the NSX book execute immediately when matched against a marketable incoming contra-side Auto-Ex order.

[12] 15 U.S.C. 78f(b)(5).

basis to ensure that it remains reasonable, equitable and not unfairly discriminatory among all ETP Holders.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Order Delivery Notification Fee is a mechanism under which the Exchange can recoup the costs associated with Order Delivery Mode. Order Delivery Participants are eligible to submit (or not submit) liquidity adding quotes, and may do so at their discretion in the daily volumes they choose during any given trading day. The Order Delivery Notification Fee is designed solely to allow the Exchange to recover the costs associated with operating Order Delivery Mode and applies to all Order Delivery participants. Therefore, the Exchange does not believe the modified Order Delivery Notification Fee imposes any burden on completion that is not necessary or appropriate in furtherance of the Act.

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 proposed rule change has taken effect upon filing pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act [13] and subparagraph (f)(2) of Rule 19b–4.[14] At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NSX–2012–27 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NSX–2012–27. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSX–2012–27, and should be submitted on or before February 5, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00663 Filed 1–14–13; 8:45 am]

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[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4.

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68613; File No. SR–NASDAQ–2012–141]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC Notice; of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Penny Pilot Options

January 9, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 31, 2012, The NASDAQ Stock Market LLC (''NASDAQ'' 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 NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes to modify Chapter XV, Section 2 of the rules governing the NASDAQ Options Market (''NOM''), NASDAQ's facility for executing and routing standardized equity and index options. Specifically, NOM proposes to amend its pricing to modify the Professional Rebate to Add Liquidity in Penny Pilot Options.[3]

While the changes proposed herein are effective upon filing, the Exchange

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Penny Pilot was established in March 2008, expanded in October 2009, and, through a series of orders, extended through December 31, 2012. *See* Securities Exchange Act Release Nos. 57579 (March 28, 2008), 73 FR 18587 (April 4, 2008) (SR–NASDAQ–2008–026) (notice of filing and immediate effectiveness establishing Penny Pilot); 60874 (October 23, 2009), 74 FR 56682 (November 2, 2009) (SR–NASDAQ–2009–091) (notice of filing and immediate effectiveness expanding and extending Penny Pilot); 60965 (November 9, 2009), 74 FR 59292 (November 17, 2009) (SR–NASDAQ–2009–097) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 61455 (February 1, 2010), 75 FR 6239 (February 8, 2010) (SR–NASDAQ–2010–013) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 62029 (May 4, 2010), 75 FR 25895 (May 10, 2010) (SR–NASDAQ–2010–053) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 65969 (December 15, 2011), 76 FR 79268 (December 21, 2011) (SR–NASDAQ–2011–169) (notice of filing and immediate effectiveness extension and replacement of Penny Pilot); and 67325 (June 29, 2012), 77 FR 40127 (July 6, 2012) (SR–NASDAQ–2012–075) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through December 31, 2012). *See also* NOM Rules, Chapter VI, Section 5.

has designated that the amendments be operative on January 2, 2013.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaq.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. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ proposes to modify Chapter XV, entitled ''Options Pricing,'' at Section 2(1) governing the rebates and fees assessed for option orders entered into NOM. The Exchange is proposing to amend the Professional Rebate to Add Liquidity in Penny Pilot Options to attract additional order flow to the Exchange.

The Exchange currently pays a flat Professional Rebate to Add Liquidity in Penny Pilot Options of $0.29 per contract. The Exchange is now proposing to pay Professionals, a tiered rebate instead. Specifically, the Exchange proposes to eliminate the flat $0.29 per contract Professional Rebate to Add Liquidity and instead pay Professionals rebates based on total number of Customer and Professional contracts that add liquidity in Penny Pilot Options in a given month as follows:

Monthly volume	Rebate to add liquidity
Tier 1—Participant adds Customer and Professional liquidity of up to 34,999 contracts per day in a month	$0.26
Tier 2—Participant adds Customer and Professional liquidity of 35,000 to 74,999 contracts per day in a month	0.43
Tier 3—Participant adds Customer and Professional liquidity of 75,000 or more contracts per day in a month	0.44
Tier 4—Participant adds (1) Customer and Professional liquidity of 25,000 or more contracts per day in a month, (2) the Participant has certified for the Investor Support Program set forth in Rule 7014; and (3) the Participant executed at least one order on NASDAQ's equity market	0.42
Tier 5—Participant has Total Volume of 130,000 or more contracts per day in a month	0.46

Professionals would be entitled to the same Rebate to Add Liquidity in Penny Pilot Options that Customers receive today. The Exchange would pay a Tier 1 rebate of $0.26 per contract to market participants that add Customer and Professional liquidity of up to 34,999 contracts per day in a month. A Tier 2 rebate would pay $0.43 per contract to market participants that add Customer and Professional liquidity between 35,000 and 74,999 contracts per day in a month. A Tier 3 rebate would pay a $0.44 per contract rebate to market participants that add Customer and Professional liquidity of 75,000 contracts or more per day in a month. The Tier 4 rebate would pay a $0.42 rebate to market participants that add Customer and Professional liquidity of 25,000 or more contracts per day in a month. In addition, to qualify for Tier 4, the Participant must have certified for the Investor Support Program (''ISP'') as set forth in Rule 7014;[4] and executed at least one order on NASDAQ's equity market.[5] The Tier 5 rebate would pay a $0.46 per contract Rebate to Add Liquidity to NOM Options Participants that have Total Volume of 130,000 or more contracts per day in a month.[6] Total Volume is defined to include Customer, Professional, Firm, Non-NOM Market Maker and NOM Market Maker volume in Penny Pilot Options and Non-Penny Pilot Options which either adds or removes liquidity.[7]

The Exchange proposes to apply the Rebate to Add Liquidity tiers to Professionals transacting Penny Pilot Options. The Exchange proposes to amend Chapter XV, Section 2 by noting that the tiers would apply to Professionals.

Additionally, the Exchange also proposes to add contracts executed in the ''Professional'' capacity to the tier requirements. NOM Participants would be able to count Customer and Professional contracts toward the number of contracts eligible to qualify for a tier as specified herein. The addition of Professional orders to the number of contracts eligible for each rebate tier will enable NOM Participants to achieve higher rebates.

2. Statutory Basis

NASDAQ believes that the proposed rule changes are consistent with the provisions of Section 6 of the Act,[8] in general, and with Section 6(b)(4) of the Act,[9] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which NASDAQ operates or controls.

The Exchange believes that the proposed tier structure for Professional Rebates to Add Liquidity in Penny Pilot Options is reasonable, equitable and not unfairly discriminatory because by incentivizing NOM Participants to select the Exchange as a venue to post Customer and Professional orders, the Exchange will attract additional Professional order flow to the benefit of all market participants.

The Exchange believes that the proposed monthly volume tier Rebates to Add Liquidity in Penny Pilot Options are equitable and not unfairly discriminatory because members that account for more volume would be able to add greater value to the Exchange's trading environment. Additionally, with the exception of Tier 1, Professionals will have an opportunity to earn higher rebates than they earned in the past.

[4] For a detailed description of the ISP, see Securities Exchange Act Release No. 63270 (November 8, 2010), 75 FR 69489 (November 12, 2010) (NASDAQ–2010–141) (notice of filing and immediate effectiveness). See also Securities Exchange Act Release Nos. 63414 (December 2, 2010), 75 FR 76505 (December 8, 2010) (NASDAQ–2010–153) (notice of filing and immediate effectiveness); and 63628 (January 3, 2011), 76 FR 1201 (January 7, 2011) (NASDAQ–2010–154) (notice of filing and immediate effectiveness).

[5] For purposes of Tier 4, the Exchange will allow a NOM Participant to qualify for the rebate if a NASDAQ member under common ownership with the NOM Participant has certified for the Investor Support Program and executed at least one order on NASDAQ's equity market. Common ownership is defined as 75 percent common ownership or control.

[6] For purposes of Tier 5, the Exchange allows NOM Participants under common ownership to aggregate their volume to qualify for the rebate. Common ownership is defined as 75 percent common ownership or control.

[7] *See* the Exchange's Rules at Chapter XV, Section 2.

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(4).

With respect to Tier 1, the Exchange is proposing to pay a $0.26 per contract Rebate to Add Liquidity in Penny Pilot Options as compared to a $0.29 per contract rebate. The Exchange believes that this proposal is equitable and not unfairly discriminatory because the Professional has an opportunity to earn higher rebates with the tier structure as compared the current $0.29 per contract Rebate to Add Liquidity in Penny Pilot Options. In addition, the Exchange believes that the proposed monthly tier structure for Professional Rebates to Add Liquidity in Penny Pilot Options is equitable and not unfairly discriminatory because the Exchange would uniformly pay a Rebate to Add Liquidity to Professionals executing Penny Pilot Options based on the monthly tiers proposed herein.

The Exchange believes that paying Professionals a tiered Rebate to Add Liquidity in Penny Pilot Options as proposed herein is equitable and not unfairly discriminatory as compared to other market participants. For example, Customers are entitled to the same rebates. NOM Market Makers are entitled to a $0.30 per contract Rebate to Add Liquidity in Penny Pilot Options, and that rebate is higher than Professionals that achieve a Tier 1 rebate because NOM Market Makers add value through continuous quoting [10] and the commitment of capital. With respect to Tiers 2, 3 and 4, pursuant to this proposal, a Professional earns a higher rebate as compared to a NOM Market Maker. In addition, a Professional would earn a higher rebate with any tier as compared to a Firm and Non-NOM Market Maker. Today, Professionals are paid a higher Rebate to Add Liquidity in Penny Pilot Options as compared to Firms and Non-NOM Market Makers however the differential would become larger. The Exchange believes that paying Professionals higher Tier 2, 3 and 4 rebates as compared to NOM Market Makers and paying Professionals higher rebates as compared to Firms and Non-NOM Market Makers is equitable and not unfairly discriminatory because the Exchange does not believe that the amount of the rebate offered by the Exchange has a material impact on a NOM Participant's ability to execute orders in Penny Pilot Options. The Exchange has been assessing the impact of rebates since it first began to offer them and has also observed the impact of fees and rebates on other options exchanges in terms of quoting and liquidity. The Exchange believes that the Fees for Adding Liquidity in Penny Pilot Options, as compared to rebates, impact a market participant's decision-making more prominently with respect to posting order flow on different venues and price. In modifying its rebates, the Exchange hopes to simply remain competitive with other venues so that it remains a choice for market participants when posting orders and the result may be additional Professional order flow for the Exchange. In addition, a NOM Participant may not be able to gauge the exact rebate tier it would qualify for until the end of the month because Professional volume would be commingled with Customer volume in calculating tier volume. Other participants have a known rebate rate at which they would execute the entire month. A Professional could only otherwise presume the Tier 1 rebate would be achieved in a month when determining price.

The Exchange initially established Professional pricing in order to ''* * * bring additional revenue to the Exchange.'' [11] The Exchange noted in the Professional Filing that it believes ''* * * that the increased revenue from the proposal would assist the Exchange to recoup fixed costs.'' [12] Further, the Exchange noted in that filing that it believes that establishing separate pricing for a Professional, which ranges between that of a Customer and market maker, accomplishes this objective.[13] Herein, the Exchange is not proposing to amend fees, which fees continue to meet the objectives noted in the Professional Filing. Rather, the Exchange desires to amend the rebates it pays because it believes that NOM Participants would view NOM as a favorable venue to transact Professional volume. The Exchange does not believe that providing Professionals with the opportunity to obtain higher rebates would create a competitive environment where Professionals would be necessarily advantaged on NOM as compared to other NOM Market Makers, Firms or Non-NOM Market Makers. First, a Professional would be assessed the same fees as these other market participants, as is the case today. Second, a Professional only has the opportunity to achieve the higher rebate by sending in more than 35,000 contracts, otherwise the Professional only achieves a Tier 1 rebate with at least one trade and the differential in that scenario as between market participants remain the same.[14] The Exchange recognizes that the rebate tiers provide an incentive to Professionals, but it is not a guaranteed rebate.

Additionally, the Exchange believes the proposed tiered Rebates to Add Liquidity in Penny Pilot Options are reasonable, equitable and not unfairly discriminatory because the rebates are similar to a tiered rebate offered by NYSE Arca, Inc. (''NYSE Arca''). NYSE Arca pays a per contract rate on all posted liquidity in Customer Penny Pilot Issues by aggregating total contracts from customer posted orders in Penny Pilot Issues in a given month.[15] Of note, NYSE Arca does not have a professional category similar to NOM and therefore, orders that would otherwise be classified as Professionals orders on NOM [16] are being counted towards customer volume at NYSE Arca.

The Exchange proposes to count both Customer and Professional orders in the number of contracts eligible for the Rebate to Add Liquidity in Penny Pilot Options. NOM Participants would

[10] Pursuant to Chapter VII (Market Participants), Section 5 (Obligations of Market Makers), in registering as a market maker, an Options Participant commits himself to various obligations. Transactions of a Market Maker in its market making capacity must constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and Market Makers should not make bids or offers or enter into transactions that are inconsistent with such course of dealings. Further, all Market Makers are designated as specialists on NOM for all purposes under the Act or rules thereunder. *See* Chapter VII, Section 5.

[11] *See* Securities Exchange Act Release No. 64494 (May 13, 2011), 76 FR 29014 (May 19, 2011) (SR–NASDAQ–2011–066) (''Professional Filing''). In this filing, the Exchange addressed the perceived favorable pricing of Professionals who were assessed fees and paid rebates like a Customer prior to the filing. The Exchange noted in that filing that a Professional, unlike a retail Customer, has access to sophisticated trading systems that contain functionality not available to retail Customers.

[12] *See* Securities Exchange Act Release No. 64494 (May 13, 2011), 76 FR 29014 (May 19, 2011) (SR–NASDAQ–2011–066).

[13] *See* Securities Exchange Act Release No. 64494 (May 13, 2011), 76 FR 29014 (May 19, 2011) (SR–NASDAQ–2011–066) The Exchange also in the Professional Filing that it believes the role of the retail Customer in the marketplace is distinct from that of the Professional and the Exchange's fee proposal at that time accounted for this distinction by pricing each market participant according to their roles and obligations.

[14] If a Professional earned a Tier 1 rebate, the Professional would continue to receive a lower rebate as compared to a NOM Market Maker and a higher rebate as compared to a Firm and a Non-NOM Market Maker, as is the case today. The rebate differential, however, for a Professional as compared to a Firm and a Non-NOM Market Maker would be lower than it is today.

[15] *See* NYSE Arca's Fee Schedule.

[16] *See* Securities Exchange Act Release No. 63028 (October 1, 2010), 75 FR 62443 (October 8, 2010) (SR–NASDAQ–2012–099). In this rule filing, the Exchange noted that NOM Participants will be required appropriately to mark all Professional orders. To comply with this requirement, Participants will be required to review their Public Customers' activity on at least a quarterly basis to determine whether orders that are not for the account of a broker-dealer should be represented as Professional orders.

benefit from the addition of Professional orders to the number of contracts eligible for the rebate and as a result may qualify for a higher tier. The Exchange believes the addition of Professional orders to the types of orders eligible for a rebate tier is reasonable because it will incentivize NOM Participants to send additional Professional orders to the Exchange as well as Customer orders. The Exchange believes that adding Professional orders to the types of orders eligible for a rebate tier is equitable and not unfairly discriminatory because all NOM Participants will benefit from the additional liquidity the amendment may attract to the Exchange as a result of the increased incentive to send Professional as well as Customer orders. Also, all NOM Participants are eligible for the rebate and are able to earn a rebate by simply transacting one Customer or Professional order in a Penny Pilot Option.[17]

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

While the Exchange's proposal would result in a Professional receiving a higher rebate as compared to a NOM Market Maker if a Professional qualified for a Tier 2, 3 or 4 rebate and the differential in the rebate would increase as between a Professional and a Firm and a Non-NOM Market Maker, the Exchange does not believe the proposed rebate tiers would result in any burden on competition as between market participants on NOM. The Exchange does not believe that the amount of the rebate offered by the Exchange has a material impact on a NOM Participant's ability to execute orders in Penny Pilot Options.

The Exchange has been assessing the impact of rebates since it first began to offer them and has also observed the impact of fees and rebates on other options exchanges in terms of quoting and liquidity. The Exchange believes that the Fees for Adding Liquidity, as compared to rebates, impact a market participant's decision-making more prominently with respect to posting order flow on different venues and price. The Exchange does not believe that allowing a Professional to obtain a higher rebate than other market participants, if a certain number of contracts where to be executed on the Exchange, results in a burden on competition among market participants on NOM for the reasons noted herein.

The Exchange believes that offering Professionals the proposed tiered rebates creates competition among options exchanges because the Exchange believes that the rebates may cause market participants to select NOM as a venue to send Professional order flow. The fees that the Exchange assesses are not being amended with this proposal, rather the Exchange is offering to pay increased rebates in exchange for additional Professional order flow being executed at the Exchange, which additional order flow should benefit other market participants.

The Exchange operates in a highly competitive market comprised of eleven U.S. options exchanges in which sophisticated and knowledgeable market participants can readily send order flow to competing exchanges if they deem fee levels at a particular exchange to be excessive. The Exchange believes that the proposed rebate structure and tiers are competitive with rebates and tiers in place on other exchanges. The Exchange believes that this competitive marketplace impacts the rebates present on the Exchange today and substantially influences the proposals set forth above.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[18] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2012–141 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2012–141. 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 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2012–141, and should be submitted on or before February 5, 2013.

[17] A NOM Participant qualifies for a Tier 1 rebate of $0.26 per contract by adding Customer and Professional liquidity of up to 34,999 contracts per day in a month.

[18] 15 U.S.C. 78s(b)(3)(A)(ii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00634 Filed 1–14–13; 8:45 am]

BILLING CODE 8011–01–P

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68607; File No. SR–NYSE–2012–80]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Increasing the Fees Paid by Participants in the Exchange's Medallion Signature Program From $1,000 per Year to $1,300 per Year

January 9, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on December 28, 2012, New York Stock Exchange LLC (the ''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to increase the fees paid by participants in the Exchange's medallion signature program from $1,000 per year to $1,300 per year. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to change the application and annual charge to be paid by participants in the medallion signature program (''MSP'') maintained by the NYSE from $1,000 to $1,300 per year. In 1992, the Securities and Exchange Commission (''Commission'') approved NYSE's conversion of its existing signature service program to a signature guarantee program, now referred to as the MSP.[3] At that time, the NYSE specified that participants in the MSP would bear the administrative expenses in connection with the program, which at that time was a charge of $300 to be paid upon filing an application to the program and annually thereafter. The $300 charge to participants in the MSP was increased to $1,000 as of January 1, 2005.[4]

The Exchange has recently entered into a new agreement with the outside vendor that administers the MSP and the fees paid by the Exchange to that outside vendor have increased significantly. In addition, the Exchange's internal administrative and regulatory costs in relation to the MSP have increased significantly since the fees were last increased eight years ago. Consequently, effective January 1, 2013, the Exchange will increase the charge to members participating in the MSP to $1,300. This charge will be payable upon a participant's filing of an application to the MSP and annually thereafter. The NYSE will bill MSP participants the increased fee for 2013 in January 2013.

The proposed changes are not otherwise intended to address any other problem, and the Exchange is not aware of any significant problem that the affected market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)[5] of the Securities Exchange Act of 1934 (the ''Act''), in general, and furthers the objectives of Sections 6(b)(4)[6] and 6(b)(5)[7] of the Act, in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange believes that the proposed fee is equitable and not unfairly discriminatory in that it is charged only to those member organizations that voluntarily participate in the MSP. The Exchange believes that the proposed fee is reasonable in that it is closely related to the Exchange's actual costs in administering the program.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. In particular, the proposed fee only will be charged to those member organizations that voluntarily participate in the MSP. In addition, the increased fee amount correlates to the increased costs to the Exchange for administering the program.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[8] of the Act and subparagraph (f)(2) of Rule 19b–4[9] thereunder, because it establishes a due, fee, or other charge imposed by NYSE.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 31388 (October 30, 1992), 57 FR 53366 (November 9, 1992) (SR–NYSE–92–16) (order approving implementation of a signature guarantee program). The MSP is governed by NYSE Rule 200.

[4] *See* Securities Exchange Act Release No. 51190 (February 11, 2005), 70 FR 8867 (February 23, 2005) (SR–NYSE–2005–06).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78a.

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(2).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2012–80 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2012–80. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2012–80 and should be submitted on or before February 5, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00679 Filed 1–14–13; 8:45 am]

BILLING CODE 8011–01–P

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68606; File No. SR–CBOE–2012–131]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Amending Rule 5.5.04 To Permit the Exchange To List Additional Strike Prices Until the Close of Trading on the Second Business Day Prior to Monthly Expiration in Unusual Market Conditions

January 9, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 28, 2012, the Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal 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

CBOE proposes to amend Interpretation and Policy .04 to CBOE Rule 5.5 to permit the Exchange to list additional strike prices until the close of trading on the second business day prior to the expiration of a monthly, or standard, option in the event of unusual market conditions. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.org/legal*), 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 self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend Interpretation and Policy .04 to CBOE Rule 5.5 to permit the Exchange to add additional strikes until the close of trading on the second business day prior to a monthly expiration in the event of unusual market conditions.

This is a competitive filing that is based on two recently approved filings submitted by NYSE MKT LLC (''NYSE MKT'') and NYSE, Arca, Inc. (''NYSE Arca'').[5] The NYSE MKT and NYSE Arca filings both made changes to their respective rules governing the last day on which strikes may be added for individual stock and exchange-traded fund (''ETF'') options. Similar to CBOE Rule 5.5.04, NYSE MKT and NYSE Arca had rules that permitted the opening of additional series of individual stock and ETF options until the first calendar day of the month in which the option expires or until the fifth business day prior to expiration if unusual market conditions exist. NYSE MKT and NYSE Arca both amended their rules to permit the opening of additional series of individual stocks and ETF options until the close of trading on the second business day prior to the expiration of a monthly, or standard, option in the event of unusual market conditions.

Options market participants generally prefer to focus their trading in strike prices that immediately surround the price of the underlying security. However, if the price of the underlying stock or ETF moves significantly, there

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release Nos. 68460 (December 18, 2012), (SR–NYSEMKT–2012–41) (approval order) (''NYSE MKT filing'') and 68461 (December 18, 2012) (SR–NYSEArca–2012–94) (approval order) (''NYSE Arca filing'').

may be a market need for additional strike prices to adequately account for market participants' risk management needs in a stock or ETF. In these situations, the Exchange has the ability to add additional series at strike prices that are better tailored to the risk management needs of market participants. The Exchange may make the determination to open additional series for trading when the Exchange deems it necessary to maintain an orderly market, to meet customer demand, or when the market price of the underlying stock or ETF moves more than five strike prices from the initial exercise price or prices.[6]

If the market need occurs prior to five business days prior to expiration, then the market participants may have access to an option contract that is more tailored to the movement in the underlying stock or ETF. Under current CBOE Rule 5.5.04, however, the Exchange is unable to open additional series in response to unusual market conditions that occur between five to two days prior to expiration and market participants may be left without a contract that is tailored to manage their risk. Because of the current five-days-before expiration restriction, investors may be unable to tailor their hedging activities in options and effectively manage their risk going into expiration.

The Exchange proposes to permit the listing of additional strikes until the close of trading on the second business day prior to expiration in unusual market conditions. Since expiration of standard options on individual stocks and ETFs is on a Saturday, the close of trading on the second business day prior to expiration will typically fall on a Thursday. However, in the cases where Friday is a holiday during which the Exchange is closed, the close of trading on the second business day will occur on a Wednesday. The Exchange will continue to make the determination to open additional series for trading when the Exchange deems it necessary to maintain an orderly market, to meet customer demand, or when certain price movements take place in the underlying market. The proposed change will provide an additional four days to the Exchange to gauge market impact of the underlying stock or ETF and to react to any market conditions that would render additional series prior to expiration beneficial to market participants. The Exchange believes that the impact on the market from the proposed change will be very minimal to market participants; however, it will be extremely beneficial when unusual market conditions occur during the five to two days leading up to expiration. As a result, the proposal would allow participants to adjust their risk exposure when an unusual market event occurred on trading days 2, 3, 4, 5 prior to expiration.

This proposal does not raise any capacity concerns on the Exchange, because the changes have no material difference in impact from the current rules. The Exchange notes the proposed change allows for new strikes that would otherwise be permitted to add under existing rules either on the fifth day prior or immediately after expiration.[7] A strike which opens two days prior to expiration will have minimal impact on quoting, as it adds two series out of hundreds of thousands, and only for a small number of days.[8] Thus, any additional strikes that may be added under the proposed change would have no measurable effect on systems capacity.

The Exchange understands that The Options Clearing Corporation (''OCC'') is able to accommodate the proposal and would have no operational concerns with adding new series on any day except the last day of trading an expiring series.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder, including the requirements of Section 6(b) of the Act.[9] In particular, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[10] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that providing an additional four days to the Exchange to gauge market impact and to react to any market conditions prior to expiration is beneficial and will result in a continuing benefit to investors by giving them more flexibility to closely tailor their investment decisions and hedging decisions prior to expiration. The Exchange also believes that the additional four days will provide the investing public and other market participants with additional opportunities to hedge their investment thus allowing these investors to better manage their risk exposure with additional in the money series. While the four additional days may generate additional quote traffic, the Exchange does not believe that this increased traffic will become unmanageable since the proposal remains limited to the narrow situations when an unusual market event occurred on trading days 2, 3, 4, 5 prior to expiration. The Exchange also believes that the proposed rule change will ensure competition because CBOE will be able to list additional equity and ETF series up the second day before expiration in the same manner that NYSE MKT and NYSE Arca are currently able to do.

B. Self-Regulatory Organization's Statement on Burden on Competition

This proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to recently approved NYSE MKT and NYSE Arca. CBOE believes this proposed rule change is necessary to permit fair competition among the options exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule 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, provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing

[6] *See* CBOE Rule 5.5(c).

[7] Any new strikes added under this proposal would be added in a manner consistent with the range limitations described in CBOE Rule 5.5A.

[8] In the case of a multi-stock event where multiple stocks may be subject to unusual market conditions, a strike which opens two days prior to expiration will also have minimal impact on quoting, as it adds two series per stock out of hundreds of thousands, and only for a small number of days.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

of the proposed rule change or such shorter time as designated by the Commission, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6) thereunder.[12]

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because the proposal is substantially similar to those of other exchanges that have been approved by the Commission and would allow CBOE, also, to add additional strikes until the close of trading on the second business day prior to a monthly expiration in the event of unusual market conditions.[13] Therefore, the Commission designates the proposal operative upon filing.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2012–131 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2012–131. 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 CBOE. 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–2012–131 and should be submitted on or before February 5, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00610 Filed 1–14–13; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6).

[13] *See supra,* note 5.

[14] 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).

[15] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 8153]

Culturally Significant Objects Imported for Exhibition Determinations: ''Looking East: Rubens's Encounter With Asia''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Looking East: Rubens's Encounter with Asia,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The J. Paul Getty Museum, Los Angeles, CA, from on or about March 5, 2013, until on or about June 9, 2013, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: January 8, 2013.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–00721 Filed 1–14–13; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (formerly Subpart Q) during the Week Ending December 29, 2012. The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 et. seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2012–0219.

Date Filed: December 27, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 17, 2012.

Description: Application of 8199400 Canada Inc., DBA Arctic Sunwest Charters requesting a foreign air carrier permit and exemption authority to engage in on-demand charter transportation of passengers, property and mail between point(s) in Canada and point(s) in the United States, as well as other charters subject to pertinent national, bilateral and international laws and regulations.

Docket Number: DOT–OST–2012–0219.

Date Filed: December 28, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 22, 2012.

Description: Application of USA Jet Airlines, Inc. (''USAJ'') requesting the Department of Transportation disclaim jurisdiction over the corporate reorganization of USAJ in which USAJ will be converted, for tax proposes/planning, from a Delaware corporation to a Delaware limited liability company bearing the name USA Jet Airlines, LLC on December 31, 2012 (the ''Date of Reorganization'').

Barbara J. Hairston,

Acting Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2013–00694 Filed 1–14–13; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2012–60]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before February 4, 2013.

ADDRESSES: You may send comments identified by Docket Number FAA–2012–0897 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Keira Jones (202) 267–4024, or Tyneka Thomas (202) 267–7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Dated: Issued in Washington, DC, on January 9, 2013.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2012–0897

Petitioner: IsisCopter, LLC

Section of 14 CFR Affected: 14 CFR 21.191 and 91.319

Description of Relief Sought: IsisCopter seeks relief to operate small unmanned aircraft systems within visual line of sight of the pilot in command for commercial purposes.

[FR Doc. 2013–00625 Filed 1–14–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2012–54]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before February 4, 2013.

ADDRESSES: You may send comments identified by Docket Number FAA–2012–1212 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to

http://www.regulations.gov at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tyneka Thomas ARM–105, (202) 267–7626, FAA, Office of Rulemaking, 800 Independence Ave. SW., Washington, DC 20591. This notice is published pursuant to 14 CFR 11.85.

Dated: Issued in Washington, DC, on January 9, 2013.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2012–1212.

Petitioner: Uwe Goehl.

Section of 14 CFR Affected: 14 CFR 61.109(j)(4).

Description of Relief Sought: The relief sought would allow Uwe Goehl to meet solo flight requirements for the issuance of a weight-shift-control aircraft rating in an aircraft registered in a foreign state, conducted outside the United States, with an authorized instructor on board.

[FR Doc. 2013–00606 Filed 1–14–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2006–24278, FMCSA–2006–25854, FMCSA–2008–0355, FMCSA 2010–0203, FMCSA–2011–0089]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to grant requests from 22 individuals for exemptions from the regulatory requirement that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The regulation and the associated advisory criteria published in the Code of Federal Regulations as the ''Instructions for Performing and Recording Physical Examinations'' have resulted in numerous drivers being prohibited from operating CMVs in interstate commerce based on the fact that they have had one or more seizures and are taking anti-seizure medication, rather than an individual analysis of their circumstances by a qualified medical examiner. The Agency concluded that granting exemptions for these CMV drivers will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions. FMCSA grants exemptions that will allow these 22 individuals to operate CMVs in interstate commerce for a 2-year period. The exemptions preempt State laws and regulations and may be renewed.

DATES: The exemptions are effective January 15, 2013. The exemptions expire on January 15, 2015.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Division Chief, Physical Qualifications, Office of Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

A. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Privacy Act: Anyone may search the electronic form of all comments received into any of DOT's dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review DOT's complete Privacy Act Statement in the **Federal Register** (73 FR 3316, January 17, 2008). This statement is also available at *http://Docketinfo.dot.gov.*

B. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the 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''. The statute also allows the Agency to renew exemptions at the end of the 2-year period.

FMCSA grants 22 individuals an exemption from the regulatory requirement in § 391.41(b)(8) allowing individuals who take anti-seizure medication to operate CMVs in interstate commerce for a 2-year period. The Agency's decision on these exemption applications is based on an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s); the length of time elapsed since the individual's last seizure; and each individual's treatment regimen. In addition, the Agency reviewed the applicant's driving record found in the CDLIS,[1] for CDL holders, and interstate and intrastate inspections recorderd in MCMIS.[2] The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers covered by the exemptions have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

In reaching the decision to grant these exemption requests, the Agency considered both current medical literature and information and the 2007 recommendations of the Agency's Medical Expert Panel (MEP). The Agency previously gathered evidence for potential changes to the regulation by conducting a comprehensive review of scientific literature that was compiled into the ''*Evidence Report on Seizure Disorders and Commercial Vehicle Driving*'' (*Evidence Report*) [CD–ROM HD TL230.3 .E95 2007]. The Agency then convened a panel of medical experts in the field of neurology (MEP) on May 14–15, 2007, to review 49 CFR 391.41(b)(8) and the advisory criteria regarding individuals who have experienced a seizure, and the 2007 *Evidence Report.* The *Evidence Report* and the MEP recommendations are published on-line at *http://www.fmcsa.dot.gov/rules-regulations/topics/mep/mep-reports.htm,* under Seizure Disorders, and are in the docket for this notice.

[1] *Commercial Driver License Information System* (CDLIS) is an information system that allows the exchange of commercial driver licensing information among all the States. CDLIS includes the databases of fifty-one licensing jurisdictions and the CDLIS Central Site, all connected by a telecommunications network.

[2] *Motor Carrier Management Information System* (MCMIS) is an information system that captures data from field offices through SAFETYNET, CAPRI, and other sources. It is a source for FMCSA inspection, crash, compliance review, safety audit, and registration data.

MEP Criteria for Evaluation

On October 15, 2007, the MEP issued the following recommended criteria for evaluating whether an individual with epilepsy or a seizure disorder should be allowed to operate a CMV.[3] The MEP recommendations are included in an appendix at the end of this notice and in each of the previously published dockets.

Epilepsy diagnosis. If there is an *epilepsy diagnosis,* the applicant should be seizure-free for *8 years, on or off medication.* If the individual is taking anti-seizure medication(s), the plan for medication should be stable for *2 years.* Stable means no changes in medication, dosage, or frequency of medication administration. Recertification for drivers with an epilepsy diagnosis should be performed every year.

Single unprovoked seizure. If there is a *single unprovoked seizure* (i.e., there is no known trigger for the seizure), the individual should be seizure-free for *4 years, on or off medication.* If the individual is taking anti-seizure medication(s), the plan for medication should be stable for *2 years.* Recertification for drivers with a single unprovoked seizure should be performed every 2 years.

Single provoked seizure. If there is a *single provoked seizure* (i.e., there is a known reason for the seizure), the Agency should consider specific criteria that fall into the following two categories: low-risk factors for recurrence and moderate-to-high risk factors for recurrence.

- *Examples of low-risk factors for recurrence* include seizures that were caused by a medication; by non-penetrating head injury with loss of consciousness less than or equal to 30 minutes; by a brief loss of consciousness not likely to recur while driving; by metabolic derangement not likely to recur; and by alcohol or illicit drug withdrawal.
- *Examples of moderate-to-high-risk factors for recurrence* include seizures caused by non-penetrating head injury with loss of consciousness or amnesia greater than 30 minutes, or penetrating head injury; intracerebral hemorrhage associated with a stroke or trama; infections; intracranial hemorrhage; post-operative complications from brain surgery with significant brain hemorrhage; brain tumor; or stroke.

The MEP report indicates individuals with moderate to high-risk conditions should not be certified. Drivers with a history of a single provoked seizure with low risk factors for recurrence should be recertified every year.

Medical Review Board Recommendations and Agency Decision

FMCSA presented the MEP's findings and the *Evidence Report* to the Medical Review Board (MRB) for consideration. The MRB reviewed and considered the 2007 ''Seizure Disorders and Commercial Driver Safety'' evidence report and the 2007 MEP recommendations. The MRB recommended maintaining the current advisory criteria, which provide that ''drivers with a history of epilepsy/seizures off anti-seizure medication and seizure-free for 10 years may be qualified to drive a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off antiseizure medication for a 5 year period or more'' [Advisory criteria to 49 CFR 391.43(f)].

The Agency acknowledges the MRB's position on the issue but believes relevant current medical evidence supports a less conservative approach. The medical advisory criteria for epilepsy and other seizure or loss of consciousness episodes was based on the 1988 ''Conference on Neurological Disorders and Commercial Drivers'' (NITS Accession No. PB89–158950/AS). A copy of the report can be found in the docket referenced in this notice.

The MRB's recommendation treats all drivers who have experienced a seizure the same, regardless of individual medical conditions and circumstances. In addition, the recommendation to continue prohibiting drivers who are taking anti-seizure medication from operating a CMV in interstate commerce does not consider a driver's actual seizure history and time since the last seizure. The Agency has decided to use the 2007 MEP recommendations as the basis for evaluating applications for an exemption from the seizure regulation on an individual, case-by-case basis.

C. Exemptions

Following individualized assessments of the exemption applications, including a review of detailed follow-up information requested from each applicant, FMCSA is granting exemptions from 49 CFR 391.41(b)(8) to 22 individuals. Under current FMCSA regulations, all of the 22 drivers receiving exemptions from 49 CFR 391.41(b)(8) would have been considered physically qualified to drive a CMV in interstate commerce except that they presently take or have recently stopped taking anti-seizure medication. Twenty of the twenty-two drivers receiving an exemption currently take anti-seizure medication. For these 22 drivers, the primary obstacle to medical qualification was the FMCSA Advisory Criteria for Medical Examiners, based on the 1988 ''Conference on Neurological Disorders and Commercial Drivers,'' stating that a driver should be off anti-seizure medication in order to drive in interstate commerce. In fact, the Advisory Criterion has little if anything to do with the actual risk of a seizure and more to do with assumptions about individuals who are taking anti-seizure medication.

Of the 22 drivers being granted an exemption, only two individuals have an actual diagnosis of epilepsy. In each of these cases, the treating physician's rationale in diagnosing epilepsy is unclear, as the individual experienced only a single seizure. The two drivers diagnosed with epilepsy both have been seizure-free for more than 21 years. Of the other twenty drivers, 5 have been seizure-free for more than 20 years and 15 for more than 4 years. Seven of the total 20 drivers have had one provoked or unprovoked seizure from a head injury, a medical procedure, or other known cause.

In addition to evaluating the medical status of each applicant, FMCSA evaluated the crash and violation data for the 22 drivers, some of whom currently drive a CMV in intrastate commerce. The Commercial Drivers License Information System (CDLIS) and the FMCSA Motor Carrier Management Information System (MCMIS) were searched for crash and violation data on the 22 applicants. The CDLIS and MCMIS systems had records on 13 of the applicants. The crash and violation history on each individual driver is listed in his or her biographical profile.

These exemptions are contingent on the driver maintaining a stable treatment regimen and remaining seizure-free during the 2-year exemption period. The exempted drivers must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free. The driver must undergo an annual medical examination by a medical examiner, as defined by 49 CFR 390.5, following the FCMSA's regulations for the physical qualifications for commercial motor vehicle drivers.

FMCSA published a notice of receipt of application and requested public comment during a 30 day public comment period in a *Federal Register*

[3] Engel, J., Fisher, R.S., Krauss, G.L., Krumholz, A., and Quigg, M.S., ''Expert Panel Recommendations: Seizure Disorders and Commercial Motor Vehicle Driver Safety,'' FMCSA, October 15, 2007.

notice for each of the applicants. A short summary of the applicants' qualifications follows. A discussion of the comments received follows in section D. Comments. For those applicants who were denied an exemption, a notice will be published at a later date.

Docket # FMCSA–2006–24278

On October 13, 2006, FMCSA published a notice of receipt of exemption applications and requested public comment on four individuals (71 FR 60606; Docket number FMCSA–2006–24278). The comment period ended on November 13, 2006. Eight commenters responded to the **Federal Register** notice. A discussion of the comments is presented later in this document. FMCSA has determined that Wayne C. Sorenson, one of the applicants, should be granted an exemption. The Agency will issue a decision on the other drivers at a later date.

Wayne C. Sorenson. Mr. Sorenson is an intrastate CMV driver in Minnesota. Mr. Sorenson should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He first experienced seizures 17 years ago while sleeping, which were the result of an adverse reaction to medication. He has remained on a stable anti-seizure medication plan and has not had a seizure in 16 years. Mr. Sorenson states that he has no other diagnosed conditions, physical or psychological impairment, and no history of strength, sensory, or coordination impairment that would interfere with safe driving. Mr. Sorenson believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free for 16 years. Mr. Sorenson's driving record indicates an administrative loss of privileges for a period of 45 days in the state of Minnesota during 1994. He has no entries in MCMIS.

Docket # FMCSA–2006–25854

On August 9, 2007, FMCSA published a notice of receipt of exemption applications and requested public comments on nine individuals (72 FR 44916; Docket number FMCSA–2006–24854). The comment period ended on September 10, 2007. Five comments were received. A discussion of the comments is presented later in this document. Of the nine applicants, FMCSA determined that the following four individuals should be granted an exemption. The Agency will issue a decision on the other drivers at a later date.

David L. Basso. Mr. Basso is an intrastate CMV driver in Ohio who delivers to local grocery and convenience stores. Mr. Basso should be granted an exemption because he meets the MEP criteria of having a diagnosis of epilepsy, no seizures for the last 8 years, and being on a stable medication regimen for longer than 2 years. He states that he has a clinical diagnosis of epilepsy. His doctor certified that he has been seizure-free since 1990 on his current dose of medication. Mr. Basso believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free since 1990. He has no entries in CDLIS or MCMIS.

Dorothy Pokornowski. Ms. Pokornowski is an intrastate CMV driver in Minnesota. Ms. Pokornowski should be granted an exemption because she meets the MEP criteria of having a diagnosis of epilepsy, no seizures for the last 8 years, and being on a stable medication regimen for longer than 2 years. She was diagnosed with epilepsy at age 22. Her doctor certified that she has been stable, with no seizure activity on medication, since 1985. Her doctor stated that her anti-seizure medication was changed in 2006 due to concerns about certain adverse side effects. Ms. Pokornowski has seizure-free driving experience for the past 26 years. FMCSA believes that she would reach a level of safety that is equivalent to the level of safety obtained by complying with the regulation because she continues to take her medication as directed by her doctor and gets her blood levels checked every year. She has one listing in CDLIS for a seat belt infraction not involving a CMV in 1997 and one possible injury crash, non-CMV in 2010. She has no entries in MCMIS.

Brian J. Porter. Mr. Porter is an intrastate CMV driver in Pennsylvania. Mr. Porter should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. Mr. Porter states that he has been driving on the east coast for approximately 14 years. His neurologist states that he had a history of seizures but has not had any in the past 25 years. He is currently taking anti-seizure medication. Mr. Porter believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free for 25 years. Mr. Porter's CDLIS record indicates that he has 3 speeding violations (1999, all non-CMV) and 2 erratic (unsafe) lane changes (1982, 2005), both non-CMV. He has an illegal possession of alcohol, non-CMV, in 1989. He has no entries in MCMIS.

Michael W. Thomas. Mr. Thomas is an intrastate CMV driver in Kansas. Mr. Thomas should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He was diagnosed with a seizure disorder in 1987. His doctor certified he has been seizure-free for over 20 years. He is currently taking an anti-seizure medication. His doctor certified that he is compliant with his treatment and can safely operate any CMV he is qualified to drive. Mr. Thomas has a state waiver from Kansas, and has been crash-free throughout his 12 year commercial driving career. Mr. Thomas believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free for over 20 years through stringent medical compliance using the same medication and dosage. He has no entries in CDLIS or MCMIS.

Docket # FMCSA–2008–0355

On December 10, 2008, FMCSA published a notice of receipt of exemption applications and requested public comment on 15 individuals (73 FR 75165; Docket number FMCSA–2008–0355). The comment period ended on January 9, 2009. FMCSA received five comments. A discussion of the comments is presented later in this document. Of the 15 applicants, FMCSA determined that the following six individuals should be granted an exemption. The Agency will issue a decision on the other drivers at a later date.

Daniel Forth. Mr. Forth is an intrastate CMV driver in New York. Mr. Forth should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He was diagnosed with a seizure disorder in 1979, and is currently taking an anti-seizure medication. His doctor certified that he has been seizure-free for 31 years on his current dose of medication. Mr. Forth believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has maintained medication control and has

remained seizure-free for 31 years. His CDLIS record indicates a signaling violation in 1992 (vehicle unknown) and a possible injury crash (vehicle unknown) in 1991. He has no entries in MCMIS. The Agency would like to publish a correction to the 2008 notice. Mr. Forth was published as having been seizure-free for 27 years with his current dose of medications; however, he has maintained good medication control and been seizure-free for 31 years.

Garry A. Gantle. Mr. Gantle is an intrastate CMV driver in Florida. Mr. Gantle should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He was diagnosed with a seizure disorder due to a head injury, not epilepsy, in 1980. He had two seizures in 2000, related to another medical condition, not epilepsy. In 2006, his anti-seizure medication was changed. His neurologist certified that his seizure disorder is well controlled. Mr. Gantle believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free on anti-seizure medication for 11 years. He has no entries in CDLIS or MCMIS.

Steve L. Hunsaker. Mr. Hunsaker is an intrastate CMV driver in Idaho. Mr. Hunsaker should be granted an exemption because he meets the MEP criteria of having a diagnosis of nocturnal seizures, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He has a history of nocturnal seizures and is currently taking an anti-seizure medication. His doctor certified that he has been seizure-free for 22 years on his current dose of medication. Mr. Hunsaker believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has maintained good medication control and has remained seizure-free for 22 years. He has no entries in CDLIS or MCMIS.

Shane Klementis. Mr. Klementis is an intrastate CMV driver in New York. Mr. Klementis should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on stable medication for longer than 2 years. He was diagnosed with a seizure in 1982 and is currently taking an anti-seizure medication. His neurologist certified that his seizure disorder is well controlled. Mr. Klementis believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free on anti-seizure medication for 21 years. His MCMIS record lists one inspection infraction in 2009. He has no entries in CDLIS.

Scott M. Rohlinger. Mr. Rohlinger is an intrastate driver in Wisconsin. Mr. Rohlinger should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and has been off medication for 4 years. He was diagnosed with seizure disorder in 1987 and took anti-seizure medication for 20 years. He discontinued his medication in 2007. Mr. Rohlinger was involved in a motor vehicle crash that was linked to a possible seizure episode 24 years ago. His doctor certified that there were no seizure experiences prior to or following the event. Mr. Rohlinger believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free for 24 years. His doctor certified that he may never have experienced a seizure. His CDLIS record lists one property damage crash in 2007 (non-CMV). He has no entries in MCMIS.

John B. Yates. Mr. Yates is an intrastate CMV driver in West Virginia. Mr. Yates should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on stable medication for longer than 2 years. He has a history of seizures, diagnosed in 1976, and is currently taking an anti-seizure medication. According to his neurologist, his last seizure was in 1982. Mr. Yates believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has not had a seizure in 29 years while on medication. His CDLIS record indicates 2 charges of negligent driving not involving a CMV (1990, 1985) and one speeding violation in 1988 (non-CMV). He has no entries in MCMIS.

Docket # FMCSA–2010–0203

On July 2, 2010, FMCSA published a notice of receipt of exemption applications and requested comments from the public on 17 individuals (75 FR 38599; Docket number FMCSA–2010–0203). The comment period ended on August 2, 2010. FMCSA received 6 comments. A discussion of the comments is presented later in this document. Of the 17 applicants, FMCSA determined that the following eight individuals should be granted an exemption. The Agency will issue a decision on the other drivers at a later date.

Bruce B. Baum. Mr. Baum is an intrastate CMV driver in New Mexico. Mr. Baum should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He experienced a single episode of a seizure in 1999 and is currently taking an anti-seizure medication. His neurologist states that he has been seizure-free since 2002. Mr. Baum believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free and compliant on medication for 7 years. He has no entries in CDLIS or MCMIS.

Todd A. Davis. Mr. Davis is an intrastate CMV driver in Wisconsin. Mr. Davis should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He experienced a complex partial seizure in 2007 and is currently taking an anti-seizure medication. His neurologist certified that Mr. Davis has been seizure free for 4 years. Mr. Davis believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free and compliant with medication since 2007. He has one 2010 CDLIS violation involving a non-injury crash with non-CMV operation indicated. He has no entries in MCMIS.

James Dyer. Mr. Dyer is an intrastate CMV driver in Texas. Mr. Dyer should be granted an exemption because he meets the MEP criteria of having no diagnosis of epilepsy, no seizures for the last 4 years, and being on no anti-seizure medication regimen for longer than 2 years. He experienced a single seizure-like event in 2008. He has been off medication for 3 years. His neurologist certified that Mr. Dyer has been seizure-free for 4 years. Mr. Dyer believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free since 2008. He has no entries in CDLIS or MCMIS.

Christian E. Henry. Mr. Henry is an intrastate CMV driver in Pennsylvania. Mr. Henry should be granted an exemption because he meets the MEP criteria of having no diagnosis of

epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He has a history of seizures during medical procedures when he was a juvenile. His doctor states that he has been seizure-free for 13-plus years on his current dose of medication and is stable to drive. Mr. Henry believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free since 1998, has a safe driving record, and he is compliant with his medication. He has no entries in CDLIS or MCMIS.

Henrietta M. Ketcham. Ms. Ketcham is an intrastate CMV driver in New York. Ms. Ketcham should be granted an exemption because she meets the MEP criteria of not having a diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. She has a history of seizure disorder dating to 1992. She experienced her last seizure in 2001 and is currently taking an anti-seizure medication. Her doctor states that she has been seizure-free for 10 years on her current dose of medication and remains stable. Ms. Ketcham believes that she would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because she has maintained good medication control and has remained seizure-free for 10 years. During 1990, she had one violation listed in CDLIS for failing to obey a traffic control device (non-CMV) and two possible injury crashes (vehicle unknown). She has no entries in MCMIS.

Joseph A. Suhy. Mr. Suhy is an intrastate CMV driver in Pennsylvania. Mr. Suhy should be granted an exemption because he meets the MEP criteria of not having a diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He was diagnosed with a seizure disorder after a head injury in 1986. His last seizure was in 1991 and at the time he was on an anti-seizure medication. His anti-seizure medication was changed in 1991. He remains on this medication to date. His doctor states that he has been seizure-free for 20 years. Mr. Suhy believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has remained seizure-free and is compliant with treatment. He has no entries in CDLIS or MCMIS.

Paul C. Warren. Mr. Warren is an intrastate CMV driver in Maine. Mr. Warren should be granted an exemption because he meets the MEP criteria of not having a diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He was originally diagnosed with epilepsy in 2000. He experienced his last seizure in 2002 and is currently taking an anti-seizure medication. His neurologist states that he has been seizure-free for 9 years and is compliant with treatment. Mr. Warren believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has a history of safe driving in CMVs and has remained seizure-free for 9 years.

The Agency would like to publish a correction to the July 2, 2010, notice. Mr. Warren was described as having been diagnosed with epilepsy. His actual diagnosis is one of partial complex seizures and he qualifies for an exemption based on having the seizure-free period of 4 years recommended by the MEP. He has no entries in CDLIS or MCMIS.

Brian H. Wetzel. Mr. Wetzel is an intrastate CMV driver in Missouri. Mr. Wetzel should be granted an exemption because he meets the MEP criteria of not having a diagnosis of epilepsy, no seizures for the last 4 years, and being on a stable medication regimen for longer than 2 years. He was diagnosed with a seizure disorder after brain surgery in 1976. He experienced his last seizure in 1995 and is currently taking an anti-seizure medication. His neurologist's medical opinion is that he has been seizure-free for 16 years and is safe to drive. Mr. Wetzel believes that he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has been seizure free for 16 years and is compliant with treatment. He has no entries in CDLIS or MCMIS.

Docket # FMCSA–2011–0089

On April 5, 2011, FMCSA published a notice of receipt of exemption applications from 8 individuals, and requested comments from the public (76 FR18822). The comment period ended on May 5, 2011. FMCSA received two comments. A discussion of the comments is presented later in this document. Of the 8 applicants published, the following 3 individuals are being granted an exemption. The Agency will issue a decision on the other drivers at a later date.

Donald Schutz. Mr. Schutz is an intrastate CMV driver in Ohio. Mr. Schutz should be granted an exemption since he meets the MEP criteria and would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation. He has remained seizure-free for 9 years and has been on anti-seizure medication since 2002. He states that he was diagnosed with a brain tumor in 2002 and that he suffered a seizure due to a tumor in July of that year. He had brain surgery in November 2002 and the tumor was successfully removed. Mr. Schutz has been taking anti-seizure medication since that time and has had no further seizures. He has his medication levels checked often by blood tests and remains compliant with his regimen. Mr. Schultz's CDLIS report shows a non-CMV inability-to-control violation in 2002. He has no entries in MCMIS.

Robin L. Sherwood. Mr. Sherwood is an intrastate CMV driver in Idaho. Mr. Sherwood should be granted an exemption. He would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation. He has remained seizure-free since 1997 and is compliant with his medication regimen for seizures. He states that he had a seizure caused by a brain tumor in 1997 and that the tumor was successfully removed during the same year. Mr. Sherwood has taken anti-seizure medication since 1997 with no further seizure activity. His doctor supports Mr. Sherwood's application for exemption because of his successful surgery and medication compliance. His CDLIS report states that he has a non-CMV speeding violation in 1991. He has no entries in MCMIS.

Frank Eveland. Mr. Eveland is an intrastate CMV driver in Wisconsin. Mr. Eveland should be granted an exemption. He meets the MEP criteria and has remained seizure-free for 8 years. He has been on anti-seizure medication since 2003. He was diagnosed with one unprovoked seizure in 2003 and placed on anti-seizure medication at that time. His physician states that Mr. Eveland has had no further seizures and that his medication level is checked regularly by blood tests. The doctor states that Mr. Eveland is safe to operate a motor vehicle and that he is compliant with his medication. Mr. Eveland believes he would achieve a level of safety that is equivalent to the level of safety obtained by complying with the regulation because he has maintained good medication control and has remained seizure-free for 8 years. Mr. Eveland's CDLIS report states that he has a property damage/non-injury crash in 2011, a non-CMV violation. He has no entries in MCMIS.

D. Comments

In response to the five notices, FMCSA received 26 different comments. Comments that relate specifically to applicants other than the ones covered in this notice will be addressed in a subsequent notice of denial of application.

Individual Assessment of Applicants for Exemption

On behalf of the Epilepsy Foundation, Brien J. Smith, MD, urged the establishment of a thorough science-based process in reviewing exemption requests, including consideration of each individual's level of risk to public safety (FMCSA–2004–24278–0012). The Epilepsy Foundation expressed concern that the current standard creates a ''blanket exclusion for persons with a history of recurrent seizures, without distinction as to the type of seizure.'' The Epilepsy Foundation asserted that the Americans with Disabilities Act of 1990, 42 U.S.C. 12101 et seq. (ADA), and Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 701, et seq. (Rehabilitation Act), prohibit blanket exclusions and require individualized assessments of fitness and risk. Based on more recent medical knowledge and strides in treatment of epilepsy, it called on FMCSA to eliminate its blanket disqualification of persons with epilepsy seeking licenses to operate a CMV. The Foundation recommended that FMCSA establish new guidelines for licensing commercial drivers and give greater weight to the exemption, including documentation on an individual's medication compliance posture and the absence of other precipitating conditions.

FMCSA Response: FMCSA notes that the ADA permits the establishment of regulations concerning minimum levels of physical qualifications for CMV drivers, which may be tantamount to blanket exclusions.[4] Notwithstanding the minimum qualification requirements, FMCSA agrees with the Epilepsy Foundation that the general exemption process for CMV drivers with disabilities allows FMCSA to consider new developments in medicines or adaptations that reduce significantly the safety risk created by certain medical conditions. While FMCSA is not initiating a new exemption program, similar to the Agency's vision and diabetes exemption programs, we are acknowledging advances in treatment of individuals who have experienced a seizure.

The Agency conducted a comprehensive literature review and convened a panel of medical experts in epilepsy and neurology to address key questions and make recommendations concerning new guidelines for CMV drivers. FMCSA is conducting individualized case assessments of persons seeking an exemption from § 391.41(b)(8). The Agency seeks to assess safety risks, medical history, and compliance to determine whether there is a likelihood the individual will experience a seizure while operating a CMV in interstate commerce on or off medication. The goal is to ensure a minimal safety risk to the driver or the travelling public.

No Exemptions for Epilepsy

Dr. Merris T. Young, MD, stated, ''I personally and professionally feel that any allowance of individuals diagnosed with epilepsy to operate such potentially dangerous equipment before such updated medical information is available is unacceptable, because it would place the public health and safety and significantly increased risk'' (FMCSA–2006–24278–0007).

FMCSA Response: The Agency believes that evaluating each individual's medical history on a case-by-case basis and investigating the past driving/violation record ensures an acceptable level of safety for a driver who has not experienced a seizure for an extended period of time. Drivers, who have been seizure-free, on or off medication for at least four years, pose a minimal risk to public safety. The Agency considered the 2007 *Evidence Report* and the 2007 MEP Recommendations to determine the driver's level of risk for recurrence of seizure. The Agency believes this data and information addresses Dr. Young's concerns.

Concerns About Medical Examiners

Daniel M. Janiga, MD, a medical director for multiple companies that hire drivers who require medical examiners' certificates, indicated his concern that drivers may go ''doctor shopping'' to find a medical examiner who will support their requests for exemptions (FMCSA–2006–24278–0003). Because of the difficulty of managing seizure disorders (for example, medications may lower seizure thresholds) and monitoring drivers, he favored ''staying with our current rules/guidelines'' until there are evidence-based studies on the effects of ''fatigue, medications such as Zyban, physical conditions such as sleep apnea* * *'' on lowering seizure thresholds and how they relate to driving accidents.

FMCSA Response: The Agency acknowledges Dr. Janiga's concern about drivers who have experienced a seizure, take medication and fail to share that information with their Medical Examiners. Allowing drivers an option for an exemption, especially those who have not experienced a seizure in several years, may decrease the number of drivers who fail to disclose their medical history to the Medical Examiner. The MEP recommendations provide a practical solution to protect both public safety and the drivers, need for employment.

Inadequate Basis for the Exemption

Advocates for Highway and Auto Safety (Advocates) wrote that the Agency's position that some drivers who are seizure free should be granted exemptions is unsupported by ''medical research, statistical data, legal decisions, or any published determination by the Secretary of Transportation'' (FMCSA–2006–24278–0011). They stated that the underlying rationale for exemptions from the current rule was not based on recent scientific or medical studies and that the Agency had presented no medical or other information on which it can make a determination. In 2006, Advocates recommended waiting until ''convincing evidence [was] presented that medical authorities can determine a shorter period is appropriate for some or all persons with seizure histories.'' In a later comment, Advocates recommended that the Agency update the driver physical and medical qualifications based on current medical norms and science (FMCSA–2006–25854–0005). The FMCSA notes that in requesting public comments for an exemption application, the Agency did not offer opinions or views whether the exemption should be granted or denied.

FMCSA Response: The Agency believes the Advocates' concerns were appropriate based on information available to the Agency and the public in 2006. However, the findings of the 2007 comprehensive literature review

[4] The Conference Report specifically emphasized that the ADA is not meant to ''override any legitimate medical standards established by Federal, State or local law, or by employers for applicants for safety or security positions, if the medical standards are consistent with [the ADA].'' *See* Conference Report on S.933, Americans with Disabilities Act: Joint Explanatory Statement of the Committee of Conference, H.R. Rep. No. 596, 101st Cong., 2d Sess. at 59 (1990), *reprinted in* 136 Cong. Rec. H 4582, 4597 (Daily ed. July 12, 1990). In *Albertson's Inc.* v. *Kirkingburg,* 527 U.S. 555, (1999), the Supreme Court recognized that federal safety rules may limit application of the ADA as a matter of law, citing the Senate Labor and Human Resources Committee report on the ADA, which stated that a ''person with a disability applying for or currently holding a job subject to [Department of Transportation standards for drivers] must be able to satisfy these physical qualifications standards in order to be considered a qualified individual with a disability under [the ADA].'' 527 U.S. at 573.

and the MEP recommendations provide current information that the Agency considered in making the determination that an exemption would likely achieve a level of safety that is equivalent to or greater than the level achieved without the exemption. The Agency's advisory criteria recommending the 10-year seizure-free/off medication period for driving a CMV was established by a panel of neurologists in 1988. In 2007, the MEP updated the information regarding treatment of seizure disorders and the likelihood of seizure recurrence for a variety of seizure disorders and situations. FMCSA believes that the current research and information supersede the information presented by the panel of neurologists in the 1988, ''Conference on Neurological Disorders and Commercial Drivers.'' Also, the drivers covered by the exemptions have been free of seizures for a period of four years to more than 20 years.

Inadequate Information About Individual Applicants

Advocates stated that ''unless the Agency can document that individual applicants do not pose an increased safety risk when operating a CMV, as compared with persons who have not had a seizure or seizure history, then the Agency cannot grant exemptions'' (FMCSA–2006–24278–0011). FMCSA is required by 49 U.S.C. 31315(b)(4) to publish a notice and provide an opportunity for the public to comment on every applicant for an exemption, irrespective of whether the Agency believes the arguments offered by the applicant warrant the granting of an exemption. In fact, the Agency reserves judgement until after the notice and comment period. Advocates commented that ''the brief statements presented in the notice for each applicant do not provide the medical evidence based in individualized testing necessary to meet the legal burden for granting exemptions.'' Advocates wrote that ''FMCSA has not developed any means for performing individualized testing.''

Advocates stated that two of the applicants were diagnosed with epilepsy and therefore should not be granted an exemption. Advocates also noted difficulties with applicants in two notices including ''recent seizure events'' and the fact that some drivers continue to take anti-seizure medication: ''Thus, they do not meet the current requirements.''

Mr. Steven A. Tudor (FMCSA 2006–25854–0003) commented that three drivers did not have their home States listed and that this would preclude their States from knowing about the **Federal Register** listing.

FMCSA Response: In response to the Advocates comment regarding medical evidence, FMCSA reviews each individual applicant, assesses the driving record and the individual's medical condition, and determines on a case-by-case basis the driver's risk to public safety. FMCSA is not granting drivers with recent seizure events an exemption based on the MEP recommendations. The Agency has made the decision to use the more current 2007 MEP recommendations to grant exemptions on a case-by-case basis rather than to judge all drivers by the criteria established in the 1988 ''Conference on Neurological Disorders and Commercial Drivers'' report. The Agency evaluated each individual's medical condition, comparing it to the 2007 MEP. In addition, to ensure the safest roads possible, the Agency researched each individual's driving record. Further, we believe that each driver has shown evidence of compliance with his or her treatment regimen. Thus, we believe that the individuals listed above have a level of safety equivalent to those drivers who do not suffer from a seizure disorder.

The Agency believes, however, that a driver who has not experienced a seizure in years, should not be precluded from driving a CMV in interstate commerce merely because he remains on anti-seizure medication. Generally, the Agency does not preclude drivers with medical conditions, other than seizure disorders, from operating a CMV in interstate commerce merely because they are taking medication. In addition, all drivers must be stable on the medication for 2 years, which is a long enough period of time for the driver and his treating physician to note any adverse reactions to the medication such as excessive drowsiness. As mentioned in the background section, only those drivers meeting the MEP criteria are being granted an exemption.

In response to Advocates' concern about the brevity of FMCSA's statement on each seizure exemption applicant, the Agency does not post all the medical information provided by the drivers. The Agency provides information about the specific medical condition for which the exemption is being sought. FMCSA summarizes the information for the public's view, as we do for the **Federal Register** notices announcing application requests for vision and diabetes exemptions from the rules. FMCSA is consistent in the way that all medical exemptions are handled. We have extensive documentation used to verify that the medical condition for which the exemption is being sought is the only condition to prevent the drivers from operating a CMV in interstate commerce. The Agency provides a minimal amount of information to announce the exemption request to protect the driver from unnecessary disclosure of personal and medically confidential information.

In response to Mr. Tudor's comment, FMCSA added the home States to the each driver's biographical statement in this **Federal Register** notice.

MRB Criteria

Advocates expressed concerns that a coherent policy is needed which addresses medical and physical qualifications of CMV drivers, and urged a review of the current standards by the MRB (FMCSA–2006–25854–0005). Advocates stated that the MRB should be the body that makes the determination.

FMCSA Response: FMCSA's MRB is a Federal Advisory Committee whose role is to provide scientific and medical advice to FMCSA on ongoing medical issues, including the identification of appropriate physical qualifications of CMV drivers, medical standards, and educational curriculum for training medical examiners who certify that drivers meet the physical qualification standards and functional tests for drivers with disabilities. The MRB reviews all current FMCSA medical standards and makes recommendations to FMCSA for new science-based standards and guidelines to ensure that drivers operating CMVs in interstate commerce, as defined in 49 CFR 390.5, are physically capable. Thus, the MRB makes recommendations but the Agency is the deciding body, determining which of the MRB's advice and recommendations to adopt, 49 U.S.C. 31149(a)(1) and (c)(1). The Agency does not believe it was Congress's intent that the MRB serve as a medical certification review board for each individual seeking an exemption.

Support for Applicants and the Exemptions

Lori A. Strom wrote in support of drivers who have been seizure-free for a long time; she cited the 20-year safety record of her husband, a CMV operator with a seizure disorder on seizure medication, as a positive example (FMCSA–2006–25854–0006). Mr. Strom operates under an intrastate exemption granted by the State of California. An anonymous writer (FMCSA–2006–25854–0004) and Mr. V. Ross (FMCSA–2006–25854–0002) both agreed that drivers exhibiting long-term control of their seizure disorders (more than 5 years) should be granted exemptions. Mr. Ross warned against giving

exemptions to drivers who had shown only short-term control. Pamela Stern (FMCSA–2008–0355–0002), Eugene Dobrowolski (FMCSA–2008–0355–0005), and Kelly Dobrowolski (FMCSA–2008–0355–0005) submitted letters in support of driver John M. Dobrowolski's exemption application.

Mr. Michael W. Thomas, a CMV driver, wrote to support fair treatment for drivers with controlled seizure disorders (FMCSA–2010–0203–0002). He also stated that his application for exemption had not been acted on by FMCSA. Mr. Todd Davis wrote in favor of his own application and indicated that he has successfully complied with his current medication regimen since 2007 (FMCSA–2010–0203–0004 and 0006). Frankie Linn Eveland stated, ''I believe it is perfectly safe for these individuals to operate a Commercial Vehicle with the current conditions under complete control. It seems to be discrimination if this medical condition needs special conditions'' (FMCSA–2010–0203–0007). An anonymous commenter wrote in support of his own application (FMCSA–2010–0203–0003), identifying only that he was an exemption applicant. James Dyer commented about himself that ''according to my Neurologist, I experienced a single seizure like event in 2008. I have been seizure-free since and have been off anti-seizure medication since April 2009'' (FMCSA–2010–0203–0005).

Two commenters wrote in support of Mr. Robin Sherwood. Joe Helsley commented that he has known Mr. Sherwood for 6 years and was his employer (FMCSA–2011–0089–0002). He stated that Mr. Sherwood is a reliable and responsible truck driver and confirmed that he has never had any seizures while working for him. Mr. Dick Rankins commented that Mr. Sherwood is an exemplary driver, was safe in carrying out his duties, and that he would hire Mr. Sherwood at anytime due to his work and reputation (FMCSA–2011–0089–0003).

FMCSA Response: FMCSA acknowledges support for these exemptions. The Agency carefully reviewed all the comments about every individual. Mr. Thomas' application was reviewed and published (72 FR 44916, Aug. 9, 2007); he is granted an exemption in this notice. Mr. Dyer has been seizure free for 4 years and is granted an exemption in this notice. Comments that relate specifically to applicants other than those covered in this notice will be addressed in a subsequent notice.

Concerns About Discrimination and the ADA

Bonnie (no last name given) wrote that her husband had been discriminated against and terminated by his employer because he has a controlled seizure disorder (FMCSA–2008–0355–0007). She stated the need to rewrite the rule on seizure disorders to eliminate ''loopholes'' allowing this practice. Doug Foster stated that the current standards for exemption from the seizure rule are too high and that there is no collected data about epilepsy-related crashes (FMCSA–2008–0355–0003). Mr. Foster expressed concern that current rules may violate ADA provisions regarding people with epilepsy or seizure disorders.

FMCSA Response: FMCSA believes that the individualized assessment of exemption applicants established by this **Federal Register** notice, using the 2007 MEP Recommendations, addresses the commenters' concerns about discrimination while maintaining an equivalent level of public safety. Regarding comments related to the ADA, we note that in passing the ADA, Congress explicitly recognized that individuals must meet minimum physical qualifications for operating CMVs in interstate commerce. The Agency's current approach, articulated in this **Federal Register** notice, nevertheless meets the spirit of the ADA by conducting an individualized assessment of each exemption applicants' medical history and the concomitant level of safety risk. The Agency's case-by-case review of exemption applicants and its accompanying advisory criteria provides the best assurance of drivers being treated fairly while at the same time addressing public safety concerns. The Agency used the best available data to support the recommendations.

E. Basis for Exemption

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the epilepsy/seizure standard in 49 CFR 391.41(b)(8) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, the Agency's analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

Conclusion

The Agency is granting exemptions from the epilepsy standard, 49 CFR 391.41(b)(8), to 22 individuals based on a thorough evaluation of each driver's qualifications, safety experience, and medical condition. Safety analysis of information relating to these 22 applicants meets the burden of showing that granting the exemptions would achieve a level of safety that is equivalent to or greater than the level that would be achieved without the exemption. By granting the exemptions, the CMV industry will gain 22 highly trained and experienced drivers. In accordance with 49 U.S.C. 31315, each exemption will be valid for 2 years with annual recertification required unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

FMCSA exempts the following 22 drivers for a period of 2 years with annual medical certification required: Wayne C. Sorenson (MN); David L. Basso (OH); Michael W. Thomas (KS); Garry W. Gantle (FL); Steve L. Hunsaker (ID); John B. Yates (WV); Henrietta M. Ketcham (NY); Joseph A. Suhy (PA); Dorothy Pokornowski (MN); Brian J. Porter (PA); Daniel Forth (NY); Shane Klementis (NY); Scott M. Rohlinger (WI); Bruce B. Baum (NM); Todd A. Davis (WI); James Dyer (TX); Christian E. Henry (PA); Paul C. Warren (ME); Brian H. Wetzel (MO); Donald Schutz (OH); Robin L. Sherwood (ID), and Frank Eveland (WI) from the prohibition of CMV operations by persons with a clinical diagnosis of epilepsy or seizures. If the exemption is still in effect at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Appendix—MEP Opinion

The following is an exerpt from the ''Expert Panel Recommendations: Seizure Disorders and Commercial Motor Vehicle Driver Safety,'' presented to FMCSA on October 15, 2007.

Recommended Changes to Original Guidelines

The MEP recommended that FMCSA make substantial changes to the current seizure disorder guidelines. These recommendations were based on a combination of evidence provided by the Evidence Report titled, ''Seizure Disorders and Commercial Motor

Vehicle Driver Safety'' and other sources. Below we present the recommendations of the MEP and provide justification for these recommendations.

Guideline 1: Fitness-to-drive certification of individuals with a history of epilepsy

The MEP recommended that the current guidelines pertaining to individuals who have a diagnosis of epilepsy (Appendix A) be replaced with the following:

• A history of epilepsy precludes an individual from obtaining unconditional certification to drive a CMV for the purposes of interstate commerce.

• A history of epilepsy, however, should not unconditionally exclude all individuals from driving a CMV; conditional certification may be possible in some instances.

• An individual with a history of epilepsy may obtain conditional certification (or maintaining certification under conditional status) to drive a CMV if that individual meets the following criteria:

—Individual must have been seizure free for a minimum of 8 years on or off anti-seizure medication; *AND*

—If all anti-seizure medications have been stopped, the individual must have been seizure free for a minimum of 8 years from the time of medication cessation; *OR*

—If still using anti-seizure medication, the individual must have been on a stable medication regimen for a minimum of 2 years.

• An individual with a history of epilepsy who has been granted conditional certification to drive a CMV must be recertified on an annual basis.

Guideline 2: Fitness-to-drive certification of individuals with a history of a single unprovoked seizure

The MEP recommended that the current guideline pertaining to individuals who have experienced a single, unprovoked seizure (Appendix A) be replaced with the following guideline:

• A history of experiencing a single unprovoked seizure precludes an individual from obtaining unconditional certification to drive a CMV for the purposes of interstate commerce.

• A history of experiencing a single unprovoked seizure, however, should not unconditionally exclude all individuals from driving a CMV; conditional certification may be possible in some instances.

• An individual with a history of a single, unprovoked seizure may obtain conditional certification (or maintaining certification under conditional status) to drive a CMV if that individual meets the following criteria:

—Individual must have been seizure free for a minimum of 4 years on or off anti-seizure medication; *AND*

• If all anti-seizure medications have been stopped, the individual must have been seizure free for a minimum of 4 years from the time of medication cessation; *OR*

• If still using anti-seizure medication, the individual must have been on a stable medication regimen for a minimum of 2 years.

• An individual with a history of a single, unprovoked seizure who has been granted conditional certification to drive a CMV must be recertified on a biennial basis.

Guideline 3: Fitness-to-drive certification of individuals with a history of a provoked seizure or seizures;

This category of seizure pertains to a provoked seizure. Certification may be allowed if the individual is at low risk for again encountering the factor that precipitated the seizure or of having further seizures. Patients whose seizures are provoked by sleep deprivation, photic or visual pattern stimulation will not be considered for certification under this guideline, since these patients may have underlying epilepsy. Conditional certification of such individuals will be considered according to Guideline 1. The MEP recommended that the current guideline pertaining to individuals who have experienced a symptomatic seizure or seizures (Appendix A) be replaced with the following guideline:

• A history of experiencing a single provoked seizure should not automatically preclude an individual from obtaining unconditional certification to drive a CMV for the purposes of interstate commerce.

• Whether an individual with such a history can be unconditionally certified requires an individual evaluation to ascertain that the individual is at a sufficiently low recurrence risk for again encountering the factor that precipitated the seizure or of having further seizures.

• Examples of low risk for recurrence include:

—A lidocaine-induced seizure during a dental appointment.

—A concussive seizure, loss of consciousness ≤30 minutes, no penetrating injury.

—A seizure due to syncope not likely to recur while driving.

—A seizure from an acute metabolic derangement not likely to recur.

—Drug withdrawal.

• Conditional certification may be considered for individuals with moderate-to-high risk factors for recurrence provided that the following conditions are met:

—Individual must have been seizure free for a minimum of 8 years on or off anti-seizure medication; *AND*

—If all anti-seizure medications have been stopped, the individual must have been seizure free for a minimum of 8 years from the time of medication cessation; *OR*

—If still using anti-seizure medication, the individual must have been on a stable medication regimen for a minimum of 2 years.

• An individual with a history of epilepsy who has been granted conditional certification to drive a CMV must be recertified on an annual basis.

• Examples of seizure-provoking conditions that are at moderate-to-high risk for further seizures, and therefore would weigh against certification, include the following:

—Head injury with loss of consciousness or amnesia ≥ 30 minutes or penetrating head injury.

—Intracerebral hemorrhage of any etiology, including stroke and trauma.

—Brain infection: encephalitis, meningitis, abscess, cysticercosis.

—Stroke.

—Intracranial hemorrhage.

—Post-operative brain surgery with significant brain hemorrhage.

—Brain tumor.

Issued on: January 10, 2013.

William ''Bill'' Bronrott,

Deputy Administrator, for Federal Motor Carrier Safety Administration.

[FR Doc. 2013–00709 Filed 1–11–13; 4:15 pm]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0094]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption, request for comments.

SUMMARY: FMCSA announces receipt of applications from 14 individuals for an exemption from the prohibition against persons with a clinical diagnosis of epilepsy or any other condition which is likely to cause a loss of consciousness or any loss of ability to operate a commercial motor vehicle (CMV) from operating CMVs in interstate commerce. The regulation and the associated advisory criteria published in the Code of Federal Regulations as the ''Instructions for Performing and Recording Physical Examinations'' have resulted in numerous drivers being prohibited from operating CMVs in interstate commerce based on the fact that they have had one or more seizures and are taking anti-seizure medication, rather than an individual analysis of their circumstances by a qualified medical examiner. If granted, the exemptions would enable these individuals who have had one or more seizures and are taking anti-seizure medication to operate CMVs for 2 years in interstate commerce.

DATES: Comments must be received on or before February 14, 2013.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2012–0094—using any of the following methods:

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

• *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

• *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket ID for this Notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on January 17, 2008 (73 FR 3316; January 17, 2008). This information is also available at *http://Docketinfo.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Elaine Papp, Chief, Medical Programs Division, (202) 366–4001, or via email at *fmcsamedical@dot.gov,* or by letter FMCSA, Room W64–113, Department of Transportation, 1200 New Jersey Avenue SE., 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. 31315 and 31136(e), FMCSA may grant an exemption 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.'' The statutes also allow the Agency to renew exemptions at the end of the 2-year period. The 14 individuals listed in this notice have recently requested an exemption from the epilepsy prohibition in 49 CFR 391.41(b)(8), which applies to drivers who operate CMVs as defined in 49 CFR 390.5, in interstate commerce. Section 391.41(b)(8) states that a person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a commercial motor vehicle.

FMCSA provides medical advisory criteria for use by medical examiners in determining whether drivers with certain medical conditions should be certified to operate commercial motor vehicles in intrastate commerce. The advisory criteria indicate that if an individual has had a sudden episode of a non-epileptic seizure or loss of consciousness of unknown cause which did not require anti-seizure medication, the decision whether that person's condition is likely to cause the loss of consciousness or loss of ability to control a CMV should be made on an individual basis by the medical examiner in consultation with the treating physician. Before certification is considered, it is suggested that a 6-month waiting period elapse from the time of the episode. Following the waiting period, it is suggested that the individual have a complete neurological examination. If the results of the examination are negative and anti-seizure medication is not required, then the driver may be qualified.

In those individual cases where a driver had a seizure or an episode of loss of consciousness that resulted from a known medical condition (e.g., drug reaction, high temperature, acute infectious disease, dehydration, or acute metabolic disturbance), certification should be deferred until the driver has fully recovered from that condition, has no existing residual complications, and is not taking anti-seizure medication. Drivers who have a history of epilepsy/seizures, off anti-seizure medication and seizure-free for 10 years, may be qualified to operate a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off anti-seizure medication for a 5-year period or more.

Summary of Applications

Salvatore Gerard Adamita

Mr. Adamita is a 45 year-old CMV driver in the state of Florida. He has a history of epilepsy and has had two seizures in his lifetime; the last seizure was in 1992. He has remained seizure free for 20 years. He takes anti-seizure medication with the dosage and frequency remaining the same for 20 years. If granted the exemption, he would like to drive straight trucks or single tractor trailer trucks. His physician states he is supportive of Mr. Adamita receiving an exemption and Mr. Adamita states he feels he would operate a vehicle at the same safety level as someone who did not require an exemption.

John W. Boerth

Mr. Boerth is a 64 year-old class CML driver in the State of Wisconsin. He had brain surgery in 2002 and has since had 2 seizures, one in 2002 and the last seizure was June 2003. He takes anti-seizure medication with the dosage and frequency remaining the same for over 10 years. If granted the exemption, he would like to drive vehicles from one-half ton vans to 18,000 pound straight trucks in interstate commerce.

Michael C. Breitbach

Mr. Breitbach is a 56 year-old CMV driver in the State of Iowa. He has a history of two nocturnal seizures in his lifetime; the last seizure was in 2002. He has remained seizure free for 10 years. He takes anti-seizure medication with the dosage and frequency remaining the same for 5 years. If granted the exemption, he would like to drive tractor trailer trucks. His physician states he is supportive of Mr. Breitbach receiving an exemption.

Sonja D. Cottle

Ms. Cottle is a 55 year-old CDL driver in the State of Wisconsin. She had brain surgery with the removal of a left frontal meningioma in September 2011. She was placed on anti-seizure medication as a preventative measure during and after the surgery. She remains on the anti-seizure medication with the dosage and frequency remaining the same since September 2011. She has never had a seizure. If granted the exemption, she would like to return to driving semi-tractors with trailers. Her medical provider states that she believes it is safe for Ms. Cottle to return to driving CMVs.

Jeffrey Blake Davis

Mr. Davis is a 47 year-old CMV driver in the State of Maryland. He has a

diagnosis of seizure disorder post aneurysm with three seizures related to the diagnosis of the aneurysm. His last seizure was August 2011. He has remained seizure free for 10 months. He takes anti-seizure medication with the dosage and frequency remaining the same for 10 months. If granted the exemption, he would like to drive dump trucks in interstate commerce. His physician states he is supportive of Mr. Davis receiving an exemption.

Timothy Grant Edwards

Mr. Edwards is a 25 year-old driver in the state of Tennessee. He has a diagnosis of complex partial seizures. His last seizure was in 1992. He has remained seizure free for 20 years. He takes anti-seizure medication with the dosage and frequency remaining the same for 10 years. If granted the exemption, he would like to drive a service truck for his employer that weighs more than 10,000 pounds, but less than 26,000 pounds, in interstate commerce.

Juan Flores

Mr. Flores is a 40 year-old driver in the state of Massachusetts. He had a closed head injury at age 17 and has had 5 or 6 seizures in his lifetime, the last one being January 2011. He has remained seizure free since that time. He takes anti-seizure medication with the dosage and frequency remaining the same for 1 year. If granted the exemption, he would like to drive CMVs with aerial buckets and derrick diggers to install utility poles.

Glenn Gervais

Mr. Gervais is a 49 year-old class E driver in the state of Florida, allowing him to drive a commercial non-CDL vehicle. He has had 2 seizures, one in 2009 and the last seizure was February 2011, one year ago. This seizure was the result of his physician taking him off of his anti-seizure medication. He has remained seizure free for 1 year. He takes anti-seizure medication with the dosage and frequency remaining the same for 1 year. If granted the exemption, he would like to return to driving a package delivery truck for UPS in interstate commerce.

Daryl Goodman

Mr. Goodman is a 38 year-old CDL driver in the state of New York. He had a single seizure following brain surgery to remove a tumor in March 2010. He was taking anti-seizure medication until September 2010, when his physician stopped the medication. He has remained seizure free for 2 years. If granted the exemption, he would like to drive a tractor trailer in interstate commerce.

James Gorniak

Mr. Gorniak is a 49 year-old CMV driver in the state of Wisconsin. Mr. Gorniak had a single seizure in January 2007. It was discovered he had a brain tumor which was then removed. He was given anti-seizure medication for a short time after the surgery, but has been off the medication for 5 years and has remained seizure free since 2007. His physician states he is supportive of him receiving the exemption. If granted an exemption, he would like to return to driving tractor trailers in interstate commerce.

Brian Hanson

Mr. Hanson is a 53 year-old driver in the state of Oregon. Mr. Hanson has a diagnosis of epilepsy and his last seizure was in April 2004. He has been off of anti-seizure medication for 6 years. He has remained seizure free for 8 years. If granted the exemption, he would like to attend truck driving school and drive tractor trailer with his wife, as she is a long haul driver.

Victor Marquez

Mr. Marquez is a 23 year-old driver in the state of Idaho. Mr. Marquez has had 3 seizures in his lifetime with the last being March 2003. He has been on anti-seizure medication, with the dosage and frequency remaining the same for 9 years. His physician states that he believes Mr. Marquez is a good candidate for an exemption. If granted an exemption, he would like to drive a water truck or flatbed truck in interstate commerce.

Robert J. Mooney

Mr. Mooney is a 51 year-old CMV driver in the State of Ohio. He has a diagnosis of seizure disorder and his last seizure was in 1981. He has remained seizure free since that time. He takes anti-seizure medication with the dosage and frequency remaining the same for over 20 years. If granted the exemption, he would like to drive 18-passenger busses in interstate commerce.

Gary Osley

Mr. Osley is a 36 year-old CDL driver in the state of Kentucky. He has not ever experienced a seizure. He was given anti-seizure medication as a precaution before having brain surgery to remove a mass in October 2011. He remains on the anti-seizure medication at present for a period up to one year following the surgery, October 2012. He has remained seizure free. If granted an exemption, he would return to driving in interstate commerce.

Request for Comments

In accordance with 49 U.S.C. 31315 and 31136(e), FMCSA requests public comment from all interested persons on the exemption applications described in this notice. We will consider all comments received before the close of business on the closing date indicated earlier in the notice.

Issued on: January 10, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–00713 Filed 1–11–13; 4:15 pm]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0294

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption, request for comments.

SUMMARY: FMCSA announces receipt of applications from 9 individuals for an exemption from the prohibition against persons with a clinical diagnosis of epilepsy or any other condition which is likely to cause a loss of consciousness or any loss of ability to operate a commercial motor vehicle (CMV) from operating CMVs in interstate commerce. The regulation and the associated advisory criteria published in the Code of Federal Regulations as the ''Instructions for Performing and Recording Physical Examinations'' have resulted in numerous drivers being prohibited from operating CMVs in interstate commerce based on the fact that they have had one or more seizures and are taking anti-seizure medication, rather than an individual analysis of their circumstances by a qualified medical examiner. If granted, the exemptions would enable these individuals who have had one or more seizures and are taking anti-seizure medication to operate CMVs for 2 years in interstate commerce.

DATES: Comments must be received on or before February 14, 2013.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2012–0094—using any of the following methods:

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

• *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

• *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket ID for this Notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on December 29, 2010 (75 FR 82132). This information is also available at *http://Docketinfo.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Elaine Papp, Chief, Medical Programs Division (202) 366–4001, or via email at *fmcsamedical@dot.gov,* or by letter FMCSA, Room W64–113, Department of Transportation, 1200 New Jersey Avenue SE., 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. 31315 and 31136(e), FMCSA may grant an exemption 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.'' The statutes also allow the Agency to renew exemptions at the end of the 2-year period. The 9 individuals listed in this notice have recently requested an exemption from the epilepsy prohibition in 49 CFR 391.41(b)(8), which applies to drivers who operate CMVs as defined in 49 CFR 390.5, in interstate commerce. Section 391.41(b)(8) states that a person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a commercial motor vehicle.

FMCSA provides medical advisory criteria for use by medical examiners in determining whether drivers with certain medical conditions should be certified to operate commercial motor vehicles in intrastate commerce. The advisory criteria indicate that if an individual has had a sudden episode of a non-epileptic seizure or loss of consciousness of unknown cause which did not require anti-seizure medication, the decision whether that person's condition is likely to cause the loss of consciousness or loss of ability to control a CMV should be made on an individual basis by the medical examiner in consultation with the treating physician. Before certification is considered, it is suggested that a 6-month waiting period elapse from the time of the episode. Following the waiting period, it is suggested that the individual have a complete neurological examination. If the results of the examination are negative and anti-seizure medication is not required, then the driver may be qualified.

In those individual cases where a driver had a seizure or an episode of loss of consciousness that resulted from a known medical condition (e.g., drug reaction, high temperature, acute infectious disease, dehydration, or acute metabolic disturbance), certification should be deferred until the driver has fully recovered from that condition, has no existing residual complications, and is not taking anti-seizure medication. Drivers who have a history of epilepsy/seizures, off anti-seizure medication and seizure-free for 10 years, may be qualified to operate a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off anti-seizure medication for a 5-year period or more.

Summary of Applications

Patrick Andreasen

Mr. Andreasen is a 54 year-old Class C driver in the State of Pennsylvania. He has a history of epilepsy. His last seizure was in 1982. He has remained seizure free for 30 years. He takes anti-seizure medication with the dosage and frequency remaining the same for 20 years. If granted the exemption, he would like to drive a 15-passenger bus. His physician states he is supportive of Mr. Andreasen receiving an exemption and Mr. Andreasen states he feels he would operate a vehicle at the same safety level as someone who did not require an exemption.

Samuel D. Beverly

Mr. Beverly is a 46 year-old driver in the State of Virginia. He has a history of seizures and his last seizure was in 1995. He takes anti-seizure medication with the dosage and frequency remaining the same for over 17 years. If granted the exemption, he would like to drive a dump truck. Mr. Beverly's physician states he is highly supportive of Mr. Beverly receiving an exemption.

Craig Bugella

Mr. Bugella is a 46 year-old CMV driver in the State of Wisconsin. He has a history of complex partial and generalized seizures. He has remained seizure free for 11 years. He takes anti-seizure medication with the dosage and frequency remaining the same for 11 years. If granted the exemption, he would like to drive bucket trucks and Derrick diggers. His physician states he is extremely confident Mr. Bugella can operate commercial motor vehicles in interstate commerce.

Eric Hilmer

Ms. Hilmer is a 36 year-old Class D driver in the State of Wisconsin. He has a history of generalized seizure disorder as a child. His last seizure in October 2007, following a closed head injury and at that time, he was not taking anti-seizure medication Prior to that event, his last seizure had been at age 17. He takes anti-seizure medication with the dosage and frequency remaining the same for 5 years. If granted the exemption, she would like to drive commercial motor vehicles. His physician is supportive of Mr. Hilmer being granted an exemption.

Tye Dale Moore

Mr. Moore is a 46 year-old driver in the State of Indiana. He has a diagnosis of seizure disorder and has remained

seizure free for more than 20 years. He takes anti-seizure medication with the dosage and frequency remaining the same for 18 years. If granted the exemption, he would like to drive tractor trailers in interstate commerce. His physician states he is supportive of Mr. Moore receiving an exemption.

Michael C. Ranalli

Mr. Ranalli is a 27 year-old Class CM driver in the State of Pennsylvania. He has a diagnosis of Juvenile Myoclonic Epilepsy. His last seizure was in 2006. He has remained seizure free for over 6 years. He takes anti-seizure medication with the dosage and frequency remaining the same for 6 years. If granted the exemption, he would like to drive a Class A International Material Handler bucket truck, a single axle with a gross weight of 22,000 pounds. His physician states he is supportive of Mr. Ranalli being granted an exemption.

Robert Spencer

Mr. Spencer is a 30 year-old Class E driver in the State of Florida. He has a diagnosis of seizure disorder and his last seizure was in February 2009. He has remained seizure free for over 3 years. He takes anti-seizure medication with the dosage and frequency remaining the same for over 3years. If granted the exemption, he would like to drive a delivery van under 26,000 pounds. His physician is supportive of Mr. Spencer being granted an exemption.

Brian J. Wiggins

Mr. Wiggins is a 52 year-old CMV driver in the State of Idaho.. He has a diagnosis of seizure disorder and his last seizure was in 1996. This seizure was the result of his physician taking him off of his anti-seizure medication. He has remained seizure free for 16 years. He takes anti-seizure medication with the dosage and frequency remaining the same for 16 years. He is a diesel mechanic and, if granted the exemption, would be driving Class 6, 7, and 8 trucks for diagnosis and repair purposes. His physician is supportive of Mr. Wiggins being granted an exemption.

Timothy M. Zarahtka

Mr. Zarahtka is a 37 year-old Class D driver in the State of Minnesota. He suffered a penetrating head injury in 1993 and developed a seizure disorder following the injury. He was taking anti-seizure medications with good control until his treating physician changed his medication to a generic in 2008. His last seizure was in August 2008 and his medication was changed. He has remained seizure-free for 4 years. He takes anti-seizure medication with the dosage and frequency remaining the same for 4 years. If granted the exemption, he would like to drive a single axle dump truck. His physician states he is supportive of Mr. Zarhatka being granted an exemption.

Request for Comments

In accordance with 49 U.S.C. 31315 and 31136(e), FMCSA requests public comment from all interested persons on the exemption applications described in this notice. We will consider all comments received before the close of business on the closing date indicated earlier in the notice.

Issued on: January 10, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–00712 Filed 1–11–13; 4:15 pm]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Federal Motor Vehicle Motor Theft Prevention Standard; Toyota

AGENCY: National Highway Traffic Safety Administration, Department Of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full Toyota Motor North America, Inc.'s (Toyota) petition for an exemption of the RAV4 vehicle line in accordance with 49 CFR part 543, *Exemption from the Theft Prevention Standard.* This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR Part 541).

DATES: The exemption granted by this notice is effective beginning with the 2014 model year (MY).

FOR FURTHER INFORMATION CONTACT: Ms. Carlita Ballard, Office of International Policy, Fuel Economy and Consumer Standards, NHTSA, W43–439, 1200 New Jersey Avenue SE., Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: In a petition dated October 16, 2012, Toyota requested an exemption from the parts-marking requirements of the theft prevention standard (49 CFR part 541) for the RAV4 vehicle line beginning with MY 2014. The petition requested an exemption from parts-marking pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard,* based on the installation of an antitheft device as standard equipment for the entire vehicle line.

Under § 543.5(a), a manufacturer may petition NHTSA to grant an exemption for one vehicle line per model year. In its petition, Toyota provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the RAV4 vehicle line. Toyota stated that the MY 2014 RAV4 vehicle line will offer two entry systems but both will have an engine immobilizer device as standard equipment. Specifically, Toyota stated that the RAV4 vehicle line will offer a ''smart key'' system (keyless entry and push button start) and a ''conventional key'' entry system. Key components of the ''smart key'' system will include an engine immobilizer, certification electronic control unit (ECU), engine switch, steering lock ECU, security indicator, door control receiver, electrical key and an electronic control module (ECM). The conventional key components consist of a transponder key ECU assembly, transponder key coil, security indicator, ignition key and an ECM. Toyota will not offer an audible and visual alarm for the RAV4 vehicle line. Toyota's submission is considered a complete petition as required by 49 CFR 543.7 in that it meets the general requirements contained in 543.5 and the specific content requirements of 543.6.

On the RAV4 vehicle line, the ''smart key'' system allows the driver to press the ''ON'' button located on the instrument panel to start the vehicle. Once the driver pushes the ''ON'' button, the certification ECU verifies the electrical key, and the certification ECU and steering lock ECU receive confirmation of the valid key, allowing the ECM to start the engine. With the conventional key system, once the key is inserted into the key cylinder, the transponder chip in the key sends the key ID codes to the transponder key ECU assembly to verify the code. Once the code is verified, the immobilizer will allow the ECM to start the engine.

Toyota stated that with the smart key system, the immobilizer is activated when the power button is pushed from the ''ON'' status to any other ignition status and the certification ECU performs the calculation of the immobilizer then the immobilizer signals the ECM. For the ''conventional key'' system, activation of the immobilizer occurs when the ignition

key is turned from the ''ON'' status to any other position and/or the key is removed. Toyota also stated that the devices' security indicator will provide the immobilizer status for the RAV4 vehicle line. When the immobilizer is activated, the indicator flashes continuously. When the immobilizer is not activated, the indicator is turned off. The device is deactivated when the doors are unlocked and the device recognizes the key code from the smart key system. Deactivation of the conventional key system occurs when the doors are unlocked and the key is turned to the ''ON'' position.

Toyota also stated that there will be position switches installed in the vehicle to protect the hood and doors. Specifically, the position switches in the hood will trigger the antitheft device when they sense inappropriate opening of the hood. The position switches in the doors will trigger the antitheft device when they sense opening of the doors is being attempted without the use of a key, wireless switch or smart entry system.

In addressing the specific content requirements of 543.6, Toyota provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Toyota conducted tests based on its own specified standards. Toyota provided a detailed list of the tests conducted (i.e., high and low temperature, strength, impact, vibration, electro-magnetic interference, etc.). Toyota stated that it believes that its device is reliable and durable because it complied with its own specific design standards and that the device is installed in other vehicle lines for which the agency has granted a parts-marking exemption. As an additional measure of reliability and durability, Toyota stated that its vehicle key cylinders are covered with casting cases to prevent the key cylinder from easily being broken. Toyota further stated that there are so many key cylinder combinations and key plates for its gutter keys that it would be very difficult to unlock the doors without using a valid key.

To provide comparison, Toyota referenced NHTSA-published theft rate data for the RAV4 vehicle line for several years before and after it was equipped with a standard antitheft device with an immobilizer. Toyota stated that the average theft rate for the RAV4 for MY 2009 is 0.66 thefts per thousand vehicles produced as compared to 0.86 per 1,000 vehicles, the average theft rate for the RAV 4 for model years (MYs) 2005–2008. Toyota further stated that the antitheft device which is already installed as standard equipment beginning with MY 2009 RAV4 will continue to be installed on the MY 2014 RAV4 vehicle line. Toyota also compared its proposed device with other devices NHTSA has determined to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts-marking requirements (i.e., Toyota Prius and Prius v, Toyota Camry and Corolla, Lexus LS and GS vehicle lines). The Toyota Camry, Corolla, Lexus LS and GS vehicle lines have all been granted parts-marking exemptions by the agency. The theft rates for the Toyota Camry, Corolla, Lexus LS, GS and Prius vehicle lines using an average of three model years' data (2008–2010) are 1.8107, 1.7399, 0.9468, 0.4915 and 0.3756 respectively. Therefore, Toyota has concluded that the antitheft device proposed for its RAV4 vehicle line is no less effective than those devices in the lines for which NHTSA has already granted full exemption from the parts-marking requirements. Toyota believes that installing the immobilizer as standard equipment reduces the theft rate and expects the RAV4 to experience comparable effectiveness, ultimately being more effective than parts-marking labels.

Based on the evidence submitted by Toyota, the agency believes that the antitheft device for the RAV4 vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541).

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.7 (b), the agency grants a petition for exemption from the parts-marking requirements of Part 541, either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of Part 541. The agency finds that Toyota has provided adequate reasons for its belief that the antitheft device for the Toyota RAV4 vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). This conclusion is based on the information Toyota provided about its device.

The agency concludes that the device will provide four of the five types of performance listed in § 543.6(a)(3): promoting activation; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

For the foregoing reasons, the agency hereby grants in full Toyota's petition for exemption for the Toyota RAV4 vehicle line from the parts-marking requirements of 49 CFR Part 541. The agency notes that 49 CFR part 541, appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. 49 CFR 543.7(f) contains publication requirements incident to the disposition of all Part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts marking requirements of the Theft Prevention Standard.

If Toyota decides not to use the exemption for this line, it must formally notify the agency. If such a decision is made, the line must be fully marked according to the requirements under 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Toyota wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Section 543.7(d) states that a Part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, § 543.9(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption.''

The agency wishes to minimize the administrative burden that § 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting Part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis.* Therefore, NHTSA suggests that if the manufacturer contemplates making any changes, the effects of which might be characterized as *de minimis,* it should consult the agency before preparing and submitting a petition to modify.

Authority: 49 U.S.C. 33106; delegation of authority at 49 CFR 1.50.

Issued on: January 9, 2013.

Christopher J. Bonanti,

Associate Administrator for Rulemaking.

[FR Doc. 2013–00696 Filed 1–14–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

Release of Waybill Data

The Surface Transportation Board has received a request from Michael Behe representing Freight Resources Network, LLC (WB604–11—01/09/2013) for permission to use certain data from the Board's 2011 Carload Waybill Sample. A copy of this request may be obtained from the Office of Economics.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

Contact: Megan Conley, (202) 245–0348.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2013–00669 Filed 1–14–13; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is publishing the names of two individuals whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act (''Kingpin Act'') (21 U.S.C. 1901–1908, 8 U.S.C. 1182).

DATES: The designation by the Director of OFAC of the two individuals identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on January 9, 2013.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Office of Foreign Assets Control, U.S. Department of the Treasury, Washington, DC 20220, Tel: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available on OFAC's Web site at *http://www.treasury.gov/ofac* or via facsimile through a 24-hour fax-on-demand service at (202) 622–0077.

Background

The Kingpin Act became law on December 3, 1999. The Kingpin Act establishes a program targeting the activities of significant foreign narcotics traffickers and their organizations on a worldwide basis. It provides a statutory framework for the imposition of sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security may designate and block the property and interests in property, subject to U.S. jurisdiction, of persons who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On January 9, 2013, the Director of OFAC designated the following two individuals whose property and interests in property are blocked pursuant to section 805(b) of the Kingpin Act.

Individuals

1. LOPEZ NUNEZ, Damaso (a.k.a. ''EL LICENCIADO''), Avenida Nicolas Bravo No. 1607, Colonia Guadalupe, Culiacan, Sinaloa 80220, Mexico; Calle Escobedo No. 24, Localidad El Dorado, Culiacan, Sinaloa 80450, Mexico; DOB 22 Feb 1966; POB Culiacan, Sinaloa, Mexico; nationality Mexico; citizen Mexico; R.F.C. LOND6602221Y5 (Mexico); alt. R.F.C. LOND660222SE7 (Mexico); C.U.R.P. LOND660222HSLPXM05 (Mexico) (individual) [SDNTK].

2. CORONEL BARRERAS, Ines, La Angostura, Canelas, Durango 34500, Mexico; Avenida Puebla A No. 2209, Colonia Federal, San Luis Rio Colorado, Sonora 83489, Mexico; DOB 21 Jan 1968; POB Durango, Mexico; nationality Mexico; citizen Mexico (individual) [SDNTK].

Dated: January 9, 2013.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2013–00675 Filed 1–14–13; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

United States Mint

Revised Pricing for Five 2013 Products

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is announcing revised pricing for five 2013 products. Please see the table below.

Product	2013 retail price
United States Mint Happy Birthday Coin Set	$19.95
United States Mint Congratulations Set	64.95
American Eagle One Ounce Silver Proof Coin	62.95
American Eagle One Ounce Silver Uncirculated Coin	53.95
America the Beautiful Five-Ounce Silver Uncirculated Coin™ (5 issues)	244.95

FOR FURTHER INFORMATION CONTACT: Marc Landry, Acting Associate Director for Sales and Marketing; United States Mint; 801 9th Street NW., Washington, DC 20220; or call 202–354–7500.

Authority: 31 U.S.C. 5111, 5112 & 9701.

Dated: January 8, 2013.

Richard A. Peterson,

Acting Director, United States Mint.

[FR Doc. 2013–00670 Filed 1–14–13; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 78 Tuesday,

No. 10 January 15, 2013

Part II

Environmental Protection Agency

40 CFR Parts 50, 51, 52 et al.

National Ambient Air Quality Standards for Particulate Matter; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50, 51, 52, 53 and 58

[EPA–HQ–OAR–2007–0492; FRL–9761–8]

RIN 2060–AO47

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on its review of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the EPA is making revisions to the suite of standards for PM to provide requisite protection of public health and welfare and to make corresponding revisions to the data handling conventions for PM and to the ambient air monitoring, reporting, and network design requirements. The EPA also is making revisions to the prevention of significant deterioration (PSD) permitting program with respect to the NAAQS revisions.

With regard to primary (health-based) standards for fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), the EPA is revising the annual $PM_{2.5}$ standard by lowering the level to 12.0 micrograms per cubic meter (μg/m^3) so as to provide increased protection against health effects associated with long- and short-term exposures (including premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease), and to retain the 24-hour $PM_{2.5}$ standard at a level of 35 μg/m^3. The EPA is revising the Air Quality Index (AQI) for $PM_{2.5}$ to be consistent with the revised primary $PM_{2.5}$ standards. With regard to the primary standard for particles generally less than or equal to 10 μm in diameter (PM_{10}), the EPA is retaining the current 24-hour PM_{10} standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10-2.5}$). With regard to the secondary (welfare-based) PM standards, the EPA is generally retaining the current suite of secondary standards (i.e., 24-hour and annual $PM_{2.5}$ standards and a 24-hour PM_{10} standard). Non-visibility welfare effects are addressed by this suite of secondary standards, and PM-related visibility impairment is addressed by the secondary 24-hour $PM_{2.5}$ standard.

DATES: The final rule is effective on March 18, 2013.

ADDRESSES: Section X.B requests comments on an information collection request regarding changes to the monitoring requirements. Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2007–0492, to the EPA by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: a-and-r-Docket@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* Docket No. EPA–HQ–OAR–2007–0492, Environmental Protection Agency, Mail code 6102T, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Please include a total of two copies.
- *Hand Delivery:* Docket No. EPA–HQ–OAR–2007–0492, Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2007–0492. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* Comments on this information collection request should also be sent to the Office of Management and Budget (OMB). See section X.B below for additional information regarding submitting comments to OMB.

Docket: The EPA has established a docket for this action under Docket No. EPA–HQ–OAR–2007–0492. All documents in the docket are listed on the *www.regulations.gov* Web site. This includes documents in the rulemaking docket (Docket ID No. EPA–HQ–OAR–2007–0492) and a separate docket, established for 2009 Integrated Science Assessment (Docket No. EPA–HQ–ORD–2007–0517), that has have been incorporated by reference into the rulemaking docket. All documents in these dockets are listed on the *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, is not placed on the Internet and may be viewed, with prior arrangement, at the EPA Docket Center. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air and Radiation Docket 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.*

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SUPPLEMENTARY INFORMATION:

General Information

Availability of Related Information

A number of the documents that are relevant to this rulemaking are available through the EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html.*

These documents include the *Plan for Review of the National Ambient Air Quality Standards for Particulate Matter* (U.S. EPA, 2008a), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html,* the *Integrated Science Assessment for Particulate Matter* (U.S. EPA, 2009a), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html,* the *Quantitative Health Risk Assessment for Particulate Matter* (U.S. EPA, 2010a), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html,* the *Particulate Matter Urban-Focused Visibility Assessment* (U.S. EPA 2010b), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html,* and the *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards* (U.S. EPA, 2011a), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

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I. Executive Summary

A. 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 national ambient air quality standards (NAAQS) to protect public health and welfare. The CAA requires periodic review of the air quality criteria—the science upon which the standards are based—and the standards themselves. This rulemaking is being done pursuant to these statutory requirements. The schedule for completing this review is established by a court order.

In 2006, the EPA completed its last review of the PM NAAQS. In that review, the EPA took three principal actions: (1) With regard to fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), at that time, the EPA revised the level of the primary 24-hour $PM_{2.5}$ standard from 65 to 35 μg/m³ and retained the level of the primary annual $PM_{2.5}$ standard; (2) With regard to the primary standards for particles less than or equal to 10 μm in diameter (PM_{10}), the EPA retained the primary 24-hour PM_{10} standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10-2.5}$) and revoked the primary annual PM_{10} standard; and (3) the EPA also revised the secondary standards to be identical in all respects to the primary standards.

In subsequent litigation, the U.S. Court of Appeals for the District of Columbia Circuit remanded the primary annual $PM_{2.5}$ standard to the EPA because the Agency had failed to explain adequately why the standard provided the requisite protection from both short- and long-term exposures to fine particles, including protection for at-risk populations such as children. The court remanded the secondary $PM_{2.5}$ standards to the EPA because the Agency failed to explain adequately why setting the secondary standards identical to the primary standards provided the required protection for public welfare, including protection from PM-related visibility impairment.

The EPA initiated this review in June 2007. Between 2007 and 2011, the EPA prepared draft and final Integrated Science Assessments, Risk and Exposure Assessments, and Policy Assessments. Multiple drafts of all of these documents were subject to review by the public and were peer reviewed by the EPA's Clean Air Scientific Advisory Committee (CASAC). The EPA proposed revisions to the primary and secondary PM NAAQS on June 29, 2012 (77 FR 38890). This final rulemaking is the final step in the review process.

In this rulemaking, the EPA is revising the suite of standards for PM to provide requisite protection of public health and welfare. The EPA is revising the PSD permitting regulations to address the changes in the PM NAAQS. In addition, the EPA is updating the AQI for $PM_{2.5}$ and making changes in the data handling conventions for PM and ambient air monitoring, reporting, and network design requirements to correspond with the changes to the PM NAAQS.

B. Summary of Major Provisions

With regard to the primary standards for fine particles, the EPA is revising the annual $PM_{2.5}$ standard by lowering the level from 15.0 to 12.0 μg/m³ so as to provide increased protection against health effects associated with long-and short-term exposures. The EPA is retaining the level (35 μg/m³) and the form (98th percentile) of the 24-hour $PM_{2.5}$ standard to continue to provide supplemental protection against health effects associated with short-term exposures. This action provides increased protection for children, older adults, persons with pre-existing heart and lung disease, and other at-risk populations against an array of $PM_{2.5}$-related adverse health effects that include premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease. The EPA also is eliminating spatial averaging provisions as part of the form of the annual standard to avoid potential disproportionate impacts on at-risk populations.

The final decisions for the primary annual and 24-hour $PM_{2.5}$ standards are

within the ranges that CASAC advised the Agency to consider. These decisions are based on an integrative assessment of an extensive body of new scientific evidence, which substantially strengthens what was known about $PM_{2.5}$-related health effects in the last review, including extended analyses of key epidemiological studies, and evidence of health effects observed at lower ambient $PM_{2.5}$ concentrations, including effects in areas that likely met the current standards. The revised suite of $PM_{2.5}$ standards 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 $PM_{2.5}$ standards are not requisite to protect public health with an adequate margin of safety, as required by the CAA, and that these revisions are warranted to provide the appropriate degree of increased public health protection.

With regard to the primary standard for thoracic coarse particles ($PM_{10-2.5}$), the EPA is retaining the current 24-hour PM_{10} standard, with a level of 150 μg/m^3 and a one-expected exceedance form, to continue to provide protection against effects associated with short-term exposure to $PM_{10-2.5}$ including premature mortality and increased hospital admissions and emergency department visits. In reaching this decision, the Administrator concludes that the available health evidence and air quality information for $PM_{10-2.5}$, taken together with the considerable uncertainties and limitations associated with that information, suggests that a standard is needed to protect against short-term exposure to all types of $PM_{10-2.5}$ and that the degree of public health protection provided against short-term exposures to $PM_{10-2.5}$ does not need to be increased beyond that provided by the current PM_{10} standard.

With regard to the secondary PM standards, the Administrator is retaining the current suite of secondary PM standards, except for a change to the form of the annual $PM_{2.5}$ standard. Specifically, the EPA is retaining the current secondary 24-hour $PM_{2.5}$ and PM_{10} standards, and is revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. This suite of secondary standards addresses PM-related non-visibility welfare effects including ecological effects, effects on materials, and climate impacts. With respect to PM-related visibility impairment, the Administrator has identified a target degree of protection, defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction), a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, and a level of 30 deciviews (dv), which she judges to be requisite to protect public welfare with regard to visual air quality (VAQ). The EPA's analysis of monitoring data provides the basis for concluding that the current secondary 24-hour $PM_{2.5}$ standard would provide sufficient protection, and in some areas greater protection, relative to this target protection level. Adding a distinct secondary standard to address visibility would not affect this protection. Since sufficient protection from visibility impairment will be provided for all areas of the country without adoption of a distinct secondary standard, and adoption of a distinct secondary standard will not change the degree of over-protection of VAQ provided for some areas of the country by the secondary 24-hour $PM_{2.5}$ standard, the Administrator judges that adoption of a distinct secondary standard, in addition to the current suite of secondary standards, is not needed to provide requisite protection for both visibility and non-visibility related welfare effects.

The revisions to the PM NAAQS trigger a process under which states (and tribes, if they choose) will make recommendations to the Administrator regarding designations, identifying areas of the country that either meet or do not meet the revised NAAQS. States will also review, modify and supplement their existing state implementation plans (SIPs), as needed. With regard to these implementation-related activities, the EPA intends to promulgate a separate implementation rule on a schedule that provides timely clarity to the states, tribes, and other parties responsible for NAAQS implementation. The NAAQS revisions also affect the applicable air permitting requirement, but cause no significant change to the transportation conformity and general conformity processes. The EPA is revising its PSD regulations to provide limited grandfathering from the requirements that result from the revised PM NAAQS.

On other topics, the EPA is changing the AQI for $PM_{2.5}$ to be consistent with the revised primary $PM_{2.5}$ NAAQS. The EPA also is revising the data handling procedures for $PM_{2.5}$ consistent with the revised $PM_{2.5}$ NAAQS including the computations necessary for determining when the standards are met and the measurement data that are appropriate for comparison to the standards. With regard to monitoring-related activities, the EPA is updating several aspects of the monitoring regulations and specifically requiring that a small number of $PM_{2.5}$ monitors be relocated to be collocated with measurements of other pollutants (e.g., nitrogen dioxide, carbon monoxide) in the near-road environment.

C. Costs and Benefits

In setting the NAAQS, the EPA may not consider the costs of implementing the standards. This was confirmed by the United States Supreme Court in *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001), as noted in section II.A of this rule. As has traditionally been done in NAAQS rulemaking, the EPA has conducted a Regulatory Impact Analysis (RIA) to provide the public with information on the potential costs and benefits of attaining several alternative $PM_{2.5}$ standards. In NAAQS rulemaking, the RIA is done for informational purposes only, and the final decisions on the NAAQS in this rulemaking are not in any way based on consideration of the information or analyses in the RIA. The RIA fulfills the requirements of Executive Orders 13563 and 12866. The summary of the RIA, which is discussed in more detail below in section X.A, estimates benefits ranging from $4,000 million to $9,100 million at a 3 percent discount rate and $3,600 million to $8,200 million at a 7 percent discount rate in 2020 and costs ranging from $53 million to $350 million per year at a 7 percent discount rate.

II. Background

A. Legislative Requirements

Two sections of the CAA govern the establishment, review and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in her ''judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;'' ''the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;'' and ''for which * * * [the Administrator] plans to issue air quality criteria * * *'' Air quality criteria are intended to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or

welfare which may be expected from the presence of [a] pollutant in the ambient air * * *'' 42 U.S.C. 7408(b). Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [1] A secondary standard, as defined in section 109(b)(2), must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' [2]

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *See 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 concentration levels, *see Lead Industries* v. *EPA,* 647 F.2d at 1156 n.51, 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 involved, the size of at-risk population(s), and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to 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; *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 495 (2001).

In setting standards that are ''requisite'' to protect public health and welfare, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, the EPA may not consider the costs of implementing the standards. *See* generally, *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001). Likewise, ''[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.'' *American Petroleum Institute* v. *Costle,* 665 F. 2d at 1185.

Section 109(d)(1) requires that ''not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards * * * and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate * * *'' Section 109(d)(2) requires that an independent scientific review committee ''shall complete a review of the criteria * * * and the national primary and secondary ambient air quality standards * * * and shall recommend to the Administrator any new * * * standards and revisions of existing criteria and standards as may be appropriate. * * *'' Since the early 1980's, this independent review function has been performed by the CASAC.[3]

B. Review of the Air Quality Criteria and Standards for PM

1. Previous PM NAAQS Reviews

The EPA initially established NAAQS for PM under section 109 of the CAA in 1971. Since then, the Agency has made a number of changes to these standards to reflect continually expanding scientific information, particularly with respect to the selection of indicator[4] and level. Table 1 provides a summary of the PM NAAQS that have been promulgated to date. These decisions are briefly discussed below.

TABLE 1—SUMMARY OF NATIONAL AMBIENT AIR QUALITY STANDARDS PROMULGATED FOR PM 1971–2006 [a]

Final rule	Indicator	Averaging time	Level	Form
1971—36 FR 8186 April 30, 1971.	TSP	24-hour	260 μg/m³ (primary)	Not to be exceeded more than once per year.
			150 μg/m³ (secondary)	
		Annual	75 μg/m³ (primary)	Annual average.
1987—52 FR 24634 July 1, 1987.	PM_{10}	24-hour	150 μg/m³	Not to be exceeded more than once per year on average over a 3-year period.
		Annual	50 μg/m³	Annual arithmetic mean, averaged over 3 years.

[1] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

[2] Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

[3] The CASAC PM Review Panel is comprised of the seven members of the chartered CASAC, supplemented by fifteen subject-matter experts appointed by the Administrator to provide additional scientific expertise relevant to this review of the PM NAAQS. Lists of current CASAC members and review panels are available at: *http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CommitteesandMembership?OpenDocument.* Members of the CASAC PM Review Panel are listed in the CASAC letters providing advice on draft assessment documents (Samet, 2009a–f, 2012a–d).

[4] Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes, such that the indicator for a PM NAAQS has historically been defined in terms of particle size ranges.

TABLE 1—SUMMARY OF NATIONAL AMBIENT AIR QUALITY STANDARDS PROMULGATED FOR PM 1971–2006 [a]—Continued

Final rule	Indicator	Averaging time	Level	Form
1997—62 FR 38652 July 18, 1997.	$PM_{2.5}$	24-hour	65 μg/m³	98th percentile, averaged over 3 years.[b]
		Annual	15.0 μg/m³	Annual arithmetic mean, averaged over 3 years.[c d]
	PM_{10}	24-hour	150 μg/m³	Initially promulgated 99th percentile, averaged over 3 years; when 1997 standards for PM_{10} were vacated, the form of 1987 standards remained in place (not to be exceeded more than once per year on average over a 3-year period).
		Annual	50 μg/m³	Annual arithmetic mean, averaged over 3 years.
2006—71 FR 61144 October 17, 2006.	$PM_{2.5}$	24-hour	35 μg/m³	98th percentile, averaged over 3 years.[b]
		Annual	15.0 μg/m³	Annual arithmetic mean, averaged over 3 years.[c e]
	PM_{10}	24-hour	150 μg/m³	Not to be exceeded more than once per year on average over a 3-year period.

[a] When not specified, primary and secondary standards are identical.

[b] The level of the 24-hour standard is defined as an integer (zero decimal places) as determined by rounding. For example, a 3-year average 98th percentile concentration of 35.49 μg/m³ would round to 35 μg/m³ and thus meet the 24-hour standard and a 3-year average of 35.50 μg/m³ would round to 36 and, hence, violate the 24-hour standard (40 CFR part 50, appendix N).

[c] The level of the annual standard is defined to one decimal place (i.e., 15.0 μg/m³) as determined by rounding. For example, a 3-year average annual mean of 15.04 μg/m³ would round to 15.0 μg/m³ and, thus, meet the annual standard and a 3-year average of 15.05 μg/m³ would round to 15.1 μg/m³ and, hence, violate the annual standard (40 CFR part 50, appendix N).

[d] The level of the standard was to be compared to measurements made at sites that represent "community-wide air quality" recording the highest level, or, if specific requirements were satisfied, to average measurements from multiple community-wide air quality monitoring sites ("spatial averaging").

[e] The EPA tightened the constraints on the spatial averaging criteria by further limiting the conditions under which some areas may average measurements from multiple community-oriented monitors to determine compliance (*See* 71 FR 61165 to 61167, October 17, 2006).

In 1971, the EPA established NAAQS for PM based on the original air quality criteria document (DHEW, 1969; 36 FR 8186, April 30, 1971). The reference method specified for determining attainment of the original standards was the high-volume sampler, which collects PM up to a nominal size of 25 to 45 μm (referred to as total suspended particles or TSP). The primary standards (measured by the indicator TSP) were 260 μg/m³, 24-hour average, not to be exceeded more than once per year, and 75 μg/m³, annual geometric mean. The secondary standard was 150 μg/m³, 24-hour average, not to be exceeded more than once per year.

In October 1979, the EPA announced the first periodic review of the criteria and NAAQS for PM, and significant revisions to the original standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In that decision, the EPA changed the indicator for PM from TSP to PM_{10}, the latter including particles with an aerodynamic diameter less than or equal to a nominal 10 μm, which delineates thoracic particles (i.e., that subset of inhalable particles small enough to penetrate beyond the larynx to the thoracic region of the respiratory tract). The EPA also revised the primary standards by (1) replacing the 24-hour TSP standard with a 24-hour PM_{10} standard of 150 μg/m³ with no more than one expected exceedance per year and (2) replacing the annual TSP standard with a PM_{10} standard of 50 μg/m³, annual arithmetic mean. The secondary standard was revised by replacing it with 24-hour and annual PM_{10} standards identical in all respects to the primary standards. The revisions also included a new reference method for the measurement of PM_{10} in the ambient air and rules for determining attainment of the new standards. On judicial review, the revised standards were upheld in all respects. *Natural Resources Defense Council* v. *EPA,* 902 F. 2d 962 (D.C. Cir. 1990).

In April 1994, the EPA announced its plans for the second periodic review of the criteria and NAAQS for PM, and promulgated significant revisions to the NAAQS in 1997 (62 FR 38652, July 18, 1997). Most significantly, the EPA determined that although the PM NAAQS should continue to focus on thoracic particles (PM_{10}), the fine and coarse fractions of PM_{10} should be considered separately. New standards were added, using $PM_{2.5}$ as the indicator for fine particles. The PM_{10} standards were retained for the purpose of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or $PM_{10\text{-}2.5}$).[5] The EPA established two new $PM_{2.5}$ standards: an annual standard of 15.0 μg/m³, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple monitors sited to represent community-wide air quality[6] and a 24-hour standard of 65 μg/m³, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor[7] within an area. Also, the EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and rules for determining attainment of the new standards. To continue to address thoracic coarse particles, the annual PM_{10} standard was retained, while the form, but not the level, of the 24-hour PM_{10} standard was revised to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by making them identical in all respects to the primary standards.

Following promulgation of the revised PM NAAQS in 1997, petitions for review were filed by a large number of

[5] See 40 CFR parts 50, 53, and 58 for more information on reference and equivalent methods for measuring PM in ambient air.

[6] Monitoring stations sited to represent *community-wide* air quality would typically be at the neighborhood or urban-scale; however, where a population-oriented micro or middle-scale $PM_{2.5}$ monitoring station represents many such locations throughout a metropolitan area, these smaller scales might also be considered to represent community-wide air quality [40 CFR part 58, appendix D, 4.7.1(b)].

[7] *Population-oriented* monitoring (or sites) means residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day (40 CFR 58.1).

parties, addressing a broad range of issues. In May 1998, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit issued an initial decision that upheld the EPA's decision to establish fine particle standards, holding that ''the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards.'' *American Trucking Associations* v. *EPA,* 175 F. 3d 1027, 1055–56 (D.C. Cir. 1999), rehearing granted in part and denied in part, 195 F. 3d 4 (D.C. Cir. 1999), affirmed in part and reversed in part, *Whitman* v. *American Trucking Associations,* 531 U.S. 457 (2001). The panel also found ''ample support'' for the EPA's decision to regulate coarse particle pollution, but vacated the 1997 $P.M._{10}$ standards, concluding, in part, that PM_{10} is a ''poorly matched indicator for coarse particulate pollution'' because it includes fine particles. *Id.* at 1053–55. Pursuant to the court's decision, the EPA removed the vacated 1997 $P.M._{10}$ standards from the CFR (69 FR 45592, July 30, 2004) and deleted the regulatory provision (at 40 CFR 50.6(d)) that controlled the transition from the pre-existing 1987 $P.M._{10}$ standards to the 1997 $P.M._{10}$ standards. The pre-existing 1987 $P.M._{10}$ standards remained in place (65 FR 80776, December 22, 2000). The court also upheld the EPA's determination not to establish more stringent secondary standards for fine particles to address effects on visibility (175 F. 3d at 1027).

More generally, the panel held (over a strong dissent) that the EPA's approach to establishing the level of the standards in 1997, both for the PM and for the ozone NAAQS promulgated on the same day, effected ''an unconstitutional delegation of legislative authority.'' *Id.* at 1034–40. Although the panel stated that ''the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable,'' it remanded the rule to the EPA, stating that when the EPA considers these factors for potential non-threshold pollutants ''what EPA lacks is any determinate criterion for drawing lines'' to determine where the standards should be set. Consistent with the EPA's long-standing interpretation and D.C. Circuit precedent, the panel also reaffirmed its prior holdings that in setting NAAQS, the EPA is ''not permitted to consider the cost of implementing those standards.'' *Id.* at 1040–41.

On EPA's petition for rehearing, the panel adhered to its position on these points. *American Trucking Associations* v. *EPA,* 195 F. 3d 4 (D.C. Cir. 1999). The full Court of Appeals denied the EPA's request for rehearing *en banc,* with five judges dissenting. *Id.* at 13. Both sides filed cross appeals on these issues to the United States Supreme Court, which granted certiorari. In February 2001, the Supreme Court issued a unanimous decision upholding the EPA's position on both the constitutional and cost issues. *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 464, 475–76. On the constitutional issue, the Court held that the statutory requirement that NAAQS be ''requisite'' to protect public health with an adequate margin of safety sufficiently cabined the EPA's discretion, affirming the EPA's approach of setting standards that are neither more nor less stringent than necessary. The Supreme Court remanded the case to the Court of Appeals for resolution of any remaining issues that had not been addressed in that court's earlier rulings. *Id.* at 475–76. In March 2002, the Court of Appeals rejected all remaining challenges to the standards, holding under the statutory standard of review that the EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not ''arbitrary and capricious.'' *American Trucking Association* v. *EPA,* 283 F. 3d 355, 369–72 (D.C. Cir. 2002).

In October 1997, the EPA published its plans for the next periodic review of the air quality criteria and NAAQS for PM (62 FR 55201, October 23, 1997). After CASAC and public review of several drafts, the EPA's National Center for Environmental Assessment (NCEA) finalized the *Air Quality Criteria Document for Particulate Matter* (henceforth, AQCD or the ''Criteria Document'') in October 2004 (U.S. EPA, 2004) and OAQPS finalized an assessment document, *Particulate Matter Health Risk Assessment for Selected Urban Areas* (Abt Associates, 2005), and the *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information,* in December 2005 (henceforth, ''Staff Paper,'' U.S. EPA, 2005). In conjunction with its review of the Staff Paper, CASAC provided advice to the Administrator on revisions to the PM NAAQS (Henderson, 2005a). In particular, most CASAC PM Panel members favored revising the level of the primary 24-hour $PM_{2.5}$ standard within the range of 35 to 30 μg/m³ with a 98th percentile form, in concert with revising the level of the primary annual $PM_{2.5}$ standard within the range of 14 to 13 μg/m³ (Henderson, 2005a, p.7). For thoracic coarse particles, the Panel had reservations in recommending a primary 24-hour $PM_{10\text{-}2.5}$ standard, and agreed that there was a need for more research on the health effects of thoracic coarse particles (Henderson, 2005b). With regard to secondary standards, most Panel members strongly supported establishing a new, distinct secondary $PM_{2.5}$ standard to protect urban visibility (Henderson, 2005a, p. 9).

On January 17, 2006, the EPA proposed to revise the primary and secondary NAAQS for PM (71 FR 2620) and solicited comment on a broad range of options. Proposed revisions included: (1) Revising the level of the primary 24-hour $PM_{2.5}$ standard to 35 μg/m³; (2) revising the form, but not the level, of the primary annual $PM_{2.5}$ standard by tightening the constraints on the use of spatial averaging; (3) replacing the primary 24-hour PM_{10} standard with a 24-hour standard defined in terms of a new indicator, $PM_{10\text{-}2.5}$, which was qualified so as to include any ambient mix of $PM_{10\text{-}2.5}$ dominated by particles generated by high-density traffic on paved roads, industrial sources, and construction sources, and to exclude any ambient mix of particles dominated by rural windblown dust and soils and agricultural and mining sources (71 FR 2667 to 2668), set at a level of 70 μg/m³ based on the 3-year average of the 98th percentile of 24-hour $PM_{10\text{-}2.5}$ concentrations; (4) revoking the primary annual PM_{10} standard; and (5) revising the secondary standards by making them identical in all respects to the proposed suite of primary standards for fine and coarse particles.[8] Subsequent to the proposal, CASAC provided additional advice to the EPA in a letter to the Administrator requesting reconsideration of CASAC's recommendations for both the primary and secondary $PM_{2.5}$ standards as well as the standards for thoracic coarse particles (Henderson, 2006a).

On October 17, 2006, the EPA published revisions to the PM NAAQS to provide increased protection of public health and welfare (71 FR 61144). With regard to the primary and secondary standards for fine particles, the EPA revised the level of the primary 24-hour $PM_{2.5}$ standard to 35 μg/m³, retained the level of the primary annual $PM_{2.5}$ standard at 15.0 μg/m³, and

[8] In recognition of an alternative view expressed by most members of the CASAC PM Panel, the Agency also solicited comments on a subdaily (4- to 8-hour averaging time) secondary $PM_{2.5}$ standard to address visibility impairment, considering alternative standard levels within a range of 20 to 30 μg/m³ in conjunction with a form within a range of the 92nd to 98th percentile (71 FR 2685, January 17, 2006).

revised the form of the primary annual $PM_{2.5}$ standard by adding further constraints on the optional use of spatial averaging. The EPA revised the secondary standards for fine particles by making them identical in all respects to the primary standards. With regard to the primary and secondary standards for thoracic coarse particles, the EPA retained the level and form of the 24-hour PM_{10} standard (such that the standard remained at a level of 150 μg/m³ with a one-expected exceedance form and retained the PM_{10} indicator) and revoked the annual PM_{10} standard. The EPA also established a new Federal Reference Method (FRM) for the measurement of $PM_{10-2.5}$ in the ambient air (71 FR 61212 to 13). Although the standards for thoracic coarse particles were not defined in terms of a $PM_{10-2.5}$ indicator, the EPA adopted a new FRM for $PM_{10-2.5}$ to facilitate consistent research on $PM_{10-2.5}$ air quality and health effects and to promote commercial development of Federal Equivalent Methods (FEMs) to support future reviews of the PM NAAQS (71 FR 61212/2).

Following issuance of the final rule, CASAC articulated its concern that the ''EPA's final rule on the NAAQS for PM does not reflect several important aspects of the CASAC's advice'' (Henderson *et al.,* 2006b, p. 1). With regard to the primary $PM_{2.5}$ annual standard, CASAC expressed serious concerns regarding the decision to retain the level of the standard at 15 μg/m³. Specifically, CASAC stated, ''It is the CASAC's consensus scientific opinion that the decision to retain without change the annual $PM_{2.5}$ standard does not provide an 'adequate margin of safety * * * requisite to protect the public health' (as required by the Clean Air Act), leaving parts of the population of this country at significant risk of adverse health effects from exposure to fine PM'' (Henderson *et al.,* 2006b, p. 2). Furthermore, CASAC pointed out that its recommendations ''were consistent with the mainstream scientific advice that EPA received from virtually every major medical association and public health organization that provided their input to the Agency'' (Henderson *et al.,* 2006b, p. 2).[9] With regard to EPA's final decision to retain the 24-hour PM_{10} standard for thoracic coarse particles, CASAC had mixed views with regard to the decision to retain the 24-hour standard and the continued use of PM_{10} as the indicator of coarse particles, while also recognizing the need to have a standard in place to protect against effects associated with short-term exposures to thoracic coarse particles (Henderson *et al.,* 2006b, p. 2). With regard to the EPA's final decision to revise the secondary $PM_{2.5}$ standards to be identical in all respects to the revised primary $PM_{2.5}$ standards, CASAC expressed concerns that its advice to establish a distinct secondary standard for fine particles to address visibility impairment was not followed and emphasized ''that continuing to rely on the primary standard to protect against all PM-related adverse environmental and welfare effects assures neglect, and will allow substantial continued degradation, of visual air quality over large areas of the country'' (Henderson et al, 2006b, p. 2).

2. Litigation Related to the 2006 PM Standards

Several parties filed petitions for review following promulgation of the revised PM NAAQS in 2006. These petitions addressed the following issues: (1) Selecting the level of the primary annual $PM_{2.5}$ standard; (2) retaining PM_{10} as the indicator of a standard for thoracic coarse particles, retaining the level and form of the 24-hour PM_{10} standard, and revoking the PM_{10} annual standard; and (3) setting the secondary $PM_{2.5}$ standards identical to the primary standards. On February 24, 2009, the U.S. Court of Appeals for the District of Columbia Circuit issued its opinion in the case *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir. 2009). The court remanded the primary annual $PM_{2.5}$ NAAQS to the EPA because the EPA failed to adequately explain why the standard provided the requisite protection from both short- and long-term exposures to fine particles, including protection for at-risk populations such as children. *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512, 520–27 (D.C. Cir. 2009). With regard to the standards for PM_{10}, the court upheld the EPA's decisions to retain the 24-hour PM_{10} standard to provide protection from thoracic coarse particle exposures and to revoke the annual PM_{10} standard. *American Farm Bureau Federation* v. *EPA,* 559 F. 2d at 533–38. With regard to the secondary $PM_{2.5}$ standards, the court remanded the standards to the EPA because the Agency's decision was ''unreasonable and contrary to the requirements of section 109(b)(2)'' of the CAA. The court further concluded that the EPA failed to adequately explain why setting the secondary PM standards identical to the primary standards provided the required protection for public welfare, including protection from visibility impairment. *American Farm Bureau Federation* v. *EPA,* 559 F. 2d at 528–32.

The decisions of the court with regard to these three issues are discussed further in sections III.A.2, IV.A.2, and VI.A.2 below. The EPA is responding to the court's remands as part of the current review of the PM NAAQS.

3. Current PM NAAQS Review

The EPA initiated the current review of the air quality criteria for PM in June 2007 with a general call for information (72 FR 35462, June 28, 2007). In July 2007, the EPA held two ''kick-off'' workshops on the primary and secondary PM NAAQS, respectively (72 FR 34003 to 34004, June 20, 2007).[10] These workshops provided an opportunity for a public discussion of the key policy-relevant issues around which the EPA would structure this PM NAAQS review and the most meaningful new science that would be available to inform our understanding of these issues.

Based in part on the workshop discussions, the EPA developed a draft Integrated Review Plan outlining the schedule, process, and key policy-relevant questions that would guide the evaluation of the air quality criteria for PM and the review of the primary and secondary PM NAAQS (U.S. EPA, 2007a). On November 30, 2007, the EPA held a consultation with CASAC on the draft Integrated Review Plan (72 FR 63177, November 8, 2007), which included the opportunity for public comment. The final Integrated Review Plan (U.S. EPA, 2008a) incorporated comments from CASAC (Henderson, 2008) and the public on the draft plan as well as input from senior Agency managers.[11] [12]

[9] CASAC specifically identified input provided by the American Medical Association, the American Thoracic Society, the American Lung Association, the American Academy of Pediatrics, the American College of Cardiology, the American Heart Association, the American Cancer Society, the American Public Health Association, and the National Association of Local Boards of Health (Henderson *et al.,* 2006b, p. 2).

[10] See workshop materials available at: *http://www.regulations.gov/search/Regs/home.html#home* Docket ID numbers EPA–HQ–OAR–2007–0492–008; EPA–HQ–OAR–2007–0492–009; EPA–HQ–OAR–2007–0492–010; and EPA–HQ–OAR–2007–0492–012.

[11] The process followed in this review varies from the NAAQS review process described in section 1.1 of the Integrated Review Plan (U.S. EPA, 2008a). On May 21, 2009, Administrator Jackson called for key changes to the NAAQS review process including reinstating a policy assessment document that contains staff analyses of the scientific bases for alternative policy options for consideration by senior Agency management prior to rulemaking. In conjunction with this change, the EPA will no longer issue a policy assessment in the form of an advance notice of proposed rulemaking (ANPR) as

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A major element in the process for reviewing the NAAQS is the development of an Integrated Science Assessment. This document provides a concise evaluation and integration of the policy-relevant science, including key science judgments upon which the risk and exposure assessments build. As part of the process of preparing the PM Integrated Science Assessment, NCEA hosted a peer review workshop in June 2008 on preliminary drafts of key Integrated Science Assessment chapters (73 FR 30391, May 27, 2008). CASAC and the public reviewed the first external review draft Integrated Science Assessment (U.S. EPA, 2008b; 73 FR 77686, December 19, 2008) at a meeting held on April 1 to 2, 2009 (74 FR 2688, February 19, 2009). Based on CASAC (Samet, 2009e) and public comments, NCEA prepared a second draft Integrated Science Assessment (U.S. EPA, 2009b; 74 FR 38185, July 31, 2009), which was reviewed by CASAC and the public at a meeting held on October 5 and 6, 2009 (74 FR 46586, September 10, 2009). Based on CASAC (Samet, 2009f) and public comments, NCEA prepared the final Integrated Science Assessment titled *Integrated Science Assessment for Particulate Matter,* December 2009 (U.S. EPA, 2009a; 74 FR 66353, December 15, 2009).

Building upon the information presented in the PM Integrated Science Assessment, the EPA prepared Risk and Exposure Assessments that provide a concise presentation of the methods, key results, observations, and related uncertainties. In developing the Risk and Exposure Assessments for this PM NAAQS review, OAQPS released two planning documents: *Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment* and *Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Urban Visibility Impact Assessment* (henceforth, Scope and Methods Plans, U.S. EPA, 2009c,d; 74 FR 11580, March 18, 2009). These planning documents outlined the scope and approaches that staff planned to use in conducting quantitative assessments as well as key issues that would be addressed as part of the assessments. In designing and conducting the initial health risk and visibility impact assessments, the Agency considered CASAC comments (Samet 2009a,b) on the Scope and Methods Plans made during an April 2009 consultation (74 FR 7688, February 19, 2009) as well as public comments. CASAC and the public reviewed two draft assessment documents, *Risk Assessment to Support the Review of the $PM_{2.5}$ Primary National Ambient Air Quality Standards: External Review Draft,* September 2009 (U.S. EPA, 2009e) and *Particulate Matter Urban-Focused Visibility Assessment—External Review Draft,* September 2009 (U.S. EPA, 2009f) at a meeting held on October 5 and 6, 2009 (74 FR 46586, September 10, 2009). Based on CASAC (Samet 2009c,d) and public comments, OAQPS staff revised these draft documents and released second draft assessment documents (U.S. EPA, 2010d,e) in January and February 2010 (75 FR 4067, January 26, 2010) for CASAC and public review at a meeting held on March 10 and 11, 2010 (75 FR 8062, February 23, 2010). Based on CASAC (Samet, 2010a,b) and public comments on the second draft assessment documents, the EPA revised these documents and released final assessment documents titled *Quantitative Health Risk Assessment for Particulate Matter,* June 2010 (henceforth, ''Risk Assessment,'' U.S. EPA, 2010a) and *Particulate Matter Urban-Focused Visibility Assessment—Final Document,* July 2010 (henceforth, ''Visibility Assessment,'' U.S. EPA, 2010b) (75 FR 39252, July 8, 2010).

Based on the scientific and technical information available in this review as assessed in the Integrated Science Assessment and Risk and Exposure Assessments, the EPA staff prepared a Policy Assessment. The Policy Assessment is intended to help ''bridge the gap'' between the relevant scientific information and assessments and the judgments required of the Administrator in reaching decisions on the NAAQS (Jackson, 2009, attachment, p. 2). *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 521. The Policy Assessment is not a decision document; rather it presents the EPA staff conclusions related to the broadest range of policy options that could be supported by the currently available information. A preliminary draft Policy Assessment (U.S. EPA, 2009g) was released in September 2009 for informational purposes and to facilitate discussion with CASAC at the October 5 and 6, 2009 meeting on the overall structure, areas of focus, and level of detail to be included in the Policy Assessment. The EPA considered CASAC's comments on this preliminary draft in developing a first draft Policy Assessment (U.S. EPA, 2010c; 75 FR 4067, January 26, 2010) that built upon the information presented and assessed in the final Integrated Science Assessment and second draft Risk and Exposure Assessments. The EPA presented an overview of the first draft Policy Assessment at a CASAC meeting on March 10, 2010 (75 FR 8062, February 23, 2010) and it was discussed during public CASAC teleconferences on April 8 and 9, 2010 (75 FR 8062, February 23, 2010) and May 7, 2010 (75 FR 19971, April 16, 2010).

The EPA developed a second draft Policy Assessment (U.S. EPA, 2010f; 75 FR 39253, July 8, 2010) based on CASAC (Samet, 2010c) and public comments on the first draft Policy Assessment. CASAC reviewed the second draft document at a meeting on July 26 and 27, 2010 (75 FR 32763, June 9, 2010). The EPA staff considered CASAC (Samet, 2010d) and public comments on the second draft Policy Assessment in preparing a final Policy Assessment titled *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards,* April, 2011 (U.S. EPA, 2011a; 76, FR 22665, April 22, 2011). This document includes final staff conclusions on the adequacy of the current PM standards and alternative standards for consideration.

The schedule for the rulemaking in this review is subject to a court order in a lawsuit filed in February 2012 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 PM NAAQS within the period provided by statute. *American Lung Association and National Parks Conservation Association* v. *EPA,* D.D.C. No. 12–cv–00243 (consol. with No. 12–cv–00531) Court orders in that case provide that the EPA sign a notice of proposed rulemaking concerning its review of the PM NAAQS no later than June 14, 2012 and a notice of final rulemaking no later than December 14, 2012.

On June 14, 2012, the EPA issued its proposed decision to revise the NAAQS for PM (77 FR 38890, June 29, 2012) (henceforth ''proposal''). In the proposal, the EPA identified revisions to the standards, based on the air quality criteria for PM, and to related data handling conventions and ambient air monitoring, reporting, and network design requirements. The EPA proposed revisions to the PSD permitting program with respect to the proposed NAAQS revisions. The Agency also proposed

discussed in the Integrated Review Plan (U.S. EPA, 2008a, p. 3). For more information on the overall process followed in this review including a description of the major elements of the process for reviewing NAAQS see Jackson (2009).

[12] All written comments submitted to the Agency are available in the docket for this PM NAAQS review (EPA–HQ–OAR–2007–0429). Transcripts of public meetings and teleconferences held in conjunction with CASAC's reviews are also included in the docket.

changes to the AQI for $PM_{2.5}$, consistent with the proposed primary $PM_{2.5}$ standards. The proposal solicited public comments on alternative primary and secondary standards and related matters. The proposal is summarized in section II.D below.

The EPA held two public hearings to receive public comment on the proposed revisions to the PM NAAQS (77 FR 39205, July 2, 2012). One hearing took place in Philadelphia, PA on July 17, 2012 and a second hearing took place in Sacramento, CA on July 19, 2012. At these public hearings, the EPA heard testimony from 168 individuals representing themselves or specific interested organizations.

The EPA received more than 230,000 comments from members of the public and various interest groups on the proposed revisions to the PM NAAQS by the close of the public comment period on August 31, 2012. Major issues raised in the public comments are discussed throughout the preamble of this final action. A more detailed summary of all significant comments, along with the EPA's responses (henceforth ''Response to Comments'') can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2007–0492) (U.S. EPA, 2012a).

In the proposal, the EPA recognized that there were a number of new scientific studies on the health effects of PM that had been published since the mid-2009 cutoff date for inclusion in the Integrated Science Assessment.[13] As in the last PM NAAQS review, the EPA committed to conduct a provisional review and assessment of any significant ''new'' studies published since the close of the Integrated Science Assessment, including studies submitted to the EPA during the public comment period. The purpose of the provisional science assessment was to ensure that the Administrator was fully aware of the ''new'' science that has developed since 2009 before making final decisions on whether to retain or revise the current PM NAAQS. The EPA screened and surveyed the recent health literature, including studies submitted during the public comment period, and conducted a provisional assessment (U.S. EPA, 2012b) that places the results of those studies of potentially greatest policy relevance in the context of the findings of the Integrated Science Assessment (U.S. EPA, 2009a). This provisional assessment, including a summary of the key conclusions, can be found in the rulemaking docket (EPA–HQ–OAR–2007–0492).

The provisional assessment found that the ''new'' studies expand the scientific information considered in the Integrated Science Assessment and provide important insights on the relationship between PM exposure and health effects. The provisional assessment also found that the ''new'' studies generally strengthen the evidence that long- and short-term exposures to fine particles are associated with a wide range of health effects. Some of the ''new'' epidemiological studies report effects in areas with lower $PM_{2.5}$-concentrations than those in earlier studies considered in the Integrated Science Assessment. ''New'' toxicological and epidemiological studies continue to link various health effects with a range of fine particle sources and components. With regard to thoracic coarse particles, the provisional assessment recognized that a limited number of ''new'' studies provide evidence of an association with short-term $PM_{10\text{-}2.5}$ exposures and increased asthma-related emergency department visits in children, but continue to provide no evidence of an association between long-term $PM_{10\text{-}2.5}$ exposure and mortality. Further, the provisional assessment found that the results reported in ''new'' studies do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Integrated Science Assessment.

The EPA believes it was important to conduct a provisional assessment in this proceeding, so that the Administrator would be aware of the science that developed too recently for inclusion in the Integrated Science Assessment. However, it is also important to note that the EPA's review of that science to date has been limited to screening, surveying, and preparing a provisional assessment of these studies. Having performed this limited provisional assessment, the EPA must decide whether to consider the ''new'' studies in this review and to take such steps as may be necessary to include them in the basis for the final decision, or to reserve such action for the next review of the PM NAAQS.

As in prior NAAQS reviews, the EPA is basing its decision in this review on studies and related information included in the Integrated Science Assessment, Risk and Exposure Assessment, and Policy Assessment, which have undergone CASAC and public review. The studies assessed in the Integrated Science Assessment, and the integration of the scientific evidence presented in that document, have undergone extensive critical review by the EPA, CASAC, and the public during the development of the Integrated Science Assessment. 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. 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, CASAC, and have been subject as well to the public review that accompanies this process. As described above, the provisional assessment did not and could not provide that kind of in-depth critical review.

This decision is consistent with the EPA's practice in prior NAAQS reviews. 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. *See* e.g., 36 FR 8186 (April 30, 1971) (the EPA based original NAAQS for six pollutants on scientific studies discussed in air quality criteria documents and limited consideration of comments to those concerning validity of scientific basis); 38 FR 25678, 25679–25680 (September 14, 1973) (the EPA revised air quality criteria for sulfur oxides to provide basis for reevaluation of secondary NAAQS). This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the CAA concerning CASAC review of air quality criteria. The EPA has consistently followed this approach. 52 FR 24634, 24637 (July 1, 1987) (after review by CASAC, the EPA issued a post-proposal addendum to the PM Air Quality Criteria Document, to address certain new scientific studies not included in the 1982 Air Quality Criteria Document); 61 FR 25566, 25568 (May 22, 1996) (after review by CASAC, the EPA issued a post-proposal supplement to the 1982 Air Quality Criteria Document to address certain new health studies not included in the 1982 Air Quality Criteria Document or 1986

[13] For ease of reference, these studies will be referred to as ''new'' studies or ''new'' science, using quotation marks around the word *new*. Referring to studies that were published too recently to have been included in the 2009 Integrated Science Assessment as ''new'' studies is intended to clearly differentiate such studies from those that have been published since the last review and which are included in the Integrated Science Assessment (these studies are sometimes referred to as new (without quotation marks) or more recent studies, to indicate that they were not included in the Integrated Science Assessment and thus are newly available in this review).

Addendum). The EPA reaffirmed this approach in its decision not to revise the ozone NAAQS in 1993, as well as in its final decision on the PM NAAQS in the 1997 and 2006 reviews. 58 FR 13008, 13013 to 13014 (March 9, 1993) (ozone review); 62 FR 38652, 38662 (July 18, 1997) and 71 FR 61141, 61148 to 61149 (October 17, 2006) (PM reviews) (The EPA conducted a provisional assessment but based the final PM decisions on studies and related information included in the air quality criteria that had been reviewed by CASAC).

As discussed in the EPA's 1993 decision not to revise the NAAQS for ozone, 'new' studies may sometimes be of such significance that it is appropriate to delay a decision on revision of NAAQS and to supplement the pertinent air quality criteria so the ''new'' studies can be taken into account (58 FR, 13013 to 13014, March 9, 1993). In this proceeding, the provisional assessment of recent studies concludes that, taken in context, the ''new'' information and findings do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Integrated Science Assessment (U.S. EPA, 2012b). 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 PM air quality criteria that have undergone CASAC and public review. The EPA will consider the ''new'' published studies for purposes of decision making in the next periodic review of the PM NAAQS, which will provide the opportunity to fully assess them through a more rigorous review process involving the EPA, CASAC, and the public.

C. Related Control Programs To Implement PM Standards

States are primarily responsible for ensuring attainment and maintenance of NAAQS once the EPA has established them. Under section 110 of the CAA and related provisions, states are to submit, for the EPA's approval, SIPs that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the PSD permitting program (CAA sections 160 to 169). In addition, federal programs provide for nationwide reductions in emissions of PM and other air pollutants through the federal motor vehicle and motor vehicle fuel control program under title II of the Act (CAA sections 202 to 250) which involves controls for emissions from mobile sources and controls for the fuels used by these sources, and new source performance standards (NSPS) for stationary sources under section 111 of the CAA.

Currently, there are 35 areas in the U.S. that are designated as nonattainment for the current annual $PM_{2.5}$ standard and 32 areas in the U.S. that are designated as nonattainment for the current 24-hour $PM_{2.5}$ standards. With the revisions to the PM NAAQS that are being finalized in this rule, the EPA will work with the states to conduct a new area designation process. Those states with new nonattainment areas will be required to develop SIPs to attain the standards. In developing their attainment plans, states will have to take into account projected emission reductions from federal and state rules that have already been adopted at the time of plan submittal. A number of significant emission reduction programs that will lead to reductions of PM and its precursors are in place today or are expected to be in place by the time any new SIPs will be due. Examples of such rules include regulations for onroad and nonroad engines and fuels, the utility and industrial boilers toxics rules, 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 standards ''as expeditiously as practicable'' and adopt new state regulations, as appropriate. Section IX includes additional discussion of designation and implementation issues associated with the revised PM NAAQS.

D. Summary of Proposed Revisions to the PM NAAQS

For reasons discussed in the proposal, the Administrator proposed to revise the current primary and secondary PM standards. With regard to the primary $PM_{2.5}$ standards, the Administrator proposed to revise the level of the annual $PM_{2.5}$ standard from 15.0 μg/m^3 to a level within a range of 12.0 to 13.0 μg/m^3 and to retain the level of the 24-hour $PM_{2.5}$ standard at 35 μg/m^3. The Administrator also proposed to eliminate spatial averaging provisions as part of the form of the annual standard to avoid potential disproportionate impacts on at-risk populations. The EPA proposed to revise the AQI for $PM_{2.5}$, consistent with the proposed primary $PM_{2.5}$ standards.

With regard to the primary coarse particle standard, the EPA proposed to retain the current 24-hour PM_{10} standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10\text{-}2.5}$).

With regard to the secondary PM standards, the EPA proposed to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment. The separate secondary standard was proposed to be defined in terms of a $PM_{2.5}$ visibility index, which would use speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction, translated to the deciview (dv) scale, similar to the Regional Haze Program; a 24-hour averaging time; a 90th percentile form averaged over 3 years; and a level set at one of two options—either 30 or 28 dv. The EPA also proposed to retain the current secondary standards generally to address non-visibility welfare effects.

The EPA also proposed to revise the data handling procedures consistent with the revised primary and secondary standards for $PM_{2.5}$ including the computations necessary for determining when these standards are met and the measurement data that are appropriate for comparison to the standards. With regard to monitoring-related activities, the EPA proposed to update several aspects of the monitoring regulations and specifically to require that a small number of $PM_{2.5}$ monitors be relocated to be collocated with measurements of other pollutants (e.g., nitrogen dioxide, carbon monoxide) in the near-road environment.

E. Organization and Approach to Final PM NAAQS Decisions

This action presents the Administrator's final decisions on the review of the current primary and secondary $PM_{2.5}$ and PM_{10} standards. Consistent with the decisions made by the EPA in the last review and with the conclusions in the Integrated Science Assessment and Policy Assessment, fine and thoracic coarse particles continue to be considered as separate subclasses of PM pollution. Primary standards for fine particles and for thoracic coarse particles are addressed in sections III and IV, respectively. Changes to the AQI for $PM_{2.5}$, consistent with the revised primary $PM_{2.5}$ standards, are addressed in section V. Secondary standards for fine and coarse particles are addressed in section VI. Related data handling conventions and exceptional events are addressed in section VII. Updates to the monitoring regulations are addressed in

section VIII. Implementation activities, including PSD-related actions, are addressed in section IX. Section X addresses applicable statutory and executive order reviews.

Today's final decisions addressing standards for fine and coarse particles are based on a thorough review in the Integrated Science Assessment of scientific information on known and potential human health and welfare effects associated with exposure to these subclasses of PM at levels typically found in the ambient air. These final decisions also take into account: (1) Staff assessments in the Policy Assessment of the most policy-relevant information in the Integrated Science Assessment as well as a quantitative health risk assessment and urban-focused visibility assessment based on that information; (2) CASAC advice and recommendations, as reflected in its letters to the Administrator, its discussions of drafts of the Integrated Science Assessment, Risk and Exposure Assessments, and Policy Assessment at public meetings, and separate written comments prepared by individual members of the CASAC PM Review Panel; (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.

III. Rationale for Final Decisions on the Primary $PM_{2.5}$ Standards

This section presents the Administrator's final decision regarding the need to revise the current primary $PM_{2.5}$ standards and, more specifically, regarding revisions to the level and form of the existing primary annual $PM_{2.5}$ standard in conjunction with retaining the existing primary 24-hour $PM_{2.5}$ standard. As discussed more fully below, the rationale for the final decision is based on a thorough review, in the Integrated Science Assessment, of the latest scientific information, published through mid-2009, on human health effects associated with long- and short-term exposures to fine particles in the ambient air. The final decisions also take into account: (1) Staff assessments of the most policy-relevant information presented and assessed in the Integrated Science Assessment and staff analyses of air quality and human risks presented in the Risk Assessment and the Policy Assessment, upon which staff conclusions regarding appropriate considerations in this review are based; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the Integrated Science Assessment, Risk Assessment, and Policy Assessment at public meetings, in separate written comments, and in CASAC's letters to the Administrator; (3) the multiple rounds of 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 proposal.

In developing this final rule, the Administrator recognizes that the CAA requires her to reach a public health policy judgment as to what standards would be requisite—neither more nor less stringent than necessary—to protect public health with an adequate margin of safety, based on scientific evidence and technical assessments that have inherent uncertainties and limitations. This judgment requires making reasoned decisions as to what weight to place on various types of evidence and assessments, and on the related uncertainties and limitations. Thus, in selecting the final standards, the Administrator is seeking not only to prevent fine particle concentrations that have been demonstrated to be harmful but also to prevent lower fine particle concentrations that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

As discussed below, as well as in more detail in the proposal, a substantial amount of new research has been conducted since the close of the science assessment in the last review of the $PM_{2.5}$ NAAQS (U.S. EPA, 2004), with important new information coming from epidemiological studies, in particular. This body of evidence includes hundreds of new epidemiological studies conducted in many countries around the world. In its assessment of the evidence judged to be most relevant to making decisions on elements of the primary $PM_{2.5}$ standards, the EPA has placed greater weight on U.S. and Canadian studies using $PM_{2.5}$ measurements, since studies conducted in other countries may reflect different demographic and air pollution characteristics.[14]

The newly available research studies as well as the earlier body of scientific evidence presented and assessed in the Integrated Science Assessment have undergone intensive scrutiny through multiple layers of peer review and opportunities for public review and comment. In developing this final rule, the EPA has drawn upon an integrative synthesis of the entire body of evidence concerning exposure to ambient fine particles and a broad range of health endpoints (U.S. EPA, 2009a, Chapters 2, 4, 5, 6, 7, and 8) focusing on those health endpoints for which the Integrated Science Assessment concludes that there is a *causal* or *likely causal relationship* with long- or short-term $PM_{2.5}$ exposures. The EPA has also considered health endpoints for which the Integrated Science Assessment concludes there is evidence *suggestive of a causal relationship* with long-term $PM_{2.5}$ exposures.

The EPA has also drawn upon a quantitative risk assessment based upon the scientific evidence described and assessed in the Integrated Science Assessment. These analyses, discussed in the Risk Assessment (U.S. EPA, 2010a) and Policy Assessment (U.S. EPA, 2011a, chapter 2), have also undergone intensive scrutiny through multiple layers of peer review and multiple opportunities for public review and comment.

Although important uncertainties remain in the qualitative and quantitative characterizations of health effects attributable to ambient fine particles, progress has been made in addressing these uncertainties in this review. The EPA's review of this information has been extensive and deliberate. This intensive evaluation of the scientific evidence and quantitative assessments has provided a comprehensive and adequate basis for regulatory decision making at this time.

This section describes the integrative synthesis of the evidence and technical information contained in the Integrated Science Assessment, the Risk Assessment, and the Policy Assessment with regard to the current and alternative standards. The EPA notes that the final decision for retaining or revising the current primary $PM_{2.5}$ standards is a public health policy judgment made by the Administrator. The Administrator's final decision draws upon scientific information and analyses related to health effects and risks; judgments about uncertainties that are inherent in the scientific evidence and analyses; CASAC advice; and comments received in response to the proposal.

In presenting the rationale for the final decisions on the primary $PM_{2.5}$ standards, this section begins with a summary of the approaches used in setting the initial primary $PM_{2.5}$ NAAQS in 1997 and in reviewing and revising those standards in 2006 (section III.A.1). The DC Circuit Court of Appeals remand of the primary annual $PM_{2.5}$ standard in 2009 is discussed in section III.A.2. Taking into consideration this

[14] Nonetheless, the Administrator recognizes the importance of all studies, including international studies, in the Integrated Science Assessment's considerations of the weight of the evidence that informs causality determinations.

history, section III.A.3 describes the EPA's general approach used in the current review for considering the need to retain or revise the current suite of fine particle standards, taking into account public comment on the proposed approach.

The scientific evidence and quantitative risk assessment were presented in sections III.B and III.C of the proposal, respectively (77 FR 38906 to 38917, June 29, 2012) and are outlined in sections III.B and III.C 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 it is appropriate to revise the suite of current primary $PM_{2.5}$ standards (section III.D), as well as a more complete discussion of the Administrator's rationale for retaining or revising the specific elements of the primary $PM_{2.5}$ standards, namely the indicator (section III.E.1); averaging time (section III.E.2); form (section III.E.3); and level (section III.E.4). A summary of the final decisions to revise the suite of primary $PM_{2.5}$ standards is presented in section III.F.

A. Background

There are currently two primary $PM_{2.5}$ standards providing public health protection from effects associated with fine particle exposures. The annual standard is set at a level of 15.0 μg/m^3, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple monitors sited to represent community-wide air quality. The 24-hour standard is set at a level of 35 μg/m^3, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area.

The past and current approaches for reviewing the primary $PM_{2.5}$ standards described below are all based most fundamentally on using information from epidemiological studies to inform the selection of $PM_{2.5}$ standards that, in the Administrator's judgment, protect public health with an adequate margin of safety. Such information can be in the form of air quality distributions over which health effect associations have been observed in scientific studies or in the form of concentration-response functions that support quantitative risk assessment. However, evidence- and risk-based approaches using information from epidemiological studies to inform decisions on $PM_{2.5}$ standards are complicated by the recognition that no population threshold, below which it can be concluded with confidence that $PM_{2.5}$-related effects do not occur, can be discerned from the available evidence.[15] As a result, any general approach to reaching decisions on what standards are appropriate necessarily requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards. This includes consideration of how to weigh the uncertainties in the reported associations across the distributions of $PM_{2.5}$ concentrations in the studies and the uncertainties in quantitative estimates of risk, in the context of the entire body of evidence before the Agency. Such approaches are consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

1. General Approach Used in Previous Reviews

The general approach used to translate scientific information into standards in the previous PM NAAQS reviews focused on consideration of alternative standard levels that were somewhat below the long-term mean $PM_{2.5}$ concentrations reported in key epidemiological studies (U.S. EPA, 2011a, section 2.1.1). This approach recognized that the strongest evidence of $PM_{2.5}$-related associations occurs where the bulk of the data exists, which is over a range of concentrations around the long-term (i.e., annual) mean.

In setting primary $PM_{2.5}$ annual and 24-hour standards for the first time in 1997, the Agency relied primarily on an evidence-based approach that focused on epidemiological evidence, especially from short-term exposure studies of fine particles judged to be the strongest evidence at that time (U.S. EPA, 2011a, section 2.1.1.1). The EPA selected a level for the annual standard that was at or below the long-term mean $PM_{2.5}$ concentrations in studies providing evidence of associations with short-term $PM_{2.5}$ exposures, placing greatest weight on those short-term exposure studies that reported clearly statistically significant associations with mortality and morbidity effects. Further consideration of long-term mean $PM_{2.5}$ concentrations associated with mortality and respiratory effects in children did not provide a basis for establishing a lower annual standard level. The EPA did not place much weight on quantitative risk estimates from the very limited risk assessment conducted, but did conclude that the risk assessment results confirmed the general conclusions drawn from the epidemiological evidence that a serious public health problem was associated with ambient PM levels allowed under the then current PM_{10} standards (62 FR 38665/1, July 18, 1997).

The EPA considered the epidemiological evidence and data on air quality relationships to set an annual $PM_{2.5}$ standard that was intended to be the ''generally controlling'' standard; i.e., the primary means of lowering both long- and short-term ambient concentrations of $PM_{2.5}$.[16] In conjunction with the annual standard, the EPA also established a 24-hour $PM_{2.5}$ standard to provide supplemental protection against days with high peak concentrations, localized ''hotspots,'' and risks arising from seasonal emissions that might not be well controlled by an annual standard (62 FR 38669/3).

In 2006, the EPA used a different evidence-based approach to assess the appropriateness of the levels of the 24-hour and annual $PM_{2.5}$ standards (U.S. EPA, 2011a, section 2.1.1.2). Based on an expanded body of epidemiological evidence that was stronger and more robust than that available in the 1997 review, including additional studies of both short- and long-term exposures, the EPA decided that using evidence of effects associated with periods of exposure that were most closely matched to the averaging time of each standard was the most appropriate public health policy approach for evaluating the scientific evidence to inform selecting the level of each standard. Thus, the EPA relied upon evidence from the short-term exposure studies as the principal basis for revising the level of the 24-hour $PM_{2.5}$ standard from 65 to 35 μg/m^3 to protect against effects associated with short-term exposures. The EPA relied upon evidence from long-term exposure

[15] The term ''evidence-based'' approach or consideration generally refers to using the information in the scientific evidence to inform judgments on the need to retain or revise the NAAQS. The term ''risk-based'' generally refers to using the quantitative information in the Risk Assessment to inform such judgments.

[16] In so doing, the EPA noted that because an annual standard would focus control programs on annual average $PM_{2.5}$ concentrations, it would not only control long-term exposure levels, but would also generally control the overall distribution of 24-hour exposure levels, resulting in fewer and lower 24-hour peak concentrations. Alternatively, a 24-hour standard that focused controls on peak concentrations could also result in lower annual average concentrations. Thus, the EPA recognized that either standard could provide some degree of protection from both short- and long-term exposures, with the other standard serving to address situations where the daily peaks and annual averages are not consistently correlated (62 FR 38669, July 18, 1997). In the circumstances presented in that review, the EPA determined that it was appropriate to focus on the annual standard as the standard best suited to control both annual and daily air quality distributions (62 FR 38670).

studies as the principal basis for retaining the level of the annual $PM_{2.5}$ standard at 15 μg/m³ to protect against effects associated with long-term exposures. This approach essentially took the view that short-term studies were not appropriate to inform decisions relating to the level of the annual standard, and long-term studies were not appropriate to inform decisions relating to the level of the 24-hour standard. With respect to quantitative risk-based considerations, the EPA determined that the estimates of risks likely to remain upon attainment of the 1997 suite of $PM_{2.5}$ standards were indicative of risks that could be reasonably judged important from a public health perspective and, thus, supported revision of the standards. However, the EPA judged that the quantitative risk assessment had important limitations and did not provide an appropriate basis for selecting the levels of the revised standards in 2006 (71 FR 61174/1–2, October 17, 2006).

2. Remand of Primary Annual $PM_{2.5}$ Standard

As noted above in section II.B.2, several parties filed petitions for review in the U.S. Court of Appeals for the District of Columbia Circuit following promulgation of the revised PM NAAQS in 2006. These petitions challenged several aspects of the final rule including the level of the primary $PM_{2.5}$ annual standard. The primary 24-hour $PM_{2.5}$ standard was not challenged by any of the litigants and, thus, was not considered in the court's review and decision.

On judicial review, the D.C. Circuit remanded the primary annual $PM_{2.5}$ NAAQS to the EPA on grounds that the Agency failed to adequately explain why the annual standard provided the requisite protection from both short- and long-term exposures to fine particles including protection for at-risk populations. *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir. 2009). With respect to human health protection from short-term $PM_{2.5}$ exposures, the court considered the different approaches used by the EPA in the 1997 and 2006 p.m. NAAQS decisions, as summarized in section III.A.1 above. The court found that the EPA failed to adequately explain why a primary 24-hour $PM_{2.5}$ standard by itself would provide the protection needed from short-term exposures and remanded the primary annual $PM_{2.5}$ standard to the EPA ''for further consideration of whether it is set at a level requisite to protect the public health while providing an adequate margin of safety from the risk of short-term exposures to $PM_{2.5}$.'' *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 520–24.

With respect to protection from long-term exposure to fine particles, the court found that the EPA failed to adequately explain how the primary annual $PM_{2.5}$ standard provided an adequate margin of safety for children and other at-risk populations. The court found that the EPA did not provide a reasonable explanation of why certain morbidity studies, including a study of children in Southern California showing lung damage associated with long-term $PM_{2.5}$ exposure (Gauderman et al., 2000) and a multi-city study (24-Cities Study) evaluating decreased lung function in children associated with long-term $PM_{2.5}$ exposures (Raizenne *et al.,* 1996), did not warrant a more stringent annual $PM_{2.5}$ standard. *Id.* at 522–23. Specifically, the court found that:

> EPA was unreasonably confident that, even though it relied solely upon long-term mortality studies, the revised standard would provide an adequate margin of safety with respect to morbidity among children. Notably absent from the final rule, moreover, is any indication of how the standard will adequately reduce risk to the elderly or to those with certain heart or lung diseases despite (a) the EPA's determination in its proposed rule that those subpopulations are at greater risk from exposure to fine particles and (b) the evidence in the record supporting that determination. *Id.* at 525.

In addition, the court held that the EPA had not adequately explained its decision to base the level of the annual standard essentially exclusively on the results of long-term studies and the 24-hour standard level essentially exclusively on the results of short-term studies. *See* 559 F. 3d at 522 (''[e]ven if the long-term studies available today are useful for setting an annual standard * * * it is not clear why the EPA no longer believes it useful to look as well to short-term studies in order to design the suite of standards that will most effectively reduce the risks associated with short-term exposure''); *see* also *Id.* at 523–24 (holding that the EPA had not adequately explained why a standard based on levels in short-term exposure studies alone provided appropriate protection from health effects associated with short-term $PM_{2.5}$ exposures given the stated need to lower the entire air quality distribution, and not just peak concentrations, in order to control against short-term effects).

In remanding the primary annual $PM_{2.5}$ standard for reconsideration, the court did not vacate the standard, *Id.* at 530, so the standard remains in effect and is therefore the standard considered by the EPA in this review.

3. General Approach Used in the Policy Assessment for the Current Review

This review is based on an assessment of a much expanded body of scientific evidence, more extensive air quality data and analyses, and a more comprehensive quantitative risk assessment relative to the information available in past reviews, as presented and assessed in the Integrated Science Assessment and Risk Assessment and discussed in the Policy Assessment. As a result, the EPA's general approach to reaching conclusions about the adequacy of the current suite of $PM_{2.5}$ standards and potential alternative standards that are appropriate to consider was broader and more integrative than in past reviews. Our general approach also reflected consideration of the issues raised by the court in its remand of the primary annual $PM_{2.5}$ standard as discussed in section III.A.2 above, since decisions made in this review, and the rationales for those decisions, will comprise the Agency's response to the remand.

The EPA's general approach took into account both evidence-based and risk-based considerations and the uncertainties related to both types of information, as well as advice from CASAC (Samet, 2010c,d) and public comments on the first and second draft Policy Assessments (U.S. EPA, 2010c,f). In so doing, the EPA staff developed a final Policy Assessment (U.S. EPA, 2011a) which provided as broad an array of policy options as was supported by the available information, recognizing that the selection of a specific approach to reaching final decisions on the primary $PM_{2.5}$ standards will reflect the judgments of the Administrator as to what weight to place on the various approaches and types of information available in the current review.

The Policy Assessment concluded it was most appropriate to consider the protection against $PM_{2.5}$-related mortality and morbidity effects, associated with both long- and short-term exposures, afforded by the annual and 24-hour standards taken together, as was done in the 1997 review, rather than to consider each standard separately, as was done in the 2006 review (U.S. EPA, 2011a, section 2.1.3).[17] As the EPA recognized in 1997,

[17] By utilizing this approach, the Agency also is responsive to the remand of the 2006 standard. As noted in section III.A.2, the D.C. Circuit, in remanding the 2006 primary annual $PM_{2.5}$ standard, concluded that the Administrator had failed to

Continued

there are various ways to combine two standards to achieve an appropriate degree of public health protection. The extent to which these two standards are interrelated in any given area depends in large part on the relative levels of the standards, the peak-to-mean ratios that characterize air quality patterns in an area, and whether changes in air quality designed to meet a given suite of standards are likely to be of a more regional or more localized nature.

In considering the combined effect of annual and 24-hour standards, the Policy Assessment recognized that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in lower annual average $PM_{2.5}$ concentrations but also in fewer and lower peak 24-hour $PM_{2.5}$ concentrations. The Policy Assessment also recognized that changes designed to meet a 24-hour standard would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations but also in lower annual average $PM_{2.5}$ concentrations. Thus, either standard could be viewed as providing protection from effects associated with both short- and long-term exposures, with the other standard serving to address situations where the daily peak and annual average concentrations are not consistently correlated.

In considering the currently available evidence, the Policy Assessment recognized that the short-term exposure studies were primarily drawn from epidemiological studies that associated variations in area-wide health effects with monitor(s) that measured the variation in daily $PM_{2.5}$ concentrations over the course of several years. The strength of the associations in these data was demonstrably in the numerous ''typical'' days within the air quality distribution, not in the peak days. *See* also 71 FR 61168, October 17, 2006 and *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 523, 524 (making the same point). The quantitative risk assessments conducted for this and previous reviews demonstrated the same point; that is, much, if not most of the aggregate risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low-to mid-range, below the peak 24-hour concentrations (U.S. EPA, 2011a, section 2.2.2; U.S. EPA, 2010a, section 3.1.2.2). In addition, there was no evidence suggesting that risks associated with long-term exposures were likely to be disproportionately driven by peak 24-hour concentrations.[18]

For these reasons, the Policy Assessment concluded that strategies that focused primarily on reducing peak days were less likely to achieve reductions in the $PM_{2.5}$ concentrations that were most strongly associated with the observed health effects. Furthermore, the Policy Assessment concluded that a policy approach that focused on reducing peak exposures would most likely result in more uneven public health protection across the U.S. by either providing inadequate protection in some areas or overprotecting in other areas (U.S. EPA, 2011a, p. 2–9; U.S. EPA, 2010a, section 5.2.3). This is because, as discussed above, reductions based on control of peak days are less likely to control the bulk of the air quality distribution.

The Policy Assessment concluded that a policy goal of setting a ''generally controlling'' annual standard that will lower a wide range of ambient 24-hour $PM_{2.5}$ concentrations, as opposed to focusing on control of peak 24-hour $PM_{2.5}$ concentrations, was the most effective and efficient way to reduce total population risk and so provide appropriate protection. This approach, in contrast to one focusing on a generally controlling 24-hour standard, would likely reduce aggregate risks associated with both long- and short-term exposures with more consistency and would likely avoid setting national standards that could result in relatively uneven protection across the country, due to setting standards that are either more or less stringent than necessary in different geographical areas (U.S. EPA, 2011a, p. 2–9).

The Policy Assessment also concluded that an annual standard intended to serve as the primary means for providing protection from effects associated with both long- and short-term $PM_{2.5}$ exposures cannot be expected to offer sufficient protection against the effects of all short-term $PM_{2.5}$ exposures. As a result, in conjunction with a generally controlling annual standard, the Policy Assessment concluded it was appropriate to consider setting a 24-hour standard to provide supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods (U.S. EPA, 2011a, p. 2–10).

The Policy Assessment's consideration of the protection afforded by the current and alternative suites of standards focused on $PM_{2.5}$-related health effects associated with long-term exposures for which the magnitude of quantitative estimates of risks to public health generated in the risk assessment was appreciably larger in terms of overall incidence and percent of total mortality or morbidity effects than for short-term $PM_{2.5}$-related effects. Nonetheless, the EPA also considered health effects and estimated risks associated with short-term exposures. In both cases, the Policy Assessment placed greatest weight on health effects that had been judged in the Integrated Science Assessment to have a causal or likely causal relationship with $PM_{2.5}$ exposures, while also considering health effects judged to be suggestive of a causal relationship or evidence that focused on specific at-risk populations. The Policy Assessment placed relatively greater weight on statistically significant associations that yielded relatively more precise effect estimates and that were judged to be robust to confounding by other air pollutants. In the case of short-term exposure studies, the Policy Assessment placed greatest weight on evidence from large multi-city studies, while also considering associations in single-city studies.

In translating information from epidemiological studies into the basis for reaching staff conclusions on the adequacy of the current suite of standards, the Policy Assessment considered a number of factors. As an initial matter, the Policy Assessment considered the extent to which the currently available evidence and related uncertainties strengthens or calls into question conclusions from the last review regarding associations between fine particle exposures and health effects. The Policy Assessment also considered evidence of health effects in at-risk populations and the potential impacts on such populations. Further, the Policy Assessment explored the extent to which $PM_{2.5}$-related health effects had been observed in areas where air quality distributions extend to lower concentrations than previously reported or in areas that would likely have met the current suite of standards.

In translating information from epidemiological studies into the basis for reaching staff conclusions on

adequately explain why an annual standard was sufficiently protective in the absence of consideration of the long-term mean $PM_{2.5}$ concentrations in short-term exposure studies as well, and likewise had failed to explain why a 24-hour standard was sufficiently protective in the absence of consideration of the effect of an annual standard on reducing the overall distribution of 24-hour average $PM_{2.5}$ concentrations. 559 F. 3d at 520–24.

[18] In confirmation, a number of studies have presented analyses excluding higher PM concentration days and reported a limited effect on the magnitude of the effect estimates or statistical significance of the association (e.g., Dominici, 2006b; Schwartz et al., 1996; Pope and Dockery, 1992).

standard levels for consideration (U.S. EPA, 2011a, sections 2.1.3 and 2.3.4), the Policy Assessment first recognized the absence of discernible thresholds in the concentration-response functions from long- and short-term $PM_{2.5}$ exposure studies (U.S. EPA, 2011a, section 2.4.3).[19] In the absence of any discernible thresholds, the Agency's general approach for identifying appropriate standard levels for consideration involved characterizing the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in epidemiological studies. In so doing, the Policy Assessment recognized that there is no single factor or criterion that comprises the ''correct'' approach, but rather there are various approaches that are reasonable to consider for characterizing the confidence in the associations and the limitations and uncertainties in the evidence. Identifying the implications of various approaches for reaching conclusions on the range of alternative standard levels that is appropriate to consider can help inform the final decisions to either retain or revise the standards. Today's final decisions also take into account public health policy judgments as to the degree of health protection that is to be achieved.

In reaching staff conclusions on the range of annual standard levels that was appropriate to consider, the Policy Assessment focused on identifying an annual standard that provided requisite protection from effects associated with both long- and short-term exposures. In so doing, the Policy Assessment explored different approaches for characterizing the range of $PM_{2.5}$ concentrations over which our confidence in the nature of the associations for both long- and short-term exposures is greatest, as well as the extent to which our confidence is reduced at lower $PM_{2.5}$ concentrations.

First, the Policy Assessment recognized that the approach that most directly addressed this issue considered studies that analyzed confidence intervals around concentration-response relationships and in particular, analyses that averaged across multiple concentration-response models rather than considering a single concentration-response model.[20] The Policy Assessment explored the extent to which such analyses had been published for studies of health effects associated with long- or short-term $PM_{2.5}$ exposures. Such analyses could potentially be used to characterize a concentration below which uncertainty in a concentration-response relationship substantially increases or is judged to be indicative of an unacceptable degree of uncertainty about the existence of a continuing concentration-response relationship. The Policy Assessment concluded that identifying this area of uncertainty in the concentration-response relationship could be used to inform identification of alternative standard levels that are appropriate to consider.

Further, the Policy Assessment explored other approaches that considered different statistical metrics from epidemiological studies. The Policy Assessment first took into account the general approach used in previous PM reviews which focused on consideration of alternative standard levels that were somewhat below the long-term mean $PM_{2.5}$ concentrations reported in epidemiological studies using air quality distributions based on composite monitor concentrations.[21] This approach recognized that the strongest evidence of $PM_{2.5}$-related associations occurs at concentrations around the long-term (i.e., annual) mean. In using this approach, the Policy Assessment placed greatest weight on those long- and short-term exposure studies that reported statistically significant associations with mortality and morbidity effects.

In extending this approach, the Policy Assessment also considered information beyond a single statistical metric of $PM_{2.5}$ concentrations (i.e., the mean) to the extent such information was available. Pursuant to an express comment from CASAC (Samet 2010d, p. 2), the Policy Assessment utilized distributional statistics (i.e., statistical characterization of an entire distribution of data) to identify the broader range of $PM_{2.5}$ concentrations that had the most influence on the calculation of relative risk estimates in both long- and short-term exposure epidemiological studies. Thus, the Policy Assessment considered the part of the distribution of $PM_{2.5}$ concentrations in which the data analyzed in the study (i.e., air quality and population-level data, as discussed below) were most concentrated, specifically, the range of $PM_{2.5}$ concentrations around the long-term mean over which our confidence in the magnitude and significance of associations observed in the epidemiological studies was greatest. The Policy Assessment then focused on the lower part of the distribution to characterize where the data became appreciably more sparse and, thus, where our understanding of the magnitude and significance of the associations correspondingly became more uncertain. The Policy Assessment recognized there was no single percentile value within a given distribution that was most appropriate or ''correct'' to use to characterize where our confidence in the associations becomes appreciably lower. The Policy Assessment concluded that the range from the 25th to 10th percentiles is a reasonable range to consider as a region where we had appreciably less confidence in the associations observed in epidemiological studies.[22]

In considering distributional statistics from epidemiological studies, the final Policy Assessment focused on two types of population-level metrics that CASAC advised were most useful to consider in identifying the $PM_{2.5}$ concentrations

[19] The epidemiological studies evaluated in the Integrated Science Assessment that examined the shape of concentration-response relationships and the potential presence of a threshold focused on cardiovascular-related hospital admissions and emergency department visits associated with short-term PM_{10} exposures and premature mortality associated with long-term $PM_{2.5}$ exposure (U.S. EPA, 2009a, sections 6.5, 6.2.10.10 and 7.6). Overall, the Integrated Science Assessment concluded that the studies evaluated support the use of a no-threshold, log-linear model but recognized that ''additional issues such as the influence of heterogeneity in estimates between cities, and the effect of seasonal and regional differences in PM on the concentration-response relationship still require further investigation'' (U.S. EPA, 2009a, section 2.4.3).

[20] This is distinct from confidence intervals around concentration-response relationships that are related to the magnitude of effect estimates generated at specific $PM_{2.5}$ concentrations (i.e., point-wise confidence intervals) and that are relevant to the precision of the effect estimate across the air quality distribution, rather than to our confidence in the existence of a continuing concentration-response relationship across the entire air quality distribution on which a reported association was based.

[21] Using the term ''composite monitor'' does not imply that the EPA can identify one monitor that represents the air quality evaluated in a specific study area. Rather, the composite monitor concentration represents the average concentration across monitors within each area with more than one monitor included in a given study as typically reported in epidemiological studies. For multi-city studies, this metric reflects concentrations averaged across multiple monitors or from single monitors within each area and then averaged across study areas for an overall study mean $PM_{2.5}$ concentration. This is consistent with the epidemiological evidence considered in other NAAQS reviews.

[22] In the PM NAAQS review completed in 2006, the Staff Paper similarly recognized that the evidence of an association in any epidemiological study is ''strongest at and around the long-term average where the data in the study are most concentrated. For example, the interquartile range of long-term average concentrations within a study [with a lower bound of the 25th percentile] or a range within one standard deviation around the study mean, may reasonably be used to characterize the range over which the evidence of association is strongest'' (U.S. EPA, 2005, p. 5–22). A range of one standard deviation around the mean represents approximately 68 percent of normally distributed data, and below the mean falls between the 25th and 10th percentiles.

most influential in generating the health effect estimates reported in the epidemiological studies.[23] Consistent with CASAC advice, the most relevant information was the distribution of health events (e.g., deaths, hospitalizations) occurring within a study population in relation to the distribution of $PM_{2.5}$ concentrations. However, in recognizing that access to health event data can be restricted, the Policy Assessment also considered the number of study participants within each study area as an appropriate surrogate for health event data.

The Policy Assessment recognized that an approach considering analyses of confidence intervals around concentration-response functions was intrinsically related to an approach that considered different distributional statistics. Both of these approaches could be employed to understand the broader distribution of $PM_{2.5}$ concentrations which correspond to the health events reported in epidemiological studies. In applying these approaches, the Policy Assessment, consistent with CASAC advice (Samet, 2010d, p. 3), considered $PM_{2.5}$ concentrations from long- and short-term $PM_{2.5}$ exposure studies using composite monitor distributions.

In reaching staff conclusions on alternative standard levels that were appropriate to consider, the Policy Assessment also included a broader consideration of the uncertainties and limitations of the current scientific evidence. Most notably, these uncertainties are related to the heterogeneity observed in the epidemiological studies in the eastern versus western parts of the U.S., the relative toxicity of $PM_{2.5}$ components, and the potential role of co-pollutants (U.S. EPA, 2011a, pp. 2–25 to 2–26). The limitations and uncertainties associated with the currently available scientific evidence, including the availability of fewer studies toward the lower range of alternative annual standard levels being considered in this proposal, are summarized in section III.B below and further discussed in section III.B.2 of the proposal.

The Policy Assessment recognized that the level of protection afforded by the NAAQS relies both on the level and the form of the standard. The Policy Assessment concluded that a policy approach that used data based on composite monitor distributions to identify alternative standard levels, and then compared those levels to concentrations at maximum monitors to determine whether an area meets a given standard, inherently has the potential to build in some margin of safety (U.S. EPA, 2011a, p. 2–14).[24] This conclusion was consistent with CASAC's comments on the second draft Policy Assessment, in which CASAC expressed its preference for focusing on an approach using composite monitor distributions ''because of its stability, and for the additional margin of safety it provides'' when ''compared to the maximum monitor perspective'' (Samet, *et al.,* 2010d, pp. 2 to 3).

In reaching staff conclusions on alternative 24-hour standard levels that are appropriate to consider for setting a 24-hour standard intended to supplement the protection afforded by a generally controlling annual standard, the Policy Assessment considered currently available short-term $PM_{2.5}$ exposure studies. The evidence from these studies informed our understanding of the protection afforded by the suite of standards against effects associated with short-term exposures. In considering the short-term exposure studies, the Policy Assessment evaluated both the distributions of 24-hour $PM_{2.5}$ concentrations, with a focus on the 98th percentile concentrations (to the extent such data were available) to match the form of the current 24-hour $PM_{2.5}$ standard, as well as the long-term mean $PM_{2.5}$ concentrations reported in these studies. In addition to considering the epidemiological evidence, the Policy Assessment also considered air quality information based on county-level 24-hour and annual design values[25] to understand the policy implications of the alternative standard levels supported by the underlying science. In particular, the Policy Assessment considered the extent to which different combinations of alternative annual and 24-hour standards would support the policy goal of focusing on a generally controlling annual standard in conjunction with a 24-hour standard that would provide supplemental protection. In so doing, the Policy Assessment discussed the roles that each standard might be expected to play in the protection afforded by alternative suites of standards.

Beyond these evidence-based considerations, the Policy Assessment also considered the quantitative risk estimates and the key observations presented in the Risk Assessment. This assessment included an evaluation of 15 urban case study areas and estimated risk associated with a number of health endpoints associated with long- and short-term $PM_{2.5}$ exposures (U.S. EPA, 2010a). As part of the risk-based considerations, the Policy Assessment considered estimates of the magnitude of $PM_{2.5}$-related risks associated with recent air quality levels and air quality simulated to just meet the current and alternative suites of standards using alternative simulation approaches. The Policy Assessment also characterized the risk reductions, relative to the risks remaining upon just meeting the current standards, associated with just meeting alternative suites of standards. In so doing, the Policy Assessment recognized the uncertainties inherent in such risk estimates, and took such uncertainties into account by considering the sensitivity of the ''core'' risk estimates to alternative assumptions and methods likely to have substantial impact on the estimates. In addition, the Policy Assessment considered additional analyses characterizing the representativeness of the urban study areas within a broader national context to understand the roles that the annual and 24-hour standards may play in affording protection against effects related to both long- and short-term $PM_{2.5}$ exposures.

Based on the approach discussed above, the Policy Assessment reached conclusions related to the primary $PM_{2.5}$ standards that reflected an

[23] The second draft Policy Assessment focused on the distributions of ambient $PM_{2.5}$ concentrations and associated population data across areas included in several multi-city studies for which such data were available in seeking to identify the most influential range of concentrations (U.S. EPA, 2010f, section 2.3.4.1). In its review of the second draft Policy Assessment, CASAC advised that it ''would be preferable to have information on the concentrations that were most influential in generating the health effect estimates in individual studies'' (Samet, 2010d, p.2). Therefore, in the final Policy Assessment, the EPA considered population-level data (i.e., area-specific health event data and study area population data) along with corresponding $PM_{2.5}$ concentrations to generate a cumulative distribution of the population-level data relative to long-term mean $PM_{2.5}$ concentrations to determine the most influential part of the air quality distribution (U.S. EPA, 2011a, Figure 2–7 and associated text).

[24] Statistical metrics (e.g., means) based on composite monitor distributions may be identical to or below the same statistical metrics based on maximum monitor distributions. For example, some areas may have only one monitor, in which case the composite and maximum monitor distributions will be identical in those areas. Other areas may have multiple monitors that may be very close to the monitor measuring the highest concentrations, in which case the composite and maximum monitor distributions could be similar in those areas. As noted in Hassett-Sipple et al. (2010), for studies involving a large number of areas, the composite and maximum concentrations are generally within 5 percent of each other (77 FR 38905, fn. 30). Still other areas may have multiple monitors that may be separately impacted by local sources in which case the composite and maximum monitor distributions could be quite different (U.S. EPA, 2011a, p. 2–14). See further discussion of this issue in section III.E.4.c.i below.

[25] Design values are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance.

understanding of both evidence-based and risk-based considerations to inform two overarching questions related to: (1) The adequacy of the current suite of $PM_{2.5}$ standards and (2) revisions to the standards that were appropriate to consider in this review to protect against health effects associated with both long- and short-term exposures to fine particles. When evaluating the health protection afforded by the current or any alternative suites of standards considered, the Policy Assessment took into account the four basic elements of the NAAQS: The indicator, averaging time, form, and level.

The general approach for reviewing the primary $PM_{2.5}$ standards described above provided a comprehensive basis that helped to inform the Administrator's judgments in reaching her proposed and final decisions to revise the current suite of primary fine particle NAAQS and in responding to the remand of the 2006 primary annual $PM_{2.5}$ standard.

B. Overview of Health Effects Evidence

This section outlines the key information presented in section III.B of the proposal (77 FR 38906 to 38911, June 29, 2012) and discussed more fully in the Integrated Science Assessment (Chapters 2, 4, 5, 6, 7, and 8) and the Policy Assessment (Chapter 2) related to health effects associated with fine particle exposures. Section III.B. of the proposal discusses available information on the health effects associated with exposures to $PM_{2.5}$, including the nature of such health effects (section III.B.1) and associated limitations and uncertainties (section III.B.2), at-risk populations (section III.B.3), and potential $PM_{2.5}$-related impacts on public health (section III.B.4). As was true in the last two reviews, evidence from epidemiological, controlled human exposure and animal toxicological studies played a key role in the Integrated Science Assessment's evaluation of the scientific evidence.

The 2006 PM NAAQS review concluded that there was ''strong epidemiological evidence'' for linking long-term $PM_{2.5}$ exposures with cardiovascular-related and lung cancer mortality and respiratory-related morbidity and for linking short-term $PM_{2.5}$ exposures with cardiovascular-related and respiratory-related mortality and morbidity (U.S. EPA, 2004, p. 9–46; U.S. EPA, 2005, p. 5–4). Overall, the evidence from epidemiological, toxicological, and controlled human exposure studies supported ''likely causal associations'' between $PM_{2.5}$ and both mortality and morbidity from cardiovascular and respiratory diseases, based on ''an assessment of strength, robustness, and consistency in results'' (U.S. EPA, 2004, p. 9–48).[26]

In this review, based on the expanded body of evidence, the EPA finds that:

(1) In looking across the extensive new scientific evidence available in this review, our overall understanding of health effects associated with fine particle exposures has been greatly expanded. The currently available evidence is largely consistent with evidence available in the last review and substantially strengthens what is known about the effects associated with fine particle exposures.

(2) A number of large multi-city epidemiological studies have been conducted throughout the U.S., including extended analyses of long-term exposure studies that were important to inform decision-making in the last review. The body of currently available scientific evidence has also been expanded greatly by the publication of a number of new multi-city, time-series studies that have used uniform methodologies to investigate the effects of short-term $PM_{2.5}$ exposures on public health. This body of evidence provides a more expansive data base and considers multiple locations representing varying regions and seasons that provide evidence of the influence of different air pollution mixes on $PM_{2.5}$-associated health effects. These studies provide more precise estimates of the magnitude of effects associated with short-term $PM_{2.5}$ exposure than most smaller-scale single-city studies that were more commonly available in the last review. These studies have reported consistent increases in morbidity and/or premature mortality related to ambient $PM_{2.5}$ concentrations, with the strongest evidence reported for cardiovascular-related effects.

(3) In addition, the findings of new toxicological and controlled human exposure studies greatly expand and provide stronger support for a number of potential biological mechanisms or pathways for cardiovascular and respiratory effects associated with long- and short-term PM exposures. These studies provide coherence and biological plausibility for the effects observed in epidemiological studies.

(4) Using a more formal framework for reaching causal determinations than used in prior reviews,[27] the EPA concludes that a causal relationship exists between both long- and short-term exposures to $PM_{2.5}$ and premature mortality and cardiovascular effects and a likely causal relationship exists between long- and short-term $PM_{2.5}$ exposures and respiratory effects. Further, there is evidence suggestive of a causal relationship between long-term $PM_{2.5}$ exposures and other health effects, including developmental and reproductive effects (e.g., low birth weight, infant mortality) and carcinogenic, mutagenic, and genotoxic effects (e.g., lung cancer mortality).[28]

(5) The newly available evidence significantly strengthens the link between long- and short-term exposure to $PM_{2.5}$ and premature mortality, while providing indications that the magnitude of the $PM_{2.5}$-mortality association with long-term exposures may be larger than previously estimated. The strongest evidence comes from recent studies investigating long-term exposure to $PM_{2.5}$ and cardiovascular-related mortality. The evidence supporting a causal relationship between long-term $PM_{2.5}$ exposure and mortality also includes consideration of new studies that demonstrated an improvement in community health following reductions in ambient fine particles.

(6) Several new studies have examined the association between cardiovascular effects and long-term $PM_{2.5}$ exposures in multi-city studies conducted in the U.S. and Europe. While studies were not available in the last review with regard to long-term exposure and cardiovascular-related morbidity, recent studies have provided new evidence linking long-term exposure to $PM_{2.5}$ with an array of cardiovascular effects such as heart attacks, congestive heart failure, stroke, and mortality. This evidence is coherent with studies of short-term exposure to $PM_{2.5}$ that have observed associations with a continuum of effects ranging from subtle changes in indicators of cardiovascular health to serious clinical events, such as increased hospitalizations and emergency department visits due to cardiovascular disease and cardiovascular mortality.

(7) Extended analyses of studies available in the last review as well as new epidemiological studies conducted in the U.S. and abroad provide stronger evidence of respiratory-related morbidity effects associated with long-term $PM_{2.5}$ exposure. The strongest evidence for respiratory-related

[26] The term ''likely causal association'' was used in the 2004 Criteria Document to summarize the strength of the available evidence available in the last review for $PM_{2.5}$. However, this terminology was not based on a formal framework for evaluating evidence for inferring causation. Since the last review, the EPA has developed a more formal framework for reaching causal determinations with standardized language to express evaluation of the evidence (U.S. EPA, 2009a, section 1.5).

[27] The causal framework draws upon the assessment and integration of evidence from across epidemiological, controlled human exposure, and toxicological studies, and the related uncertainties that ultimately influence our understanding of the evidence. This framework employs a five-level hierarchy that classifies the overall weight of evidence and causality using the following categorizations: causal relationship, likely to be causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (U.S. EPA, 2009a, Table 1–3). The development of the causal framework reflects considerable input from CASAC and the public, with CASAC concluding that, ''The five-level classification of strength of evidence for causal inference has been systemically applied [for PM]; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future ISAs'' (Samet, 2009f, p. 1).

[28] These causal inferences are based not only on the more expansive epidemiological evidence available in this review but also reflect consideration of important progress that has been made to advance our understanding of a number of potential biologic modes of action or pathways for PM-related cardiovascular and respiratory effects (U.S. EPA, 2009a, chapter 5).

effects is from studies that evaluated decrements in lung function growth, increased respiratory symptoms, and asthma development. The strongest evidence from short-term $PM_{2.5}$ exposure studies has been observed for increased respiratory-related emergency department visits and hospital admissions for chronic obstructive pulmonary disease (COPD) and respiratory infections.

(8) The body of scientific evidence is somewhat expanded from the 2006 review but is still limited with respect to associations between long-term $PM_{2.5}$ exposures and developmental and reproductive effects as well as cancer, mutagenic, and genotoxic effects. The strongest evidence for an association between $PM_{2.5}$ and developmental and reproductive effects comes from epidemiological studies of low birth weight and infant mortality, especially due to respiratory causes during the post-neonatal period (i.e., 1 month–12 months of age). With regard to cancer effects, ''[m]ultiple epidemiologic studies have shown a consistent positive association between $PM_{2.5}$ and lung cancer mortality, but studies have generally not reported associations between $PM_{2.5}$ and lung cancer incidence'' (U.S. EPA 2009a p. 2–13).

(9) Efforts to evaluate the relationships between PM composition and health effects continue to evolve. While many constituents of $PM_{2.5}$ can be linked with differing health effects, the evidence is not yet sufficient to allow differentiation of those constituents or sources that may be more closely related to specific health outcomes nor to exclude any individual component or group of components associated with any source categories from the fine particle mixture of concern.

(10) Specific groups within the general population are at increased risk for experiencing adverse health effects related to PM exposures. The currently available evidence expands our understanding of previously identified at-risk populations (i.e., children, older adults, and individuals with pre-existing heart and lung disease) and supports the identification of additional at-risk populations (e.g., persons with lower socioeconomic status, genetic differences). Evidence for PM-related effects in these at-risk populations has expanded and is stronger than previously observed. There is emerging, though still limited, evidence for additional potentially at-risk populations, such as those with diabetes, people who are obese, pregnant women, and the developing fetus.

(11) The population potentially affected by $PM_{2.5}$ is large. In addition, large subgroups of the U.S. population have been identified as at-risk populations. While individual effect estimates from epidemiological studies may be small in size, the public health impact of the mortality and morbidity associations can be quite large given the extent of exposure. Taken together, this suggests that exposure to ambient $PM_{2.5}$ concentrations can have substantial public health impacts.

(12) While the currently available scientific evidence is stronger and more consistent than in previous reviews, providing a strong basis for decision making in this review, the EPA recognizes that important uncertainties and limitations in the health effects evidence remain. Epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in responses between cities and geographic regions within the U.S. This heterogeneity may be attributed, in part, to differences in the fine particle composition or related to exposure measurement error, which can introduce bias and increased uncertainty in associated health effect estimates. Variability in the associations observed across $PM_{2.5}$ epidemiological studies may be due in part to exposure error related to measurement-related issues, the use of central fixed-site monitors to represent population exposure to $PM_{2.5}$, models used in lieu of or to supplement ambient measurements, and our limited understanding of factors that may influence exposures (e.g., topography, the built environment, weather, source characteristics, ventilation usage, personal activity patterns, photochemistry). In addition, where $PM_{2.5}$ and other pollutants (e.g., ozone, nitrogen dioxide, and carbon monoxide) are correlated, it can be difficult to distinguish the effects of the various pollutants in the ambient mixture (i.e., co-pollutant confounding).[29]

While uncertainties and limitations still remain in the available health effects evidence, the Administrator judges the currently available scientific data base to be stronger and more consistent than in previous reviews providing a strong basis for decision making in this review.

C. Overview of Quantitative Characterization of Health Risks

In addition to a comprehensive evaluation of the health effects evidence available in this review, the EPA conducted an expanded quantitative risk assessment for selected health endpoints to provide additional information and insights to inform decisions on the primary $PM_{2.5}$ NAAQS.[30] As discussed in section III.C of the proposal, the approach used to develop quantitative risk estimates associated with $PM_{2.5}$ exposures was built on the approach used and lessons learned in the last review and focused on improving the characterization of the overall confidence in the risk estimates, including related uncertainties, by incorporating a number of enhancements, in terms of both the methods and data used in the analyses.

The goals of this quantitative risk assessment were largely the same as those articulated in the risk assessment conducted for the last review. These goals included: (1) To provide estimates of the potential magnitude of premature mortality and/or selected morbidity effects in the population associated with recent ambient levels of $PM_{2.5}$ and with simulating just meeting the current and alternative suites of $PM_{2.5}$ standards in 15 selected urban study areas,[31] including, where data were available, consideration of impacts on at-risk populations; (2) to develop a better understanding of the influence of various inputs and assumptions on the risk estimates to more clearly differentiate among alternative suites of standards; and (3) to gain insights into the distribution of risks and patterns of risk reductions and the variability and uncertainties in those risk estimates. In addition, the quantitative risk assessment included nationwide estimates of the potential magnitude of premature mortality associated with long-term exposure to recent ambient $PM_{2.5}$ concentrations to more broadly characterize this risk on a national scale and to support the interpretation of the more detailed risk estimates generated for selected urban study areas.

The expanded and updated risk assessment conducted in this review included estimates of risk for: (1) All-cause, ischemic heart disease-related, cardiopulmonary-related, and lung cancer-related mortality associated with long-term $PM_{2.5}$ exposure; (2) non-accidental, cardiovascular-related, and respiratory-related mortality associated with short-term $PM_{2.5}$ exposure; and (3) cardiovascular-related and respiratory-related hospital admissions and asthma-related emergency department visits

[29] A copollutant meets the criteria for potential confounding in PM-health associations if: (1) It is a potential risk factor for the health effect under study; (2) it is correlated with PM; and (3) it does not act as an intermediate step in the pathway between PM exposure and the health effect under study (U.S. EPA, 2004, p. 8–10).

[30] The quantitative risk assessment conducted for this review is more fully described and presented in the Risk Assessment (U.S. EPA, 2010a) and summarized in detail in the Policy Assessment (U.S. EPA, 2011a, sections 2.2.2. and 2.3.4.2). The scope and methodology for this risk assessment were developed over the last few years with considerable input from CASAC and the public as described in section II.B.3 above.

[31] The Risk Assessment concluded that these 15 urban study areas were generally representative of urban areas in the U.S. likely to experience relatively elevated levels of risk related to ambient $PM_{2.5}$ exposure with the potential for better characterization at the higher end of that distribution (U.S. EPA, 2011a, p. 2–42; U.S. EPA, 2010a, section 4.4, Figure 4–17). The representativeness analysis also showed that the 15 urban study areas do not capture areas with the highest baseline morality risks or the oldest populations (both of which can result in higher $PM_{2.5}$-related mortality estimates). However, some of the areas with the highest values for these attributes had relatively low $PM_{2.5}$ concentrations (e.g., urban areas in Florida) and, consequently, the Risk Assessment concluded failure to include these areas in the set of urban study areas was unlikely to exclude high $PM_{2.5}$-risk locations (U.S. EPA, 2010a, section 4.4.1).

associated with short-term $PM_{2.5}$ exposure.[32]

The Risk Assessment included a core set of risk estimates supplemented by an alternative set of risk results generated using single-factor and multi-factor sensitivity analyses. The core set of risk estimates was developed using the combination of modeling elements and input data sets identified in the Risk Assessment as having higher confidence relative to inputs used in the sensitivity analyses. The results of the sensitivity analyses provided information to evaluate and rank the potential impacts of key sources of uncertainty on the core risk estimates. In addition, the sensitivity analyses represented a set of reasonable alternatives to the core set of risk estimates that fell within an overall set of plausible risk estimates surrounding the core estimates.

The EPA recognized that there were many sources of variability and uncertainty inherent in the inputs to its quantitative risk assessment.[33] The design of the risk assessment included a number of elements to address these issues in order to increase the overall confidence in the risk estimates generated for the 15 urban study areas, including using guidance from the World Health Organization (WHO, 2008) as a framework for characterizing uncertainty in the analyses.[34]

With respect to the sources of variability, the Risk Assessment considered those that contributed to differences in risk across urban study areas, but did not directly affect the degree of risk reduction associated with the simulation of just meeting current or alternative standard levels (e.g., differences in baseline incidence rates, demographics and population behavior). The Risk Assessment also focused on factors that not only introduced variability into risk estimates across study areas, but also played an important role in determining the magnitude of risk reductions upon simulation of just meeting current or alternative standard levels (e.g., peak-to-mean ratios of ambient $PM_{2.5}$ concentrations within individual urban study areas and the nature of the rollback approach used to simulate just meeting the current or alternative standards). Key sources of potential variability that were likely to affect population risks included the following: (1) Intra-urban variability in ambient $PM_{2.5}$ concentrations, including $PM_{2.5}$ composition; (2) variability in the patterns of reductions in $PM_{2.5}$ concentrations associated with different rollback approaches when simulating just meeting the current or alternative standards; (3) co-pollutant exposures; (4) factors related to demographic and socioeconomic status; (5) behavioral differences across urban study areas (e.g., time spent outdoors); (6) baseline incidence rates; and (7) longer-term temporal variability in ambient $PM_{2.5}$ concentrations reflecting meteorological trends as well as future changes in the mix of $PM_{2.5}$ sources, including changes in air quality related to future regulatory actions.

With regard to uncertainties, single and multi-factor sensitivity analyses were combined with a qualitative analysis to assess the impact of potential sources of uncertainty on the core risk estimates. Key sources of uncertainty included: (1) Characterizing intra-urban population exposure in the context of epidemiological studies linking $PM_{2.5}$ to specific health effects; (2) statistical fit of the concentration-response functions for short-term exposure-related health endpoints; (3) shape of the concentration-response functions; (4) specifying the appropriate lag structure for short-term exposure studies; (5) transferability of concentration-response functions from study locations to urban study area locations for long-term exposure-related health endpoints; (6) use of single-city versus multi-city studies in the derivation of concentration-response functions; (7) impact of historical air quality on estimates of health risk associated with long-term $PM_{2.5}$ exposures; and (8) potential variation in effect estimates reflecting compositional differences in $PM_{2.5}$.

Beyond characterizing uncertainty and variability, a number of design elements were included in the risk assessment to increase the overall confidence in the risk estimates generated for the 15 urban study areas (U.S. EPA, 2011a, pp. 2–38 to 2–41). These elements included: (1) Use of a deliberative process for specifying components of the risk model that reflects consideration of the latest research on $PM_{2.5}$ exposure and risk (U.S. EPA, 2010a, section 5.1.1); (2) integration of key sources of variability into the design as well as the interpretation of risk estimates (U.S. EPA, 2010a, section 5.1.2); (3) assessment of the degree to which the urban study areas are representative of areas in the U.S. experiencing higher $PM_{2.5}$-related risk (U.S. EPA, 2010a, section 5.1.3); and (4) identification and assessment of important sources of uncertainty and the impact of these uncertainties on the core risk estimates (U.S. EPA, 2010a, section 5.1.4). Further, additional analyses examined potential bias and overall confidence in the risk estimates. Greater confidence is associated with risk estimates based on simulated annual mean $PM_{2.5}$ concentrations that are within the region of the air quality distribution used in deriving the concentration-response functions where the bulk of the data reside (e.g., within one standard deviation around the long-term mean $PM_{2.5}$ concentration) (U.S. EPA, 2011a, p. 2–38).

Key observations and insights from the $PM_{2.5}$ risk assessment, together with important caveats and limitations, were discussed in section III.C.3 of the proposal. In general, in considering the set of quantitative risk estimates and related uncertainties and limitations related to long- and short-term $PM_{2.5}$ exposure together with consideration of the health endpoints which could not be quantified, the Policy Assessment concluded this information provided strong evidence that risks estimated to remain upon simulating just meeting the current suite of $PM_{2.5}$ standards are important from a public health perspective, both in terms of severity and magnitude of effects. Patterns of increasing estimated risk reductions were generally observed as either the annual or 24-hour standard level, or both, were reduced over the ranges considered in the Risk Assessment.

The magnitude of both long- and short-term exposure-related risk estimated to remain upon just meeting the current suite of standards as well as alternative standard levels was strongly associated with the simulated change in annual mean $PM_{2.5}$ concentrations. Although long- and short-term exposure-related mortality rates have similar patterns in terms of the subset of urban study areas experiencing risk reductions for the current suite of standard levels, the magnitude of risk remaining is higher for long-term exposure-related mortality and substantially lower for short-term exposure-related mortality. Short-term exposure-related morbidity risk estimates were greater for cardiovascular-related than respiratory-related events and emergency

[32] The evidence available for these selected health effect endpoints generally focused on the entire population, although some information was available to support analyses that considered differences in estimated risk for at-risk populations including older adults and persons with pre-existing cardiovascular and respiratory diseases.

[33] *Variability* refers to the heterogeneity of a variable of interest within a population or across different populations. *Uncertainty* refers to the lack of knowledge regarding the actual values of inputs to an analysis (U.S. EPA, 2010a, p. 3–63).

[34] The extent to which key sources of potential variability were (or were not) fully captured in the design of the risk assessment are discussed in section 3.5.2 of the Risk Assessment (U.S. EPA, 2010a, pp. 3–67 to 3–69).

department visits for asthma-related events were significant: Furthermore, most of the aggregate risk associated with short-term exposures was not primarily driven by the small number of days with $PM_{2.5}$ concentrations in the upper tail of the air quality distribution, but rather by the large number of days with $PM_{2.5}$ concentrations at and around the mean of the distribution, that is, the 24-hour average concentrations that are in the low- to mid-range, well below the peak 24-hour concentrations (U.S. EPA, 2011a, p. 2–3).

With regard to characterizing estimates of $PM_{2.5}$-related risk associated with simulation of alternative standards, the Policy Assessment recognized that greater overall confidence was associated with estimates of *risk reduction* than for estimates of *absolute risk remaining* (U.S. EPA, 2011a, p. 2–94). Furthermore, the Policy Assessment recognized that estimates of absolute risk remaining for each of the alternative standard levels considered, particularly in the context of long-term exposure-related mortality, may be underestimated.[35] In addition, the Policy Assessment observed that in considering the overall confidence associated with the quantitative analyses, the Risk Assessment recognized that: (1) Substantial variability existed in the magnitude of risk remaining across urban study areas and (2) in general, higher confidence was associated with risk estimates based on $PM_{2.5}$ concentrations near the mean $PM_{2.5}$ concentrations in the underlying epidemiological studies providing the concentration-response functions (e.g., within one standard deviation of the mean $PM_{2.5}$ concentration reported). Furthermore, although the Risk Assessment estimated that the alternative 24-hour standard levels considered (when controlling) would result in additional estimated risk reductions beyond those estimated for alternative annual standard levels alone, these additional estimated reductions were highly variable. Conversely, the Risk Assessment recognized that alternative annual standard levels, when controlling, resulted in more consistent risk reductions across urban study areas, thereby potentially providing a more consistent degree of public health protection (U.S. EPA, 2010a, p. 5–17).

D. Conclusions on the Adequacy of the Current Primary $PM_{2.5}$ Standards

1. Introduction

The initial issue to be addressed in the current review of the primary $PM_{2.5}$ standards is whether, in view of the advances in scientific knowledge and other information reflected in the Integrated Science Assessment, the Risk Assessment, and the Policy Assessment, the existing standards should be retained or revised. In considering the adequacy of the current suite of $PM_{2.5}$ standards, the Administrator has considered the large body of evidence presented and assessed in the Integrated Science Assessment (U.S. EPA, 2009a), the quantitative assessment of risks, staff conclusions and associated rationales presented in the Policy Assessment, views expressed by CASAC, and public comments. The Administrator has taken into account both evidence- and risk-based considerations[36] in developing final conclusions on the adequacy of the current primary $PM_{2.5}$ standards.

a. Evidence- and Risk-based Considerations in the Policy Assessment

In considering the available epidemiological evidence in this review, the Policy Assessment took a broader approach than was used in the last review. This approach reflected the more extensive and stronger body of evidence available since the last review on health effects related to both long- and short-term exposure to $PM_{2.5}$. As discussed in section III.A.3 above, this broader approach focused on setting the annual standard as the ''generally controlling'' standard for lowering both short- and long-term $PM_{2.5}$ concentrations and so providing requisite protection to public health. In conjunction with such an annual standard, this approach focused on setting the 24-hour standard to provide supplemental protection against days with high peak $PM_{2.5}$ concentrations.

In addressing the question whether the evidence now available in this review supports consideration of standards that are more protective than the current $PM_{2.5}$ standards, the Policy Assessment considered whether: (1) Statistically significant health effects associations with long- or short-term exposures to fine particles occur in areas that would likely have met the current $PM_{2.5}$ standards [see *American Trucking Associations,* 283 F. 3d at 369, 376 (revision of level of PM NAAQS justified when health effects are observed in areas meeting the existing standard)], and (2) associations with long-term exposures to fine particles extend down to lower air quality concentrations than had previously been observed. With regard to associations observed in long-term $PM_{2.5}$ exposure studies, the Policy Assessment recognized that extended follow-up analyses of the ACS and Harvard Six Cities studies provided consistent and stronger evidence of an association with mortality at lower air quality distributions than had previously been observed (U.S. EPA, 2011a, pp. 2–31 to 2–32). The original and reanalysis of the ACS study reported positive and statistically significant effects associated with a long-term mean $PM_{2.5}$ concentration of 18.2 $\mu g/m^3$ across 50 metropolitan areas for 1979 to 1983 (Pope *et al.,* 1995; Krewski *et al.,* 2000).[37] In extended analyses, positive and statistically significant effects of approximately similar magnitude were associated with declining $PM_{2.5}$ concentrations, from an aggregate long-term mean in 58 metropolitan areas of 21.2 $\mu g/m^3$ in the original monitoring period (1979 to 1983) to 14.0 $\mu g/m^3$ for 116 metropolitan areas in the most recent years evaluated (1999–2000), with an overall average across the two study periods in 51 metropolitan areas of 17.7 $\mu g/m^3$ (Pope *et al.,* 2002; Krewski *et al.,* 2009). With regard to the Harvard Six Cities Study, the original and reanalysis reported positive and statistically significant effects associated

[35] Based on the consideration of both the qualitative and quantitative assessments of uncertainty, the Risk Assessment concluded that it is unlikely that the estimated risks are over-stated, particularly for premature mortality related to long-term $PM_{2.5}$ exposures. In fact, the Policy Assessment and the Risk Assessment concluded that the core risk estimates for this category of health effects may well be biased low based on consideration of alternative model specifications evaluated in the sensitivity analyses (U.S. EPA, 2011a, p. 2–41; U.S. EPA, 2010a, p. 5–16; Figures 4–7 and 4–8). In addition, the Policy Assessment recognized that the currently available scientific information included evidence for a broader range of health endpoints and at-risk populations beyond those included in the quantitative risk assessment, including decrements in lung function growth and respiratory symptoms in children as well as reproductive and developmental effects (U.S. EPA, 2011a, section 2.2.1).

[36] Evidence-based considerations include the assessment of epidemiological, toxicological, and controlled human exposure studies evaluating long- or short-term exposures to $PM_{2.5}$, with supporting evidence related to dosimetry and potential pathways/modes of action, as well as the integration of evidence across each of these disciplines, as assessed in the Integrated Science Assessment (U.S. EPA, 2009a) and focus on the policy-relevant considerations as discussed in section III.B above and in the Policy Assessment (U.S. EPA, 2011a, section 2.2.1). Risk-based considerations draw from the results of the quantitative analyses presented in the Risk Assessment (U.S. EPA, 2010a) and focus on the policy-relevant considerations as discussed in section III.C above and in the Policy Assessment (U.S. EPA, 2011a, section 2.2.2).

[37] The study periods referred to in the Policy Assessment (U.S. EPA, 2011a) and in this final rule reflect the years of air quality data that were included in the analyses, whereas the study periods identified in the Integrated Science Assessment (U.S. EPA, 2009a) reflect the years of health event data that were included.

with a long-term mean $PM_{2.5}$ concentration of 18.0 μg/m³ for 1980 to 1985 (Dockery *et al.,* 1993; Krewski *et al.,* 2000). In an extended follow-up of this study, the aggregate long-term mean concentration across all years evaluated was 16.4 μg/m³ for 1980 to 1988 [38] (Laden *et al.,* 2006). In an additional analysis of the extended follow-up of the Harvard Six Cities study, investigators reported that the concentration-response relationship was linear and ''clearly continuing below the level'' of the current annual standard (U.S. EPA, 2009a, p. 7–92; Schwartz *et al.,* 2008).

Cohort studies conducted since the last review provided additional evidence of mortality associated with air quality distributions that are generally lower than those reported in the ACS and Harvard Six Cities studies, with effect estimates that were similar or, in some studies, significantly greater in magnitude than in the ACS and Harvard Six Cities studies (see also, section III.D.1.a of the proposal, 77 FR 38918 to 28919; U.S. EPA, 2011a, pp. 2–32 to 2–33). The Women's Health Initiative (WHI) study reported positive and most often statistically significant associations between long-term $PM_{2.5}$ exposure and cardiovascular-related mortality as well as morbidity effects, with much larger relative risk estimates for mortality than in the ACS and Harvard Six Cities studies, at an aggregate long-term mean $PM_{2.5}$ concentration of 12.9 μg/m³ for 2000 (Miller *et al.,* 2007).[39]

Using the Medicare cohort, Eftim *et al.* (2008) reported somewhat higher effect estimates than in the ACS and Harvard Six Cities studies with aggregate long-term mean concentrations of 13.6 μg/m³ and 14.1 μg/m³, respectively, for 2000 to 2002. Zeger *et al.* (2008) reported associations between long-term $PM_{2.5}$ exposure and mortality for the eastern region of the U.S. at an aggregated long-term $PM_{2.5}$ median concentration of 14.0 μg/m³, although no association was reported for the western region with an aggregate long-term $PM_{2.5}$ median concentration of 13.1 μg/m³ (U.S. EPA, 2009a, p. 7–88).[40]

Premature mortality in children reported in a national infant mortality study as well as mortality in a cystic fibrosis cohort including both children and adults reported positive but statistically nonsignificant effects associated with long-term aggregate mean concentrations of 14.8 μg/m³ and 13.7 μg/m³, respectively (Woodruff *et al.,* 2008; Goss *et al.,* 2004).

With respect to respiratory morbidity effects associated with long-term $PM_{2.5}$ exposure, the across-city mean of 2-week average $PM_{2.5}$ concentrations reported in the initial Southern California Children's Health Study was approximately 15.1 μg/m³ (Peters *et al.,* 1999). These results were found to be consistent with results of cross-sectional analyses of the 24-Cities Study (Dockery *et al.,* 1996; Raizenne *et al.,* 1996), which reported a long-term cross-city mean $PM_{2.5}$ concentration of 14.5 μg/m³.[41] In this review, extended analyses of the Southern California Children's Health Study provide stronger evidence of $PM_{2.5}$-related respiratory effects, at lower air quality concentrations than had previously been reported, with a four-year aggregate mean concentration of 13.8 μg/m³ across the 12 study communities (McConnell *et al.,* 2003; Gauderman *et al.,* 2004, U.S. EPA, 2009a, Figure 7–4).

In also considering health effects for which the Integrated Science Assessment concluded evidence was suggestive of a causal relationship, the Policy Assessment noted a limited number of birth outcome studies that reported positive and statistically significant effects related to aggregate long-term mean $PM_{2.5}$ concentrations down to approximately 12 μg/m³ (U.S. EPA, 2011a, p. 2–33).

Collectively, the Policy Assessment concluded that currently available evidence provided support for associations between long-term $PM_{2.5}$ exposure and mortality and morbidity effects that extend to distributions of $PM_{2.5}$ concentrations that are lower than those that had previously been associated with such effects, with aggregate long-term mean $PM_{2.5}$ concentrations extending to well below the level of the current annual standard.

The Policy Assessment also considered the long-term mean $PM_{2.5}$ concentrations in short-term exposure studies in assessing the appropriateness of the level of the current annual standard. See *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 522, 523–24 (remanding 2006 standard because the EPA had not adequately explained its choice not to consider long-term means of short-term exposure studies in assessing adequacy of primary annual $PM_{2.5}$ standard). In light of the mixed findings reported in single-city, short-term exposure studies, the Policy Assessment placed comparatively greater weight on the results from multi-city studies in considering the adequacy of the current suite of standards (U.S. EPA, 2011a, pp. 2–34 to 2–35).

With regard to associations reported in short-term $PM_{2.5}$ exposure studies, the Policy Assessment recognized that long-term mean concentrations reported in new multi-city U.S. and Canadian studies provided evidence of associations between short-term $PM_{2.5}$ exposure and mortality at similar air quality distributions to those that had previously been observed in an 8-cities Canadian study (Burnett and Goldberg, 2003; aggregate long-term mean $PM_{2.5}$ concentration of 13.3 μg/m³). In a multi-city time-series analysis of 112 U.S. cities, Zanobetti and Schwartz (2009) reported a positive and statistically significant association with all-cause, cardiovascular-related (e.g., heart attacks, stroke), and respiratory-related mortality and short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 13.2 μg/m³ (U.S. EPA, 2009a, Figure 6–24). Furthermore, city-specific effect estimates indicated the association between short-term exposure to $PM_{2.5}$ and total mortality and cardiovascular- and respiratory-related mortality was consistently positive for an overwhelming majority (99 percent) of the 112 cities across a wide range of air quality concentrations (long-term mean concentrations ranging from 6.6 μg/m³ to 24.7 μg/m³; U.S. EPA, 2009a, Figure 6–24, p. 6–178 to 179). The EPA staff noted that for all-cause mortality, city-specific effect estimates were statistically significant for 55 percent of the 112 cities, with long-term city-mean $PM_{2.5}$ concentrations ranging from 7.8 μg/m³ to 18.7 μg/m³ and 24-hour $PM_{2.5}$ city-mean 98th percentile concentrations ranging from 18.4 to 64.9

[38] Aggregate mean concentration provided by study author (personal communication from Dr. Francine Laden, 2009).

[39] The Policy Assessment noted that in comparison to other long-term exposure studies, the Miller et al. (2007) study was more limited in that it was based on only one year of air quality data (U.S. EPA, 2011a, p. 2–82). The proposal further noted that the air quality data considered were extrapolated from that one single year of air quality data (2000) to the whole study, and that the air quality data post-dated the years of health events considered (i.e., 1994 to 1998) (77 FR 38918, fn 62).

[40] Zeger et al. (2008) also reported positive and statistically significant effects for the central region, with an aggregate long-term mean $PM_{2.5}$ concentration of 10.7 μg/m³. However, in contrast to the eastern and western risk estimates, the central risk estimate increased with adjustment for COPD (used as a proxy for smoking status). Due to the potential for confounding bias influencing the risk estimate for the central region, the Policy Assessment did not focus on the results reported in the central region to inform the adequacy of the current suite of standards or alternative annual standard levels (U.S. EPA, 2011a, p. 2–32).

[41] See *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 525 (noting the importance of these studies, as well as EPA's failure to properly take them into account).

μg/m³ (personal communication with Dr. Antonella Zanobetti, 2009).[42]

With regard to cardiovascular and respiratory morbidity effects, in the first analysis of the Medicare cohort conducted by Dominici *et al.* (2006a) across 204 U.S. counties, investigators reported a statistically significant association with hospitalizations for cardiovascular and respiratory diseases and short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 13.4 μg/m³. Furthermore, a sub-analysis restricted to days with 24-hour average concentrations of $PM_{2.5}$ at or below 35 μg/m³ indicated that, in spite of a reduced statistical power from a smaller number of study days, statistically significant associations were still observed between short-term exposure to $PM_{2.5}$ and hospital admissions for cardiovascular and respiratory diseases (Dominici, 2006b).[43] In an extended analysis of this cohort, Bell *et al.* (2008) reported a positive and statistically significant increase in cardiovascular hospitalizations associated with short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 12.9 μg/m³. These results, along with the observation that approximately 50 percent of the 204 county-specific mean 98th percentile $PM_{2.5}$ concentrations in the study aggregated across all years were below the 24-hour standard of 35 μg/m³, not only indicated that effects are occurring in areas that would meet the current standards but also suggested that the overall health effects observed across the U.S. are not primarily driven by the higher end of the $PM_{2.5}$ air quality distribution (Bell, 2009a, personal communication from Dr. Michelle Bell regarding air quality data for Bell *et al.,* 2008 and Dominici *et al.,* 2006a).

Collectively, the Policy Assessment concluded that the findings from short-term $PM_{2.5}$ exposure studies provided evidence of $PM_{2.5}$-associated health effects occurring in areas that would likely have met the current suite of $PM_{2.5}$ standards (U.S. EPA, 2011a, p. 2–35). These findings were further bolstered by evidence of statistically significant $PM_{2.5}$-related health effects occurring in analyses restricted to days in which 24-hour average $PM_{2.5}$ concentrations were below 35 μg/m³ (Dominici, 2006b).

In evaluating the currently available scientific evidence, as summarized in section III.B of the proposal, the Policy Assessment first concluded that there was stronger and more consistent and coherent support for associations between long- and short-term $PM_{2.5}$ exposures and a broad range of health outcomes than was available in the last review, providing the basis for fine particle standards at least as protective as the current $PM_{2.5}$ standards (U.S. EPA, 2011a, p. 2–26). Having reached this initial conclusion, the Policy Assessment addressed the question of whether the available evidence supported consideration of standards that were more protective than the current standards. In so doing, the Policy Assessment considered whether there was now evidence that health effect associations have been observed in areas that likely met the current suite of $PM_{2.5}$ standards. As discussed above, long- and short-term $PM_{2.5}$ exposure studies provided evidence of associations with mortality and cardiovascular and respiratory effects both at lower ambient $PM_{2.5}$ concentrations than had been observed in the previous review and at concentrations allowed by the current standards (U.S. EPA, 2011a, p. 2–35).

In reviewing this information, the Policy Assessment recognized that important limitations and uncertainties associated with this expanded body of scientific evidence, as discussed in section III.B.2 of the proposal, needed to be carefully considered in determining the weight to be placed on the body of studies available in this review. Taking these limitations and uncertainties into consideration, the Policy Assessment concluded that the currently available evidence clearly calls into question whether the current suite of primary $PM_{2.5}$ standards protects public health with an adequate margin of safety from effects associated with long- and short-term exposures. Furthermore, the Policy Assessment concluded this evidence provides strong support for considering fine particle standards that would afford increased protection beyond that afforded by the current standards (U.S. EPA, 2011a, p. 2–35).

In addition to evidence-based consideration, the Policy Assessment also considered the extent to which health risks estimated to occur upon simulating just meeting the current $PM_{2.5}$ standards may be judged to be important from a public health perspective, taking into account key uncertainties associated with the quantitative health risk estimates. In so doing, the Policy Assessment first noted that the quantitative risk assessment addresses: (1) The core $PM_{2.5}$-related risk estimates; (2) the related uncertainty and sensitivity analyses, including additional sets of reasonable risk estimates generated to supplement the core analysis; (3) an assessment of the representativeness of the urban study areas within a national context;[44] and (4) consideration of patterns in design values and air quality monitoring data to inform interpretation of the risk estimates, as discussed in section III.C above.

In considering the health risks estimated to remain upon simulation of just meeting the current suite of standards and considering both the qualitative and quantitative assessment of uncertainty completed as part of the assessment, the Policy Assessment concluded these risks are important from a public health standpoint and provided strong support for consideration of alternative standards that would provide increased protection beyond that afforded by the current $PM_{2.5}$ (U.S. EPA, 2011a, pp. 2–47 to 2–48). This conclusion reflected consideration of both the severity and the magnitude of the effects. For example, the Risk Assessment indicated the possibility that premature deaths related to ischemic heart disease associated with long-term $PM_{2.5}$ exposure alone would likely be on the order of thousands of deaths per year in the 15 urban study areas upon simulating just meeting the current standards[45] (U.S. EPA, 2011a, pp. 2–46 to 2–47). Moreover, additional risks were anticipated for premature mortality related to cardiopulmonary effects and lung cancer associated with long-term $PM_{2.5}$ exposure as well as mortality and cardiovascular- and respiratory-related morbidity effects (e.g., hospital admissions, emergency department visits) associated with short-term $PM_{2.5}$ exposures. Based on the consideration of both qualitative and

[42] Single-city Bayes-adjusted effect estimates for the 112 cities analyzed in Zanobetti and Schwartz (2009) were provided by the study authors (personal communication with Dr. Antonella Zanobetti, 2009; see also U.S. EPA, 2009a, Figure 6–24).

[43] This sub-analysis was not included in the original publication (Dominici *et al.,* 2006a). The study authors provided sub-analysis results for the Administrator's consideration as a letter to the docket following publication of the proposed rule in January 2006 (personal communication with Dr. Francesca Dominici, 2006b). As noted in section III.A.3, this study is part of the basis for the conclusion that there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations.

[44] Based on analyses of the representativeness of the 15 urban study areas in the broader national context, the Policy Assessment concludes that these study areas are generally representative of urban areas in the U.S. likely to experience relatively elevated levels of risk related to ambient $PM_{2.5}$ exposures (U.S. EPA, 2011a, p. 2–42).

[45] Premature mortality for all causes attributed to $PM_{2.5}$ exposure was estimated to be on the order of tens of thousands of deaths per year on a national scale based on 2005 air quality data (U.S. EPA, 2010a, Appendix G, Table G–1).

quantitative assessments of uncertainty completed as part of the quantitative risk assessment, the Risk Assessment concluded that it was unlikely that the estimated risks are over-stated, particularly for mortality related to long-term $PM_{2.5}$ exposure, and may well be biased low based on consideration of alternative model specifications evaluated in the sensitivity analyses (U.S. EPA, 2010a, p. 5–16; U.S. EPA, 2011a, p. 2–41). Furthermore, the currently available scientific information summarized in section III.B of the proposal provided evidence for a broader range of health endpoints and at-risk populations beyond those included in the quantitative risk assessment (U.S. EPA, 2011a, p. 2–47).

b. CASAC Advice

The CASAC, based on its review of drafts of the Integrated Science Assessment, the Risk Assessment, and the Policy Assessment, provided an array of advice both with regard to interpreting the scientific evidence and quantitative risk assessment, as well as with regard to consideration of the adequacy of the current $PM_{2.5}$ standards (Samet, 2009a,b,c,d,e,f; Samet 2010a,b,c,d). With regard to the adequacy of the current standards, CASAC concluded that the ''currently available information clearly calls into question the adequacy of the current standards'' (Samet, 2010d, p. i) and that the current standards are ''not protective'' (Samet, 2010d, p. 1). Further, in commenting on the first draft Policy Assessment, CASAC noted:

> With regard to the integration of evidence-based and risk-based considerations, CASAC concurs with EPA's conclusion that the new data strengthens the evidence available on associations previously considered in the last round of the assessment of the $PM_{2.5}$ standard. CASAC also agrees that there are significant public health consequences at the current levels of the standard that justify consideration of lowering the $PM_{2.5}$ NAAQS further (Samet, 2010c, p. 12).

c. Administrator's Proposed Conclusions Concerning the Adequacy of the Current Primary $PM_{2.5}$ Standards

At the time of the proposal, in considering the body of scientific evidence, the Administrator concluded there was stronger and more consistent and coherent support for associations between long- and short-term $PM_{2.5}$ exposure and a broader range of health outcomes than was available in the last review, providing the basis for fine particle standards at least as protective as the current $PM_{2.5}$ standards. In particular, the Administrator recognized in section III.D.4 of the proposal that the Integrated Science Assessment concluded that the results of epidemiological and experimental studies form a plausible and coherent data set that supports a causal relationship between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects and a likely causal relationship between long- and short-term $PM_{2.5}$ exposures and respiratory effects. Furthermore, the Administrator reflected that effects had been observed at lower ambient $PM_{2.5}$ concentrations than what had been observed in the last review, including at ambient $PM_{2.5}$ concentrations in areas that likely met the current $PM_{2.5}$ NAAQS. With regard to the results of the quantitative risk assessment, the Administrator noted that the Risk Assessment concluded that the risks estimated to remain upon simulation of just meeting the current standards were important from a public health standpoint in terms of both the severity and magnitude of the effects.

At the time of the proposal, in considering whether the current suite of $PM_{2.5}$ standards should be revised to provide requisite public health protection, the Administrator carefully considered the staff conclusions and rationales presented in the Policy Assessment, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator placed primary consideration on the evidence obtained from the epidemiological studies and provisionally found the evidence of serious health effects reported in long- and short-term exposure studies conducted in areas that would have met the current standards to be compelling, especially in light of the extent to which such studies are part of an overall pattern of positive and frequently statistically significant associations across a broad range of studies that collectively represent a strong and robust body of evidence.

As discussed in the Integrated Science Assessment and Policy Assessment, the Administrator recognized that much progress has been made since the last review in addressing some of the key uncertainties that were important considerations in establishing the current suite of $PM_{2.5}$ standards. For example, progress made since the last review provides increased confidence in the long- and short-term exposure studies as a basis for considering whether any revision of the annual standard is appropriate and increased confidence in the short-term exposure studies as a basis for considering whether any revision of the 24-hour standard is appropriate.[46]

Based on her consideration of these conclusions, as well as consideration of CASAC's conclusion that the evidence and risk assessment clearly called into question the adequacy of the public health protection provided by the current $PM_{2.5}$ NAAQS and public comments on the proposal, the Administrator provisionally concluded that the current primary $PM_{2.5}$ standards, taken together, were not requisite to protect public health with an adequate margin of safety and that revision was needed to provide increased public health protection. The Administrator provisionally concluded that the scientific evidence and information on risk provided strong support for consideration of alternative standards that would provide increased public health protection beyond that afforded by the current $PM_{2.5}$ standards.

2. Comments on the Need for Revision

This section addresses general comments based on relevant facts that either support or oppose any change to the current suite of primary $PM_{2.5}$ standards. Comments on specific long- and short-term exposure studies that relate to consideration of the appropriate levels of the annual and 24-hour standards are addressed in section III.E.4 below. Many public comments asserted that the current $PM_{2.5}$ standards are insufficient to protect public health with an adequate margin of safety and that revisions to the standards are therefore appropriate, indeed necessitated.

Among those calling for revisions to the current standards were the Children's Health Protection Advisory Committee (CHPAC); major medical and public health groups including the American Heart Association (AHA), American Lung Association (ALA), American Public Health Association (APHA), American Thoracic Society (ATS); the Physicians for Social Responsibility (PSR); major environmental groups such as the Clean Air Council, Clean Air Task Force, Earthjustice, Environmental Defense Fund (EDF), National Resources Defense Council (NRDC), and Sierra Club; many environmental justice organizations as

[46] The EPA notes that this increased confidence in the long- and short-term associations generally reflects less uncertainty as to the likely causal nature of such associations, but does not address directly the question of the extent to which such associations remain toward the lower end of the range of ambient $PM_{2.5}$ concentrations. This question is central to the Agency's evaluation of the relevant evidence to determine appropriate standards levels, as discussed below in section III.E.4.

well as medical doctors, academic researchers, health professionals, and many private citizens. For example, the American Heart Association and other major national public health and medical organizations stated that, ''[o]ur organizations are keenly aware of the public health and medical threats from particulate matter'' and called on the EPA to ''significantly strengthen'' both the annual and 24-hour $PM_{2.5}$ standards ''to help us protect the health of our patients and our nation'' (AHA *et al.,* 2012, pp. 1 and 13). AHA *et al.* and ALA *et al.,* as well as a group of more than 350 physicians, environmental health researchers, and public health and medical professionals articulated similar comments on the available evidence:

> Ample scientific evidence supports adopting tighter standards to protect the health of people who are most susceptible to the serious health effects of these pollutants. More than 10,000 peer-reviewed scientific studies have been published since 1997 when EPA adopted the current annual standard. These studies validate and extend earlier epidemiologic research linking both acute and chronic fine particle pollution with serious morbidity and mortality. The newer research has also expanded our understanding of the range of health outcomes associated with PM and has identified adverse respiratory and cardiovascular health effects at lower exposure levels than previously reported. As discussed and interpreted in the EPA's 2009 Integrated Science Assessment for Particulate Matter, the new evidence reinforces already strong existing studies and supports the conclusion that $PM_{2.5}$ is causally associated with numerous adverse health effects in humans at exposure levels far below the current standard. Such a conclusion demands prompt action to protect human health. (AHA *et al.,* 2012, pp. 1 to 2; ALA *et al.,* pp. 4 to 5; similar comment submitted by Rom *et al.,* 2012, p. 1).

All of these medical and public health commenters stated that the current $PM_{2.5}$ standards need to be revised, and that even more protective standards than those proposed by the EPA are needed to adequately protect public health, particularly for at-risk populations. Many environmental justice organizations and individual commenters also expressed such views.

The National Association of Clean Air Agencies (NACAA), the Northeast States for Coordinated Air Use Management (NESCAUM), and many State and local air agencies and health departments who commented on the $PM_{2.5}$ standards supported revision of the suite of current $PM_{2.5}$ standards, as did five state attorneys general (Schneiderman *et al.,* 2012) and the National Tribal Air Association (NTAA).

These commenters based their views chiefly on the body of evidence and technical analyses presented and discussed in the Integrated Science Assessment, the Risk Assessment, and the Policy Assessment finding the available scientific information to be stronger and more compelling than in the last review. These commenters generally placed much weight on CASAC's recommendation to revise the $PM_{2.5}$ standards to provide increased public health protection and on the EPA staff conclusions presented in the final Policy Assessment.

Some of these commenters specifically mentioned extended analyses of seminal long-term exposure studies—the ACS (Krewski *et al.,* 2009), Harvard Six Cities (Laden *et al.,* 2006), and Southern California Children's Health (Gauderman *et al.,* 2004) studies. These commenters also highlighted the availability of additional long-term exposure studies in this review, specifically a study of premature mortality in older adults (Eftim *et al.,* 2008) and the WHI study of cardiovascular morbidity and mortality effects in women (Miller *et al.,* 2007) providing stronger evidence of mortality and morbidity effects associated with long-term $PM_{2.5}$ exposures at lower concentrations than had previously been observed, including studies of effects in at-risk populations. For example, some commenters asserted:

> Evidence during the last review showed clearly that the annual average standard needed to be much lower than the standard of 15 μg/m³ that was first set in 1997. The evidence has only grown since then. Multiple, multi-city studies over long periods of time have shown clear evidence of premature death, cardiovascular and respiratory harm as well as reproductive and developmental harm at contemporary concentrations far below the level of the current (annual) standard (ALA *et al.,* 2012, p. 39; AHA *et al.,* 2012, p. 10).

These commenters also highlighted the availability of a number of short-term $PM_{2.5}$ exposure studies as providing evidence of mortality and morbidity effects at concentrations below the level of the current 24-hour $PM_{2.5}$ standard. Specifically, these commenters made note of multi-city studies of premature mortality (Zanobetti and Schwartz, 2009) and increased hospitalizations for cardiovascular and respiratory-related effects in older adults (Bell *et al.,* 2008). These commenters also asserted the importance of many of the single-city studies, arguing that these studies ''provide valuable information regarding impacts on susceptible populations and on health risk in areas with high peak to mean concentration ratios'' (ALA, *et al.,* 2012, p. 65). Collectively, considering the multi- and single-city short-term exposure studies, these commenters asserted ''the record clearly supports a more stringent 24-hour standard of 25 μg/m³ to provide uniform protection in all regions of the country particularly from short-term spikes in pollution and from the sub-daily exposures that trigger heart attacks and strokes'' (ALA *et al.,* 2012, p. 62). A group of more than 350 physicians, environmental health researchers, and public health and medical professionals argued, ''[s]tudies of short-term exposure demonstrate that $PM_{2.5}$ air pollution increases the risk of hospital admissions for heart and lung problems even when you exclude days with pollution concentrations at or above the current daily standard of 35 μg/m³. Daily concentrations must be capped at lower levels to protect against peak exposure days that occur due to local and seasonal sources of emissions'' (Rom *et al.,* 2012, p. 2).

In addition, many of these commenters generally concluded that progress had been made in reducing many of the uncertainties identified in the last review, in better understanding mechanisms by which $PM_{2.5}$ may be causing the observed health effects, and in improving our understanding of at-risk populations. Further, a number of commenters argued that by making the standards more protective, the $PM_{2.5}$ NAAQS would be more consistent with other existing standards (e.g., California's annual average standard of 12 μg/m³) (CARB, 2012; CA OEHHA, 2012). Other commenters argued that revising the primary $PM_{2.5}$ standards would be more consistent with the recommendations of the World Health Organization (WHO) and/or Canada (e.g., ALA *et al.,* 2012, p. 62; ISEE, 2012, p. 2; MOE-Ontario, 2012, p. 1).

With regard to the scope of the literature reviewed for $PM_{2.5}$-related health effects, some commenters asserted that the EPA inappropriately narrowed the scope of the review by excluding a number of categories of relevant studies, specifically related to studies of diesel pollution and traffic-related pollution (ALA, *et al.,* 2012, p. 17). These commenters argued that, based upon the exclusion of these types of studies, the Integrated Science Assessment ''came to the erroneous conclusion that the causal relationship between PM and cancer is merely suggestive. This conclusion does not square with the International Agency Research on Cancer (IARC) finding that diesel emissions are a known human carcinogen nor with the conclusions of

the extended analyses of the [Harvard] Six Cities and ACS cohort studies that report positive and statistically significant associations between $PM_{2.5}$ and lung cancer.'' *Id.*

Some of these commenters also noted the results of the EPA's quantitative risk assessment, concluding that it showed that the risks estimated to remain when the current standards are met are large and important from a public health perspective and warrant increased protection. For example, ALA *et al.,* noted that the Risk Assessment indicated the quantitative risk analyses likely underestimated $PM_{2.5}$-related mortality (U.S. EPA, 2010a, p. 5–16) and argued that ''the measurements of risk should be treated conservatively'' (ALA, *et al.,* 2012, p. 73). These commenters also summarized an expanded analysis of alternative $PM_{2.5}$ standard levels that they argued documented the need for more protective standards (McCubbin, 2011).

In general, all of these commenters agreed on the importance of results from the large body of scientific studies reviewed in the Integrated Science Assessment and on the need to revise the suite of $PM_{2.5}$ standards as articulated in the EPA's proposal, while generally differing with the EPA's proposed judgments about the extent to which the standards should be revised based on this evidence, specifically for providing protection for at-risk populations.

The EPA generally agrees with these commenters' conclusion regarding the need to revise the current suite of $PM_{2.5}$ standards. The scientific evidence noted by these commenters was generally the same as that assessed in the Integrated Science Assessment and the Policy Assessment, and the EPA agrees that this evidence provides a strong basis for concluding that the current $PM_{2.5}$ standards, taken together, are not requisite to protect public health with an adequate margin of safety, and they need to be revised to provide increased protection. For reasons discussed in section III.E.4.c below, however, the EPA disagrees with aspects of these commenters' views on the level of protection that is appropriate.

The EPA disagrees with these commenters' views that diesel exhaust studies were excluded from the Integrated Science Assessment and were not considered when making the causality determination for cancer, mutagenicity, and genotoxicity. As discussed in section 7.5 of the Integrated Science Assessment, diesel exhaust studies were integrated within the broader body of scientific evidence that was considered in reaching the causality determination for these health endpoints. Additionally, as discussed in section 1.5.3 of the Integrated Science Assessment, the evidence from diesel exhaust studies was also considered as part of the collective evidence evaluated when making determinations for other, noncancer health outcomes (e.g., cardiovascular and respiratory effects).[47] Specifically, when evaluating this evidence, the focus was on understanding the effects of diesel exhaust particles.

It is important to recognize that the Integrated Science Assessment focused on experimental studies of diesel exhaust that evaluated exposures that were relevant to ambient concentrations, i.e., ''within one or two orders of magnitude of ambient PM concentrations'' (U.S. EPA, 2009a, section 1.3). The causal determination for cancer, mutagenicity, and genotoxicity presented in the Integrated Science Assessment represents an integration of experimental and observational evidence of exposures to ambient PM concentrations. The EPA fully considered the findings of studies that assessed these and other health effects associated with exposure to diesel particles in reaching causality determinations regarding health outcomes associated with $PM_{2.5}$ exposures. Furthermore, CASAC supported the EPA's change to the causal determination for cancer and long-term $PM_{2.5}$ concentrations from ''inadequate'' to ''suggestive'' (Samet, 2009f, p. 2).

With regard to traffic studies, the EPA disagrees with the commenters' views that traffic studies that focused on exposure indicators such as distance to roadways should have been included in the Integrated Science Assessment. These studies were excluded from consideration because they did not measure ambient concentrations of specific air pollutants, including $PM_{2.5}$, but instead were studies evaluating exposure to the undifferentiated ''traffic related air pollution'' mixture (ALA *et al.,* 2012, p. 17) (U.S. EPA, 2009a, section 1.3). As a result, these studies do not add to the collective body of evidence on the relationship between long- or short-term exposure to ambient concentrations of $PM_{2.5}$ and health effects.

Some of these commenters also identified ''new'' studies that were not included in the Integrated Science Assessment as providing further support for the need to revise the primary $PM_{2.5}$ standards. As discussed in section II.B.3 above, the EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review and will consider the ''new'' studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments (see Response to Comments document), the EPA notes that its provisional assessment of ''new'' science found that such studies did not materially change the conclusions in the Integrated Science Assessment (U.S. EPA, 2012b).

Another group of commenters opposed revising the current $PM_{2.5}$ standards. These views were most extensively presented in comments from the Utility Air Regulatory Group (UARG), representing a group of electric generating companies and organizations and several national trade associations; the American Petroleum Institute (API) representing more than 500 oil and natural gas companies; the National Association of Manufacturers (NAM), the American Chemistry Council (ACC), the American Fuel & Petroleum Manufacturers (AFPM), the Alliance of Automobile Manufacturers (AAM), and other manufacturing associations; the Electric Power Research Institute (EPRI); and the Texas Commission on Environmental Quality (Texas CEQ). These commenters generally mentioned many of the same studies that were cited by the commenters who supported revising the standards, as well as other studies, but highlighted different aspects of these studies in reaching 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. Furthermore, they asserted that the evidence that has become available since the last review does not establish a more certain risk or a risk of effects that are significantly different in character to those that provided a basis for the current standards, nor does the evidence demonstrate that the risk to public health upon attainment of the current standards would be greater than was

[47] In developing the second draft Integrated Science Assessment, the EPA reexamined the controlled human exposure and toxicological studies of fresh diesel and gasoline exhaust. This information, in addition to other considerations, supported a change in the causal determinations for ultrafine particles. Specifically, in reevaluating the causal determinations for short-term ultrafine particle exposures and cardiovascular and respiratory effects, the EPA changed the classification from ''inadequate'' to ''suggestive'' for both categories of health outcomes (Vandenberg, 2009, p. 3). CASAC agreed with the EPA's rationale for revising these causal determinations (Samet, 2009f, p. 10).

understood when the EPA established the current standards in 2006.

These commenters generally expressed the view that the current standards provide the requisite degree of public health protection. In supporting their view, these commenters generally argued that the EPA's conclusions are inconsistent with the current state of the science and questioned the underlying scientific evidence including the causal determinations reached in the Integrated Science Assessment. More specifically, this group of commenters argued that: (1) The EPA did not apply its framework for causal determination consistently across studies or health outcomes and, in the process, the EPA relied on a selective group of long- and short-term exposure studies to reach conclusions regarding causality; (2) toxicological and controlled human exposure studies do not provide supportive evidence that the health effects observed in epidemiological studies are biologically plausible; (3) uncertainties in the underlying health science are as great or greater than in 2006; (4) there is no evidence of greater risk since the last review to justify tightening the current annual $PM_{2.5}$ standard; and (5) ''new'' studies not included in the Integrated Science Assessment continue to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$. These comments are discussed in turn below.

(l) Some of these commenters asserted that the EPA did not apply its framework for causal determinations consistently across studies or health outcomes (e.g., ACC, 2012, Attachment A, pp. 1 to 2; API, 2012, Attachment 1, p. 30; NAM *et al.,* 2012, pp. 22 to 25; Texas CEQ, 2012, pp 2 to 3).[48] These commenters argued that the EPA downplayed epidemiological studies with null or inconsistent results, inappropriately used the Hill criteria when evaluating the epidemiological evidence, and used the same study and the same underlying database to conclude that there was a causal association between mortality and multiple criteria pollutants.

The EPA disagrees with these commenters' views. First, the EPA recognizes that the evaluation of the scientific evidence and its application of the causal framework used in the current PM NAAQS review was the subject of exhaustive and detailed review by CASAC and the public. As summarized in section II.B.3 above, prior to finalizing the Integrated Science Assessment, two drafts were released for CASAC and public review to evaluate the scientific integrity of the documents. Evidence related to the substantive issues raised by CASAC and public commenters with regard to the content of the first and second draft Integrated Science Assessments were discussed at length during these public CASAC meetings and considered in developing the final Integrated Science Assessment. CASAC supported the development of the EPA's causality framework and its use in the current PM NAAQS review and concluded:

> The five-level classification of strength of evidence for causal inference has been systematically applied; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future Integrated Science Assessments (Samet 2009f, p. 1).

These commenters asserted that during the application of the causal framework the EPA inappropriately relied on a selective group of long- and short-term exposure studies in reaching causal inferences (API, 2012, pp 12 to 17; ACC, 2012, Attachment A, pp 1 to 2; NAM *et al.,* 2012, pp. 22 to 25; Texas CEQ, 2012, pp 2 to 3). Additionally, these commenters expressed the view that the EPA focused on a subset of epidemiological studies that reported positive and statistically significant results while ignoring other studies, especially those that reported no statistically significant associations, those that reported potential thresholds, or those that highlighted uncertainties and limitations in study design or results. Furthermore, some of these commenters argued that epidemiological studies are observational in nature and cannot provide evidence of a causal association.

The EPA disagrees with these commenters' views on assessing the health effects evidence and on the conclusions regarding the causality determinations reached in the Integrated Science Assessment. In conducting a comprehensive evaluation of the evidence in the Integrated Science Assessment, the EPA recognized the distinction between the evaluation of the *relative scientific quality of individual study results* and the evaluation of the *pattern of results within the broader body of scientific evidence* and considered both in reaching causality determinations. The more detailed characterizations of individual studies included an assessment of the quality of the study based on specific criteria as described in the Integrated Science Assessment (U.S. EPA, 2009a, section 1.5.3).

In developing an integrated assessment of the health effects evidence for PM, the EPA emphasized the importance of examining the pattern of results across various studies and did not focus solely on statistical significance[49] as a criterion of study strength. This approach is consistent with views clearly articulated throughout the epidemiological and causal inference literature, specifically, that it is important not to focus on results of statistical tests to the exclusion of other information.[50] The concepts underlying the EPA's approach to evaluating statistical associations have been discussed in numerous publications, including a report by the U.S. Surgeon General on the health consequences of smoking (Centers for Disease Control and Prevention, 2004). This report cautions against over-reliance on statistical significance in evaluating the overall evidence for an exposure-response relationship. Criteria characterized by Hill (1965) also addressed the value, or lack thereof, of statistical tests in the determination of cause:

> No formal tests of significance can answer those [causal] questions. Such tests can, and should, remind us of the effects the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that, they contribute nothing to the 'proof' of our hypothesis (Hill, 1965, p. 299).

The statistical significance of individual study findings has played an important role in the EPA's evaluation of the study's results and the EPA has placed greater emphasis on studies reporting statistically significant results. However, in the broader evaluation of the evidence from many

[48] The EPA notes that the same concerns about the causal determinations presented in the Integrated Science Assessment were raised in comments to CASAC on the draft Integrated Science Assessments (e.g., UARG, 2009; API, 2009; ACC, 2012, Appendix B). CASAC, therefore, had the opportunity to consider these comments in reaching consensus conclusions on this issue.

[49] Statistical significance is an indicator of the precision of a study's results, which is influenced by a variety of factors including, but not limited to, the size of the study, exposure and measurement error, and statistical model specifications. Studies typically calculate ''p-values'' to determine whether the study results are statistically significant or whether the study results are likely to occur simply by chance. In general practice, effects are considered statistically significant if p values are less than 0.05.

[50] For example, Rothman (1998) stated, ''Many data analysts appear to remain oblivious to the qualitative nature of significance testing [and that] * * * statistical significance is itself only a dichotomous indicator. As it has only two values, significant or not significant * * *. Nevertheless, p-values still confound effect size with study size, the two components of estimation that we believe need to be reported separately.'' As a result, Rothman recommended that p-values be omitted as long as point and interval estimates are available.

epidemiological studies, and subsequently during the process of forming causality determinations in integrating evidence across epidemiological, controlled human exposure, and toxicological studies, the EPA has emphasized the *pattern of results* across epidemiological studies, and whether the effects observed were *coherent* across the scientific disciplines for drawing conclusions on the relationship between $PM_{2.5}$ and different health outcomes. Thus, the EPA did not limit its focus or consideration to just studies that reported positive associations or where the results were statistically significant.

In addition, some commenters asserted that the EPA inappropriately used the Hill criteria by failing to consider the limitations of studies with weak associations, thereby overstating the consistency of the observed associations (API, 2012, Attachment 1, pp. 30 to 35). These commenters argued that risk estimates greater than 3 to 4 reflect strong associations supportive of a causal link, while smaller risk estimates (i.e., 1.5 to 3) are considered to be weak and require other lines of evidence to demonstrate causality.

As discussed in section 1.5.3 of the Integrated Science Assessment, the EPA thoroughly considered the limitations of all studies during its evaluation of the scientific literature (U.S. EPA,, 2009a, p. 1–14). This collective body of evidence, including known uncertainties and limitations of the studies evaluated, were considered during the process of forming causality determinations as discussed in chapters 6 and 7 of the Integrated Science Assessment. For example, the EPA concluded that ''a causal relationship exists between short-term $PM_{2.5}$ exposure and cardiovascular effects,'' however, in reaching this conclusion, the Agency recognized and considered limitations of the current evidence that still requires further examination (U.S. EPA, 2009a., in section 6.2.12.1). Therefore, the EPA disagrees with these commenters' views that the Hill criteria were inappropriately used in that the limitations of studies were not considered.

The EPA also disagrees with the commenters' assertion that the magnitude of the association must be large to support a determination of causality. As discussed in the Integrated Science Assessment, the strength of the observed association is an important aspect to aid in judging causality and ''while large effects support causality, modest effects therefore do not preclude it'' (U.S. EPA, 2009a, Table 1–2, section 1.5.4). The weight of evidence approach used by the EPA encompasses a multitude of factors of which the magnitude of the association is only one component (U.S. EPA, 2009a, Table 1–3). An evaluation of the association across multiple investigators and locations supports the ''reproducibility of findings [which] constitutes one of the strongest arguments for causality'' (U.S. EPA, 2009a, Table 1–2). Even though the risk estimates for air pollution studies may be modest, the associations are consistent across hundreds of studies as demonstrated in the Integrated Science Assessment. Furthermore, the causality determinations rely on different lines of evidence, by integrating evidence across disciplines, including animal toxicological studies and controlled human exposure studies.

Furthermore, as summarized in section III.B above and discussed more fully in section III.B.3 of the proposal, the EPA recognizes that the population potentially affected by $PM_{2.5}$ is considerable, including large subgroups of the U.S. population that have been identified as at-risk populations (e.g., children, older adults, persons with underlying cardiovascular or respiratory disease). While individual effect estimates from epidemiological studies may be modest in size, the public health impact of the mortality and morbidity associations can be quite large given that air pollution is ubiquitous. Indeed, with the large population exposed, exposure to a pollutant causally associated at a population level with mortality and serious illness has significant public health consequences, virtually regardless of the relative risk. Taken together, this information indicates that exposure to ambient $PM_{2.5}$ concentrations has substantial public health impacts.

In addition, these commenters believed that the EPA downplayed null or inconsistent findings in numerous long-term mortality studies with reported $PM_{2.5}$ concentrations above and below the level of the current annual standard. The EPA disagrees that studies with null or inconsistent findings were not accurately presented and considered in the Integrated Science Assessment. For example, as discussed throughout section 7.6 and depicted in Figures 7–6 and 7–7 of the Integrated Science Assessment, the EPA presented the collective evidence from all studies that examined the association between long-term $PM_{2.5}$ exposure and mortality. Overall, across these studies there was evidence of consistent positive associations in different cohorts. That evidence, in combination with the biological plausibility provided by experimental and toxicological studies evaluated in sections 7.1 and 7.2 of the Integrated Science Assessment, supported a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality.

Lastly, some of these commenters argued that in some cases, the EPA used the same study and the same underlying database to conclude that there is a causal association between mortality and multiple criteria pollutants. These commenters argued, ''[i]n doing so, EPA attributes the cause of the mortality effects observed to whichever criteria pollutant it is reviewing at the time'' (API, 2012, pp. 14 to 16).

The EPA strongly disagrees that the Agency ''attributes the cause of mortality effects observed to whichever criteria pollutant it is reviewing at the time.'' The EPA consistently recognizes that other pollutants are also associated with health outcomes, as is reflected in the fact that the EPA has established regulations to limit emissions of particulate criteria pollutants as well as other gaseous criteria pollutants. Epidemiological studies often examine the association between short- and long-term exposures to multiple air pollutants and mortality within a common dataset in an attempt to identify the air pollutant(s) of the complex mixture most strongly associated with mortality. In evaluating these studies, the EPA employs specific study selection criteria to identify those studies most relevant to the review of the NAAQS. In its assessment of the health evidence regarding $PM_{2.5}$, the EPA has carefully evaluated the potential for confounding, effect measure modification, and the role of $PM_{2.5}$ as a component of a complex mixture of air pollutants (U.S. EPA, 2009a, p. 1–9). The EPA used a rigorous weight of evidence approach to inform causality that evaluated consistency across studies within a discipline, evidence for coherence across disciplines, and biological plausibility. Additionally, during this process, the EPA assessed the limitations of each study in the context of the collective body of evidence. It was the collective evidence, not one individual study that ultimately determined whether a causal relationship exists between a pollutant and health outcome. In the Integrated Science Assessment, the combination of epidemiological and experimental evidence formed the basis for the Agency concluding for the first time that a causal relationship exists between short- or long-term exposure to a criteria pollutant and mortality (U.S. EPA, 2009, sections 2.3.1.1 and 2.3.1.2).

Additionally, while the EPA has evaluated some of the studies used to inform the causality determination for PM in the Integrated Science Assessments for other criteria air pollutants, the Agency has done so in the context of examining the collective body of evidence for each of the respective criteria air pollutants. As such, the body of evidence to inform causality has varied from pollutant to pollutant resulting in the association between each criteria air pollutant and mortality being classified at a different level of the five-level hierarchy used to inform causation (e.g., U.S. EPA, 2008e, U.S. EPA, 2008f, U.S. EPA, 2010k).

The EPA notes that the final causality determinations presented in the Integrated Science Assessment reflected CASAC's recommendations on the second draft Integrated Science Assessment (Samet, 2009f, pp. 2 to 3). Specifically, CASAC supported the EPA's changes (in the second versus first draft Integrated Science Assessment) from ''likely causal'' to ''causal'' for long-term exposure to $PM_{2.5}$ and cardiovascular effects and for cancer and $PM_{2.5}$ (from ''inadequate'' to ''suggestive''). *Id.* Furthermore, CASAC recommended ''upgrading'' the causal classification for $PM_{2.5}$ and total mortality to ''causal'' for both the short- and long-term timeframes. *Id.* With regard to mortality, the ''EPA carefully reevaluated the body of evidence, including the collective evidence for biological plausibility for mortality effects, and determined that a causal relationship exists for short- and long-term exposure to $PM_{2.5}$ and mortality, consistent with the CASAC comments'' (Jackson, 2010).

(2) With regard to toxicological and controlled human exposure studies, these commenters argued that the available evidence does not provide coherence or biological plausibility for health effects observed in epidemiological studies (API, 2012, pp. 21 to 22, Attachment 1, pp. 25 to 29; AAM, 2012, pp. 15 to 16; Texas CEQ, 2012, p. 3). With regard to the issue of mechanisms, these commenters noted that although the EPA recognizes that new evidence is now available on potential mechanisms and plausible biological pathways, the evidence provided by toxicological and controlled human exposure studies still does not resolve all questions about how $PM_{2.5}$ at ambient concentrations could produce the mortality and morbidity effects observed in epidemiological studies. More specifically, for example, some of these commenters argued that:

> A review of the Integrated Science Assessment, however, suggests that the experimental evidence is inconsistent and not coherent with findings in epidemiology studies. Specifically, the findings of mild and reversible effects in most experimental studies conducted at elevated exposures are not consistent with the more serious associations described in epidemiology studies (e.g., hospital admissions and mortality). Also, both animal studies and controlled human exposure studies have identified no effect levels for acute and chronic exposure to PM and PM constituents at concentrations considerably above ambient levels. EPA should consider the experimental findings in light of these higher exposure levels and what the relevance may be for ambient exposures (API, 2012, Attachment 1, p. 25).

The EPA notes that in the review completed in 1997, the Agency considered the lack of demonstrated biological mechanisms for the varying effects observed in epidemiological studies to be an important caution in its integrated assessment of the health evidence upon which the standards were based (71 FR 61157, October 17, 2006). In the review completed in 2006, the EPA recognized the findings from additional research that indicated that different health responses were linked with different particle characteristics and that both individual components and complex particle mixtures appeared to be responsible for many biologic responses relevant to fine particle exposures. *Id.* Since that review, there has been a great deal of research directed toward advancing our understanding of biologic mechanisms. While this research has not resolved all questions, and further research is warranted (U.S. EPA, 2011a, section 2.5), it has provided important insights as discussed in section III.B.1 of the proposal (77 FR at 38906 to 38909) and discussed more fully in the Integrated Science Assessment (U.S. EPA, 2009a, Chapter 5).

As noted in the proposal, toxicological studies provide evidence to support the biological plausibility of cardiovascular and respiratory effects associated with long- and short-term PM exposures observed in epidemiological studies (77 FR 38906) and provide supportive mechanistic evidence that the cardiovascular morbidity effects observed in long-term exposure epidemiological studies are coherent with studies of cardiovascular-related mortality (77 FR 38907). The Integrated Science Assessment concluded that the new evidence available in this review ''greatly expands'' upon the evidence available in the last review ''particularly in providing greater understanding of the underlying mechanisms for $PM_{2.5}$ induced cardiovascular and respiratory effects for both short- and long-term exposures'' (U.S. EPA, 2009a, p. 2–17). The mechanistic evidence now available, taken together with newly available epidemiological evidence, increases the Agency's confidence that a causal relationship exists between long- and short-term exposure to $PM_{2.5}$ and cardiovascular effects and mortality.[51] In addition, CASAC supported the Integrated Science Assessment approach and characterization of potential mechanisms or modes of action (Samet, 2009e, pp. 7 to 8; Samet, 2009f, p. 11), as well as the findings of a causal relationship at the population level between exposure to $PM_{2.5}$ and mortality and cardiovascular effects (Samet, 2009f, pp. 2 to 3).[52]

Additionally, the EPA disagrees with commenters that the mild and reversible effects observed in controlled human exposure studies are inconsistent with the more serious effects observed in epidemiological studies. Ethical considerations regarding the types of studies that can be performed with human subjects generally limit the effects that can be evaluated to those that are transient, reversible, and of limited short-term consequence. The relatively small number of subjects recruited for controlled exposure studies should also be expected to have less variability in health status and risk factors than occurring in the general population.[53] Consequently, the severity

[51] See *American Trucking Associations* v. *EPA,* 175 F. 3d 1027, 1055–56 (DC Cir. 1999) reversed in part and affirmed in part *sub nom,* Whitman v. American Trucking Associations, 531 U.S. 457 (2001) holding that the EPA could establish NAAQS without identifying a biological mechanism (''To begin with, the statute itself requires no such proof. The Administrator may regulate air pollutants ''emissions of which, in his judgment, *cause or contribute* to air pollution which may *reasonably be anticipated* to endanger public health or welfare.'' (emphasis added by the court). Moreover, this court has never required the type of explanation petitioners seek from EPA. In fact, we have expressly held that EPA's decision to adopt and set air quality standards need only be based on 'reasonable extrapolations from some reliable evidence'* * *. Indeed, were we to accept petitioners' view, EPA (or any agency for that matter) would be powerless to act whenever it first recognizes clear trends of mortality or morbidity in areas dominated by a particular pathogen.'').

[53] For example, the EPA excludes from its controlled human exposure studies involving exposure to $PM_{2.5}$ any individual with a significant risk factor for experiencing adverse effects from such exposure. Thus, the EPA excludes *a priori* the following categories of persons: those with a history of angina, cardiac arrhythmias, and ischemic myocardial infarction or coronary bypass surgery; those with a cardiac pacemaker; those with uncontrolled hypertension (greater than 150 systolic and 90 diastolic); those with neurogenetive diseases; those with a history of bleeding diathesis; those taking beta-blockers; those using oral anticoagulants; those who are pregnant, attempting to become pregnant, or breastfeeding; those who

of health effects observed in controlled human exposure studies evaluating the effects of PM should be expected to be less than observed in epidemiologic studies. Nonetheless, that effects are observed in relatively healthy individuals participating in controlled exposure studies serves as an indicator that PM is initiating health responses and that more severe responses may reasonably be expected in a more diverse population.

It should also be noted that there is a small body of toxicological evidence demonstrating mortality in rodents exposed to PM (e.g., Killingsworth *et al.* 1997). Overall it is not surprising that lethality is not induced in more toxicological research, as these types of studies do not readily lend themselves to this endpoint. Epidemiological studies have observed associations between PM and mortality in communities with populations in the range of many thousands to millions of people. Clearly, it is not feasible to expose hundreds (if not thousands) of animals to ambient PM (potentially over many years) in a laboratory setting to induce enough lethalities to distinguish between natural deaths and those attributable to PM. Furthermore, the heterogeneous human populations sampled in epidemiological studies are comprised of individuals with different physical, genetic, health, and socioeconomic backgrounds which may impact the outcome. However, in toxicological studies, the rodent groups are typically inbred, such that inter-individual variability is minimized. Thus, if the rodent strain used is quite robust, PM-induced effects may not be observed at low exposure concentrations.

(3) In asserting that the uncertainties in the underlying health science are as great or greater than in the last review and therefore do not support revision to the standards at this time, commenters in this group variously discussed a number of issues related to: (a) Confounding, (b) heterogeneity in risk estimates, (c) exposure measurement error, (d) model specification, (e) the shape of the concentration-response relationship, and (f) understanding the relative toxicity of components within the mixture of fine particles. Each of these issues is addressed below and some are discussed in more detail in the Response to Comments document.

In summary, these commenters concluded that the substantial uncertainties present in the last review have not been resolved and/or that the uncertainty about the possible health risks associated with $PM_{2.5}$ exposure has not diminished. As discussed below, the EPA believes that the overall uncertainty about possible health risks associated with both long- and short-term $PM_{2.5}$ exposure has diminished to an important degree since the last review. While the EPA agrees that important uncertainties remain, and that future research directed toward addressing these uncertainties is warranted, the EPA disagrees with commenters' views that the remaining uncertainties in the scientific evidence are too great to warrant revising the current $PM_{2.5}$ NAAQS.

(a) Confounding

Some commenters have criticized the EPA for not adequately addressing the issue of confounding in both long- and short-term exposure studies of mortality and morbidity. This includes confounding due to copollutants, as well as unmeasured confounding.[54]

With regard to copollutant confounding, these commenters asserted that the EPA has not adequately interpreted the results from studies that examined the effect of copollutants on the relationship between long- and short-term $PM_{2.5}$ exposures and mortality and morbidity outcomes. These commenters contend that the EPA has inappropriately concluded that $PM_{2.5}$-related mortality and morbidity associations are generally robust to confounding. The commenters stated that statistically significant $PM_{2.5}$ associations in single-pollutant models in epidemiological studies do not remain statistically significant in copollutant models.

The loss of statistical significance or the reduction in the magnitude of the effect estimate when a co-pollutant model is used may be the result of factors other than confounding. These changes do not prove either the existence or absence of confounding. These impacts must be evaluated in a broader context that considers the entire body of evidence. The broader examination of this issue in the Integrated Science Assessment included a focus on evaluating the stability of the size of the effect estimates in epidemiological studies conducted by a number of research groups using single- and copollutant models (U.S. EPA, 2009a, sections 6.2.10.9, 6.3.8.5, and 6.5, Figures 6–5, 6–9, and 6–15). This examination found that, for most epidemiological studies, there was little change in effect estimates based on single- and copollutant models, although the Integrated Science Assessment recognized that in some cases, the $PM_{2.5}$ effect estimates were markedly reduced in size and lost statistical significance. Additionally, the EPA notes that these comments do not adequately reflect the complexities inherent in assessing the issue of copollutant confounding. As discussed in the proposal (77 FR 38907, 38909, and 38910) and more fully in the Integrated Science Assessment (U.S.EPA, 2009a, sections 6.2, 6.3, and 6.5), although copollutant models may be useful tools for assessing whether gaseous copollutants may be potential confounders, such models alone cannot determine whether copollutants are in fact confounders. Interpretation of the results of copollutant models is complicated by correlations that often exist among air pollutants, by the fact that some pollutants play a role in the atmospheric reactions that form other pollutants such as secondary fine particles, and by the statistical power of the studies in question inherent in the study methodology. For example, the every-third or sixth-day sampling schedule often employed for $PM_{2.5}$ measurements compared to daily measurements of gaseous copollutants drastically reduces the overall sample size to assess the effect of copollutants on the $PM_{2.5}$-morbidity or mortality relationship, such that the reduced sample size can lead to less precise effect estimates (e.g., wider confidence intervals).

The EPA recognizes that when $PM_{2.5}$ is correlated with gaseous pollutants it can be difficult to identify the effect of individual pollutants in the ambient mixture (77 FR 38910). However, based on the available evidence, the EPA

have experienced a respiratory infection within four weeks of exposure; those experiencing eye or abdominal surgery within six weeks of exposure; those with active allergies; those with a history of chronic illnesses such as diabetes, cancer, rheumatologic diseases, immunodeficiency state, known cardiovascular disease, or chronic respiratory diseases; smokers. The EPA ''Application for Independent Review Board Approval of Human Subjects Research: Cardiopulmonary Effects of healthy Older GSTM1 Null and Sufficient individuals to Concentrated Ambient Air Particles (CAPTAIN)'', Nov. 9, 2011, p. 9.

[54] The Integrated Science Assessment defines confounding as ''a confusion of effects. Specifically, the apparent effect of the exposure of interest is distorted because the effect of an extraneous factor is mistaken for or mixed with the actual exposure effect (which may be null) (Rothman and Greenland, 1998)'' (U.S. EPA, 2009a, p. 1–16). Epidemiological analyses attempt to adjust or control for these characteristics (i.e., potential confounders) that differ between exposed and non-exposed individuals (U.S. EPA, 2009a, section 1.5.3). Not all risk factors can be controlled for within a study design/model and are termed ''unmeasured confounders.'' An unmeasured confounder is a confounder that has not previously been measured and therefore is not included in the study design/model.

concludes epidemiological studies continue to support the conclusion that $PM_{2.5}$ associations with mortality and morbidity outcomes are robust to the inclusion of gaseous copollutants in statistical models. The EPA evaluated the potential confounding effects of gaseous copollutants and, although it is recognized that uncertainties and limitations still remain, the Agency concluded the collective body of scientific evidence is ''stronger and more consistent than in previous reviews providing a strong basis for decision making in this review'' (77 FR 38910/1).

Several commenters offered detailed comments on the long-term $PM_{2.5}$ exposure studies arguing that associations from mortality studies are subjected to unmeasured confounding and as a result are not appropriately characterized as providing evidence of a causal relationship between long-term $PM_{2.5}$ exposure and mortality (e.g., UARG, 2012, pp. 10 to 11, Attachment A, pp. 17 to 23; API, 2012, pp. 13 to 14, Attachment 1, pp. 11 to 14, Attachment 7, pp. 2–10; ACC, 2012, p. 18 to 21; AFPM, 2012, p. 8; Texas CEQ, 2012, p. 4). Specifically, commenters cited two studies (i.e., Janes *et al.,* 2007 and Greven *et al.,* 2011) that used a new type of statistical analysis to examine associations between annual (long-term) and monthly (sub-chronic) $PM_{2.5}$ exposure and mortality. The commenters interpreted the results of these analyses as evidence of unmeasured confounding in the long-term $PM_{2.5}$ exposure-mortality relationship. These commenters interpreted these studies as raising fundamental questions regarding the EPA's determination that a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality. In addition to the commenters mentioned above, all of the authors of the publications by Janes *et al.* (2007) and Greven *et al.* (2011) (i.e., Francesca Dominici, Scott Zeger, Holly Janes, and Sonja Greven) submitted a joint comment to the public docket in order to clarify specific points regarding these two studies (Dominici *et al.,* 2012).

The first study, Janes *et al.* (2007), was evaluated in the Integrated Science Assessment (U.S. EPA, 2009a, p. 7–88). The second study, Greven *et al.* (2011), an extension of the Janes *et al.* (2007) study adding three more years of data, is a ''new'' study discussed in the Provisional Science Assessment (U.S. EPA, 2012). Both studies used nationwide Medicare mortality data to examine the association between monthly average $PM_{2.5}$ concentrations over the preceding 12 months and monthly mortality rates in 113 U.S. counties and examined whether community-specific trends in monthly $PM_{2.5}$ concentrations and mortality declined at the same rate as the national rate. The investigators examined this by decomposing the association between $PM_{2.5}$ and mortality into two components: (1) National trends, defined as the association between the national average trend in monthly $PM_{2.5}$ concentrations averaged over the previous 12 months and the national average trend in monthly mortality rates, and (2) local trends, defined as county-specific deviations in monthly $PM_{2.5}$ concentrations and monthly mortality rates from national trends.

The EPA does not question the results of the national trends analyses conducted by Janes *et al.* (2007) and Greven *et al.* (2011).[55] Both Janes *et al.* (2007) and Greven *et al.* (2011) observed positive and statistically significant associations between long-term exposure to $PM_{2.5}$ and mortality in their national analyses. However, Janes *et al.* (2007) and Greven *et al.* (2011) eliminated all of the spatial variation in air pollution and mortality in their data set when estimating the national effect, focusing instead on both chronic (yearly) and sub-chronic (monthly) temporal differences in the data (Dominici *et al.* 2012). Janes *et al.* (2007) (Table 1) highlighted that over 90 percent of the variance in the data set used for the analyses conducted by both Janes *et al.* (2007) and Greven *et al.* (2011) was attributable to spatial variability, which the authors chose to discard. As noted above, the focus of the analyses by Janes *et al.* (2007) and Greven *et al.* (2011) was on two components: (1) A temporal or time component, i.e., the ''national'' trends analysis, which examined the association between the national average trend in monthly $PM_{2.5}$ concentrations averaged over the previous 12 months and the national average trend in monthly mortality rates and (2) a space-by-time component, i.e., the ''local'' trends analysis, which examined county-specific deviations in monthly $PM_{2.5}$ concentrations and monthly mortality rates from national trends. These two components combined comprised less than 10 percent of the variance in the data set. The authors included a focus on the space-by-time component, which represented approximately 5 percent of the variance in the data set, in an attempt to identify, absent confounding, if $PM_{2.5}$ was associated with mortality at this unique exposure window. Thus, these studies are not directly comparable to other cohort studies investigating the relationship between long-term exposure to $PM_{2.5}$ and mortality, which make use of spatial variability in air pollution and mortality data.[56] This point was highlighted by the study authors who stated that ''when one considers that this wealth of information is not accounted for in [Janes 2007], it is not as surprising that * * * vastly different estimates of the $PM_{2.5}$/mortality relationship [were observed] than in other studies that do exploit that variability'' (Dominici *et al.,* 2012, p. 2).

The EPA notes that the results of the local trends analyses conducted by Janes *et al.* (2007) and Greven *et al.* (2011) are limited by the monthly timescale used in these analyses. This view is consistent with comments on the Janes *et al.* (2007) study articulated in Pope and Burnett (2007),[57] which noted that an important limitation of the local scale analysis conducted by Janes *et al.* (2007) and subsequently by Greven *et al.* (2011) was the subchronic exposure window considered in these analyses. Both studies used annual average $PM_{2.5}$ concentrations to characterize long-term national trends which was consistent with exposure windows considered in other studies of long-term exposure to $PM_{2.5}$ and mortality.[58] However, the local scale analyses used monthly average $PM_{2.5}$ concentrations to characterize county-specific deviations from national trends (the local scale). The use of monthly average data likely does not provide

[55] In its evaluation of Janes et al. (2007) in the Integrated Science Assessment, the EPA did not identify limitations in the statistical methods used *per se* (U.S. EPA, 2009a, p. 7–88) and included the results of the national-scale analyses in that study in the body of evidence that supported the determination that there is a causal relationship between long-term $PM_{2.5}$ exposure and mortality.

[56] Though not directly comparable, the national effect estimates for mortality reported by Janes *et al.* (2007) and Greven *et al.* (2011) are coincidentally similar in magnitude to those previously reported. It is important to note that previous cohort studies have focused on identifying spatial differences in $PM_{2.5}$ concentrations between cities, while Janes *et al.* (2007) and Greven *et al.* (2011) focus primarily on temporal differences in $PM_{2.5}$ concentrations. In fact, Greven *et al.* (2011) state ''We do not focus here on a third type [of statistical approach] used in cohort studies, measuring the association between average $PM_{2.5}$ levels and average age-adjusted mortality rates across cities (purely spatial or cross-sectional association).''

[57] Some commenters argued that there were flaws in the criticisms offered by Pope and Burnett (2007) on the paper by Janes *et al.* (2007) (UARG, 2012, Attachment A, pp. 19 to 23). The EPA responds to each of these specific comments in the Response to Comments document.

[58] As noted above, however, Janes *et al.* (2007) and Greven *et al.* (2011) focused on temporal variability and other studies of long-term exposure to $PM_{2.5}$ and mortality focus on spatial variability.

enough exposure contrast to observe temporal changes in mortality at the local scale. It also represents a different exposure window than considered in the large body of evidence of health effects related to short-term (from less than one day to up to several days) and chronic (one or more years) measures of $PM_{2.5}$.

Furthermore, the EPA disagrees with commenters that studies by Janes *et al.* (2007) and Greven *et al.* (2011) provide evidence that other studies of long-term exposure to $PM_{2.5}$ and mortality are affected by unmeasured confounding. As noted above, the design of the studies conducted by Janes *et al.* (2007) and Greven *et al.* (2011) are fundamentally different than those used in other studies of long-term exposure to $PM_{2.5}$ and mortality, including the ACS cohort and the Harvard Six Cities study. Studies, such as the ACS and Harvard Six Cities studies, used the spatial variation between cities to measure the effect of long-term (annual) exposures to $PM_{2.5}$ on mortality risk, and did not conduct any analyses relying on the temporal variation in $PM_{2.5}$. The opposite is true of the Janes *et al.* (2007) and Greven *et al.* (2011) studies which first removed the spatial variability in $PM_{2.5}$ and then examined the temporal variation at both the national and local scale to measure the effects of temporal differences in $PM_{2.5}$ on mortality risk. Janes *et al.* (2007) and Greven *et al.* (2011) focus on changes in $PM_{2.5}$ concentrations over time and, therefore, control for confounders would be based on including variables that vary over time rather than over space. As a result, any evidence of potential confounding of the $PM_{2.5}$-mortality risk relationship derived from Janes *et al.* (2007) and Greven *et al.* (2011) cannot be extrapolated to draw conclusions related to potential spatial confounding in studies based on the spatial variation in $PM_{2.5}$ concentrations.

As detailed in the Integrated Science Assessment (U.S. EPA, 2009a, section 7.6), and recognized by the authors of Janes *et al.* (2007) and Greven *et al.* (2011), the cohort studies that informed the causality determination for long-term $PM_{2.5}$ exposure and mortality ''have developed approaches to adjust for measured and unmeasured confounders'' (Dominici *et al.,* 2012, p. 2). These approaches were specifically designed to adjust for spatial confounding. The hypothesis that the authors of Janes *et al.* (2007) and Greven *et al.* (2011) chose to examine was that differences in the local and national effects indicated unmeasured temporal confounding in either the local or national effect estimate. This hypothesis was specific to these two studies that examined temporal variability in exposure to air pollution and did not include known potential confounders at either the national or local scale as time-varying covariates in the statistical model. The authors acknowledged that the interpretation of either the national or local estimates needs to occur with an appreciation of the potential confounding effects of national and local scale covariates that were omitted from the model (Dominici *et al.,* 2012).

It is important to recognize that because Janes *et al.* (2007) and Greven *et al.* (2011) focused on variations in $PM_{2.5}$ over time and not space, the results from these two studies do not provide any indication that other studies of long-term exposure to $PM_{2.5}$ and mortality exhibit spatial confounding, or that $PM_{2.5}$ does not cause mortality.[59] The authors of Janes *et al.* (2007) and Greven *et al.* (2011) recognized that ''it is entirely possible that these papers are looking for an association at a timescale for which no association truly exists'' (Dominici *et al.,* 2012, p. 3). Furthermore, as highlighted in the Integrated Science Assessment and discussed by Pope and Burnett (2007), the conclusions of Janes *et al.* (2007) ''are overstated * * * [T]heir analysis tells us little or nothing about unmeasured confounding in those and related studies because the methodology of Janes *et al.* largely excludes the sources of variability that are exploited in those other studies. By using monthly mortality counts and lagged 12-month average pollution concentrations, the authors eliminate the opportunity to exploit short-term or day-to-day variability.''

In conclusion, the EPA interprets the results of the analyses conducted by Janes *et al.* (2007) and Greven *et al.* (2011) as being consistent with prior knowledge of examining associations with long-term exposure to $PM_{2.5}$ at the national scale using long-term average $PM_{2.5}$ concentrations. For the reasons presented above and discussed in more detail in the Response to Comments document, the Agency disagrees with the commenters' assumption that the results of Janes *et al.* (2007) and Greven *et al.* (2011) indicate unmeasured confounding in the results of other cohort studies of long-term exposure to $PM_{2.5}$ and mortality. Therefore, the EPA concludes that these studies do not invalidate the large body of epidemiological evidence that supports the EPA's determination that a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality.[60]

(b) Heterogeneity in Risk Estimates

Some commenters argued that the heterogeneity in risk estimates observed in multi-city epidemiological studies and the lack of statistical significance in many regional or seasonal estimates highlights a potential bias associated with combined multi-city epidemiological study results (e.g., API, 2012, Attachment 1, pp. 15 to 19). These commenters further argued that more refined intra-urban exposure estimates conducted for two of the largest cities included in the ACS study, Los Angeles and New York City, based on land-use regression models and/or kriging methods (Krewski *et al.,* 2009) ''underscore the importance of considering city-specific health estimates, which may account for heterogeneity in $PM_{2.5}$ concentrations or other differences among cities, rather than relying on pooled nationwide results from multi-city studies'' (API, 2012, Attachment 1, p. 17).

With respect to understanding the nature and magnitude of $PM_{2.5}$-related risks, the EPA agrees that epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in responses between cities and effect estimates across geographic regions of the U.S. (U.S. EPA, 2009a, sections 6.2.12.1, 6.3.8.1, 6.5.2, and 7.6.1; U.S. EPA, 2011a, p. 2–25). For example, when focusing on short-term $PM_{2.5}$ exposure, the Integrated Science Assessment found that multi-city studies that examined associations with mortality and cardiovascular and respiratory hospital admissions and emergency department visits demonstrated greater cardiovascular effects in the eastern versus the western U.S. (Dominici, *et al.,* 2006a; Bell *et al.,* 2008; Franklin *et al.* (2007, 2008)).

In addition, the Integrated Science Assessment evaluated studies that provided some evidence for seasonal differences in $PM_{2.5}$ risk estimates, specifically in the northeast. The Integrated Science Assessment found evidence indicating that individuals may be at greater risk of dying from higher exposures to $PM_{2.5}$ in the warmer months, and at greater risk of $PM_{2.5}$ associated hospitalization for

[59] Further, the EPA notes that Janes *et al.* (2007) and Greven *et al.* (2011) provide no information relevant to examining confounding in studies of short-term exposure to $PM_{2.5}$.

[60] The EPA notes that the EPA's conclusion with regard to interpretation of the results from Janes *et al.* (2007) and Greven *et al.* (2012) is supported by the study authors' conclusion that ''*[o]ur results do not invalidate previous epidemiological studies*'' (Dominici, 2012, p. 1 (emphasis original)).

cardiovascular and respiratory diseases during colder months of the year. The limited influence of seasonality on PM risk estimates in other regions of the U.S. may be due to a number of factors including varying PM composition by season, exposure misclassification due to regional tendencies to spend more or less time outdoors and air conditioning usage, and the prevalence of infectious diseases during the winter months (U.S. EPA, 2009a, p. 3–182).

Overall, the EPA took note in the proposal that uncertainties still remain regarding various factors that contribute to heterogeneity observed in epidemiological studies (77 FR 38909/3). Nonetheless, the EPA recognizes that this heterogeneity could be attributed, at least in part, to differences in $PM_{2.5}$ composition across the U.S., as well as to exposure differences that vary regionally such as personal activity patterns, microenvironmental characteristics, and the spatial variability of $PM_{2.5}$ concentrations in urban areas (U.S. EPA, 2009a, section 2.3.2; 77 FR 38910).

As recognized in the Policy Assessment, the current epidemiological evidence and the limited amount of city-specific speciated $PM_{2.5}$ data do not allow conclusions to be drawn that specifically differentiate effects of $PM_{2.5}$ in different locations (U.S. EPA, 2011a, p. 2–25). Furthermore, the Integrated Science Assessment concluded ''that many constituents of $PM_{2.5}$ can be linked with multiple health effects, and the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes'' (U.S. EPA, 2009a, p. 2–17). CASAC thoroughly reviewed the EPA's presentation of the scientific evidence indicating heterogeneity in $PM_{2.5}$ effect estimates in epidemiological studies and concurred with the overall conclusions presented in the Integrated Science Assessment.

(c) Exposure Measurement Error

Some commenters argued that the EPA did not adequately consider exposure measurement error, which they asserted is an important source of bias in epidemiological studies that can bias effect estimates in either direction (e.g., API, 2012, Attachment 1, pp. 19 to 20).

The EPA agrees that exposure measurement error is an important source of uncertainty and that the variability in risk estimates observed in multi-city studies could be attributed, in part, to exposure error due to measurement-related issues (77 FR 38910). However, the Agency disagrees with the commenters' assertion that exposure measurement error was not adequately considered in this review. The Integrated Science Assessment included an extensive discussion that addresses issues of exposure measurement error (U.S. EPA, 2009a, sections 2.3.2 and 3.8.6). Exposure measurement error may lead to bias in effect estimates in epidemiological studies. A number of studies evaluated in the last review (U.S. EPA, 2004, section 8.4.5) and in the current review (U.S. EPA, 2009a, section 3.8.6) have discussed the direction and magnitude of bias resulting from specified patterns of exposure measurement error (Armstrong 1998; Thomas *et al.* 1993; Carroll *et al.* 1995) and have generally concluded ''classical'' (i.e., random, within-person) exposure measurement error can bias effect estimates towards the null. Therefore, consistent with conclusions reached in the last review, the Integrated Science Assessment concluded ''in most circumstances, exposure error tends to bias a health effect estimate *downward*'' (U.S. EPA, 2009a, sections 2.3.2 and 3.8.6) (emphasis added). Thus, the EPA has both considered and accounted for the possibility of exposure measurement error, and the possible bias would make it more difficult to detect true associations, not less difficult.

(d) Model Specification

Commenters contended that the EPA did not account for the fact that ''selecting an appropriate statistical model for epidemiologic studies of air pollution involves several choices that involve much ambiguity, scant biological evidence, and a profound impact on analytic results, given that many estimated associations are weak'' (ACC, 2012, p. 5). For short-term exposure studies, the EPA recognizes, as summarized in the HEI review panel commentary that selecting a level of control to adjust for time-varying factors, such as temperature, in time-series epidemiological studies involves a trade-off (HEI, 2003). For example, if the model does not sufficiently adjust for the relationship between the health outcome and temperature, some effects of temperature could be falsely ascribed to the pollution variable. Conversely, if an overly aggressive approach is used to control for temperature, the result would possibly underestimate the pollution-related effect and compromise the ability to detect a small but true pollution effect (U.S. EPA, 2004, p. 8–236; HEI, 2003, p. 266). The selection of approaches to address such variables depends in part on prior knowledge and judgments made by the investigators, for example, about weather patterns in the study area and expected relationships between weather and other time-varying factors and health outcomes considered in the study. As demonstrated in section 6.5 of the Integrated Science Assessment, the EPA thoroughly considered each of these issues and the overall effect of different model specifications on the association between short-term $PM_{2.5}$ exposure and mortality. Regardless of the model employed, consistent positive associations were observed across studies that controlled for the potential confounding effects of time and weather using different approaches (U.S. EPA 2009a, Figure 6–27). The EPA also considered the influence of model specification in the examination of long-term $PM_{2.5}$ exposure studies. For example, in section 7.6 of the Integrated Science Assessment, Figures 7–6 and 7–7 summarize the collective evidence that evaluated the association between long-term $PM_{2.5}$ exposure and mortality. Regardless of the model used, these studies collectively found evidence of consistent positive associations between long-term $PM_{2.5}$ exposure and mortality.

The EPA, therefore, disagrees with commenters that model specification was not considered when evaluating the epidemiological evidence used to form causality determinations. The EPA specifically points out that the process of assessing the scientific quality and relevance of epidemiological studies includes examining ''important methodological issues (e.g., lag or time period between exposure and effects, model specifications, thresholds, mortality displacement) related to interpretation of the health evidence (U.S. EPA, 2009, p. 1–9).'' Consistent with the conclusions of the 2004 PM Air Quality Criteria Document, the EPA recognizes that there is still no clear consensus at this time as to what constitutes appropriate control of weather and temporal trends in short-term exposure studies, and that no single statistical modeling approach is likely to be most appropriate in all cases (U.S. EPA, 2004, p. 8–238). However, the EPA believes that the available evidence interpreted in light of these remaining uncertainties does provide increased confidence relative to the last review in the reported associations between short- and long-term $PM_{2.5}$ exposures and mortality and morbidity effects, alone and in combination with other pollutants.

(e) Concentration-Response Relationship

Additionally, commenters questioned the interpretation of the shape of the

concentration-response relationship, specifically stating that multiple studies have demonstrated that there is a threshold in the PM-health effect relationship and that the log-linear model is not biologically plausible (API, 2012, Attachment 9; ACC, 2012, Appendix A, pp. 7 to 8). The EPA disagrees with this assertion due to the number of studies evaluated in the Integrated Science Assessment that continue to support the use of a no-threshold, log-linear model to most appropriately represent the PM concentration-response relationship (U.S. EPA, 2009a, section 2.4.3). While recognizing that uncertainties remain, the EPA believes that our understanding of this issue for both long- and short-term exposure studies has advanced since the last review. As discussed in the Integrated Science Assessment, both long- and short-term exposure studies have employed a variety of statistical approaches to examine the shape of the concentration-response function and whether a threshold exists. While the EPA recognizes that there likely are individual biological thresholds for specific health responses, the Integrated Science Assessment concluded the overall evidence from existing epidemiological studies does not support the existence of thresholds at the population level, for effects associated with either long-term or short-term PM exposures within the ranges of air quality observed in these studies (U.S. EPA, 2009a, section 2.4.3).[61] The Integrated Science Assessment concluded that this evidence collectively supported the conclusion that a no-threshold, log-linear model is most appropriate (U.S. EPA, 2009a, sections 6.2.10.10, 6.5.2.7, and 7.6.4). CASAC likewise advised that ''[a]lthough there is increasing uncertainty at lower levels, there is no evidence of a threshold'' (Samet, 2010d, p. ii).

The EPA recognizes that some short-term exposure studies have examined the $PM_{2.5}$ concentration-response relationship in individual cities or on a city-to-city basis and observed heterogeneity in the shape of the concentration-response curve across cities. As discussed in (b) above, these findings are a source of uncertainty that the EPA agrees requires further investigation. Nonetheless, the Integrated Science Assessment concluded that ''the studies evaluated further support the use of a no-threshold, log-linear model, but additional issues such as the influence of heterogeneity in estimates between cities and the effects of seasonal and regional differences in PM on the concentration-response-relationship still require further investigation'' (U.S. EPA, 2009a, p. 2–25).

(f) Relative Toxicity of $PM_{2.5}$ Components

Some commenters highlighted uncertainties in understanding the role of individual constituents within the mix of fine particles. These commenters asserted that a mass-based standard may not be appropriate due to the growing body of evidence indicating that certain $PM_{2.5}$ components may be more closely related to specific health outcomes (e.g., EC and OC) (EPRI, 2012, p. 2).

With regard to questions about the role of individual constituents within the mix of fine particles, as a general matter, the EPA recognizes that although new research directed toward this question has been conducted since the last review, important questions remain and the issue remains an important element in the Agency's ongoing research program. At the time of the last review, the Agency determined that it was appropriate to continue to control fine particles as a group, as opposed to singling out any particular component or class of fine particles (71 FR 61162 to 61164, October 17, 2006). This distinction was based largely on epidemiological evidence of health effects using various indicators of fine particles in a large number of areas that had significant contributions of differing components or sources of fine particles, together with some limited experimental studies that provided some evidence suggestive of health effects associated with high concentrations of numerous fine particle components.

In this review, as discussed in the proposal (77 FR 38922 to 38923) and in section III.E.1 below, while most epidemiological studies continue to be indexed by $PM_{2.5}$ mass, several recent epidemiological studies included in the Integrated Science Assessment have used $PM_{2.5}$ speciation data to evaluate health effects associated with fine particle exposures. In the Integrated Science Assessment, the EPA thoroughly evaluated the scientific evidence that examined the effect of different $PM_{2.5}$ components and sources on a variety of health outcomes (U.S. EPA, 2009a, section 6.6) and observed that the available information continues to suggest that many different chemical components of fine particles and a variety of different types of source categories are all associated with, and probably contribute to, effects associated with $PM_{2.5}$. The Integrated Science Assessment concluded that the current body of scientific evidence indicated that ''many constituents of PM can be linked with differing health effects and the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes'' (U.S. EPA, 2009a, p. 2–26 and 6–212). Furthermore, the Policy Assessment concluded that the evidence is not sufficient to support eliminating any component or group of components associated with any specific source categories from the mix of fine particles included in the $PM_{2.5}$ indicator (U.S. EPA, 2009a, p. 2–56). CASAC agreed that it was reasonable to retain $PM_{2.5}$ as an indicator for fine particles in this review as ''[t]here was insufficient peer-reviewed literature to support any other indicator at this time'' (Samet, 2010c, p. 12).

This information is relevant to the Agency's decision to retain $PM_{2.5}$ as the indicator for fine particles as discussed in section III.E.1 below. The EPA also believes that it is relevant to the Agency's conclusion as to whether revision of the suite of primary $PM_{2.5}$ standards is appropriate. While there remain uncertainties about the role and relative toxicity of various components of fine PM, the current evidence continues to support the view that fine particles should be addressed as a group for purposes of public health protection.

In summary, in considering the above issues related to uncertainties in the underlying health science, on balance, the EPA believes that the available evidence interpreted in light of these remaining uncertainties does provide increased confidence relative to the last review in the reported associations between long- and short-term $PM_{2.5}$ exposures and mortality and morbidity effects, alone and in combination with other pollutants, and supports stronger inferences as to the causal nature of the associations. The EPA also believes that this increased confidence, when taken in context of the entire body of available health effects evidence and in light of the evidence from epidemiological studies of associations observed in areas meeting the current primary $PM_{2.5}$ standards, specifically in areas meeting the current primary annual $PM_{2.5}$ standard, adds support to its conclusion that the current suite of $PM_{2.5}$ standards needs to be revised to provide increased public health protection.

(4) In asserting that there is no evidence of greater risk since the 2006

[61] While epidemiological analyses have not identified a population threshold in the range of air quality concentrations evaluated in these studies, the EPA recognizes that it is possible that such thresholds exist towards the lower end of these ranges (or below these ranges).

review to justify lowering the current annual $PM_{2.5}$ standard, some commenters argued that, ''if the current primary $PM_{2.5}$ annual standard of 15 μg/m³ was considered to be adequately protective of public health in 2006, given relative risk estimates that EPA was using at that time, then that standard would surely still be adequately protective of the public health if relative risk estimates remain at the same level (or lower)'' (UARG, 2012, Attachment 1, p. 24). These commenters compared risk coefficients used for mortality in the EPA's risk assessment done in the last review with those from the Agency's core risk assessment done as part of this review, and they concluded that ''the entire range of the core relative risk for long-term mortality is lower now than it was in the prior review'' (UARG, 2012, Attachment 1, p. 24). These commenters used this conclusion as the basis for a claim that there is no reason to revise the current annual $PM_{2.5}$ standard.

The EPA believes that this claim is fundamentally flawed. In comparing the scientific understanding of the risk presented by exposure to $PM_{2.5}$ between the last and current reviews, one must examine not only the quantitative estimate of risk from those exposures (e.g., the numbers of premature deaths or increased hospital admissions at various concentrations), but also the degree of confidence that the Agency has that the observed health effects are causally linked to $PM_{2.5}$ exposure at those concentrations. As documented in the Integrated Science Assessment and in the recommendations and conclusions of CASAC, the EPA recognizes significant advances in our understanding of the health effects of $PM_{2.5}$, based on evidence that is stronger than in the last review. As a result of these advances, the EPA is now more certain that fine particles, alone or in combination with other pollutants, present a significant risk to public health at concentrations allowed by the current primary $PM_{2.5}$ standards. From this more comprehensive perspective, since the risks presented by $PM_{2.5}$ are more certain, similar or even somewhat lower relative risk estimates would not be a basis to conclude that no revision to the suite of $PM_{2.5}$ standards is ''requisite'' to protect public health with an adequate margin of safety. This also ignores that the relative risk estimate is only one factor considered by the Administrator, e.g. it ignores that epidemiological studies since the last review indicate associations between $PM_{2.5}$ and mortality and morbidity in areas meeting the current annual standard.

In any case, the commenters' reliance on the flawed 2006 review is misplaced. As discussed in section III.A.2 above, the D.C. Circuit remanded Administrator Johnson's 2006 decision to retain the primary annual $PM_{2.5}$ standard because the Agency failed to adequately explain why the annual standard provided the requisite protection from both short- and long-term exposure to fine particles including protection for at-risk populations. The 2006 standard was also at sharp odds with CASAC advice and recommendations as to the requisite level of protection (Henderson, 2006a,b). In other words, the 2006 primary annual $PM_{2.5}$ standard is not an appropriate benchmark for comparison.

(5) Some of these commenters also identified ''new'' as well as older studies that had been included in prior reviews as providing additional evidence that the causality determinations presented in the Integrated Science Assessment did not consider the totality of the scientific literature, further supporting their view that a revision of the $PM_{2.5}$ is unwarranted. As discussed in section II.B.3 above, the EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the Integrated Science Assessment that have undergone CASAC and public review, and will consider newly published studies for purposes of decisionmaking in the next PM NAAQS review. In provisionally evaluating commenters' arguments (see Response to Comments document), the EPA notes that its provisional assessment of ''new'' science found that such studies did not materially change the conclusions reached in the Integrated Science Assessment (U.S. EPA, 2012b).

3. Administrator's Final Conclusions Concerning the Adequacy of the Current Primary $PM_{2.5}$ Standards

Having carefully considered the public comments, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of $PM_{2.5}$ reached in the Integrated Science Assessment, and discussed in the Policy Assessment, are valid. In considering whether the suite of primary $PM_{2.5}$ standards should be revised, the Administrator places primary consideration on the evidence obtained from the epidemiological studies. The Administrator believes that this literature, combined with the other scientific evidence discussed in the Integrated Science Assessment, collectively represents a strong and generally robust body of evidence of serious health effects associated with both long- and short-term exposures to $PM_{2.5}$. As discussed in the Integrated Science Assessment and Policy Assessment, the EPA believes that much progress has been made since the last review in reducing some of the major uncertainties that were important considerations in establishing the current suite of $PM_{2.5}$ standards. In that context, the Administrator finds the evidence of serious health effects reported in exposure studies conducted in areas with long-term mean concentrations ranging from approximately at or above the level of the annual standard to long-term mean concentrations significantly below the level of the annual standard to be compelling, especially in light of the extent to which such studies are part of an overall pattern of positive and frequently statistically significant associations across a broad range of studies. The information in the quantitative risk assessment lends support to this conclusion.

There has been extensive critical review of this body of evidence, the quantitative risk assessment, and related uncertainties, including review by CASAC and the public. The public comments on the basis for the EPA's proposed decision to revise the suite of primary $PM_{2.5}$ standards have identified a number of issues about which different parties disagree including issues for which additional research is warranted. Having weighed all comments and the advice of CASAC, the Administrator believes that since the last review the overall uncertainty about the public health risks associated with both long- and short-term exposure to $PM_{2.5}$ has been diminished to an important degree. The remaining uncertainties in the available evidence do not diminish confidence in the associations between exposure to fine particles and mortality and serious morbidity effects. Based on her increased confidence in the association between exposure to $PM_{2.5}$ and serious public health effects, combined with evidence of such an association in areas that would meet the current standards, the Administrator agrees with CASAC that revision of the current suite of $PM_{2.5}$ standards to provide increased public health protection is necessary. Based on these considerations, the Administrator concludes that the current suite of primary $PM_{2.5}$ standards is not sufficient, and thus not requisite, to protect public health with an

adequate margin of safety, and that revision is needed to increase public health protection.

It is important to note that this conclusion, and the reasoning on which it is based, do not resolve the question of what specific revisions are appropriate. That requires looking specifically at the current 24-hour and annual $PM_{2.5}$ standards, including their indicator, averaging times, forms, and levels, and evaluating the scientific evidence and other information relevant to determining the appropriate revision of the suite of standards.

E. Conclusions on the Elements of the Primary Fine Particle Standards

1. Indicator

In initially setting standards for fine particles in 1997, the EPA concluded it was appropriate to control fine particles as a group, rather than singling out any particular component or class of fine particles. The EPA noted that community health studies had found significant associations between various indicators of fine particles, and that health effects in a large number of areas had significant mass contributions of differing components or sources of fine particles. In addition, a number of toxicological and controlled human exposure studies had reported health effects associations with high concentrations of numerous fine particle components. It was also not possible to rule out any component within the mix of fine particles as not contributing to the fine particle effects found in the epidemiologic studies (62 FR 38667, July 18, 1977). In establishing a size-based indicator in 1977 to distinguish fine particles from particles in the coarse mode, the EPA noted that the available epidemiological studies of fine particles were based largely on $PM_{2.5}$ and also considered monitoring technology that was generally available. The selection of a 2.5 μm size cut reflected the regulatory importance of defining an indicator that would more completely capture fine particles under all conditions likely to be encountered across the U.S., especially when fine particle concentrations and humidity are likely to be high, while recognizing that some small coarse particles would also be captured by current methods to monitor $PM_{2.5}$ (62 FR 38666 to 38668, July 18, 1997). In the last review, based on the same considerations, the EPA again recognized that the available information supported retaining the $PM_{2.5}$ indicator and remained too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components associated with any source categories of fine particles (71 FR 61162 to 61164, October 17, 2006).

In this current review, the same considerations continue to apply for selection of an appropriate indicator for fine particles. As an initial matter, the Policy Assessment recognizes that the available epidemiological studies linking mortality and morbidity effects with long- and short-term exposures to fine particles continue to be largely indexed by $PM_{2.5}$. For the same reasons discussed in the last two reviews, the Policy Assessment concluded that it was appropriate to consider retaining a $PM_{2.5}$ indicator to provide protection from effects associated with long- and short-term fine particle exposures (U.S. EPA, 2011a, p. 2–50).

The Policy Assessment also considered the expanded body of evidence available in this review to consider whether there was sufficient evidence to support a separate standard for ultrafine particles [62] or whether there was sufficient evidence to establish distinct standards focused on regulating specific $PM_{2.5}$ components or a group of components associated with any source categories of fine particles (U.S. EPA, 2011a, section 2.3.1).

A number of studies available in this review have evaluated potential health effects associated with short-term exposures to ultrafine particles. As noted in the Integrated Science Assessment, the enormous number and larger, collective surface area of ultrafine particles are important considerations for focusing on this particle size fraction in assessing potential public health impacts (U.S. EPA, 2009a, p. 6–83). Per unit mass, ultrafine particles may have more opportunity to interact with cell surfaces due to their greater surface area and their greater particle number compared with larger particles (U.S. EPA, 2009a, p. 5–3). Greater surface area also increases the potential for soluble components (e.g., transition metals, organics) to adsorb to ultrafine particles and potentially cross cell membranes and epithelial barriers (U.S. EPA, 2009a, p. 6–83). In addition, evidence available in this review suggests that the ability of particles to enhance allergic sensitization is associated more strongly with particle number and surface area than with particle mass (U.S. EPA, 2009a, p. 6–127).

New evidence, primarily from controlled human exposure and toxicological studies, expands our understanding of cardiovascular and respiratory effects related to short-term ultrafine particle exposures. However, the Policy Assessment concluded that this evidence was still very limited and largely focused on exposure to diesel exhaust, for which the Integrated Science Assessment concluded it was unclear whether the effects observed are due to ultrafine particles, larger particles within the $PM_{2.5}$ mixture, or the gaseous components of diesel exhaust (U.S. EPA, 2009a, p. 2–22). In addition, the Integrated Science Assessment noted uncertainties associated with the controlled human exposure studies using concentrated ambient particle systems which have been shown to modify the composition of ultrafine particles (U.S. EPA, 2009a, p. 2–22, see also section 1.5.3).

The Policy Assessment recognized that there are relatively few epidemiological studies that have examined potential cardiovascular and respiratory effects associated with short-term exposures to ultrafine particles (U.S. EPA, 2011a, p. 2–51). These studies have reported inconsistent and mixed results (U.S. EPA, 2009a, section 2.3.5).

Collectively, in considering the body of scientific evidence available in this review, the Integrated Science Assessment concluded that the currently available evidence was suggestive of a causal relationship between short-term exposures to ultrafine particles and cardiovascular and respiratory effects. Furthermore, the Integrated Science Assessment concluded that evidence was inadequate to infer a causal relationship between short-term exposure to ultrafine particles and mortality as well as long-term exposure to ultrafine particles and all outcomes evaluated (U.S. EPA, 2009a, sections 2.3.5, 6.2.12.3, 6.3.10.3, 6.5.3.3, 7.2.11.3, 7.3.9, 7.4.3.3, 7.5.4.3, and 7.6.5.3; Table 2–6).

With respect to our understanding of ambient ultrafine particle concentrations, at present, there is no national network of ultrafine particle samplers; thus, only episodic and/or site-specific data sets exist (U.S. EPA, 2009a, p. 2–2). Therefore, the Policy Assessment recognized a national characterization of concentrations, temporal and spatial patterns, and trends was not possible at this time, and the availability of ambient ultrafine measurements to support health studies was extremely limited (U.S. EPA, 2011a, p. 2–51). In general, measurements of ultrafine particles are highly dependent on monitor location and, therefore, more subject to exposure error than

[62] Ultrafine particles, generally including particles with a mobility diameter less than or equal to 0.1 μm, are emitted directly to the atmosphere or are formed by nucleation of gaseous constituents in the atmosphere (U.S. EPA, 2009a, p. 3–3).

accumulation mode particles (U.S. EPA, 2009a, p. 2–22). Furthermore, the number of ultrafine particles generally decreases sharply downwind from sources, as ultrafine particles may grow into the accumulation mode by coagulation or condensation (U.S. EPA, 2009a, p. 3–89). Limited studies of ambient ultrafine particle measurements have suggested that these particles exhibit a high degree of spatial and temporal heterogeneity driven primarily by differences in nearby source characteristics (U.S. EPA, 2009a, p. 3–84). Internal combustion engines and, therefore, roadways are a notable source of ultrafine particles, so concentrations of these particles near roadways are generally expected to be elevated (U.S. EPA, 2009a, p. 2–3). Concentrations of ultrafine particles have been reported to drop off much more quickly with distance from roadways than fine particles (U.S. EPA, 2009a, p. 3–84).

In considering both the currently available health effects evidence and the air quality data, the Policy Assessment concluded that this information was still too limited to provide support for consideration of a distinct PM standard for ultrafine particles (U.S. EPA, 2011a, p. 2–52).

In addressing the issue of particle composition, the Integrated Science Assessment concluded that, ''[f]rom a mechanistic perspective, it is highly plausible that the chemical composition of PM would be a better predictor of health effects than particle size'' (U.S. EPA, 2009a, p. 6–202). Heterogeneity of ambient concentrations of $PM_{2.5}$ constituents (e.g., elemental carbon, organic carbon, sulfates, nitrates) observed in different geographical regions as well as regional heterogeneity in $PM_{2.5}$-related health effects reported in a number of epidemiological studies are consistent with this hypothesis (U.S. EPA, 2009a, section 6.6).

With respect to the availability of ambient measurement data for fine particle components in this review, the Policy Assessment noted that there were now more extensive ambient $PM_{2.5}$ speciation measurement data available through the Chemical Speciation Network (CSN) than in previous reviews (U.S. EPA, 2011a, section 1.3.2 and Appendix B, section B.1.3). The Integrated Science Assessment observed that data from the CSN provided further evidence of spatial and seasonal variation in both $PM_{2.5}$ mass and composition among cities and geographic regions (U.S. EPA, 2009a, pp. 3–50 to 3–60; Figures 3–12 to 3–18; Figure 3–47). Some of this variation may be related to regional differences in meteorology, sources, and topography (U.S. EPA, 2009a, p. 2–3).

The currently available epidemiological, toxicological, and controlled human exposure studies evaluated in the Integrated Science Assessment on the health effects associated with ambient $PM_{2.5}$ constituents and categories of fine particle sources used a variety of quantitative methods applied to a broad set of $PM_{2.5}$ constituents, rather than selecting a few constituents a priori (U.S. EPA, 2009a, p. 2–26). Epidemiological studies have used measured ambient $PM_{2.5}$ speciation data, including monitoring data from the CSN, while all of the controlled human exposure and most of the toxicological studies have used concentrated ambient particles and analyzed the constituents therein (U.S. EPA, 2009a, p. 6–203).[63] The CSN provides $PM_{2.5}$ speciation measurements generally on a one-in-three or one-in-six day sampling schedule and, thus, does not capture data every day at most sites.[64]

The Policy Assessment recognized that several new multi-city studies evaluating short-term exposures to fine particle constituents are now available. These studies continued to show an association between mortality and cardiovascular and/or respiratory morbidity effects and short-term exposures to various $PM_{2.5}$ components including nickel, vanadium, elemental carbon, organic carbon, nitrates, and sulfates (U.S. EPA, 2011a, section 2.3.1; U.S. EPA, 2009a, sections 6.5.2.5 and 6.6).

Limited evidence is available to evaluate the health effects associated with long-term exposures to $PM_{2.5}$ components (U.S. EPA, 2009a, section 7.6.2). The Policy Assessment noted the most significant new evidence was provided by a study that evaluated multiple $PM_{2.5}$ components and an indicator of traffic density in an assessment of health effects related to long-term exposure to $PM_{2.5}$ (Lipfert *et al.,* 2006a). Using health data from a cohort of U.S. military veterans and $PM_{2.5}$ measurement data from the CSN, Lipfert *et al.* (2006a) reported positive associations between mortality and long-term exposures to nitrates, elemental carbon, nickel, and vanadium as well as traffic density and peak ozone concentrations (U.S. EPA, 2011a, p. 2–54; U.S. EPA, 2009a, pp. 7–89 to 7–90).

With respect to source categories of fine particles potentially associated with a range of health endpoints, the Integrated Science Assessment reported that the currently available evidence suggests associations between cardiovascular effects and a number of specific $PM_{2.5}$-related source categories, including oil combustion, wood or biomass burning, motor vehicle emissions, and crustal or road dust sources (U.S. EPA, 2009a, section 6.6; Table 6–18). In addition, a few studies have evaluated associations between $PM_{2.5}$-related source categories and mortality. For example, one study reported an association between mortality and a $PM_{2.5}$ coal combustion factor (Laden *et al.,* 2000), while other studies linked mortality to a secondary sulfate long-range transport $PM_{2.5}$ source (Ito *et al.,* 2006; Mar *et al.,* 2006) (U.S. EPA, 2009a, section 6.6.2.1). Other studies have looked at different components of particulate matter. There was less consistency in associations observed between selected sources of fine particles and respiratory health endpoints, which may be partially due to the fact that fewer studies have evaluated respiratory-related outcomes and measures. However, there was some evidence for $PM_{2.5}$-related associations with secondary sulfate and decrements in lung function in asthmatic and healthy adults (U.S. EPA, 2009a, p. 6–211; Gong *et al.,* 2005; Lanki *et al.,* 2006). A couple of studies have observed an association between respiratory endpoints in children and adults with asthma and surrogates for the crustal/soil/road dust and traffic sources of PM (U.S. EPA, 2009a, p. 6–205; Gent *et al.,* 2009; Penttinen *et al.,* 2006).

Recent studies have shown that source apportionment methods have the potential to add useful insights into which sources and/or PM constituents may contribute to different health effects. Of particular interest are several epidemiological studies that compared source apportionment methods and reported consistent results across research groups (U.S. EPA, 2009a, p. 6–211; Hopke *et al.,* 2006; Ito *et al.,* 2006; Mar *et al.,* 2006; Thurston *et al.,* 2005).

[63] Most studies considered between 7 to 20 ambient $PM_{2.5}$ constituents, with elemental carbon, organic carbon, sulfates, nitrates, and metals most commonly measured. Many of the studies grouped the constituents with various factorization or source apportionment techniques to examine the relationship between the grouped constituents and various health effects. However, not all studies labeled the constituent groupings according to their presumed source and a small number of controlled human exposure and toxicological studies did not use any constituent grouping. These differences across studies substantially limit any integrative interpretation of these studies (U.S. EPA, 2009a, p. 6–203).

[64] To expand our understanding of the role of specific $PM_{2.5}$ components and sources with respect to the observed health effects, researchers have expressed a strong interest in having access to $PM_{2.5}$ speciation measurements collected more frequently (U.S. EPA, 2011a, p. 2–53, including footnote 47).

These studies reported associations between total mortality and secondary sulfate in two cities for two different lag times. The sulfate effect was stronger for total mortality in Washington, DC and for cardiovascular-related mortality in Phoenix (U.S. EPA, 2009a, p. 6–204). These studies also found some evidence for associations with mortality and a number of source categories (e.g., biomass/wood combustion, traffic, copper smelter, coal combustion, sea salt) at various lag times (U.S. EPA, 2009a, p. 6–204). Sarnat *et al.* (2008) compared three different source apportionment methods and reported consistent associations between emergency department visits for cardiovascular diseases with mobile sources and biomass combustion as well as increased respiratory-related emergency department visits associated with secondary sulfate (U.S. EPA, 2009a, pp. 6–204 and 6–211).

Collectively, in considering the currently available evidence for health effects associated with specific $PM_{2.5}$ components or groups of components associated with any source categories of fine particles as presented in the Integrated Science Assessment, the Policy Assessment concluded that additional information available in this review continues to provide evidence that many different constituents of the fine particle mixture as well as groups of components associated with specific source categories of fine particles are linked to adverse health effects (U.S. EPA, 2011a, p. 2–55). However, as noted in the Integrated Science Assessment, while ''[t]here is some evidence for trends and patterns that link particular ambient PM constituents or sources with specific health outcomes * * * there is insufficient evidence to determine whether these patterns are consistent or robust'' (U.S. EPA, 2009a, p. 6–210). Assessing this information, the Integrated Science Assessment concluded that ''the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes'' (U.S. EPA, 2009a, pp. 2–26 and 6–212). Therefore, the Policy Assessment concluded that the currently available evidence is not sufficient to support consideration of a separate indicator for a specific $PM_{2.5}$ component or group of components associated with any source category of fine particles. Furthermore, the Policy Assessment concluded that the evidence is not sufficient to support eliminating any component or group of components associated with any source categories of fine particles from the mix of fine particles included in the $PM_{2.5}$ indicator (U.S. EPA, 2011a, p. 2–56).

The CASAC agreed with the EPA staff conclusions presented in the Policy Assessment and concluded that it is appropriate to consider retaining $PM_{2.5}$ as the indicator for fine particles and further asserted, ''There [is] insufficient peer-reviewed literature to support any other indicator at this time'' (Samet, 2010c, p. 12). CASAC expressed a strong desire for the EPA to ''look ahead to future review cycles and reinvigorate support for the development of evidence that might lead to newer indicators that may correlate better with the health effects associated with ambient air concentrations of PM * * *'' (Samet, 2010c, p 2).

Consistent with the staff conclusions presented in the Policy Assessment and CASAC advice, the Administrator proposed to retain $PM_{2.5}$ as the indicator for fine particles. Further, the Administrator provisionally concluded that currently available scientific information does not provide a sufficient basis for supplementing mass-based, primary fine particle standards with standards using a separate indicator for ultrafine particles or a separate indicator for a specific $PM_{2.5}$ component or group of components associated with any source categories of fine particles. In addition, the Administrator also provisionally concluded that the currently available scientific information did not provide a sufficient basis for eliminating any individual component or group of components associated with any source categories from the mix of fine particles included in the $PM_{2.5}$ mass-based indicator.

The EPA received comparatively few public comments on issues related to the indicator for fine particles.[65] Some commenters emphasized the need to conduct additional research to more fully understand the effect of specific $PM_{2.5}$ components and/or sources on public health. These commenters expressed views about the importance of evaluating health effect associations with various fine particle components and types of source categories as a basis for focusing ongoing and future research to reduce uncertainties in this area and for considering whether alternative indicator(s) may be appropriate to consider in future PM NAAQS reviews for standards intended to protect against the array of health effects that have been associated with fine particles as indexed by $PM_{2.5}$. For example, the PSR encouraged more research and monitoring related to $PM_{2.5}$ components and noted the importance of components associated with coal combustion (PSR, 2012, pp. 5 to 6). EPRI asserted that ''new'' studies support focusing on EC and OC and encouraged the EPA to seriously consider the mass-based approach (EPRI, 2012, p. 2). Likewise, Georgia Mining Association supported additional monitoring and research efforts related to $PM_{2.5}$ composition and specifically encouraged the evaluation of using particle number (e.g., particle count) (GMA, 2012, pp. 2 to 3).

The Administrator agrees with CASAC as well as these commenters that the results of additional research and monitoring efforts will be helpful for informing future PM NAAQS reviews. Information from such studies could also help inform the development of strategies that emphasize control of specific types of emission sources so as to address particles of greatest concern to public health. However, based upon the scientific information considered in the Integrated Science Assessment as well as the public comments summarized above, the Administrator continues to take note there is evidence that many different constituents of the fine particle mixture as well as groups of components associated with specific sources of fine particles are linked to adverse health effects. Furthermore, she recognizes that the evidence is not yet sufficient to differentiate those constituents or sources that are most closely related to specific health outcomes nor to exclude any $PM_{2.5}$ components or sources of fine particles from the mix of particles included in the $PM_{2.5}$ indicator.

Having considered the public comments on this issue, the Administrator concurs with the Policy Assessment conclusions and CASAC recommendations and concludes that it is appropriate to retain $PM_{2.5}$ as the indicator for fine particles.

2. Averaging Time

In 1997, the EPA initially set both an annual standard, to provide protection from health effects associated with both long- and short-term exposures to $PM_{2.5}$, and a 24-hour standard to supplement the protection afforded by the annual standard (62 FR 38667 to 38668, July, 18, 1997). In the last review, the EPA retained both annual and 24-hour averaging times (71 FR 61164, October 17, 2006). These decisions were based, in part, on evidence of health effects related to both long-term (from a year to several years) and short-term (from less than one day to up to several days) measures of $PM_{2.5}$.

[65] No public comments were submitted regarding the use of a different size cut for fine particles.

The overwhelming majority of studies conducted since the last review continue to utilize annual (or multi-year) and 24-hour averaging times, reflecting the averaging times of the current $PM_{2.5}$ standards. These studies continue to provide evidence that health effects are associated with annual and 24-hour averaging times. Therefore, the Policy Assessment concluded it is appropriate to retain the current annual and 24-hour averaging times to provide protection from effects associated with both long- and short-term $PM_{2.5}$ exposures (U.S. EPA, 2011a, p. 2–57).

In considering whether the information available in this review supports consideration of different averaging times for $PM_{2.5}$ standards specifically with regard to considering a standard with an averaging time less than 24 hours to address health effects associated with sub-daily $PM_{2.5}$ exposures, the Policy Assessment noted there continues to be a growing body of studies that provide additional evidence of effects associated with exposure periods less than 24-hours (U.S. EPA, 2011a, p. 2–57). Relative to information available in the last review, recent studies provide additional evidence for cardiovascular effects associated with sub-daily (e.g., one to several hours) exposure to PM, especially effects related to cardiac ischemia, vasomotor function, and more subtle changes in markers of systemic inflammation, hemostasis, thrombosis and coagulation (U.S. EPA, 2009a, section 6.2). Because these studies have used different indicators (e.g., $PM_{2.5}$, PM_{10}, $PM_{10\text{-}2.5}$, ultrafine particles), averaging times (e.g., 1, 2, and 4 hours), and health outcomes, it is difficult to draw conclusions about cardiovascular effects associated specifically with sub-daily exposures to $PM_{2.5}$.

With regard to respiratory effects associated with sub-daily $PM_{2.5}$ exposures, the currently available evidence was much sparser than for cardiovascular effects and continues to be very limited. The Integrated Science Assessment concluded that for several studies of hospital admissions or medical visits for respiratory diseases, the strongest associations were observed with 24-hour average or longer exposures, not with less than 24-hour exposures (U.S. EPA, 2009a, section 6.3).

Collectively, the Policy Assessment concluded that this information, when viewed as a whole, is too unclear, with respect to the indicator, averaging time and health outcome, to serve as a basis for consideration of establishing a primary $PM_{2.5}$ standard with an averaging time shorter than 24-hours at this time (U.S. EPA, 2011a, p. 2–57).

With regard to health effects associated with $PM_{2.5}$ exposure across varying seasons in this review, Bell *et al.* (2008) reported higher $PM_{2.5}$ risk estimates for hospitalization for cardiovascular and respiratory diseases in the winter compared to other seasons. In comparison to the winter season, smaller statistically significant associations were also reported between $PM_{2.5}$ and cardiovascular morbidity for spring and autumn, and a positive, but statistically non-significant association was observed for the summer months. In the case of mortality, Zanobetti and Schwartz (2009) reported a 4-fold higher effect estimate for $PM_{2.5}$-associated mortality for the spring as compared to the winter. Taken together, these results provided emerging but limited evidence that individuals may be at greater risk of dying from higher exposures to $PM_{2.5}$ in the warmer months and may be at greater risk of $PM_{2.5}$-associated hospitalization for cardiovascular and respiratory diseases during colder months of the year (U.S. EPA, 2011a, p. 2–58).

Overall, the Policy Assessment observed that there are few studies presently available to deduce a general pattern in $PM_{2.5}$-related risk across seasons. In addition, these studies utilized 24-hour exposure periods within each season to assess the $PM_{2.5}$-associated health effects and do not provide information on health effects associated with a season-long exposure to $PM_{2.5}$. Due to these limitations in the currently available evidence, the Policy Assessment concluded that there was no basis to consider a seasonal averaging time separate from a 24-hour averaging time.

Based on the above considerations, the Policy Assessment concluded that the currently available information provided strong support for consideration of retaining the current annual and 24-hour averaging times but does not provide support for considering alternative averaging times (U.S. EPA, 2011a, p. 2–58). In addition, CASAC considered it appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$ standards (Samet, 2010c, pp. 2 to 3). At the time of the proposal, the Administrator concurred with the staff conclusions and CASAC advice and proposed that the averaging times for the primary $PM_{2.5}$ standards should continue to include annual and 24-hour averages to protect against health effects associated with long- and short-term exposures. Furthermore, the Administrator provisionally concluded, consistent with conclusions reached in the Policy Assessment and by CASAC, that the currently available information was too limited to support consideration of alternative averaging times to establish a national standard with a shorter-than 24-hour averaging time or with a seasonal averaging time.

The EPA received no significant public comments on the issue of averaging time for the $PM_{2.5}$ primary standards. The Administrator concurs with recommendations made by CASAC and the staff conclusions presented in the Policy Assessment and concludes, as proposed, that it is appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$ standards to protect against health effects associated with long- and short-term exposure periods.

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 the standard. In this review, the EPA considers whether currently available information supports retaining or revising the forms for the annual or 24-hour $PM_{2.5}$ standards.

a. Annual Standard

In 1997, the EPA established the form of the annual $PM_{2.5}$ standard as an annual arithmetic mean, averaged over 3 years, from single or multiple community-oriented monitors. This form was intended to represent a relatively stable measure of air quality and to characterize longer-term area-wide $PM_{2.5}$ concentrations, in conjunction with a 24-hour standard designed to provide adequate protection against localized peak or seasonal $PM_{2.5}$ concentrations. The level of the standard was to be compared to measurements made at each community-oriented monitoring site, or, if specific criteria were met, measurements from multiple community-oriented monitoring sites could be averaged (i.e., spatial averaging)[66] (62 FR 38671 to 38672, July 18, 1997). The constraints were intended to ensure that spatial averaging would not result in inequities in the level of protection provided by the standard (62 FR 38672, July 18, 1997). This approach was consistent with the epidemiological studies on which the $PM_{2.5}$ standard was primarily based, in which air quality data were generally averaged across multiple monitors in an

[66] Spatial averaging as part of the form of the annual $PM_{2.5}$ standard is unique to this standard and is not used with other PM standards nor with other NAAQS.

area or were taken from a single monitor that was selected to represent community-wide exposures.

In the last review, the EPA tightened the criteria for use of spatial averaging to provide increased protection for vulnerable populations exposed to $PM_{2.5}$. This change was based in part on an analysis of the potential for disproportionate impacts on potentially at-risk populations, which found that the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding population is more likely to have lower education and income levels and higher percentages of minority populations (71 FR 61166/2, October 17, 2006; U.S. EPA, 2005, section 5.3.6.1).

In this review, as outlined in section III.B above and discussed more fully in section III.B.3 of the proposal, there now exist more health data such that the Integrated Science Assessment has identified persons from lower socioeconomic strata as an at-risk population (U.S. EPA, 2009a, section 8.1.7; U.S. EPA, 2011a, section 2.2.1). Moreover, there now exist more years of $PM_{2.5}$ air quality data than were available in the last review. Consideration in the Policy Assessment of the spatial variability across urban areas that was revealed by this expanded data base has raised questions as to whether an annual standard that allows for spatial averaging, even within specified constraints as narrowed in 2006 (71 FR 61165 to 61167, October 17, 2006), would provide appropriate public health protection.

In considering the potential for disproportionate impacts on at-risk populations, the Policy Assessment considered an update of an air quality analysis conducted for the last review (U.S. EPA, 2011a, pp. 2–59 to 60; Schmidt, 2011, Analysis A). This analysis focused on determining whether the spatial averaging provisions, as modified in 2006, could introduce inequities in protection for at-risk populations exposed to $PM_{2.5}$. Specifically, the Policy Assessment considered whether persons of lower socioeconomic status, minority groups, or different age groups (i.e., children or older adults) are more likely than the general population to live in areas in which the monitors recording the highest air quality values in an area are located. Data used in this analysis included demographic parameters measured at the Census Block or Census Block Group level, including percent minority population, percent minority subgroup population, percent of persons living below the poverty level, percent of persons 18 years of age or older, and percent of persons 65 years of age and older. In each candidate geographic area, data from the Census Block(s) or Census Block Group(s) surrounding the location of the monitoring site (as delineated by radii buffers of 0.5, 1.0, 2.0, and 3.0 miles) in which the highest air quality value was monitored were compared to the average of monitored values in the area. This analysis looked beyond areas that would meet the current spatial averaging criteria and considered all urban areas (i.e., Core Based Statistical Areas or CBSAs) with at least two valid annual design value monitors (Schmidt, 2011, Analysis A). Recognizing the limitations of such cross-sectional analyses, the Policy Assessment observed that the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding populations are more likely to live below the poverty line and to have higher percentage of minorities (U.S. EPA, 2011a, p. 2–60).

Based upon the analysis described above, the Policy Assessment concluded that the existing constraints on spatial averaging, as modified in 2006, may be inadequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on at-risk populations of persons with lower SES levels as well as minorities. Therefore, the Policy Assessment concluded that it was appropriate to consider revising the form of the annual $PM_{2.5}$ standard such that it did not allow for the use of spatial averaging across monitors. In doing so, the level of the annual $PM_{2.5}$ standard would be compared to measurements made at the monitoring site that represents area-wide air quality recording the highest $PM_{2.5}$ concentrations [67] (U.S. EPA, 2011a, p. 2–60).

The CASAC agreed with staff conclusions that it was ''reasonable'' for the EPA to eliminate the spatial averaging provisions (Samet, 2010d, p. 2). Further, in CASAC's comments on the first draft Policy Assessment, it noted, ''Given mounting evidence showing that persons with lower SES levels are a susceptible group for PM-related health risks, CASAC recommends that the provisions that allow for spatial averaging across monitors be eliminated for the reasons cited in the (first draft) Policy Assessment'' (Samet, 2010c, p. 13). In its review of the second draft Policy Assessment, CASAC recognized ''although much of the epidemiological research has been conducted using community-wide averages, several key studies reference the nearest measurement site, so that some risk estimates are not necessarily biased by the averaging process. Further, the number of such studies is likely to expand in the future'' (Samet, 2010d, pp. 1 to 2).

Only two areas in the country used the initial spatial averaging provisions for demonstrating attainment with the primary annual $PM_{2.5}$ standard set in 1997 (70 FR 19847, April 14, 2005; U.S. EPA, 2006c). Since these provisions were tightened in 2006, no area has used spatial averaging to demonstrate attainment. No areas in the country are currently using the spatial averaging provisions to demonstrate attainment with the current primary annual $PM_{2.5}$ standard.

In considering the Policy Assessment's conclusions based on the results of the analysis discussed above and concern over the evidence of potential disproportionate impacts on at-risk populations as well as CASAC advice, the Administrator proposed to revise the form of the annual $PM_{2.5}$ standard to eliminate the use of spatial averaging. Thus, the Administrator proposed revising the form of the annual $PM_{2.5}$ standard to compare the level of the standard with measurements from each ''appropriate'' monitor in an area [68] with no allowance for spatial averaging. Thus, for an area with multiple monitors, the appropriate reporting monitor with the highest design value would determine the attainment status for that area.

Of the commenters noted in section III.D.2 above who supported a more stringent annual $PM_{2.5}$ standard, those who commented on the form of the annual $PM_{2.5}$ standard supported the EPA's proposal to eliminate the spatial averaging provisions. These commenters contended that the EPA's analyses of the potential impacts of spatial averaging, discussed above and in the proposal (77 FR 38924), demonstrated that the current form results in uneven public health protection leading to disproportionate impacts on at-risk populations. Specifically, the ALA and other environmental and public health commenters contended that ''spatial averaging allows exposure of people to unhealthy levels of pollution at specific locales even within an area meeting the standard'' (ALA *et al.,* 2012, p. 23).

[67] As discussed in section VIII.B.1 below, the EPA is revising several terms associated with $PM_{2.5}$ monitor placement. Specifically, the EPA is revoking the term ''community-oriented'' and replacing it with the term ''area-wide'' monitoring.

[68] As discussed in section VIII.B.2.b below, the EPA concludes that $PM_{2.5}$ monitoring sites at micro- and middle-scale locations are comparable to the annual standard if the monitoring site has been approved by the Regional Administrator as representing an area-wide location.

These commenters particularly focused on the importance for low-income and minority populations of eliminating the spatial averaging provisions. They concluded that spatial averaging ''is an environmental justice concern because poor people are more likely to live near roads, depots, factories, ports, and other pollution sources.'' *Id.* p. 24.

Other commenters (e.g., AAM, 2012; Dow, 2012) also supported the elimination of spatial averaging in order to ''avoid potential disproportionate impacts on at-risk populations'' and to maximize ''the benefits to public health of reducing the annual $PM_{2.5}$ standard.'' However, these groups expressed concern that the elimination of spatial averaging, in combination with the requirement for near road monitors (as discussed in section VIII.B.3.b.i of the proposal), would effectively and inappropriately increase the stringency of the annual $PM_{2.5}$ standard.

This concern was also shared by other commenters who disagreed with the elimination of spatial averaging. For example, the Class of '85 RRG emphasized concerns about increasing the stringency of the standard while providing few health benefits if spatial averaging is eliminated, particularly in combination with the requirement for near-road monitors. These commenters contended that ''[b]ecause EPA proposes to use the readings from the highest single worst case monitor (rather than the average of all community area monitors), and since roadway monitoring locations will likely be worst case monitors, the proposed NAAQS will become more stringent without targeting the $PM_{2.5}$ species most harmful to human health'' (Class of '85 RRG, 2012, p. 6).

Several commenters also maintained that because spatial averaging is consistent with how air quality data are considered in the underlying epidemiological studies, such averaging should not be eliminated. Specifically, commenters including NAM *et al.,* AFPM, and ACC pointed out that $PM_{2.5}$ epidemiological studies use spatially averaged multi-monitor concentrations, rather than the single highest monitor, when evaluating health effects. Therefore, these commenters contended that allowing spatial averaging would make the $PM_{2.5}$ standard more consistent with the approaches used in the epidemiological studies upon which the standard is based. In addition, some commenters also contended that the EPA failed to consider whether modifying, rather than eliminating, the constraints on spatial averaging would have been sufficient to protect the public health. If so, these commenters argued that ''elimination of spatial averaging would go beyond what is requisite to protect the public health'' (NAM *et al.,* 2012, p. 20).

In considering the public comments on the form of the annual standard, the EPA recognizes a number of commenters agreed with the basis for the EPA's proposal to eliminate spatial averaging. While other commenters expressed disagreement or concern with the proposed decision to eliminate the spatial averaging provisions, the Agency notes that these commenters did not challenge the analyses or considerations that provided the fundamental basis for the Administrator's proposed decision. Rather, these commenters generally raised concerns that eliminating the option for spatial averaging would increase the stringency of the standard, especially in light of additional monitoring sites in near-road environments (as discussed in section VIII.B.3.b.1 below).

The EPA does not agree with the comment that siting some monitors in near roadway environments makes the standard more stringent or impermissibly more stringent. As discussed in section VIII.B.3.b.i below, a significant fraction of the population lives in proximity to major roads, and these exposures occur in locations that represent ambient air. Monitoring in such areas does not make the standard more stringent than warranted, but rather affords the intended protection to the exposed populations, among them at-risk populations, exposed to fine particles in these areas. Thus, in cases where monitors in near roadway environments are deemed to be representative of area-wide air quality they would be compared to the annual standard (as discussed more fully in section VIII below). The 24-hour and annual NAAQS are designed to protect the public with an adequate margin of safety, and this siting provision is fully consistent with providing the protection the standard is designed to provide and does not make the standard more stringent or more stringent than necessary.

Monitors that are representative of area-wide air quality may be compared to the annual standard. This is consistent with the use of monitoring data in the epidemiological studies that provide the primary basis for determining the level of the annual standard. In addition, the EPA notes that the annual standard is designed to protect against both long- and short-term exposures through controlling the broad distribution of air quality across an area over time.[69] It is fully consistent with the protection the standard is designed to provide for near road monitors to be compared to the annual standard if the monitor is representative of area-wide air quality. This does not make the standard either more stringent or impermissibly more stringent.

In further considering these comments, the EPA notes that the stringency or level of protection provided by each NAAQS is not based solely on the form of the standard; rather, the four elements of the standard that together serve to define each standard (i.e., indicator, averaging time, form, and level) must be considered collectively in evaluating the protection afforded by each standard. Therefore, the EPA considers these comments are also appropriate to discuss collectively with other issues related to the appropriate level for annual standard, and are discussed below in sections III.E.4.c–d.

In reaching a final decision on the form of the annual standard, the Administrator considers the available analyses, CASAC advice, and public comments on form as discussed above. She also considers related issues in the public comments on the level of the annual standard as discussed in section III.E.4.c below. She notes that even when the annual $PM_{2.5}$ standard was first set in 1997, the spatial averaging provisions included constraints intended to ensure that inequities in the level of protection would not result. These constraints on spatial averaging were tightened in the last review, based on an analysis showing the potential for spatial averaging to allow higher $PM_{2.5}$ concentrations in locations where subgroups within the general population were potentially disproportionately exposed and hence, at disproportionate risk (e.g., low income and minority communities). The Administrator notes that in proposing to eliminate spatial averaging altogether in this review, she has relied on further analyses in the current review (Schmidt, 2011, Analysis A). As discussed above and in the proposal (77 FR 38924), these analyses showed that the current constraints on spatial averaging may be inadequate in some areas to avoid substantially greater exposures for people living near monitors recording the highest $PM_{2.5}$ concentrations. Such exposures could result in

[69] This is in contrast to the 24-hour standard which is designed to provide supplemental protection, addressing peak exposures that might not otherwise be addressed by the annual standard. Consistent with this, monitors are not required to be representative of area-wide air quality to be compared to the 24-hour standard.

disproportionate impacts to at-risk populations, including low-income populations as well as minority groups.

On this basis, the Administrator concludes that public health would not be protected with an adequate margin of safety in all locations, as required by law, if disproportionately higher exposure concentrations in at-risk populations such as low income communities as well as minority communities were averaged together with lower concentrations measured at other sites in a large urban area. See *ALA* v. *EPA,* 134 F. 3d 388, 389 (D.C. Cir., 1998) (''this court has held that 'NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children,' and 'if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard'''') and *Coalition of Battery Recyclers Association* v. *EPA,* 604 F 3d. 613, 617 (D.C. Cir., 2010) (''Petitioners' assertion that the revised lead NAAQS is overprotective because it is more stringent than necessary to protect the entire population of young U.S. children ignores that the Clean Air Act allows protection of sensitive subpopulations.'') In reaching this conclusion, the Administrator further notes that her concern over possible disproportionate $PM_{2.5}$-related health impacts in at-risk populations extends to populations living near important sources of $PM_{2.5,}$ including the large populations that live near major roadways.[70]

In light of all of the above considerations, including consideration of available analyses, CASAC advice, and public comments, the Administrator concludes that the current form of the annual $PM_{2.5}$ standard should be revised to eliminate spatial averaging provisions. Thus, the level of the revised annual $PM_{2.5}$ standard established with this rule will be compared with measurements from each appropriate monitor in an area, with no allowance for spatial averaging. The Administrator's conclusions with regard to the appropriate level of the annual $PM_{2.5}$ standard to set in conjunction with this form are discussed below in section III.E.4.d.

b. 24-Hour Standard

In 1997, the EPA established the form of the 24-hour $PM_{2.5}$ standard as the 98th percentile of 24-hour concentrations at each population-oriented monitor within an area, averaged over three years (62 FR at 38671 to 38674, July 18, 1997). The Agency selected the 98th percentile as an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability which, when averaged over 3 years, facilitated effective health protection through the development of more stable implementation programs. By basing the form of the standard on concentrations measured at population-oriented monitoring sites, the EPA intended to provide protection for people residing in or near localized areas of elevated concentrations. In the last review, in conjunction with lowering the level of the 24-hour standard, the EPA retained this form based in part on a comparison with the 99th percentile form.[71]

In revisiting the stability of a 98th versus 99th percentile form for a 24-hour standard intended to provide supplemental protection for a generally controlling annual standard, an analysis presented in the Policy Assessment considered air quality data reported in 2000 to 2008 to update our understanding of the ratio between peak-to-mean $PM_{2.5}$ concentrations. This analysis provided evidence that the 98th percentile value was a more stable metric than the 99th percentile (U.S. EPA, 2011a, Figure 2–2, p. 2–62).

At the time of the proposal, the Agency recognized that the selection of the appropriate form of the 24-hour standard includes maintaining adequate protection against peak 24-hour concentrations while also providing a stable target for risk management programs, which serves to provide for the most effective public health protection in the long run.[72] As in previous reviews, the EPA recognized that a concentration-based form, compared to an exceedance-based form, was more reflective of the health risks posed by elevated pollutant concentrations because such a form gives proportionally greater weight to days when concentrations are well above the level of the standard than to days when the concentrations are just above the level of the standard. Further, the Agency provisionally concluded that a concentration-based form, when averaged over three years, provided an appropriate balance between limiting peak pollutant concentrations and providing a stable regulatory target, thus facilitating the development of more stable implementation programs.

In considering the information provided in the Policy Assessment and recognizing that the degree of public health protection likely to be afforded by a standard is a result of the combination of the form and the level of the standard, the Administrator proposed to retain the 98th percentile form of the 24-hour standard. The Administrator provisionally concluded that the 98th percentile form represents an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability relative to an alternative 99th percentile form.

Few public commenters commented specifically on the form of the 24-hour standard. None of the public commenters raised objections to continuing the use of a concentration-based form for the 24-hour standard. Many of the individuals and groups who supported a more stringent 24-hour $PM_{2.5}$ standard noted in section III.D.2 above, however, recommended a more restrictive concentration-based percentile form, specifically a 99th percentile form. The limited number of these commenters who provided a specific rationale for this recommendation generally expressed their concern that the 98th percentile form could allow too many days where concentrations exceeded the level of the standard, and thus fail to adequately protect public health. Other public commenters representing state and local air agencies and industry groups generally supported retaining the current 98th percentile form. In most cases, these groups expressed the overall view that the current 24-hour $PM_{2.5}$ standard, including the form of the current standard, should be retained.

The EPA notes that the viewpoints represented in this review are similar to comments submitted in the last review and through various NAAQS reviews. The EPA recognizes that the selection of the appropriate form includes maintaining adequate protection against peak 24-hour values while also providing a stable target for risk management programs, which serves to provide for the most effective public

[70] Section VIII.B.3.b.i below discusses public comments specifically related to the proposed requirement for near-road monitors.

[71] In reaching this final decision, the EPA recognized a technical problem associated with a potential bias in the method used to calculate the 98th percentile concentration for this form. The EPA adjusted the sampling frequency requirement in order to reduce this bias. Accordingly, the Agency modified the final monitoring requirements such that areas that are within 5 percent of the standards are required to increase the sampling frequency to every day (71 FR 61164 to 61165, October 17, 2006).

[72] See *ATA III,* 283 F.3d at 374–376 which concludes that it is legitimate for the EPA to consider overall stability of the standard and its resulting promotion of overall effectiveness of NAAQS control programs in setting a standard that is requisite to protect the public health.

health protection in the long run.[73] Nothing in the commenters' views has provided a reason to change the Administrator's previous conclusion regarding the appropriate balance represented in the proposed form of the 24-hour $PM_{2.5}$ standard. Therefore, the Administrator concurs with staff conclusions presented in the Policy Assessment and CASAC recommendations and concludes that it is appropriate to retain the 98th percentile form for the 24-hour $PM_{2.5}$ standard.

4. Level

In the last review, the EPA selected levels for the annual and the 24-hour $PM_{2.5}$ standards using evidence of effects associated with periods of exposure that were most closely matched to the averaging time of each standard. Thus, as discussed in section III.A.1, the EPA relied upon evidence from long-term exposure studies as the principal basis for selecting the level of the annual $PM_{2.5}$ standard that would protect against effects associated with long-term exposures. The EPA relied upon evidence from the short-term exposure studies as the principal basis for selecting the level of the 24-hour $PM_{2.5}$ standard that would protect against effects associated with short-term exposures. As summarized in section III.A.2 above, the 2006 decision to retain the level of the annual $PM_{2.5}$ standard at 15 $\mu g/m^3$ [74] was challenged and on judicial review, the DC Circuit remanded the primary annual $PM_{2.5}$ standard to the EPA, finding that EPA's explanation for its approach to setting the level of the annual standard was inadequate.

a. General Approach for Considering Standard Levels

Building upon the lessons learned in the previous PM NAAQS reviews, in considering alternative standard levels supported by the currently available scientific information, the Policy Assessment used an approach that integrated evidence-based and risk-based considerations, took into account CASAC advice, and considered the issues raised by the court in remanding the primary annual $PM_{2.5}$ standard. Following the general approach outlined in section III.A.3 above, for the reasons discussed below, the Policy Assessment concluded it was appropriate to consider the protection afforded by the annual and 24-hour standards taken together against mortality and morbidity effects associated with both long- and short-term $PM_{2.5}$ exposures. This was consistent with the approach taken in the review completed in 1997 rather than considering each standard separately, as was done in the review completed in 2006.

Beyond looking directly at the relevant epidemiologic evidence, the Policy Assessment considered the extent to which specific alternative $PM_{2.5}$ standard levels were likely to reduce the nature and magnitude of both long-term exposure-related mortality risk and short-term exposure-related mortality and morbidity risk (U.S. EPA, 2011a, section 2.3.4.2; U.S.EPA, 2010a, section 4.2.2). As noted in section III.C above, patterns of increasing estimated risk reductions were generally observed as either the annual or 24-hour standard, or both, were reduced below the level of the current standards (U.S. 2011a, Figures 2–11 and 2–12; U.S. EPA, 2010a, sections 4.2.2, 5.2.2, and 5.2.3).

Based on the quantitative risk assessment, the Policy Assessment observed, as discussed in section III.A.3, that analyses conducted for this and previous reviews demonstrated that much, if not most, of the aggregate risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low-to mid-range, below the peak 24-hour concentrations (U.S. EPA, 2011a, p. 2–9). Furthermore, as discussed in section III.C above and in section III.C.3 of the proposal, the Risk Assessment observed that alternative annual standard levels, when controlling, resulted in more consistent risk reductions across urban study areas, thereby potentially providing a more consistent degree of public health protection (U.S. EPA, 2010a, pp. 5–15 to 5–16). In contrast, the Risk Assessment noted that the results of simulating alternative suites of $PM_{2.5}$ standards including different combinations of alternative annual and 24-hour standard levels suggested that an alternative 24-hour standard level can produce additional estimated risk reductions beyond that provided by an alternative annual standard alone. However, the degree of estimated risk reduction provided by alternative 24-hour standard levels was highly variable, in part due to the choice of rollback approached used (U.S. EPA, 2010a, p. 5–17).

Based on its review of the second draft Policy Assessment, CASAC agreed with the EPA staff's general approach for translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on alternative standards for consideration. Furthermore, CASAC agreed ''that it is appropriate to return to the strategy used in 1997 that considers the annual and the short-term standards together, with the annual standard as the controlling standard, and the short-term standard supplementing the protection afforded by the annual standard'' and ''considers it appropriate to place the greatest emphasis'' on health effects judged to have evidence supportive of a causal or likely causal relationship as presented in the Integrated Science Assessment (Samet, 2010d, p. 1).

Therefore, the Policy Assessment concluded, consistent with specific CASAC advice, that it was appropriate to set a ''generally controlling'' annual standard that will lower a wide range of ambient 24-hour concentrations. The Policy Assessment concluded this approach would likely reduce aggregate risks associated with both long- and short-term exposures with more consistency than a generally controlling 24-hour standard and would be the most effective and efficient way to reduce total $PM_{2.5}$-related population risk and so provide appropriate protection. The staff believed this approach, in contrast to one focusing on a generally controlling 24-hour standard, would likely reduce aggregate risks associated with both long- and short-term exposures with more consistency and would likely avoid setting national standards that could result in relatively uneven protection across the country due to setting standards that were either more or less stringent than necessary in different geographical areas.

The Policy Assessment recognized that an annual standard intended to serve as the primary means for providing protection against effects associated with both long- and short-term $PM_{2.5}$ exposures cannot be expected to offer an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures. As a result, in conjunction with a generally controlling annual standard, the Policy Assessment concluded it was appropriate to

[73] As just noted above, it is legitimate for the EPA to consider promotion of overall effectiveness of risk management programs designed to attain the NAAQS, including their overall stability, in setting a standard that is requisite to protect the public health. The context for the court's discussion in *ATA III* is identical to that here; whether to adopt a 98th percentile form for a 24-hour standard intended to provide supplemental protection for a generally controlling annual standard.

[74] Throughout this section, the annual standard levels are denoted as integer values for simplicity, although, as noted above in section II.B.1, Table 1, the annual standard level is defined to one decimal place, such that the current annual standard level is 15.0 $\mu g/m^3$. Alternative annual standard levels discussed in this section are similarly defined to one decimal place.

consider setting a 24-hour standard to provide supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods.

At the time of the proposal, the Administrator agreed with the approach discussed in the Policy Assessment as summarized in section III.A.3 above, and supported by CASAC, of considering the protection afforded by the annual and 24-hour standards taken together for mortality and morbidity effects associated with both long- and short-term exposures to $PM_{2.5}$. Furthermore, based on the evidence and quantitative risk assessment, the Administrator provisionally concluded it was appropriate to set a ''generally controlling'' annual standard that will lower a wide range of ambient 24-hour concentrations, with a 24-hour standard focused on providing supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods. The Administrator provisionally concluded this approach would likely reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and would be the most effective and efficient way to reduce total PM_{2-5}-related population risk.

The Administrator is mindful that considering what standards are requisite to protect public health with an adequate margin of safety requires public health policy judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. At the time of the proposal, in considering how to translate the available information into appropriate standard levels, the Administrator weighed the available scientific information and associated uncertainties and limitations. For the purpose of determining what standard levels were appropriate to propose, the Administrator recognized, as did the EPA staff in the Policy Assessment, that there was no single factor or criterion that comprised the ''correct'' approach to weighing the various types of available evidence and information, but rather there were various approaches that were appropriate to consider. The Administrator further recognized that different evaluations of the evidence and other information before the Administrator could reflect placing different weight on the relative strengths and limitations of the scientific information, and different judgments could be made as to how such information should appropriately be used in making public health policy decisions on standard levels. This recognition led the Administrator to consider various approaches to weighing the evidence so as to identify appropriate standard levels to propose. In so doing, the Administrator encouraged extensive public comment on alternative approaches to weighing the evidence and other information so as to inform her public health policy judgments before reaching final decisions on appropriate standard levels.

b. Proposed Decisions on Standard Levels

i. Consideration of the Alternative Standard Levels in the Policy Assessment

In recognizing the absence of a discernible population threshold below which effects would not occur, the Policy Assessment's general approach for identifying alternative annual standard levels that were appropriate to consider focused on characterizing the part of the distribution of $PM_{2.5}$ concentrations in which we had the most confidence in the associations reported in the epidemiological studies and conversely where our confidence in the association became appreciably lower. The most direct approach to address this issue, consistent with CASAC advice (Samet, 2010c, p. 10), was to consider epidemiological studies reporting confidence intervals around concentration-response relationships (U.S. EPA, 2011a, p. 2–63). Based on a thorough search of the available evidence, the Policy Assessment identified only one study (Schwartz *et al.,* 2008) that conducted a multi-model analysis to characterize confidence intervals around the estimated concentration-response relationship. The Policy Assessment concluded that this single relevant analysis was too limited to serve as the principal basis for identifying alternative standard levels in this review (U.S. EPA, 2011a, p. 2–70).

The Policy Assessment explored other approaches to characterize the part of the distributions of long-term mean $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in long- and short-term epidemiological studies, and placed greatest weight on those studies that reported positive and statistically significant associations (U.S. EPA, 2011a, p. 2–63). First, as discussed in section III.A.3 above, the Policy Assessment considered the statistical metric used in previous reviews. This approach recognized the EPA's views that the strongest evidence of associations occurs at concentrations around the long-term mean concentration. Thus, in earlier reviews, the EPA focused on identifying standard levels that were somewhat below the long-term mean concentrations reported in $PM_{2.5}$ epidemiological studies. The long-term mean concentrations represented air quality data typically used in epidemiological analyses and provided a direct link between $PM_{2.5}$ concentrations and the observed health effects. Further, these data were available for all long- and short-term exposure studies analyzed and, therefore, represented the data set available for the broadest set of epidemiological studies.

However, consistent with CASAC's comments on the second draft Policy Assessment [75] (Samet, 2010d, p. 2), in preparing the final Policy Assessment, the EPA staff explored ways to take into account additional information from epidemiological studies, when available (Rajan *et al.,* 2011). These analyses focused on evaluating different statistical metrics, beyond the long-term mean concentration, to characterize the part of the distribution of $PM_{2.5}$ concentrations in which staff continued to have confidence in the associations observed in epidemiological studies and below which there was a comparative lack of data such that the staff's confidence in the relationship was appreciably less. This would also be the part of the distribution of $PM_{2.5}$ concentrations which had the most influence on generating the health effect estimates reported in epidemiological studies. As discussed in section III.A.3 above, the Policy Assessment recognized there was no one percentile value within a given distribution that was the most appropriate or ''correct'' way to characterize where our confidence in the associations becomes appreciably lower. The Policy Assessment concluded that focusing on concentrations within the lower quartile of a distribution, such as the range from the 25th to the 10th percentile, was reasonable to consider as a region within which we begin to have appreciably less confidence in the associations observed in epidemiological studies.[76] In the EPA staff's view, considering lower $PM_{2.5}$ concentrations, down to the lowest concentration observed in a study, would be a highly uncertain basis for selecting alternative standard levels (U.S. EPA, 2009a, p. 2–71).

As outlined in section III.A.3 above, the Policy Assessment recognized that there were two types of population-level information to consider in identifying the range of $PM_{2.5}$ concentrations which have the most influence on generating the health effect estimates reported in epidemiological studies. The most relevant information to consider was the number of health events (e.g., deaths, hospitalizations) occurring within a study population in relation to the distribution of $PM_{2.5}$ concentrations likely experienced by study participants. However, in recognizing that access to health event data may be restricted, and consistent with advice from CASAC (Samet 2010d, p. 2), EPA staff also considered the number of participants within each study area, in relation to the distribution of $PM_{2.5}$ concentrations (i.e., study population data), as a surrogate for health event data.

In applying this approach, the Policy Assessment focused on identifying the part of the distribution of $PM_{2.5}$ concentrations which had the most influence on generating health effect estimates in epidemiological studies, as discussed in section III.A.3 above. As discussed below, in working with study investigators, the EPA staff was able to obtain health event data for three large multi-city studies (Krewski *et al.,* 2009; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008) and population data for the same three studies and one additional long-term exposure study (Miller *et al.,* 2007), as documented in a staff memorandum (Rajan *et al.,* 2011).[77] For the three studies for which both health event and study population data were available, the EPA staff analyzed the reliability of using study population data as a surrogate for health event data. Based on these analyses, the EPA staff recognized that the 10th and 25th percentiles of the health event and study population distributions are nearly identical and concluded that the distribution of population data can be a useful surrogate for event data, providing support for consideration of the study population data for Miller *et al.* (2007), for which health event data were not available (Rajan *et al.,* 2011, Analysis 1 and Analysis 2, in particular, Table 1 and Figures 1 and 2).

With regard to the long-term mean $PM_{2.5}$ concentrations which are relevant to the first approach, Figures 1 through 3 (U.S. EPA, 2011a, Figures 2–4, 2–5, 2–6, and 2–8) summarize data available for multi-city, long- and short-term exposure studies that evaluated endpoints classified in the Integrated Science Assessment as having evidence of a causal or likely causal relationship or evidence suggestive of a causal relationship, showing the studies with long-term mean $PM_{2.5}$ concentrations below 17 $\mu g/m^3$.[78] As discussed in more detail in section III.E.4.b of the proposal, Figures 1 and 3 summarize the health outcomes evaluated, relative risk estimates, air quality data, and geographic scope for long- and short-term exposure studies, respectively, that evaluated mortality (evidence of a causal relationship); cardiovascular effects (evidence of a causal relationship); and respiratory effects (evidence of a likely causal relationship) in the general population, as well as in older adults, an at-risk population. Figure 2 provides this same summary information for long-term exposure studies that evaluated respiratory effects (evidence of a likely causal relationship) in children, an at-risk population, as well as developmental effects (evidence suggestive of a causal relationship).

[75] While CASAC expressed the view that it would be most desirable to have information on concentration-response relationships, they recognized that it would also be ''preferable to have information on the concentrations that were most influential in generating the health effect estimates in individual studies'' (Samet, 2010d, p. 2).

[76] In the last review, staff believed it was appropriate to consider a level for an annual $PM_{2.5}$ standard that was somewhat below the averages of the long-term concentrations across the cities in each of the key long-term exposures studies, recognizing that the evidence of an association in any such study was strongest at and around the long-term average where the data in the study are most concentrated. For example, the interquartile range of long-term average concentrations within a study and a range within one standard deviation around the study mean were considered reasonable approaches for characterizing the range over which the evidence of association is strongest (U.S. EPA, 2005, pp. 5–22 to 5–23). In this review, the Policy Assessment noted the interrelatedness of the distributional statistics and a range of one standard deviation around the mean which contains approximately 68 percent of normally distributed data, in that one standard deviation below the mean falls between the 25th and 10th percentiles (U.S. EPA, 2011a, p. 2–71).

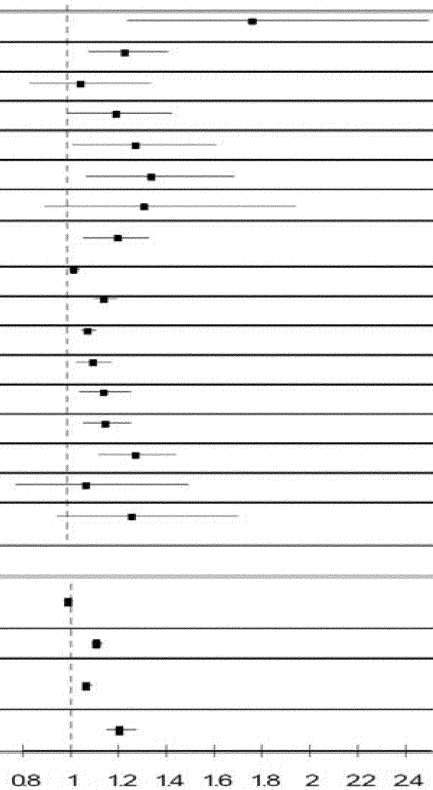
[77] The distributional statistical analysis of population-level data built upon an earlier analysis that evaluated the distributions of air quality and associated population data for three long-term exposure studies and three short-term exposure studies (Schmidt *et al.,* 2010, Analysis 2).

[78] Additional studies presented and assessed in the Integrated Science Assessment report effects at higher long-term mean $PM_{2.5}$ concentrations (e.g., U.S. EPA, 2009a, Figures 2–1, 2–2, 7–6, and 7–7).

[79] The long-term mean $PM_{2.5}$ concentrations reported by the study authors for the Miller *et al.* (2007) and Lipfert *et al.* (2006a) studies are discussed more fully in the Response to Comments document (U.S. EPA, 2012a).

Figure 1. Summary of Effect Estimates (per 10 μg/m^3) and Air Quality Distributions for Multi-City, Long-term $PM_{2.5}$ Exposure Studies of the General Population and Older Adults[79]

Study	Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (μg/m^3) Author Reported Data: Mean	Mean - 1SD	Range	Effect Estimate (95% CI)
General Population								
WHI	Miller et al. (2007)	36 US cities	2000	Mortality-CV	12.9[a]	10.2	3.4 – 28.3	
				All CVD				
				Incident MI				
				Revascularization				
				Stroke				
				CBVD				
Cystic Fibrosis	Goss et al. (2004)[b]	6 US regions (NE, SE, NC, SC, NW, SW)	2000	Mortality-All-cause	13.7	9.5	11.8-15.9 (IQR)	
				Pulmonary exacerbation				
ACS-Reanalysis II	Krewski et al. (2009)	116 US MSAs	1999-2000	Mortality-all cause	14.0	11.0	5.8 - 22	
				Mortality-IHD				
				Mortality-CPD				
				Mortality-Lung cancer				
VA	Lipfert et al. (2006)		1999-2001	Mortality-all cause	14.3	11.3	5.0 - ?	
Harvard Six Cities (SCS)-Extended	Laden et al. (2006)	6 US cities (Northeast/ Midwest)	1979-1998	Mortality-all cause	16.4[c]	10.8	10-22	
				Mortality-CV				
				Mortality-Respiratory				
				Mortality-Lung cancer				
Older Adults								
MCAPS-Western US	Zeger et al. (2008)	62 US counties	2000-2005	Mortality-all cause	13.1[d]	-	10.4-18.5 (IQR)	
Medicare-ACS	Eftim et al. (2008)	51 US MSAs	2000-2002	Mortality-all cause	13.6	10.8	6.0-25.1	
MCAPS-Eastern US	Zeger et al. (2008)	421 US counties	2000-2005	Mortality-all cause	14.0[c]	-	12.3-15.3 (IQR)	
Medicare -SCS	Eftim et al. (2008)	6 US cities	2000-2002	Mortality-all cause	14.1	11.0	9.6-19. 1	

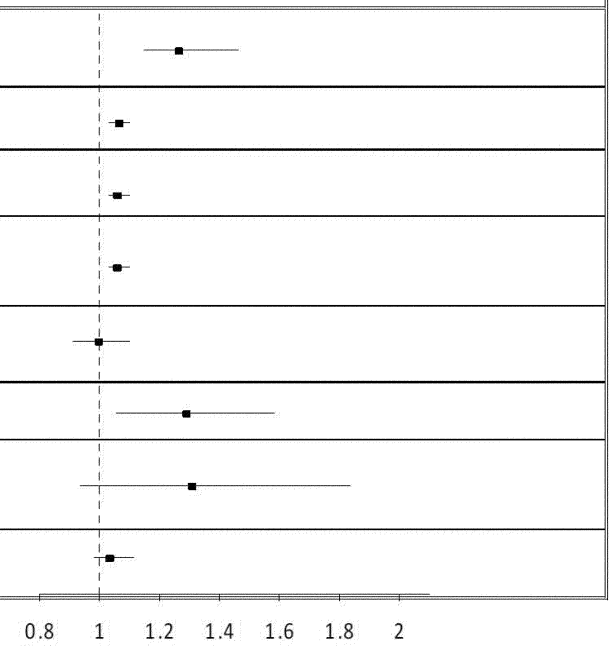


[a]Update of Miller et al. (2007) $PM_{2.5}$ data included in Curl, 2009
[b]Cohort included persons with cystic fibrosis age 6 and older, mean age: 18.4 yrs
[c]Estimated from data provided by study author (Laden, 2009)
[d]Median (IQR: Interquartile range); overall US reported median (IQR) of 13.2 μg/m^3 (11.1-14.9)

Source: U.S. EPA, 2011a, Figure 2-4

Figure 2. Summary of Effect Estimates (per 10 μg/m^3) and Air Quality Distributions for Multi-City, Long-term $PM_{2.5}$ Exposure Studies of Children

Children								
Study	**Cite**	**Geographic Area**	**Years of Air Quality Data**	**Endpoint**	**Air Quality Data (μg/m^3)**			**Effect Estimate (95% CI)**
					Mean	**Mean – 1SD**	**Range**	
	Bell et al. (2007)	CT,MA	1998-2002	Low Birth Weight	11.9[a]	10.3		
	Liu et al. (2007)	3 Canadian cities	1985-1999	IUGR -1nd trimester	12.2	-	6.3-15	
				IUGR -2nd trimester				
				IUGR – 3rd trimester				
	Parker and Woodruff (2008)	Continental US	2000-2003	Low Birth Weight	13.5[a]	-	10.9-16.1 (IQR)	
S CA CHS	McConnell et al. (2003)	12 communities – S CA	1996-1999	Bronchitic Symptoms	13.8	6.1	6-29	
24-Cities	Dockery et al. (1996)	24 communities – US, Canada	1988-1991	Bronchitis	14.5	10.3	5.8-20.7	
	Woodruff et al. (2008)	96 US counties	1999-2002	Infant mortality	14.9[b]	--	12.0-18.6 (IQR)	



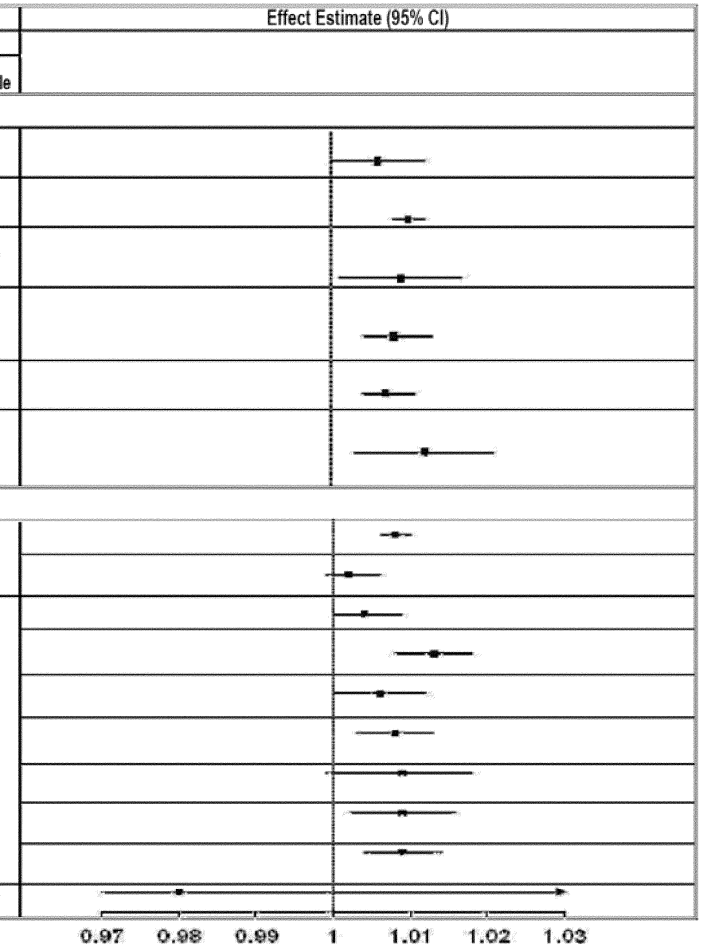
[a]Gestational mean

[b]Median for all cause mortality; median (IQR: interquartile range) for survivors = 14.8 (11.7-18.7) μg/m^3. Exposure period was first 2 months of life.

Source: U.S. EPA, 2011a, Figure 2-5

Figure 3. Summary of Effect Estimates (per 10 μg/m^3) and Air Quality Distributions for Multi-City, Short-term $PM_{2.5}$ Exposure Studies of the General Population and Older Adults

Study/Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (μg/m^3) Author Reported Data: Mean	Mean - 1SD	Range	98th percentile	Effect Estimate (95% CI)
General Population								
Burnett et al. (2004)	12 Canadian Cities	1981-1999	Nonaccidental mortality	12.8	-	-	38.0	
Zanobetti & Schwartz (2009)	112 US counties	1999-2005	Nonaccidental mortality	13.2[a]	10.3[a]	6.6-24.7	34.3	
Burnett & Goldberg (2003)	8 Canadian Cities	1986-1996	Nonaccidental mortality	13.3	3.9[b]	-	38.9[a]	
Harvard Six Cities/ Klemm and Mason (2003)	6 US cities (Northeast/ Midwest)	1979-1988	Nonaccidental mortality	14.7[c]	-	9-23 (IQR)	-	
Franklin et al. (2008)	25 US communities	2000-2005	Nonaccidental mortality	14.8[a]	-	9.9-27.4[a]	43.0	
Franklin et al. (2007)	27 US communities	1997-2002	Nonaccidental mortality	15.6[a]	-	8.8-23.9	45.8	
Older Adults/Children[d]								
MCAPS/Bell et al. (2008)	202 US counties	1999-2005	CVD HA	12.9[a]	10.2[a]	4-20	34.2	
			Resp HA					
MCAPS/Dominici et al. 2006	204 US counties	1999-2002	IHD HA	13.4[a]	10.5[a]	4-23	34.8	
			CHF HA					
			Dysrhythmia HA					
			CBVD HA					
			PVD HA					
			COPD HA					
			RTI HA					
O' Connor (2008)	7 US Cities	1998-2001	Wheeze/Cough	14.0	-	-	39.0[a]	



[a]Estimated from data provided by study author or published study
[b]Estimated from coefficient of variation reported in original study by Burnett et al. (2000)
[c]Mean value not reported in study, median presented from original study by Schwartz et al. (1996)
[d]MCAPS cohort included adults ≥ 65 yrs; O'Connor (2008) cohort included children, mean age: 7.7 yrs
IQR: interquartile range

Source: U.S. EPA, 2011a, Figure 2-6

With regard to consideration of additional information from epidemiological studies which was relevant to the second approach, the EPA staff compiled a summary of the range of $PM_{2.5}$ concentrations

corresponding with the 25th to 10th percentiles of health event or study population data from the four multi-city studies, for which distributional statistics are available [80] (U.S. EPA, 2011a, Figure 2–7; Rajan *et al.,* 2011, Table 1). By considering this approach, one could focus on the range of $PM_{2.5}$ concentrations below the long-term mean ambient concentrations over which we continue to have confidence in the associations observed in epidemiological studies (e.g., above the 25th percentile) where commensurate public health protection could be obtained for $PM_{2.5}$-related effects and, conversely, identify the range in the distribution below which our confidence in the associations is appreciably less, to identify alternative annual standard levels.

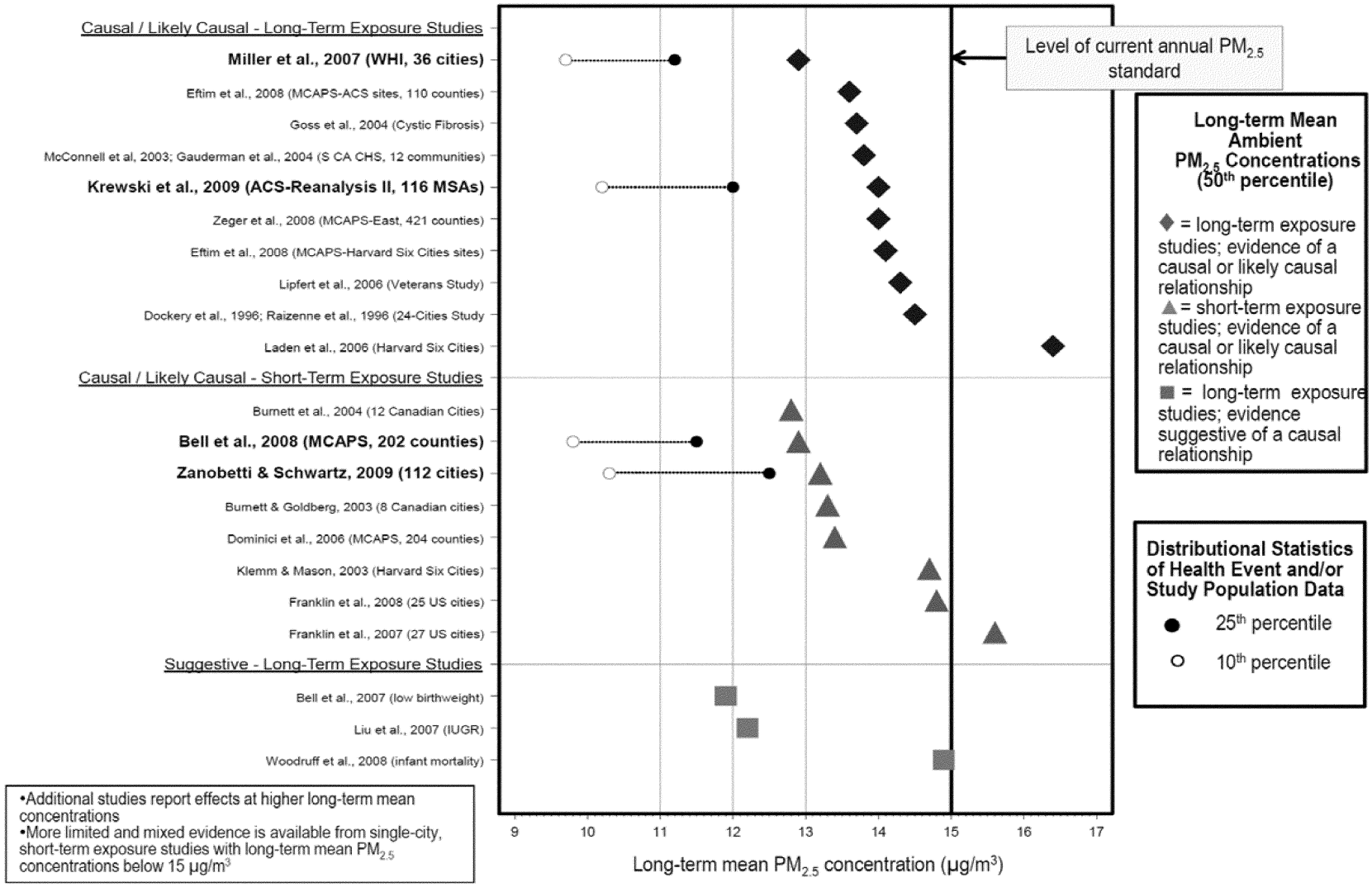
The mean $PM_{2.5}$ concentrations associated with the studies summarized in Figures 1, 2, and 3 and with the distributional statistics analyses (Rajan *et al.,* 2011) are based on concentrations averaged across ambient monitors within each area included in a given study and then averaged across study areas to calculate an overall study mean concentration, as discussed above. Figure 4, discussed in more detail in section III.E.4.a of the proposal, summarizes statistical metrics for those key studies [81] included in Figures 1, 2, and 3 that provide evidence of positive and generally statistically significant $PM_{2.5}$-related effects, which are relevant to the two approaches for translating epidemiological evidence into potential standard levels as discussed above. The top of Figure 4 includes information for *long-term* exposure studies evaluating health outcomes classified as having evidence of a *causal* or *likely causal relationship* with $PM_{2.5}$ exposures (long-term mean $PM_{2.5}$ concentrations indicated by diamond symbols). The middle of Figure 4 includes information for *short-term* exposure studies evaluating health outcomes classified as having evidence of a *causal* or *likely causal* relationship with $PM_{2.5}$ exposures (long-term mean $PM_{2.5}$ concentrations indicated by triangle symbols). The bottom of Figure 4 includes information for *long-term* exposures studies evaluating health outcomes classified as having evidence *suggestive of a causal relationship* (long-term mean $PM_{2.5}$ concentrations indicated by square symbols). Figure 4 also summarizes the range of $PM_{2.5}$ concentrations corresponding with the 25th (indicated by solid circles) to 10th (indicated by open circles) percentiles of the health event or study population data from the four multi-city studies (highlighted in bold text) for which distributional statistics are available.

[80] The EPA staff obtained health event data (e.g., number of deaths, hospitalizations) occurring in a study population for three multi-city studies (Krewski *et al.,* 2009; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008) and study population data were obtained for the same three studies and one additional study (Miller *et al.,* 2007) (U.S. EPA, 2011a, p. 2–71). If health event or study population data were available for additional studies, the EPA could employ distributional statistics to identify the broader range of $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in those studies.

[81] Long- and short-term exposure studies considered ''key'' studies for consideration are summarized in Figure 4 and include those studies observing effects for which the evidence supported a causal or likely causal association. This figure represents the subset of multi-city studies included in Figures 1 through 3 that provided evidence of positive and generally statistically significant effects associated in whole or in part with more recent air quality data, generally representing health effects associated with lower $PM_{2.5}$ concentrations than had previously been considered in the last review. The EPA notes that many of these studies evaluated multiple health endpoints, and not all of the effects evaluated provided evidence of positive and statistically significant effects. For purposes of informing the Administrator's decision on the appropriate standard levels, the Agency considers the full body of scientific evidence and focuses on those aspects of the key studies that provided evidence of positive and generally statistically significant effects.

[82] The long-term mean $PM_{2.5}$ concentrations reported by the study authors for the Miller *et al.* (2007) and Lipfert *et al.* (2006a) studies are discussed more fully in the Response to Comments document (U.S. EPA, 2012a).

Figure 4. Translating Epidemiological Evidence from Multi-City Exposure Studies into an Annual $PM_{2.5}$ Standard[82]



Source: U.S. EPA, 2011a, Figure 2-8

In considering the evidence, the Policy Assessment recognized that NAAQS are standards set so as to provide requisite protection, neither more nor less stringent than necessary to protect public health, with an adequate margin of safety. This judgment, ultimately made by the Administrator, involves weighing the strength of the evidence and the inherent uncertainties and limitations of that evidence. Therefore, depending on

the weight placed on different aspects of the evidence and inherent uncertainties, consideration of different alternative standard levels could be supported.

Given the currently available evidence discussed in more detail in section III.E.4.b of the proposal and considering the various approaches discussed above, the Policy Assessment concluded it was appropriate to focus on an annual standard level within a range of about 12 to 11 μg/m³ (U.S. EPA, 2011a, pp. 2–82, 2–101, and 2–106). As illustrated in Figure 4, the Policy Assessment recognized that a standard level of 12 μg/m³, at the upper end of this range, was somewhat below the long-term mean $PM_{2.5}$ concentrations reported in all the multi-city, long- and short-term exposure studies that provided evidence of positive and statistically significant associations with health effects classified as having evidence of a causal or likely causal relationship, including premature mortality and hospitalizations and emergency department visits for cardiovascular and respiratory effects as well as respiratory effects in children. Further, a level of 12 μg/m³ would reflect consideration of additional population-level information from such epidemiological studies in that it generally corresponded with approximately the 25th percentile of the available distributions of health events data in the studies for which population-level information was available. In addition, a level of 12 μg/m³ would reflect some consideration of studies that provided more limited evidence of reproductive and developmental effects, which were suggestive of a causal relationship, in that it was about at the same level as the lowest long-term mean $PM_{2.5}$ concentrations reported in such studies (see Figure 4).

Alternatively the Policy Assessment recognized that an annual standard level of 11 μg/m³, at the lower end of this range, was well below the lowest long-term mean $PM_{2.5}$ concentrations reported in all multi-city long- and short-term exposure studies that provide evidence of positive and statistically significant associations with health effects classified as having evidence of a causal or likely causal relationship. A level of 11 μg/m³ would reflect placing more weight on the distributions of health event and population data, in that this level was within the range of $PM_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of all the available distributions of such data. In addition, a level of 11 μg/m³ was somewhat below the lowest long-term mean $PM_{2.5}$ concentrations reported in reproductive and developmental effects studies that are suggestive of a causal relationship. Thus, a level of 11 μg/m³ would reflect an approach to translating the available evidence that places relatively more emphasis on margin of safety considerations and less certain causal relationships than would a standard set at a higher level. Such a policy approach would tend to weigh uncertainties in the evidence in such a way as to avoid potentially underestimating $PM_{2.5}$-related risks to public health. Further, recognizing the uncertainties inherent in identifying any particular point at which our confidence in reported associations becomes appreciably less, the Policy Assessment concluded that the available evidence did not provide a sufficient basis to consider alternative annual standard levels below 11 μg/m³ (U.S. EPA, 2011a, p. 2–81).

The Policy Assessment also considered the extent to which the available evidence provided a basis for considering alternative annual standard levels above 12 μg/m³. As discussed below, the Policy Assessment concluded that it could be reasonable to consider a standard level up to 13 μg/m³ based on a policy approach that weighed uncertainties in the evidence in such a way as to avoid potentially overestimating $PM_{2.5}$-related risks to public health, especially to the extent that primary emphasis was placed on long-term exposure studies as a basis for an annual standard level. A level of 13 μg/m³ was somewhat below the long-term mean $PM_{2.5}$ concentrations reported in all but one of the long-term exposure studies providing evidence of positive and statistically significant associations with $PM_{2.5}$-related health effects classified as having a causal or likely causal relationship. As shown in Figure 4, the one long-term exposure study with a long-term mean $PM_{2.5}$ concentration just below 13 μg/m³ was the Miller *et al.,* (2007) study. However, as noted in section III.D.1.a of the proposal and discussed in more detail in the Response to Comments document, the Policy Assessment observed that in comparison to other long-term exposure studies, the Miller *et al.* study was more limited in that it was based on only one year of air quality data and the one year was after the health outcomes were reported (U.S. EPA, 2011a, pp. 2–81 to 2–82). Thus, to the extent that less weight was placed on the Miller *et al.* study than on other long-term exposure studies with more robust air quality data, a level of 13 μg/m³ could be considered as being protective of long-term exposure related effects classified as having a causal or likely causal relationship. In also considering short-term exposure studies, however, the Policy Assessment noted that a level of 13 μg/m³ was below the long-term mean $PM_{2.5}$ concentrations reported in most but not all such studies. In particular, two studies—Burnett *et al.* (2004) and Bell *et al.* (2008)—reported long-term mean $PM_{2.5}$ concentrations of 12.8 and 12.9 μg/m³, respectively. In considering these studies, the Policy Assessment found no basis to conclude that these two studies were any more limited or uncertain than the other short-term exposure studies shown in Figures 3 and 4 (U.S. EPA, 2011a, p. 2–82). On this basis, as discussed below, the Policy Assessment concluded that consideration of an annual standard level of 13 μg/m³ would have implications for the degree of protection that would need to be provided by the 24-hour standard, in order that the suite of $PM_{2.5}$ standards, taken together, would provide appropriate protection from effects on public health related to short-term exposure to $PM_{2.5}$ (U.S. EPA, 2011a, p. 2–82).

The Policy Assessment also noted that a standard level of 13 μg/m³ would reflect a judgment that the uncertainties in the epidemiological evidence as summarized in section III.B above and discussed in more detail in section III.B.2 of the proposal, including uncertainties related to the heterogeneity observed in the epidemiological studies in the eastern versus western parts of the U.S., the relative toxicity of $PM_{2.5}$ components, and the potential role of co-pollutants, are too great to warrant placing any weight on the distributions of health event and population data that extend down below the long-term mean concentrations into the lower quartile of the data. This level would also reflect a judgment that the evidence from reproductive and developmental effects studies that is suggestive of a causal relationship was too uncertain to support consideration of any lower level.

Beyond evidence-based considerations, the Policy Assessment also considered the extent to which the quantitative risk assessment supported consideration of these alternative standard levels or provided support for lower levels. In considering simulations of just meeting alternative annual standard levels within the range of 13 to 11 μg/m³ (in conjunction with the current 24-hour standard level of 35 μg/m³), the Policy Assessment concluded that important public health improvements are associated with risk

reductions estimated for standard levels of 13 and 12 μg/m³ and noted that the level of 11 μg/m³ was not included in the quantitative risk assessment. The Policy Assessment noted that the overall confidence in the quantitative risk estimates varied for the different alternative standard levels evaluated and was stronger for the higher levels and substantially lower for the lowest level evaluated (i.e., 10 μg/m³). Based on the above considerations, the Policy Assessment concluded that the quantitative risk assessment provided support for considering alternative annual standard levels within a range of 13 to 11 μg/m³, but did not provide strong support for considering lower alternative standard levels (U.S. EPA, 2011a, pp. 2–102 to 2–103).

Taken together, the Policy Assessment concluded that consideration of alternative annual standard levels in the range of 13 to 11 μg/m³ may be appropriate. Furthermore, the Policy Assessment concluded that the currently available evidence most strongly supported consideration of an alternative annual standard level in the range of 12 to 11 μg/m³ (U.S. EPA, 2011a, p. 2–82). The Policy Assessment concluded that an alternative level within the range of 12 to 11 μg/m³ would more fully take into consideration the available information from all long- and short-term $PM_{2.5}$ exposure studies, including studies of at-risk populations, than would a higher level. This range also reflected placing weight on information from studies that helped to characterize the range of $PM_{2.5}$ concentrations over which we continue to have confidence in the associations observed in epidemiological studies, as well as the extent to which our confidence in the associations was appreciably less at lower concentrations.

As recognized in sections III.A.3 and III.E.4.a above, an annual standard intended to serve as the primary means for providing protection from effects associated with both long- and short-term $PM_{2.5}$ exposures is not expected to provide appropriate protection against the effects of all short-term $PM_{2.5}$ exposures (unless established at a level so low as to undoubtedly provide more protection than necessary for long-term exposures). Of particular concern are areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods. As a result, the Policy Assessment concluded that it was appropriate to consider alternative 24-hour $PM_{2.5}$ standard levels that would supplement the protection provided by an annual standard.

As outlined in section III.A.3 above, the Policy Assessment considered the available evidence from short-term $PM_{2.5}$ exposure studies, as well as the uncertainties and limitations in that evidence, to assess the degree to which alternative annual and 24-hour $PM_{2.5}$ standards can be expected to reduce the estimated risks attributed to short-term fine particle exposures. In considering the available epidemiological evidence, the Policy Assessment took into account information from multi-city studies as well as single-city studies. The Policy Assessment considered the distributions of 24-hour $PM_{2.5}$ concentrations reported in short-term exposure studies, focusing on the 98th percentile concentrations to match the form of the 24-hour standard as discussed in section III.E.3.b above. In recognizing that the annual and 24-hour standards work together to provide protection from effects associated with short-term $PM_{2.5}$ exposures, the Policy Assessment also considered information on the long-term mean $PM_{2.5}$ concentrations from these studies.

In addition to considering the epidemiological evidence, the Policy Assessment considered air quality information, specifically peak-to-mean ratios using county-level 24-hour and annual design values, to characterize air quality patterns in areas possibly associated with strong local or seasonal sources. These patterns helped in understanding the extent to which different combinations of annual and 24-hour standards would be consistent with the policy goal of setting a generally controlling annual standard with a 24-hour standard that provides supplemental protection especially for areas with high peak-to-mean ratios (U.S. EPA, 2011a, p. 2–14).

In considering the information provided by the short-term exposure studies, the Policy Assessment recognized that to the extent these studies were conducted in areas that likely did not meet one or both of the current standards, such studies did not help inform the characterization of the potential public health improvements of alternative standards set at lower levels. Therefore, in considering the short-term exposure studies to inform staff conclusions regarding levels of the 24-hour standard that are appropriate to consider, the Policy Assessment placed greatest weight on studies conducted in areas that likely met both the current annual and 24-hour standards.

With regard to multi-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures, as summarized in Figure 3 above and discussed in more detail in section III.E.4.c of the proposal, the Policy Assessment noted that, to the extent air quality distributions were reduced to reflect just meeting the current 24-hour standard, additional protection would be anticipated for the effects observed in the three multi-city studies with 98th percentile values greater than 35 μg/m³ (Burnett *et al.,* 2004; Burnett and Goldberg, 2003; Franklin *et al.,* 2008). In the three additional studies with 98th percentile values below 35 μg/m³, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 μg/m³, the Policy Assessment noted that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 μg/m³, respectively (Bell *et al.,* 2008; Zanobetti and Schwartz, 2009; Dominici *et al.,* 2006a). To the extent that consideration was given to revising the level of the annual standard, as discussed in section III.E.4.b of the proposal, the Policy Assessment recognized that potential changes associated with meeting such an alternative annual standard would result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures. Consequently, in considering a 24-hour standard that would operate in conjunction with an annual standard to provide appropriate public health protection, the Policy Assessment noted that to the extent that the level of the annual standard was revised to within a range of 13 to 11 μg/m³, in particular in the range of 12 to 11 μg/m³, additional protection would be provided for the long-term effects observed in these multi-city studies (U.S. EPA, 2011a, p. 2–84).

Based on this information, the Policy Assessment concluded that the multi-city, short-term exposure studies generally provided support for retaining the 24-hour standard level at 35 μg/m³ so long as the standard is in conjunction with an annual standard level revised to within a range of 12 to 11 μg/m³ (U.S. EPA, 2011a, p. 2–84). Alternatively, in conjunction with an annual standard level of 13 μg/m³, the Policy Assessment concluded that the multi-city studies provided limited support for revising the 24-hour standard level somewhat below 35 μg/m³, such as down to 30 μg/m³, based on one study (Bell *et al.,* 2008) that reported positive and statistically significant effects with an overall 98th percentile value below the level of the current 24-hour standard and an overall long-term mean concentration slightly less than 13 μg/m³ (Figure 3; U.S. EPA, 2011a, p. 2–84).

In reaching staff conclusions regarding alternative 24-hour standard levels that were appropriate to consider,

the Policy Assessment also took into account relevant information from single-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures. The Policy Assessment recognized that these studies may provide additional insights regarding impacts on at-risk populations and/or on areas with isolated peak concentrations.

As discussed in more detail in section III.E.4.c of the proposal, although a number of single-city studies reported effects at appreciably lower $PM_{2.5}$ concentrations than multi-city short-term exposure studies, the uncertainties and limitations associated with the single-city studies were considerably greater than those associated with the multi-city studies and, thus, the Policy Assessment concluded there was less confidence in using these studies as a basis for setting the level of a standard. Therefore, the Policy Assessment concluded that the multi-city short-term exposure studies provided the strongest evidence to inform decisions on the level of the 24-hour standard, and the single-city studies did not warrant consideration of 24-hour standard levels different from those supported by the multi-city studies (U.S. EPA, 2011a, p. 2–88).

In addition to considering the epidemiological evidence, the Policy Assessment took into account air quality information based on county-level 24-hour and annual design values to understand the public health implications of the alternative standard levels supported by the currently available scientific evidence, as discussed in this section. Consistent with the general approach discussed in section III.A.3 above, the Policy Assessment considered the extent to which different combinations of alternative annual and 24-hour standard levels based on the evidence would support the policy goal of lowering annual and 24-hour air quality distributions by using the annual standard to be the ''generally controlling'' standard in conjunction with setting the 24-hour standard to provide supplemental protection (U.S. EPA, 2011a, pp 2–88 to 2–91, Figure 2–10).

Using information on the relationship of the 24-hour and annual design values, the Policy Assessment examined the implications of three alternative suites of $PM_{2.5}$ standards identified as appropriate to consider based on the currently available scientific evidence, as discussed above. The Policy Assessment concluded that an alternative suite of $PM_{2.5}$ standards that would include an annual standard level of 11 or 12 μg/m³ and a 24-hour standard with a level of 35 μg/m³ (i.e., 11/35 or 12/35) would result in the annual standard being the generally controlling standard in most areas although the 24-hour standard would continue to be the generally controlling standard in the Northwest (U.S. EPA, 2011a, pp. 2–89 to 2–91 and Figure 2–10). These Northwest counties generally represented areas where the annual mean $PM_{2.5}$ concentrations have historically been low but where relatively high 24-hour concentrations occur, often related to seasonal wood smoke emissions. Alternatively, combining an alternative annual standard of 13 μg/m³ with a 24-hour standard of 30 μg/m³ would result in many more areas across the country in which the 24-hour standard would likely become the controlling standard (the standard driving air quality distributions lower) than if an alternative annual standard of 12 or 11 μg/m³ were paired with the current level of the 24-hour standard (i.e., 35 μg/m³).

The Policy Assessment concluded that consideration of retaining the 24-hour standard level at 35 μg/m³ would reflect placing greatest weight on evidence from multi-city studies that reported positive and statistically significant associations with health effects classified as having a causal or likely causal relationship. In conjunction with lowering the annual standard level, especially within a range of 12 to 11 μg/m³, this alternative recognized additional public health protection against effects associated with short-term $PM_{2.5}$ exposures which would be provided by lowering the annual standard such that revision to the 24-hour standard would not be warranted (U.S. EPA, 2011a, p. 2–91).

Beyond evidence-based considerations, the Policy Assessment also considered the extent to which the quantitative risk assessment supported consideration of retaining the current 24-hour standard level or provided support for lower standard levels. In considering simulations of just meeting the current 24-hour standard level of 35 μg/m³ or alternative levels of 30 or 25 μg/m³ (in conjunction with alternative annual standard levels within a range of 13 to 11 μg/m³), the Policy Assessment noted that the overall confidence in the quantitative risk estimates varied for the different standard levels evaluated and was stronger for the higher levels and substantially lower for the lowest level evaluated (i.e., 25 μg/m³). Based on this information, the Policy Assessment concluded that the quantitative risk assessment provided support for considering a 24-hour standard level of 35 or 30 μg/m³ (in conjunction with an alternative standard level within a range of 13 to 11 μg/m³) but did not provide strong support for considering lower alternative 24-hour standard levels (U.S. EPA, 2011a, pp. 2–102 to 2–103).

Taken together, the Policy Assessment concluded that while it was appropriate to consider an alternative 24-hour standard level within a range of 35 to 30 μg/m³, the currently available evidence most strongly supported consideration for retaining the current 24-hour standard level at 35 μg/m³ in conjunction with lowering the level of the annual standard within a range of 12 to 11 μg/m³ (U.S. EPA, 2011a, p. 2–92).

ii. CASAC Advice

Based on its review of the second draft Policy Assessment, CASAC agreed with the general approach for translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on alternative standards for consideration. Furthermore, CASAC agreed ''that it is appropriate to return to the strategy used in 1997 that considers the annual and the short-term standards together, with the annual standard as the controlling standard, and the short-term standard supplementing the protection afforded by the annual standard'' and ''considers it appropriate to place the greatest emphasis'' on health effects judged to have evidence supportive of a causal or likely causal relationship as presented in the Integrated Science Assessment (Samet, 2010d, p. 1).

CASAC concluded that the range of levels presented in the second draft Policy Assessment (i.e., alternative annual standard levels within a range of 13 to 11 μg/m³ and alternative 24-hour standard levels within a range of 35 to 30 μg/m³) ''are supported by the epidemiological and toxicological evidence, as well as by the risk and air quality information compiled'' in the Integrated Science Assessment, Risk Assessment, and second draft Policy Assessment. CASAC further noted that ''[a]lthough there is increasing uncertainty at lower levels, there is no evidence of a threshold (i.e., a level below which there is no risk for adverse health effects)'' (Samet, 2010d, p. ii).

Although CASAC supported the alternative standard level ranges presented in the second draft Policy Assessment, it did not express support for any specific levels or combinations of standards. Rather, CASAC encouraged the EPA to develop a clearer rationale in the final Policy Assessment for staff conclusions regarding annual

and 24-hour standards that were appropriate to consider, including consideration of the combination of these standards supported by the available information (Samet, 2010d, p. ii). Specifically, in commenting on a distributional statistical analysis of air quality and associated population data presented in the second draft Policy Assessment, CASAC encouraged staff to focus on information related to the concentrations that were most influential in generating the health effect estimates in individual studies to inform alternative standard levels. CASAC urged that the EPA redo that analysis using health event or study population data (Samet, 2010d, p. 2). CASAC also commented that the approach presented in the second draft Policy Assessment to identify alternative 24-hour standard levels which focused on peak-to-mean ratios was not relevant for informing the actual level (Samet 2010d, p. 4). Further, they expressed the concern that the combinations of annual and 24-hour standard levels discussed in the second draft Policy Assessment (i.e., in the range of 13 to 11 μg/m³ for the annual standard, in conjunction with retaining the current 24-hour $PM_{2.5}$ standard level of 35 μg/m³; alternatively, revising the level of the 24-hour standard to 30 μg/m³ in conjunction with an annual standard level of 11 μg/m³) ''may not be adequately inclusive'' and ''[i]t was not clear why, for example a daily standard of 30 μg/m³ should only be considered in combination with an annual level of 11 μg/m³'' (Samet, 2010d, p. ii). CASAC encouraged the EPA to more clearly explain its rationale for identifying the 24-hour/annual combinations that are appropriate for consideration (Samet 2010d, p. ii).

In considering CASAC's advice as well as public comment on the second draft Policy Assessment, the EPA staff conducted additional analyses and modified their conclusions regarding alternative standard levels that were appropriate to consider. The staff conclusions in the final Policy Assessment (U.S. EPA, 2011a, section 2.3.4.4) differed somewhat from the alternative standard levels discussed in the second draft Policy Assessment (U.S. EPA, 2010f, section 2.3.4.3), upon which CASAC based its advice. Changes made in the final Policy Assessment were primarily focused on improving and clarifying the approach for translating the epidemiological evidence into a basis for staff conclusions on the broadest range of alternative standard levels supported by the available scientific information and more clearly articulating the rationale for the staff's conclusions (Wegman, 2011, pp. 1 to 2). Consistent with CASAC's advice to consider more information from epidemiological studies, as discussed in section III.E.4.b.1 above, the EPA analyzed additional population-level data obtained from several study authors (Rajan *et al.,* 2011). In transmitting the final Policy Assessment to CASAC, the Agency notified CASAC that the final staff conclusions reflected consideration of CASAC's advice and that those staff conclusions were based, in part, on the specific distributional analysis that CASAC had urged the EPA to conduct (Wegman, 2011, p.2). Thus, CASAC had an opportunity to comment on the final Policy Assessment, but chose not to provide any additional comments or advice after receiving it.

iii. Administrator's Proposed Decisions on the Primary $PM_{2.5}$ Standard Levels

In reaching her conclusions regarding appropriate alternative standard levels to consider, the Administrator considered the epidemiological and other scientific evidence, estimates of risk reductions associated with just meeting alternative annual and/or 24-hour standards, air quality analyses, related limitations and uncertainties, staff conclusions as presented in the Policy Assessment, and the advice of CASAC. As an initial matter, the Administrator agreed with the general approach discussed in the Policy Assessment as summarized in sections III.A.3 and III.E.4.a above, and supported by CASAC, of considering the protection afforded by the annual and 24-hour standards taken together for mortality and morbidity effects associated with both long- and short-term exposures to $PM_{2.5}$ (77 FR 38939). Furthermore, based on the evidence and quantitative risk assessment, the Administrator provisionally concluded it is appropriate to set a ''generally controlling'' annual standard that will lower a wide range of ambient 24-hour concentrations, with a 24-hour standard focused on providing supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods. The Administrator provisionally concluded this approach would likely reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and would be the most effective and efficient way to reduce total $PM_{2.5}$-related population risk. *Id.*

In reaching decisions on alternative standard levels to propose, the Administrator judged that it was most appropriate to examine where the evidence of associations observed in the epidemiological studies was strongest and, conversely, where she had appreciably less confidence in the associations observed in the epidemiological studies. Based on the characterization and assessment of the epidemiological and other studies presented and assessed in the Integrated Science Assessment and the Policy Assessment, the Administrator recognized the substantial increase in the number and diversity of studies available in this review including extended analyses of the seminal studies of long-term $PM_{2.5}$ exposures (i.e., ACS and Harvard Six Cities studies) as well as important new long-term exposure studies (as summarized in Figures 1 and 2). Collectively, the Administrator noted that these studies, along with evidence available in the last review, provided consistent and stronger evidence of an association with premature mortality, with the strongest evidence related to cardiovascular-related mortality, at lower ambient concentrations than previously observed. The Administrator also recognized the availability of stronger evidence of morbidity effects associated with long-term $PM_{2.5}$ exposures, including evidence of cardiovascular effects from the WHI study and respiratory effects, including decreased lung function growth, from the extended analyses for the Southern California Children's Health Study. Furthermore, the Administrator recognized new U.S. multi-city studies that greatly expanded and reinforced our understanding of mortality and morbidity effects associated with short-term $PM_{2.5}$ exposures, providing stronger evidence of associations at ambient concentrations similar to those previously observed (as summarized in Figure 3). *Id.* at 38939–40.

The newly available scientific evidence built upon the previous scientific data base to provide evidence of generally robust associations and to provide a basis for greater confidence in the reported associations than in the last review. The Administrator recognized that the weight of evidence, as evaluated in the Integrated Science Assessment, was strongest for health endpoints classified as having evidence of a causal relationship. These relationships included those between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects. She recognized that the weight of evidence was also

strong for health endpoints classified as having evidence of a likely causal relationship, which included those between long- and short-term $PM_{2.5}$ exposures and respiratory effects. In addition, the Administrator made note of the much more limited evidence for health endpoints classified as having evidence suggestive of a causal relationship, including developmental, reproductive and carcinogenic effects. *Id.* at 38940.

Based on information discussed and presented in the Integrated Science Assessment, the Administrator recognized that health effects may occur over the full range of concentrations observed in the long- and short-term epidemiological studies and that no discernible threshold for any effects can be identified based on the currently available evidence (U.S. EPA, 2009a, section 2.4.3). She also recognized, in taking note of CASAC advice and the distributional statistics analysis discussed in section III.E.4.b.i above and in the Policy Assessment, that there was significantly greater confidence in observed associations over certain parts of the air quality distributions in the studies, and conversely, that there was significantly diminished confidence in ascribing effects to concentrations toward the lower part of the distributions.

Consistent with the general approach summarized in section III.A.3 above, and supported by CASAC as discussed in section III.E.4.a above, the Administrator generally agreed that it was appropriate to consider a level for an annual standard that was somewhat below the long-term mean $PM_{2.5}$ concentrations reported in long- and short-term exposure studies. In recognizing that the evidence of an association in any such study was strongest at and around the long-term average where the data in the study are most concentrated, she understood that this approach did not provide a bright line for reaching decisions about appropriate standard levels. The Administrator noted that long-term mean $PM_{2.5}$ concentrations were available for each study considered and, therefore, represented the most robust data set to inform her decisions on appropriate annual standard levels. She also noted that the overall study mean $PM_{2.5}$ concentrations were generally calculated based on monitored concentrations averaged across monitors in each study area with multiple monitors, referred to as a composite monitor concentration, in contrast to the highest concentration monitored in each study area, referred to as a maximum monitor concentration, which are used to determine whether an area meets a given standard. In considering such long-term mean concentrations, the Administrator understood that it was appropriate to consider the weight of evidence for the health endpoints evaluated in such studies in giving weight to this information. *Id.*

Based on the information summarized in Figure 4 above and presented in more detail in the Policy Assessment (U.S. EPA, 2011a, chapter 2) for effects classified in the Integrated Science Assessment as having a causal or likely causal relationship with $PM_{2.5}$ exposures, the Administrator observed an overall pattern of statistically significant associations reported in studies of long-term $PM_{2.5}$ exposures with long-term mean concentrations ranging from somewhat above the current standard level of 15 μg/m³ down to the lowest mean concentration in such studies of 12.9 μg/m³ (in Miller *et al.,* 2007).[83] She observed a similar pattern of statistically significant associations in studies of short-term $PM_{2.5}$ exposures with long-term mean concentrations ranging from around 15 μg/m³ down to 12.8 μg/m³ (in Burnett *et al.,* 2004). With regard to effects classified as providing evidence suggestive of a causal relationship, the Administrator observed a small number of long-term exposure studies related to developmental and reproductive effects that reported statistically significant associations with overall study mean $PM_{2.5}$ concentrations down to 11.9 μg/m³ (in Bell *et al.,* 2007).[84] *Id.*

The Administrator also considered additional information from epidemiological studies, consistent with CASAC advice, to take into account the broader distribution of $PM_{2.5}$ concentrations and the degree of confidence in the observed associations over the broader air quality distribution. In considering this additional information, she understood that the Policy Assessment presented information on the 25th and 10th percentiles of the distributions of $PM_{2.5}$ concentrations available from four multi-city studies to provide a general frame of reference as to the part of the distribution in which the data become appreciably more sparse and, thus, where her confidence in the associations observed in epidemiological studies would become appreciably less.

As summarized in Figure 4 above, the Administrator took note of additional population-level data that were available for four studies (Krewski *et al.,* 2009; Miller *et al.,* 2007; Bell *et al.,* 2008; Zanobetti and Schwartz, 2009), each of which reported statistically significant associations with health endpoints classified as having evidence of a causal relationship. In considering the long-term $PM_{2.5}$ concentrations associated with the 25th percentile values of the population-level data for these four studies, she observed that these values ranged from somewhat above to somewhat below 12 μg/m³. The Administrator recognized that these studies include some of the strongest evidence available within the overall body of scientific evidence and noted that three of these studies (Krewski *et al.,* 2009; Bell *et al.,* 2008; Zanobetti and Schwartz, 2009) were used as the basis for concentration-response functions used in the quantitative risk assessment (U.S. EPA, 2010a, section 3.3.3).

In considering this information, the Administrator noted that CASAC advised that information about the long-term $PM_{2.5}$ concentrations that were most influential in generating the health effect estimates in epidemiological studies can help to inform selection of an appropriate annual standard level. However, the Administrator also recognized that additional population-level data were available for only these four studies and, therefore, she believed that these studies comprised a more limited data set than one based on long-term mean $PM_{2.5}$ concentrations for which data were available for all studies considered, as discussed above.

The Administrator recognized, as summarized in section III.B above, that important uncertainties remain in the evidence and information considered in this review of the primary fine particle standards. These uncertainties are generally related to understanding the relative toxicity of the different components in the fine particle mixture, the role of $PM_{2.5}$ in the complex ambient mixture, exposure measurement errors inherent in epidemiological studies based on concentrations measured at

[83] The EPA notes that the Miller *et al.,* (2007) study provides strong evidence of cardiovascular related effects associated with long-term $PM_{2.5}$ exposures. At the time of the proposal, the EPA recognized the limited nature of the air quality data considered in this study (77 FR 38918, fn. 62). The EPA has reviewed those limitations, in conjunction with consideration of public comments received on the proposal as discussed in section III.E.4.c, in conjunction with reaching a final decision on the level of the annual standard.

[84] With respect to suggestive evidence related to cancer, mutagenic, and genotoxic effects, the $PM_{2.5}$ concentrations reported in studies generally included ambient concentrations that are equal to or greater than ambient concentrations observed in studies that reported mortality and cardiovascular and respiratory effects (U.S. EPA, 2009a, section 7.5), such that in selecting alternative standard levels that provide protection from mortality and cardiovascular and respiratory effects, it is reasonable to anticipate that protection will also be provided for carcinogenic effects.

fixed monitor sites, and the nature, magnitude, and confidence in estimated risks related to increasingly lower ambient $PM_{2.5}$ concentrations. Furthermore, the Administrator noted that epidemiological studies have reported heterogeneity in responses both within and between cities and geographic regions across the U.S. She recognized that this heterogeneity may be attributed, in part, to differences in fine particle composition in different regions and cities. The Administrator also recognized that there are additional limitations associated with evidence for reproductive and developmental effects, identified as being suggestive of a causal relationship with long-term $PM_{2.5}$ exposures, including: the limited number of studies evaluating such effects; uncertainties related to identifying the relevant exposure time periods of concern; and limited toxicological evidence providing little information on the mode of action(s) or biological plausibility for an association between long-term $PM_{2.5}$ exposures and adverse birth outcomes. *Id.* at 38941.

The Administrator was mindful that considering what standards were requisite to protect public health with an adequate margin of safety required public health policy judgments that neither overstated nor understated the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. In considering how to translate the available information into appropriate standard levels, the Administrator weighed the available scientific information and associated uncertainties and limitations. For the purpose of determining what standard levels were appropriate to propose, the Administrator recognized, as did EPA staff in the Policy Assessment, that there was no single factor or criterion that comprised the sole ''correct'' approach to weighing the various types of available evidence and information, but rather there were various approaches that are appropriate to consider. The Administrator further recognized that different evaluations of the evidence and other information before the Administrator could reflect placing different weight on the relative strengths and limitations of the scientific information, and different judgments could be made as to how such information should appropriately be used in making public health policy decisions on standard levels. This recognition led the Administrator to consider various approaches to weighing the evidence so as to identify appropriate standard levels to propose. In so doing, the Administrator encouraged extensive public comment on alternative approaches to weighing the evidence and other information so as to inform her public health policy judgments before reaching final decisions on appropriate standard levels.

In considering the available information, the Administrator noted the advice of CASAC that the currently available scientific information, including epidemiological and toxicological evidence as well as risk and air quality information, provided support for considering an annual standard level within a range of 13 to 11 $\mu g/m^3$ and a 24-hour standard level within a range of 35 to 30 $\mu g/m^3$. In addition, the Administrator recognized that the Policy Assessment concluded that the available evidence and risk-based information support consideration of annual standard levels in the range of 13 to 11 $\mu g/m^3$, and that the Policy Assessment also concluded that the evidence most strongly supported consideration of an annual standard level in the range of 12 to 11 $\mu g/m^3$. In considering how the annual and 24-hour standards work together to provide appropriate public health protection, the Administrator observed that CASAC did not express support for any specific levels or combinations of standards within these ranges. Nor did CASAC choose to comment on additional information and analyses presented in the final Policy Assessment prepared in response to CASAC's recommendations on the second draft Policy Assessment (Wegman, 2011).

In considering the extent to which the currently available evidence and information provided support for specific standard levels within the ranges identified by CASAC and the Policy Assessment as appropriate for consideration, the Administrator initially considered standard levels within the range of 13 to 11 $\mu g/m^3$ for the annual standard. In so doing, the Administrator first considered the long-term mean $PM_{2.5}$ concentrations reported in studies of effects classified as having evidence of a causal or likely causal relationship, as summarized in Figure 4 above and discussed more broadly above. She noted that a level at the upper end of this range would be below most but not all the overall study mean concentrations from the multi-city studies of long- and short-term exposures, whereas somewhat lower levels within this range would be below all such overall study mean concentrations. In considering the appropriate weight to place on this information, the Administrator again noted that the evidence of an association in any such study was strongest at and around the long-term average where the data in the study are most concentrated, and that long-term mean $PM_{2.5}$ concentrations were available for each study considered and, therefore, represented the most robust data set to inform her decisions on appropriate annual standard levels. Further, she was mindful that this approach did not provide a bright line for reaching decisions about appropriate standard levels. *Id.*

In considering the long-term mean $PM_{2.5}$ concentrations reported in studies of effects classified as having evidence suggestive of a causal relationship, as summarized in Figure 4 for reproductive and developmental effects, the Administrator noted that a level at the upper end of this range would be below the overall study mean concentration in one of the three studies, while levels in the mid- to lower part of this range would be below the overall study mean concentrations in two or three of these studies. In considering the appropriate weight to place on this information, the Administrator noted the very limited nature of this evidence of such effects and the additional uncertainties in these epidemiological studies relative to the studies that provide evidence of causal or likely causal relationships.

The Administrator also considered the distributional analyses of population-level information that were available from four of the epidemiological studies that provide evidence of effects identified as having a causal relationship with long- or short-term $PM_{2.5}$ concentrations for annual standard levels within the same range of 13 to 11 $\mu g/m^3$. In so doing, the Administrator first noted that a level in the mid-part of this range generally corresponds with approximately the 25th percentile of the distributions of health events data available in three of these studies. The Administrator also noted that standard levels toward the upper part of this range would reflect placing substantially less weight on this information, whereas standard levels toward the lower part of this range would reflect placing substantially more weight on this information. In considering this information, the Administrator noted that there was no bright line that delineates the part of the distribution of $PM_{2.5}$ concentrations within which the data become appreciably more sparse and, thus, where her confidence in the associations observed in epidemiological studies became appreciably less.

In considering mean $PM_{2.5}$ concentrations and distributional

analyses from the various sets of epidemiological studies noted above, the Administrator was mindful, as noted above, that such studies typically report concentrations based on composite monitor distributions, in which concentrations may be averaged across multiple ambient monitors that may be present within each area included in a given study. Thus, a policy approach that used data based on composite monitors to identify potential alternative standard levels would inherently build in a margin of safety of some degree relative to an alternative standard level based on measurements at the monitor within an area that records the highest concentration, or the maximum monitor, since once a standard was set, concentrations at appropriate maximum monitors within an area were generally used to determine whether an area meets a given standard.

The Administrator also recognized that judgments about the appropriate weight to place on any of the factors discussed above should reflect consideration not only of the relative strength of the evidence but also on the important uncertainties that remained in the evidence and information being considered in this review. The Administrator noted that the extent to which these uncertainties influenced judgments about appropriate annual standard levels within the range of 13 to 11 μg/m^3 would likely be greater for standard levels in the lower part of this range which would necessarily be based on fewer available studies than would higher levels within this range.

Based on the above considerations, the Administrator concluded that it was appropriate to propose to set a level for the primary annual $PM_{2.5}$ standard within the range of 12 to 13 μg/m^3. The Administrator provisionally concluded that a standard set within this range would reflect alternative approaches to appropriately placing the most weight on the strongest available evidence, while placing less weight on much more limited evidence and on more uncertain analyses of information available from a relatively small number of studies. Further, she provisionally concluded that a standard level within this range would reflect alternative approaches to appropriately providing an adequate margin of safety for the populations at risk for the serious health effects classified as having evidence of a causal or likely causal relationship, depending in part on the emphasis placed on margin of safety considerations. The Administrator recognized that setting an annual standard level at the lower end of this range would reflect an approach that placed more emphasis on the entire body of the evidence, including the analysis of the distribution of air quality concentrations most influential in generating health effect estimates in the studies, and on margin of safety considerations, than would setting a level at the upper end of the range. Conversely, an approach that would support a level at the upper end of this range would generally support a view that the uncertainties remaining in the evidence are such that the evidence does not warrant setting a lower annual standard level. *Id.* at 38942.

At the time of the proposal, while the Administrator recognized that CASAC advised, and the Policy Assessment concluded, that the available scientific information provided support for considering a range that extended down to 11 μg/m^3, she concluded that proposing such an extended range would reflect a public health policy approach that placed more weight on relatively limited evidence and more uncertain information and analyses than she considered appropriate at this time. Nonetheless, the Administrator solicited comment on a level down to 11 μg/m^3 as well as on approaches for translating scientific evidence and rationales that would support such a level. Such an approach might reflect a view that the uncertainties associated with the available scientific information warrant a highly precautionary public health policy response that would incorporate a large margin of safety.

The Administrator recognized that potential air quality changes associated with meeting an annual standard set at a level within the range of 12 to 13 μg/m^3 will result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures. However, the Administrator recognized that such an annual standard intended to serve as the primary means for providing protection from effects associated with both long- and short-term $PM_{2.5}$ exposures would not by itself be expected to offer requisite protection with an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures. As a result, in conjunction with proposing an annual standard level in the range of 12 to 13 μg/m^3, the Administrator provisionally concluded that it was appropriate to continue to provide supplemental protection by means of a 24-hour standard set at the appropriate level, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or for $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods.

Based on the approach discussed in section III.A.3 above, at the time of the proposal the Administrator relied upon evidence from the short-term exposure studies as the principal basis for selecting the level of the 24-hour standard. In considering these studies as a basis for the level of a 24-hour standard, and having selected a 98th percentile form for the standard, the Administrator agreed with the focus in the Policy Assessment of looking at the 98th percentile values, as well as at the long-term mean $PM_{2.5}$ concentrations in these studies.

In considering the information provided by the short-term exposure studies, the Administrator recognized that to the extent these studies were conducted in areas that likely did not meet one or both of the current standards, such studies did not help inform the characterization of the potential public health improvements of alternative standards set at lower levels. By reducing the $PM_{2.5}$ concentrations in such areas to just meet the current standards, the Administrator anticipated that additional public health protection would occur. Therefore, the Administrator focused on studies that reported positive and statistically significant associations in areas that would likely have met both the current 24-hour and annual standards. She also considered whether or not these studies were conducted in areas that would likely have met an annual standard level of 12 to 13 μg/m^3 to inform her decision regarding an appropriate 24-hour standard level. As discussed in section III.E.4.a, consistent with the Policy Assessment, the Administrator concluded that multi-city, short-term exposure studies provided the strongest data set for informing her decisions on appropriate 24-hour standard levels. The Administrator viewed the single-city, short-term exposure studies as a much more limited data set providing mixed results and, therefore, she had less confidence in using those studies as a basis for setting the level of a 24-hour standard. With regard to the limited number of single-city studies that reported positive and statistically significant associations for a range of health endpoints related to short-term $PM_{2.5}$ concentrations in areas that would likely have met the current suite of $PM_{2.5}$ standards, the Administrator recognized that many of those studies had significant limitations (e.g., limited statistical power, limited exposure data) or equivocal results (mixed results within the same study area) that made them unsuitable to form the basis for setting the level of a 24-hour standard.

With regard to multi-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures, the Administrator observed an overall pattern of positive and statistically significant associations in studies with 98th percentile values averaged across study areas in the range of 45.8 to 34.2 μg/m³ (Burnett *et al.,* 2004; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008; Dominici *et al.,* 2006a, Burnett and Goldberg, 2003; Franklin *et al.,* 2008). The Administrator noted that, to the extent air quality distributions were reduced to reflect just meeting the current 24-hour standard, additional protection would be anticipated for the effects observed in the three multi-city studies with 98th percentile values greater than 35 μg/m³ (Burnett *et al.,* 2004; Burnett and Goldberg, 2003; Franklin *et al.,* 2008). In the three additional studies with 98th percentile values below 35 μg/m³, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 μg/m³, the Administrator noted that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 μg/m³, respectively (Bell *et al.,* 2008; Zanobetti and Schwartz, 2009; Dominici *et al.,* 2006a).

In proposing to revise the level of the annual standard to within the range of 12 to 13 μg/m³, as discussed above, the Administrator recognized that additional protection would be provided for the short-term effects observed in these multi-city studies in conjunction with an annual standard level of 12 μg/m³, and in two of these three studies in conjunction with an annual standard level of 13 μg/m³. She noted that the study-wide mean concentrations were based on averaging across monitors within study areas and that compliance with the standard would be based on concentrations measured at the monitor reporting the highest concentration within each area. The Administrator believed it would be reasonable to conclude that revision to the 24-hour standard would not be appropriate in conjunction with an annual standard within this range. Based on the above considerations related to the epidemiological evidence, the Administrator provisionally concluded that it was appropriate to retain the level of the 24-hour standard at 35 μg/m³, in conjunction with a revised annual standard level in the proposed range of 12 to 13 μg/m³.

In addition to considering the epidemiological evidence, the Administrator also took into account air quality information based on county-level 24-hour and annual design values to understand the public health implications of retaining the 24-hour standard level at 35 μg/m³ in conjunction with an annual standard level within the proposed range of 12 to 13 μg/m³. She considered whether these suites of standards would meet a public health policy goal which included setting the annual standard to be the ''generally controlling'' standard in conjunction with setting the 24-hour standard to provide supplemental protection to the extent that additional protection is warranted. As discussed above, the Administrator provisionally concluded that this approach was the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures, resulting in more uniform protection across the U.S. than the alternative of setting the 24-hour standard to be the controlling standard.

In considering the air quality information, the Administrator first recognized that there was no annual standard within the proposed range of levels, when combined with a 24-hour standard at the proposed level of 35 μg/m³, for which the annual standard would be the generally controlling standard in all areas of the country. She further observed that such a suite of $PM_{2.5}$ standards with an annual standard level of 12 μg/m³ would result in the annual standard as the generally controlling standard in most regions across the country, except for certain areas in the Northwest, where the annual mean $PM_{2.5}$ concentrations have historically been low but where relatively high 24-hour concentrations occur, often related to seasonal wood smoke emissions (U.S. EPA, 2011a, pp. 2–89 to 2–91, Figure 2–10). Although not explicitly delineated on Figure 2–10 in the Policy Assessment, an annual standard of 13 μg/m³ would be somewhat less likely to be the generally controlling standard in some regions of the U.S. outside the Northwest in conjunction with a 24-hour standard level of 35 μg/m³.

Taking the above considerations into account, the Administrator proposed to revise the level of the primary annual $PM_{2.5}$ standard from 15.0 μg/m³ to within the range of 12.0 to 13.0 μg/m³ and to retain the 24-hour standard level at 35 μg/m³. In the Administrator's judgment, such a suite of primary $PM_{2.5}$ standards and the rationale supporting such levels could reasonably be judged to reflect alternative approaches to the appropriate consideration of the strength of the available evidence and other information and their associated uncertainties and the advice of CASAC.

The Administrator recognized that the final suite of standards selected from within the proposed range of annual standard levels, or the broader range of annual standard levels on which public comment was solicited, must be clearly responsive to the issues raised by the DC Circuit's remand of the 2006 primary annual $PM_{2.5}$ standard. Furthermore, at the time of the proposal, she recognized that the final suite of standards will reflect her ultimate judgment in the final rulemaking as to the suite of primary $PM_{2.5}$ standards that would be requisite to protect the public health with an adequate margin of safety from effects associated with fine particle exposures. The final judgment to be made by the Administrator will appropriately consider the requirement for a standard that is neither more nor less stringent than necessary and will recognize that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

At the time of the proposal, having reached her provisional judgment to propose revising the annual standard level from 15.0 to within a range of 12.0 to 13.0 μg/m³ and to propose retaining the 24-hour standard level at 35 μg/m³, the Administrator solicited public comment on this range of levels and on approaches to considering the available evidence and information that would support the choice of levels within this range. The Administrator also solicited public comment on alternative annual standard levels down to 11 μg/m³ and on the combination of annual and 24-hour standards that commenters may believe is appropriate, along with the approaches and rationales used to support such levels. In addition, given the importance the evidence from epidemiologic studies played in considering the appropriate annual and 24-hour levels, the Administrator solicited public comment on issues related to translating epidemiological evidence into standards, including approaches for addressing the uncertainties and limitations associated with this evidence.

c. Comments on Standard Levels

This section addresses comments that relate to consideration of the appropriate levels of the primary annual and 24-hour $PM_{2.5}$ standards, including comments on the general approach used by the EPA to translate the available scientific information into standard levels and how specific $PM_{2.5}$ exposure studies should be considered as a basis for the standard levels. These comments on standard levels expand upon the more general comments that either supported or opposed any change to the current suite of primary $PM_{2.5}$

standards, which are addressed above in section III.D.2.[85] As explained there, one group of commenters generally opposed any change to the current primary $PM_{2.5}$ standards and more specifically disagreed with the basis for the EPA's proposal to revise the annual standard level. Another group of commenters supported revising the current suite of primary $PM_{2.5}$ standards to provide increased public health protection. Some commenters in this second group argued that both the annual and 24-hour standard levels should be lowered while other commenters in this group agreed with the EPA's proposal to retain the level of the 24-hour standard in conjunction with revising the level of the annual standard. While generally supporting the EPA's proposal to lower the level of the annual standard, many commenters in this group disagreed that a level within the EPA's proposed range was adequately protective and supported a level of 11 μg/m³ or below.

i. Annual Standard Level

The group of commenters opposed to any change to the current suite of primary $PM_{2.5}$ standards generally raised questions regarding the underlying scientific evidence, including the causal determinations reached in the Integrated Science Assessment, and focused strongly on the uncertainties they saw in the scientific evidence as a basis for their conclusion that no changes to the current standard levels were warranted. In commenting on the proposed standard levels, these commenters typically relied on the arguments summarized and addressed above in section III.D.2 as to why they believed it was inappropriate for the EPA to make any revisions to the suite of primary $PM_{2.5}$ standards. That is, they asserted that the EPA's causal determinations were not adequately supported by the underlying scientific information; the biological plausibility of health effects observed in epidemiological studies has not been demonstrated in controlled human exposure and toxicological studies; uncertainties in the underlying health science are as great or greater than in 2006; there is no evidence of greater risk since the last review to justify tightening the current annual $PM_{2.5}$ standard; and ''new'' studies not included in the Integrated Science Assessment continue to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$.

With regard to the level of the annual standard, these commenters strongly disagreed with the Agency's proposed decision to revise the level to within a range of 12 to 13 μg/m³ and argued that the current standard level of 15 μg/m³ should be retained. For example, UARG, API, and other commenters in this group raised a number of issues that they asserted called into question the EPA's interpretation of the epidemiological evidence to support revising the annual standard level. These commenters raised specific questions related to the general approach used by the EPA to translate the air quality and other information from specific epidemiological studies into standard levels, including: (1) The EPA's approach for using composite monitor air quality distributions reported in epidemiological studies to select a standard level that would be compared to measurements at the monitor recording the highest value in an area to determine compliance with the standard; (2) the appropriate exposure period for effects observed in long-term exposure mortality studies; and (3) the use of the EPA's analysis of distributions of underlying population-level data (i.e., health event and study population data) for those epidemiological studies for which such information was available. These commenters also raised questions regarding the EPA's consideration of specific scientific evidence as a basis for setting a standard level, including: (4) evidence of respiratory morbidity effects in long-term exposure studies and (5) more limited evidence of health effects which have been categorized in the Integrated Science Assessment as *suggestive* of a causal relationship (i.e., developmental and reproductive outcomes). These comments are discussed in turn below.

(1) Some commenters in this group argued that one reason why they believe there is no basis for setting a standard level below 15 μg/m³ is that the air quality metric from epidemiological studies that the EPA relied on in the proposal is not the same metric that will be compared to the level of the standard to determine compliance with the standard. That is, commenters noted that the long-term mean $PM_{2.5}$ concentrations that the EPA considered, shown in Figure 4 above, are *composite monitor* mean concentrations (i.e., concentrations averaged across multiple monitors within areas with more than one monitor), whereas the $PM_{2.5}$ concentrations that will be compared to the level of the standard are *maximum monitor* concentrations (i.e., the concentration measured by the monitor within an area reporting the highest concentration). This comment was presented most specifically in UARG's comments (UARG, 2012, Attachment 1, pp. 2 to 6), which raised two overarching issues as discussed below.

First, the commenter noted that the EPA's approach of considering composite monitor mean $PM_{2.5}$ concentrations in selecting a standard level, and then comparing the maximum monitor mean $PM_{2.5}$ concentration in each area to the standard level when the standard is implemented, was characterized in the proposal as inherently having the potential to build in a margin of safety (UARG, 2012, Attachment 1, p. 4, citing 77 FR 38905). The commenter asserted that the Administrator is ignoring this distinction between composite and maximum monitor concentrations, and that this approach creates an unwarranted case for lowering the standard level, since in the commenter's view, it would result in a margin of safety that would be arbitrary, not based on evidence, and unquantified (UARG, 2012, Attachment 1, p. 4). In support of this view, the commenter asserted that there is a significant difference between composite monitor mean $PM_{2.5}$ concentrations and maximum monitor mean $PM_{2.5}$ concentrations. The commenter asserted that the maximum monitor value will always be higher than the composite monitor value (except in areas that contain only a single monitor), such that when an area just attains the NAAQS, that area's composite monitor long-term mean $PM_{2.5}$ concentration will be lower than the level of the standard (UARG, 2012, Attachment 1, p. 3).

Second, the commenter asserted that a more ''reasoned and consistent approach would be to decide on a mean composite monitor $PM_{2.5}$ level that should be achieved and then identify the maximum monitor level that would result in that composite value'' (UARG, 2012, Attachment 1, p. 4). The commenter conducted an analysis of maximum monitor versus composite monitor annual mean $PM_{2.5}$ concentrations using monitoring data[86] from 2006 to 2008 and presented results averaged across areas within two groups (i.e., those with design values[87] above the current standard level and those with design values just below the

[85] Specific comments on the forms of the annual and 24-hour standards are addressed in section III.E.3.a and III.E.3.b, respectively.

[86] The commenter indicated that this analysis was based on monitoring data for every core based statistical area (CBSA) in the EPA's Air Quality System (AQS) database.

[87] The design value is the air quality statistic that is compared to the level of the NAAQS to determine the attainment status of a given area.

current standard level) to illustrate their suggested alternative approach. The commenter interpreted this analysis as showing that the composite monitor long-term mean $PM_{2.5}$ concentrations from the subset of the epidemiological studies shown in Figure 4 (of the proposal and above) that the commenter considered to be an appropriate focus for this analysis would be achieved across the U.S. if the current annual NAAQS of 15 μg/m³ is retained and attained. The commenter considered the subset of epidemiological studies that included only long-term exposures studies of effects for which the evidence is categorized as causal or likely causal, but did not consider short-term exposure studies. On this basis, the commenter asserted that attaining the current annual $PM_{2.5}$ standard would result in composite monitor long-term mean concentrations in all areas that would be generally within or below the range of the composite monitor long-term mean concentrations from such studies and, as a result, there is no reason to lower the level of the current annual NAAQS.

In considering the first issue related to the EPA's approach, the EPA notes that in proposing to revise both the form and level of the annual standard, the Administrator clearly took into account the distinction between the composite monitor long-term mean $PM_{2.5}$ concentrations from the epidemiological studies, considered as a basis for selecting an annual standard level, and maximum monitor long-term mean $PM_{2.5}$ concentrations. In deciding to focus on the composite monitor long-term mean concentrations in selecting the standard level, and on the maximum monitor concentrations in selecting the form of the standard (i.e., consistent with proposing to eliminate the option for spatial averaging across monitors within an area when implementing the standard [88]), the Administrator reasonably considered the distinction between these metrics in a manner that was consistent with advice from CASAC (Samet *et al.,* 2010d, pp. 2 to 3).

As noted above in section III.A.3, the EPA recognizes that a statistical metric (e.g., the mean of a distribution) based on maximum monitor concentrations may be identical to or above the same statistical metric based on composite monitor concentrations. More specifically, many areas have only one monitor, in which case the composite and maximum monitor concentrations are identical. Based on the most recent data from the EPA's AQS from 2009 to 2011 in the 331 CBSAs in which valid $PM_{2.5}$ data are available, as discussed in Frank (2012a, Table 5), there were 208 such areas (with design values ranging up to about 15 μg/m³). Frank (2012a) also observed that other areas have multiple monitors with composite and maximum monitor mean $PM_{2.5}$ concentrations that were the same or relatively close, with 57 areas in which the maximum monitor mean concentration was no more than 0.5 μg/m³ higher than the composite monitor mean concentration and 56 areas in which the difference was between 0.6 and 2 μg/m³. Further, there were only a few other areas in which the maximum monitor mean concentration was appreciably higher than the composite monitor mean concentration, such as areas in which some monitors may be separately impacted by local sources. There were only 10 such areas in the country in which the maximum monitor mean concentration was between 2 to 6 μg/m³ higher than the composite monitor concentration (Frank, 2012a, Table 4).[89] Thus, the EPA does not agree that there is a significant difference between composite monitor mean $PM_{2.5}$ concentrations and maximum monitor mean $PM_{2.5}$ concentrations in the large majority of areas across the country.

In proposing to revise the form of the annual $PM_{2.5}$ standard, as discussed above in section III.E.3.a, the EPA noted that when an annual $PM_{2.5}$ standard was first set in 1997, the form of the standard included the option for averaging across measurements at appropriate monitoring sites within an area, generally consistent with the composite monitor approach used in epidemiological studies, with some constraints intended to ensure that spatial averaging would not result in inequities in the level of protection for communities within large metropolitan areas. In the last review the EPA tightened the constraints on spatial averaging, and in this review has eliminated the option altogether, on the basis of analyses in each review that showed that such constraints may be inadequate to avoid substantially greater exposures for people living in locations around the monitors recording the highest $PM_{2.5}$ concentrations in some areas, potentially resulting in disproportionate impacts on at-risk populations of persons with lower SES levels as well as minorities. In light of these analyses, and consistent with the Administrator's decision to revise the form of the annual $PM_{2.5}$ standard by eliminating the option for spatial averaging, the EPA continues to conclude that a standard level based on consideration of long-term mean concentrations from composite monitors, and applied at each monitor within an area including the monitor measuring the highest concentration, is the appropriate approach to use in setting a standard that will protect public health, including the health of at-risk populations, with an adequate margin of safety, as required by the CAA.

The EPA acknowledges that at proposal, the Agency characterized the approach of using maximum monitor concentrations to determine compliance with the standard, while selecting the standard level based on consideration of composite monitor concentrations, as one that inherently had the potential to build in a margin of safety (77 FR 38905), and CASAC reiterated that view in supporting the EPA's approach (Samet, 2010d, p. 3). Nonetheless, in light of the discussion above, the EPA more specifically recognizes that this approach does not build in any margin of safety in the large number of areas across the country with only one monitor. Further, based on the analyses done to inform consideration of the form of the standard (Schmidt, 2011, Analysis A), the EPA concludes that this approach does not provide a margin of safety for the at-risk populations that live around the monitor measuring the highest concentration, such as in those few areas in which the maximum monitor concentration is appreciably higher than the composite monitor concentration. Rather, this approach properly treats those at-risk populations the same way it does the broader populations that live in areas with only one monitor, by providing the same degree of protection for those at-risk populations that would otherwise be disproportionately impacted as it does for the broader populations in other areas, While the EPA recognizes that this approach can result in some additional margin of safety for the subset of areas with multiple monitors in which at-risk populations may not be disproportionately represented in areas around the maximum monitor, which may be the case in areas with relatively small differences between the maximum and composite monitor concentrations, the EPA notes that this margin would be relatively small in such areas.

Based on the above considerations, the EPA does not agree that the Agency's approach of using maximum monitor concentrations to determine compliance with the standard, while

[88] As discussed above in section III.E.3.a.

[89] The average difference between the maximum and composite design value among the 123 CBSAs with two or more monitors is 0.8 μg/m³ and the median difference is 0.6 μg/m³. The 25th and 75th percentiles are 0.3 and 1.0 μg/m³, respectively (Frank, 2012a, p. 4).

selecting the standard level based on consideration of composite monitor concentrations creates an unwarranted case for lowering the standard level based on a margin of safety that would be arbitrary, not based on evidence, or lack quantification. The EPA recognizes that setting a standard to protect public health, including the health of at-risk populations, with an adequate margin of safety, depends upon selecting a standard level sufficiently below where the EPA has found the strongest evidence of health effects so as to provide such protection, and that the EPA's approach regarding consideration of composite and maximum monitor concentrations is intended to, and does, serve to address this requirement as part of and not separate from the selection of an appropriate standard level based on the health effects evidence.

In considering the second issue related to the commenter's suggested alternative approach, the EPA strongly disagrees with the commenter's view that a more ''reasoned and consistent approach would be to decide on a mean composite monitor $PM_{2.5}$ level that should be achieved and then identify the maximum monitor level that would result in that composite value'' (UARG, 2012, Attachment 1, p. 4). As discussed above, the EPA notes that for areas with only one monitor, or with multiple monitors that measure concentrations that are very close in magnitude, the maximum monitor level that would limit the composite monitor $PM_{2.5}$ level to be no greater than the level that should be achieved to protect public health with an adequate margin of safety, would essentially be the same as that composite monitor level. Further, as discussed above, even for areas in which the maximum monitor concentration is appreciably higher than other monitor concentrations within the same area, public health would not be protected with an adequate margin of safety if the disproportionately higher exposures of at-risk, susceptible populations around the monitor measuring the highest concentration were in essence averaged away with measurements from monitors in other locations within large urban areas. Further, the commenter's suggested approach would be based on annual average $PM_{2.5}$ concentrations that have been measured over some past time period. Such an approach would reflect the air quality that existed in the past, but it would not necessarily provide appropriate constraints on the range of concentrations that would be allowed by such a standard in the future, when relationships between maximum and composite monitor concentrations in areas across the country may be different. For these reasons, the EPA fundamentally rejects the commenter's suggested approach because in the EPA's view it would not protect public health, including providing protection for at-risk populations, with an adequate margin of safety in areas across the country.

More specifically, in further considering the commenter's analysis of design values based on maximum versus composite monitor annual mean $PM_{2.5}$ concentrations using monitoring data from 2006 to 2008 which they assert supports retaining the current standard level of 15 μg/m³, the EPA finds flaws with the numerical results and the scope of the analysis, as well as flaws in the commenter's translation of the analysis results into the basis for selecting an annual standard level.

In considering the commenter's analysis, the EPA notes that the analysis compared maximum versus composite monitor annual mean $PM_{2.5}$ concentrations, averaged over 3 years, for two groups of areas: (1) Areas with design values that exceed the current annual standard level (i.e., greater than 15.0 μg/m³) and (2) areas with design values that are just attaining the current annual standard (i.e., between 14.5 and 15.0 μg/m³).[90] The commenter indicated that they used the full body of $PM_{2.5}$ monitoring data from the EPA's AQS database (UARG, 2012, Attachment 1, p. 4), In attempting to reproduce the commenter's results, the EPA repeated the calculations using only valid air quality data (i.e., data that meet data completeness and monitor siting criteria) from the AQS database for the same time period (Frank, 2012a).[91] Based on this corrected analysis, the EPA finds that the composite monitor concentrations averaged across the areas within each group are somewhat higher than those calculated by the commenter, and the average differences between the maximum and composite monitor concentrations are somewhat smaller (Frank, 2012a, Table 3).[92] Notably, the difference between the maximum and composite monitor average concentrations for the second group of areas is substantially reduced in the corrected analysis, such that the difference (averaged across the 10 areas with valid data in the second group) is approximately 0.5 μg/m³, not 1.2 μg/m³ as in the commenter's analysis. In addition, the commenter's analysis compared the average of the composite monitors to the average of the maximum monitors for each subset of areas. This comparison of averages across all the areas in each subset masks the fact that the large majority of areas across the country have only one monitor, with the composite monitor and maximum monitor values the same for such areas, and many other areas have a maximum monitor value that is close to the composite monitor value. As discussed above, these circumstances have a major impact on the protection that would be achieved by the approach suggested by the commenter.

With regard to the scope of the commenter's analysis, the EPA finds that by limiting the scope to a small subset of areas with design values above or just below the current annual standard level of 15 μg/m³, the analysis ignores the large number of areas across the country with lower design values that are relevant to consider in light of the epidemiological evidence of serious health effects at lower concentrations, well below the level of the current standard.

In translating the analysis results into the basis for selecting an annual standard level, the commenter's translation is premised on the view that the ''natural focal point'' for setting an annual $PM_{2.5}$ standard level should be somewhere within the range of the long-term mean $PM_{2.5}$ concentrations from the subset of epidemiological studies that included only long-term exposure studies of effects for which the evidence is categorized as causal or likely causal, but not for effects categorized as suggestive of causality, nor did it

[90] For the first group of areas (which included 33 areas), this analysis calculated an average across the areas of maximum monitor annual mean $PM_{2.5}$ concentrations, averaged over 3 years, of 17.2 μg/m³ compared to an average of composite monitor concentrations of 14.3 μg/m³. For the second group of areas (which included 11 areas), this analysis calculated an average across the areas of maximum monitor annual mean concentrations, averaged over 3 years, of 14.8 μg/m³ compared to an average of composite monitor concentrations of 13.6 μg/m³ (UARG, 2012, Attachment 1, Table 1).

[91] The EPA notes that the Frank (2012a) analysis is similar to an earlier EPA staff analysis (Hassett-Sipple et al., 2010), which used air quality data from EPA's AQS database to compare maximum versus composite monitor long-term mean $PM_{2.5}$ concentrations across the study areas in six selected multi-city epidemiological studies.

[92] The EPA's analysis was intended to repeat the commenter's analysis, but using only valid air quality data (from 2006 to 2008). For the first group of areas (which included 21 areas with valid data), the EPA's analysis calculated an average across the areas of maximum monitor annual mean concentrations, averaged of 3 years, of 16.8 μg/m³ compared to an average of composite monitor concentrations of 14.8 μg/m³. For the second group of areas (which included 10 areas with valid data), the EPA's analysis calculated an average across the areas of maximum monitor annual mean concentrations, averaged over 3 years, of 14.8 μg/m³ compared to an average of composite monitor concentrations of 14.2 μg/m³ (Frank, 2012a, Table 3).

include short-term exposure studies (which are included in Figure 4 of the proposal notice and above). Such a view is not consistent with setting a standard that would provide sufficient protection from the serious health effects reported even in the limited subset of studies considered by the commenter, including protecting public health with an adequate margin of safety. As discussed below, the EPA does not agree with the commenter's view as to the appropriate focal point for selecting the level of an annual $PM_{2.5}$ standard, or with the limited set of studies considered by the commenter as a basis for selecting the level of the annual $PM_{2.5}$ standard.

Regarding an appropriate focal point for selecting the level of the annual standard, as discussed in the proposal and as advised by CASAC, the EPA has focused on $PM_{2.5}$ concentrations somewhat *below* the lowest long-term mean concentrations from *each* of the key studies of both long- and short-term exposures of effects for which the evidence is causal or likely causal, as considered by the EPA (i.e., the first two sets of studies shown in Figure 4). If the level of the annual standard was set just somewhere *within* the range of the long-term mean concentrations from the various long-term exposure studies, then one or more of the studies would have a long-term mean concentration below the selected level of the standard. Absent some reason to ignore or discount these studies, which the commenter does not provide (and of which the EPA is unaware), setting such a standard would allow that level of air quality, where the evidence of health effects is strongest, and its associated risk of $PM_{2.5}$-related mortality and/or morbidity effects to continue. Selecting such a standard level could not be considered sufficient to protect the public health with an adequate margin of safety.

Further, focusing on just the long-term *mean* $PM_{2.5}$ concentrations in the key epidemiological studies—even the lowest long-term mean concentration from the set of key studies—is not appropriate. Concentrations at and around the long-term mean concentrations represent the part of the air quality distribution where the data in any given study are most concentrated and, thus, where the confidence in the magnitude and significance of an association in such study is strongest. However, the evidence of an association with adverse health effects in the studies is not limited to the $PM_{2.5}$ concentrations just at and around the long-term mean, but rather extends more broadly to a lower part of the distribution, recognizing that no discernible population-level threshold for any such effects can be identified based on the available evidence. This broader region of the distribution of $PM_{2.5}$ concentrations should be considered to the extent relevant information is available, recognizing that the degree of confidence in the association identified in a study would become lower as one moves below concentrations at and around the long-term mean concentration in any given study. The commenter's approach ignores this fundamental consideration.

Regarding the set of studies that is appropriate to inform the selection of the level of the annual $PM_{2.5}$ standard, the EPA finds that limiting consideration only to the *long-term exposure* studies, as this commenter suggests, would be tantamount to ignoring the *short-term exposure* studies,[93] which provide some of the strongest evidence from the entire body of epidemiological studies. Thus, selecting an annual standard level using the limited set of studies suggested by the commenter would fail to provide a degree of protection that would be sufficient to protect public health with an adequate margin of safety.

For all the reasons discussed above, the EPA finds the commenter's concerns with the EPA's approach to considering composite and maximum monitor $PM_{2.5}$ concentrations in selecting the level of the annual $PM_{2.5}$ standard to be without merit. Further, the EPA finds no support in the commenter's analysis for their suggested alternative approach.

(2) With respect to the appropriate exposure period for mortality effects observed in long-term exposure studies, some commenters in this group generally expressed views consistent with comments from UARG that argued that these studies ''are most likely detecting health risk from earlier, higher $PM_{2.5}$ levels and misattributing those risks to more recent, lower $PM_{2.5}$ levels'' (UARG, 2012, Attachment 1, p 7). Further, this commenter asserted that ''there is no knowledge or evidence indicating whether premature deaths are the result of $PM_{2.5}$ exposures in the most recent year; or due to physical damages incurred from $PM_{2.5}$ exposures much earlier in life (with the impact on lifespan only emerging later in life); or due to total accumulated $PM_{2.5}$ exposure over many years.'' *Id.* In addition, the commenter asserted that the long-term exposure studies of mortality are central to the EPA's basis for proposing to set a lower annual standard level, since most of the estimated benefits associated with a lower annual $PM_{2.5}$ standard are based on reductions in mortality related to long-term exposures to $PM_{2.5}$.

As an initial matter, the EPA has recognized the challenge in distinguishing between $PM_{2.5}$-associated effects due to past and recent long-term exposures, and in identifying the relevant latency period for long-term exposure to PM and resultant health effects (U.S. EPA, 2009a, section 7.6.4; 77 FR 38941/1). While the EPA has acknowledged that there remain important uncertainties related to characterizing the most relevant exposure periods in long-term exposure studies, the assertion that there is ''no knowledge or evidence'' that helps to inform this issue is not correct, as discussed below.

Both in the last review and in the current review, the EPA has assessed studies that used different air quality periods for estimating long-term exposure and tested associations with mortality for the different exposure periods (U.S. EPA, 2004, section 8.2.3.5; U.S. EPA 2009a, section 7.6.4). In this review, the Integrated Science Assessment discussed studies available since the last review that have assessed the relationship between long-term exposure to $PM_{2.5}$ and mortality to explore the issue of the latency period between exposure to $PM_{2.5}$ and death (U.S. EPA, 2009a, section 7.6.4).

Notably, in a recent analysis of the extended Harvard Six Cities Study, Schwartz *et al.* (2008) used model averaging (i.e., multiple models were averaged and weighted by probability of accuracy) to assess exposure periods prospectively (77 FR 38907/1–2). The exposure periods were estimated across a range of unconstrained distributed lag models (i.e., same year, one year prior, two years prior to death). In comparing lags, the authors reported that the effects of changes in exposure to $PM_{2.5}$ on mortality were strongest within a 2-year period prior to death (U.S. EPA, 2009a, p. 7–92, Figure 7–9). Similarly, a large

[93] The commenter suggests that the EPA should not place significant reliance on the long-term mean concentrations from short-term exposure studies because ''[T]he short-term studies did not use the annual average of $PM_{2.5}$ to develop their associations; they used the daily 24-hour averages of $PM_{2.5}$. Thus, short-term studies do not provide a natural indicator for the appropriate level of an annual standard * * *.'' (UARG, 2012, Attachment 1, p. 3). The EPA finds this argument unpersuasive. Quite simply, effects were observed in these studies with an air quality distribution that can meaningfully be characterized by these long-term mean concentrations. Indeed, in remanding the 2006 standard, the D.C. Circuit discussed at length the interrelationship of the long- and short-term standards and studies, and remanded the 2006 standard to the EPA, in part, for ignoring those relationships without adequate explanation. *American Farm Bureau Federation* v. *EPA. 559* F. 3d at 522–24.

multi-city study of the elderly found that the mortality risk associated with long-term exposure to PM_{10} reported cumulative effects that extended over the years that deaths were observed in the study population (i.e., the follow-up period) and for the 3-year period prior to death (Zanobetti *et al.,* 2008).

Further, in a study of two locations that experienced an abrupt decline in $PM_{2.5}$ concentrations (i.e., Utah Steel Strike, coal ban in Ireland), Röösli *et al.* (2005) reported that approximately 75 percent of health benefits were observed in the first 5 years (U.S. EPA, 2009a, Table 7–9). Schwartz *et al.* (2008) and Puett *et al.* (2008) found, in a comparison of exposure periods ranging from 1 month to 48 months prior to death, that exposure to PM_{10} 24 months prior to death exhibited the strongest association, and the weakest association was reported for exposure in the time period of 1 month prior to death.

Overall, the EPA notes that the available evidence for determining the exposure period that is causally related to the mortality effects of long-term $PM_{2.5}$ exposures, as discussed above, cannot specifically disentangle the effects observed in long-term exposure studies associated with more recent air quality measurements from effects that may have been associated with earlier, and most likely higher, $PM_{2.5}$ exposures. While the evidence suggests that a latency period of up to five years would account for the majority of deaths, it does not provide a basis for concluding that it is solely recent $PM_{2.5}$ concentrations that account for the mortality risk observed in such studies. Nonetheless, the more recent air quality data does well at explaining the relationships observed between long-term exposures to $PM_{2.5}$ and mortality, with the strongest association observed in the two years prior to death. Further, the EPA recognizes that there is no discernible population-level threshold below which effects would not occur, such that it is reasonable to consider that health effects may occur over the full range of concentrations observed in the epidemiological studies, including the lower concentrations in the latter years.

In light of this evidence and these considerations, the EPA concludes that it is appropriate to consider air quality concentrations that are generally contemporaneous with the collection of health event data (i.e., collected over the same time period) as being causally associated with at least some proportion of the deaths assessed in a long-term exposure study. This would include long-term mean $PM_{2.5}$ concentrations from most of the key long-term exposure studies of effects with causal or likely causal evidence shown in Figure 4 above, which reported long-term mean $PM_{2.5}$ concentrations ranging from 13.6 $\mu g/m^3$ to 14.3 $\mu g/m^3$. These studies include studies of mortality by Eftim *et al.* (2008), which separately analyzed the ACS and Harvard Six City sites, Zeger *et al.* (2008), and Lipfert *et al.* (2006a), as well as studies of morbidity endpoints by Goss *et al.* (2004), McConnell *et al.* (2003) and Gauderman *et al.* (2004), and Dockery *et al.* (1996) and Razienne *et al.* (1996). The EPA acknowledges that uncertainty in the relevant exposure period is most notable in two other long-term exposure studies of mortality. The Miller *et al.* (2007) reported a long-term mean $PM_{2.5}$ concentration for a 1-year exposure period that post-dated the follow-up period in which health event data were collected by two years. Also, the Krewski *et al.* (2009) study reported a long-term mean $PM_{2.5}$ concentration for an exposure period that included only the last two years of the 18-year follow-up period. Based on these considerations, the EPA does not now consider it appropriate to put weight on the reported long-term mean concentrations from these two studies for the purpose of translating the information from the long-term mortality studies into a basis for selecting the level of the annual $PM_{2.5}$ standard.[94]

In addition, the EPA acknowledges that exposure periods that extend at least a couple years prior to the follow-up period in which health event data were collected would likely more fully capture the PM-related deaths in such studies. To explore how much higher the long-term mean $PM_{2.5}$ concentrations would likely have been had air quality data prior to the follow-up years of the studies been included, the EPA conducted a sensitivity analysis of long-term mean $PM_{2.5}$ concentrations (Schmidt, 2012a) particularly considering studies that only included deaths from a relatively recent follow-up period. As examples of such studies, this analysis considered the Eftim *et al.* (2008) study of mortality in the ACS sites and the Harvard Six Cities sites, as well as sites in the eastern region in the Zeger *et al.* (2008) study. Using data from the EPA's AQS database, the analysis added the two years of air quality data just prior to the follow-up period in each study, which was 2000 to 2002 in Eftim *et al.* (2008) and 2000 to 2005 in Zeger *et al.* (2008). The analysis then calculated the extended long-term mean $PM_{2.5}$ concentration for each study. As discussed in Schmidt (2012a), in each case the long-term mean $PM_{2.5}$ concentration averaged over the extended exposure period was less than 0.4 $\mu g/m^3$ higher than the long-term mean $PM_{2.5}$ concentration averaged over the follow-up period. The EPA finds it reasonable to conclude that such a relatively small difference in long-term mean $PM_{2.5}$ concentrations would likely apply for other long-term exposure studies that used similarly recent follow-up periods as well (e.g., Goss *et al.,* 2004; Lipfert *et al.,* 2006a).

Based on the above considerations, the EPA concludes that it is appropriate to consider the available air quality information from the long-term exposure studies, while taking into account the uncertainties in the relevant long-term exposure periods in weighing the information from these studies. The EPA recognizes that considering such information in selecting an appropriate annual standard level has the potential to build in some margin of safety. The EPA further concludes that it is appropriate to consider the air quality information from the set of long-term exposure studies discussed above in the context of the broader array of epidemiological studies that inform the EPA's consideration of the level of the annual $PM_{2.5}$ standard.

The EPA also notes that while the long-term exposure studies are an important component of the epidemiological evidence that informs the Agency's consideration of the level of the annual standard, they do not provide the only relevant information, nor are they the set of studies for which the relevant long-term mean $PM_{2.5}$ concentrations are the lowest. As discussed in the proposal, the EPA also considers the long-term mean $PM_{2.5}$ concentrations from the short-term mortality and morbidity studies as providing important information in considering the level of the annual standard. As discussed above, a large proportion of the aggregate risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range of the concentrations observed in the studies. Thus, setting the level of the annual standard based on long-term mean concentrations, as well as the distribution of concentrations below the mean, in the short-term exposure studies is the most effective and efficient way to reduce total $PM_{2.5}$-

[94] Nonetheless, the EPA notes that the Krewski et al. (2009) and Miller et al. (2007) studies provide strong evidence of mortality and cardiovascular-related effects associated with long-term $PM_{2.5}$ exposures to inform causality determinations reached in the Integrated Science Assessment (U.S. EPA, 2009a, sections 7.2.11 and 7.6).

related risk from the broad array of mortality and morbidity effects associated with short-term exposures.

Further, the EPA notes that the relevant exposure period for the short-term exposure studies is the period contemporaneous with the collection of health event data, and that this exposure period is not subject to the uncertainties discussed above related to the long-term exposure studies. Recognizing that the long-term mean $PM_{2.5}$ concentrations from several of the multi-city short-term exposure studies shown in Figure 4 are below the long-term mean $PM_{2.5}$ concentrations from the long-term exposure studies (with the exception of Miller *et al.,* 2007).[95] It is reasonable that in selecting the level of the annual standard primary consideration should be given to the information from this set of short-term exposure studies. There is no reasonable basis to discount the long-term mean concentrations of the short-term exposure studies for purposes of setting the level of the annual standard. Thus, the commenter is incorrect in asserting that the long-term exposure studies, not the short-term exposure studies, would be central in the Administrator's decision on the level of the annual standard. The standard is ultimately intended to protect not just against the single type of effect that contributes the most to quantitative estimates of risk to public health, but rather to the broad array of effects, including mortality and morbidity effects from long- and short-term exposures across the range of at-risk populations impacted by $PM_{2.5}$-related effects.

(3) With regard to the EPA's analysis of distributions of underlying population-level data (i.e., health event and study population data) and corresponding air quality data from each study area in certain key multi-city epidemiological studies (Rajan *et al.,* 2011), some commenters in this group raised a number of issues related to this analysis (API, 2012, Attachment 1 pp. 5 to 6; McClellan, 2012, pp.2 to 4). Some commenters noted the limited number of studies for which health event and study population data were available, and questioned whether these distributions would apply to other studies. Commenters expressed concerns that this analysis had not been formally reviewed by CASAC and was not published in the peer-review literature. Based on such concerns, some commenters asserted that the EPA should not consider this information as a basis for selecting a standard level.

As an initial matter, as discussed in section III.E.4.b above, the EPA agrees with CASAC's advice that it is appropriate to consider additional data beyond the mean $PM_{2.5}$ concentrations in key multi-city studies to help inform selection of the level of the annual $PM_{2.5}$ standard. As both the EPA and CASAC recognize, in the absence of a discernible threshold, health effects may occur over the full range of concentrations observed in the epidemiological studies. Nonetheless, the EPA recognizes that confidence in the magnitude and significance of an association is highest at and around the long-term mean $PM_{2.5}$ concentrations reported in the studies and the degree of confidence becomes lower at lower concentrations within any given study. Following CASAC's advice (Samet, 2010d, p.2), the EPA used additional population-level and air quality data made available by study authors to conduct an analysis of the distributions of such data, to help inform consideration of how the degree of confidence in the magnitude and significance of observed associations varies across the range of long-term mean $PM_{2.5}$ concentrations in study areas within key multi-city epidemiological studies. In the EPA's view, such consideration is important in selecting a level for an annual standard that will protect public health with an adequate margin of safety.

With regard to the number of multi-city studies for which an analysis of the distributions of population-level data across the study areas and the corresponding annual mean $PM_{2.5}$ concentrations was done, the EPA noted at proposal that data for such an analysis were made available from study authors for four studies, including two long-term exposure studies and two short-term exposure studies.[96] The EPA recognized that access to health event data can be restricted due to confidentiality issues, such that it is not reasonable to expect that such information could be made available from all studies. In considering the information from these four studies, the EPA has further taken into consideration uncertainties discussed in response to the above comment related to the appropriate exposure period for long-term exposure studies. Based on these considerations, as noted above, the EPA concludes that such uncertainties are an important factor in evaluating the usefulness of the air quality information from the two long-term exposure studies in this analysis (Krewski *et al.,* 2009; Miller *et al.,* 2007) and that it would not be appropriate to place weight on the distributional analysis of health event and air quality data from these two studies specifically for the purpose of translating the information from the long-term mortality studies into a basis for selecting the level of the annual $PM_{2.5}$ standard. Such uncertainties are not relevant to the short-term exposure studies, and thus, the Agency focuses on the two short-term exposure studies in this analysis (Bell *et al.,* 2008; Zanobetti and Schwartz, (2009).

In focusing on these two short-term exposure studies, the EPA first notes that these studies are key multi-city studies that reported positive and statistically significant associations between mortality and cardiovascular-related hospital admissions across a large number of areas throughout the U.S. (112 U.S. cities in Zanobetti and Schwartz, 2009; 202 U.S. counties in Bell *et al.,* 2008) using relatively recent air quality and health event data (i.e., 1999 through 2005 in both studies). The EPA considers this to be a modest but important data set to use for this distributional analysis to help inform consideration of how much below the long-term mean $PM_{2.5}$ concentrations in key multi-city long- and short-term exposure studies the annual $PM_{2.5}$ standard level should be set. While the EPA acknowledges that having such data available from more studies would have been useful, the Agency finds the information from this limited set of studies to be an important consideration in selecting an annual standard level, consistent with CASAC advice to consider such information.

In considering the results of this distributional analysis, as discussed more fully in the Response to Comments document, the EPA considers $PM_{2.5}$ concentrations between the 25th and 10th percentiles of the distribution of health events to be a reasonable range for providing a general frame of reference for that part of the distribution in which confidence in the magnitude and significance of the association may be appreciably lower than confidence at and around the long-term mean concentration. For the two short-term exposure studies included in this analysis, the EPA notes that the $PM_{2.5}$ concentrations corresponding to the 25th percentiles of the distributions of

[95] As noted above, the EPA is not placing weight on the reported long-term mean concentrations from the Miller et al. (2007) study for the purpose of translating the information from the long-term mortality studies into a basis for selecting the level of the annual $PM_{2.5}$ standard.

[96] Health event data and study population data were available from two short-term exposure studies (Bell *et al.* 2008; Zanobetti and Schwartz, 2009) and one long-term exposure study (Krewski *et al.,* 2009). Only study population data were available from another long-term exposure study (Miller *et al.,* 2007).

health events were 12.5 μg/m³ and 11.5 μg/m³, respectively, for Zanobetti and Schwartz (2009) and for Bell *et al.* (2008), with the 10th percentiles being lower by approximately 2 μg/m³ in each study (Rajan *et al.,* 2011, Table 1). In considering this information, the EPA recognizes, however, that there is no clear dividing line or single percentile within a given distribution (including both above and below the 25th percentile) provided by the scientific evidence that is most appropriate or 'correct' to use to characterize where the degree of confidence in the associations warrants setting the annual standard level. The decision as to the appropriate standard level below the long-term mean concentrations of the key studies is largely a public health policy judgment to be made by the Administrator, taking into account all of the evidence and its related uncertainties, as discussed in section III.E.4.d below.

In response to concerns that this analysis was not reviewed by CASAC nor published in the peer-reviewed literature, the EPA notes that this analysis was conducted to directly respond to advice from CASAC, as discussed in section III.E.4.b.i above, in conjunction with their review of the Policy Assessment. The EPA notes that the same type of distributional analysis was presented in the second draft Policy Assessment based on air quality data, as well as population-weighted air quality data, rather than health event or study population data. In considering that distributional information, CASAC urged that the EPA redo the analysis using health event or study population data, which is exactly what the EPA did and presented in the final Policy Assessment. The EPA provided CASAC with the final Policy Assessment and communicated how the final staff conclusions reflected consideration of its advice and that those staff conclusions were based in part on the specific distributional analysis that CASAC had urged the EPA to conduct (Wegman, 2011, Attachment p. 2). CASAC did not choose to provide any additional comments or advice after receiving the final Policy Assessment. The EPA considers this distributional analysis to be the product of the peer review conducted by CASAC of the Policy Assessment, and thus does not agree with commenters' characterization that the analysis lacked appropriate peer review. The EPA's final analysis was based on the comments provided by CASAC, the peer review committee established pursuant to the CAA, on the draft analysis, such that the final analysis stems directly from CASAC's advice and the EPA's response to its comments.

Based on the above considerations, the EPA continues to conclude that its analysis of distributions of health event and air quality data from two key multi-city epidemiological studies provides important information related to understanding the associations between health events observed in each city (e.g., deaths, hospitalizations) and the corresponding long-term mean $PM_{2.5}$ concentrations observed in the studies. While recognizing that this is a relatively modest data set, the EPA further concludes that such information can appropriately help to inform the selection of the level of an annual standard that will protect public health with an adequate margin of safety from these types of health effects which are causally related to long- and short-term exposures to $PM_{2.5}$.

(4) Some commenters in this group asserted there were limitations in the long-term exposure studies of morbidity, including studies evaluating respiratory effects in children. For example, one commenter (UARG, 2012, p. 12, Attachment 1, pp. 14 to 16) asserted there were serious limitations in the long-term exposure studies of respiratory morbidity in each of the studies considered by the EPA (including McConnell *et al.,* 2003; Gauderman *et al.,* 2004; Dockery *et al.,* 1996; Raizenne *et al.,* 1996; and Goss *et al.,* 2004) and argued that this evidence provides only a ''weak association'' with $PM_{2.5}$ exposures. This commenter asserted that many of these long-term exposure studies evaluating respiratory effects were considered at the time the EPA reaffirmed the current annual standard level of 15 μg/m³ in 2006, that the Administrator in the last review determined that the information they provided ''was too limited to serve as the basis for setting a level of a national standard,'' and that they should be given little weight in setting the level of the annual standard in this review (UARG, 2012, Attachment 1, p. 14).

More specifically, this commenter asserted that the McConnell *et al.* (2003) and Gauderman *et al.* (2004) studies reported mixed results for associations with $PM_{2.5}$ and stronger associations with NO_2 (API, 2012, Attachment 1, pp. 14 to 15). Similarly, this commenter argued that the Dockery *et al.* (1996) and Raizenne *et al.* (1996) studies showed stronger associations with acidity than with fine particles (measured as $PM_{2.1}$). *Id.* pp. 15 to 16. With regard to the cystic fibrosis study, this commenter noted that the association between pulmonary exacerbations and $PM_{2.5}$ in this study was no longer statistically significant when the model adjusted for each individual's baseline lung function. The commenters referred to the data on lung function as an ''important explanatory variable,'' and suggested that the EPA should rely on results from the model that included individual baseline lung function information. *Id.* p. 16. For the reasons discussed below and in more detail in the Response to Comments document, the EPA disagrees with the commenters' interpretation of these studies.

As an initial matter, the EPA notes that three of these studies (McConnell *et al.,* 2003; Dockery *et al.,* 1996; Raizenne *et al.,* 1996) as well as the initial studies from the Southern California Children's Health Study (Peters *et al.,* 1999; McConnell *et al.,* 1999; Gauderman *et al.,* 2000, 2002; Avol *et al.,* 2001) were discussed and considered in the 2004 Air Quality Criteria Document (U.S. EPA, 2004) and, thus, considered within the air quality criteria supporting the EPA's final decisions in the review completed in 2006. Two additional studies (Gauderman *et al.,* 2004; Goss *et al.,* 2004) were discussed and considered in the provisional science assessment conducted for the last review (U.S. EPA, 2006a). The EPA concluded that ''new'' studies considered in the provisional assessment completed in 2006 did not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Criteria Document (71 FR 61148 to 61149, October 17, 2006). All of these studies were considered in the Integrated Science Assessment that informs the current review (U.S. EPA, 2009a).

With regard to the Southern California Children's Health Study, extended analyses considered in the Integrated Science Assessment provided evidence that clinically important deficits in lung function [97] associated with long-term exposure to $PM_{2.5}$ persist into early adulthood (U.S. EPA, 2009a, p. 7–27; Gauderman *et al.,* 2004). These effects remained positive in copollutant models.[98] Additional analyses of the

[97] Clinical significance was defined as an FEV_1 below 80 percent of the predicted value, a criterion commonly used in clinical settings to identify persons at increased risk for adverse respiratory conditions (U.S. EPA, 2009a, p. 7–29 to 7–30). The primary NAAQS for sulfur dioxide (SO_2) also included this interpretation for FEV_1 (75 FR 35525, June 22, 2010).

[98] Gauderman *et al.* (2004) clearly stated throughout their analysis that NO_2 was one component of a highly correlated mixture that contains $PM_{2.5}$. Gauderman *et al.* (2004) did not present the results from copollutants models but stated ''two-pollutant models for any pair of

Southern California Children's Health Study cohort reported an association between long-term $PM_{2.5}$ exposure and bronchitic symptoms (U.S. EPA, 2009a, p. 7–23 to 7–24; McConnell *et al.,* 2003, long-term mean concentration of 13.8 μg/m³) that remained positive in co-pollutant models, with the $PM_{2.5}$ effect estimates increasing in magnitude in some models and decreasing in others, and a strong modifying effect of $PM_{2.5}$ on the association between lung function and asthma incidence (U.S. EPA, 2009a, 7–24; Islam *et al.,* 2007). The outcomes observed in the more recent reports from the Southern California Children's Health Study, including evaluation of a broader range of endpoints and longer follow-up periods, were larger in magnitude and more precise than reported in the initial version of the study. Supporting these results were new longitudinal cohort studies conducted by other researchers in varying locations using different methods (U.S. EPA, 2009a, section 7.3.9.1). The EPA, therefore, disagrees with the commenters that the studies by McConnell *et al.* (2003) and Gauderman *et al.* (2004) are flawed and should not be used in the PM NAAQS review process.

The 24-City study [99] by Dockery *et al.* (1996) (long-term mean concentration of 14.5 μg/m³) was considered in the current as well as two previous reviews (U.S. EPA, 2009a; U.S. EPA, 2004; U.S. EPA, 1996). This study observed that PM, specifically ''particle strong acidity'' and sulfate particles (indicators of fine particles), were associated with reports of bronchitis in the previous year. Similarly, the magnitude of the associations between bronchitis and PM_{10} and $PM_{2.1}$ were similar to those for acidic aerosols and sulfate particles, though the confidence intervals for the PM_{10} and $PM_{2.1}$ associations were slightly wider and the associations were not statistically significant. Acid aerosols, sulfate, and fine particles are formed in secondary reactions of the emissions from incomplete combustion and these pollutants have similar regional and temporal distributions. As noted by the study authors, ''the strong correlations of several pollutants in this study, especially particle strong acidity with sulfate (r=0.90) and $PM_{2.1}$ (r=0.82), make it difficult to distinguish the agent of interest'' (Dockery *et al.,* 1996, p. 505). Overall, Dockery *et al.* (1996) (and, similarly, Raizenne *et al.,* 1996) observed similar associations between respiratory health effects and acid aerosols, sulfate, PM_{10} and $PM_{2.1}$ concentrations. The commenters noted that the associations with particle acidity were sensitive to the inclusion of the six Canadian sites. The EPA notes that none of these Canadian cities were in the ''sulfate belt'' where particle strong acidity was highest. Thus, the change in the effect estimate when the six Canadian cities were excluded from the analysis is likely due to the lower prevalence of bronchitis and the lower concentrations of acid aerosols in these cities, and not due to some difference in susceptibility to bronchitis between the U.S. and Canadian populations that is not due to air pollution, as suggested by the commenters (UARG, 2012, Attachment 1, p. 15). In fact, contrary to the statements made by the commenters, the authors did not observe any subgroups that appeared to be markedly more susceptible to the risk of bronchitis.

The Goss *et al.* (2004) study considered a U.S. cohort of cystic fibrosis patients and provided evidence of association between long-term $PM_{2.5}$ exposures and exacerbations of respiratory symptoms resulting in hospital admissions or use of home intravenous antibiotics (U.S. EPA, 2009a, p. 7–25; long-term mean concentration of 13.7 μg/m³). The commenters noted that the association between pulmonary exacerbations and $PM_{2.5}$ in this study was no longer statistically significant when the model adjusted for each individual's baseline lung function. The commenters referred to the data on lung function as an ''important explanatory variable,'' and suggested that the EPA should rely on results from the model that included individual baseline lung function information. The EPA disagrees with the commenters' interpretation of this study. The Agency concludes it is unlikely that lung function is a potential confounder or an important explanatory variable in this study. In fact, the authors noted that ''it is more likely that lung function decline may be intimately associated with chronic exposure to air pollutants and may be part of the causal pathway in worsening prognosis in CF [cystic fibrosis]; in support of this explanation, we found both cross-sectional and longitudinal strong inverse relationships between FEV_1 and PM levels'' (Goss *et al.,* 2004, p. 819). The EPA notes that adjusting for a variable that is on the causal pathway can lead to overadjustment bias, which is likely to attenuate the association (Schisterman *et al.* 2009); this is likely what was observed by the authors. Thus, the EPA continues to believe it is appropriate to focus on the results reported in Goss *et al.* (2004) that did not include individual baseline lung function in the model.

In addition, the EPA disagrees with commenters' reliance solely on statistical significance when interpreting the study results from individual study results and the collective evidence across studies. As discussed in section III.D.2 above, statistical significance of individual study findings has played an important role in the EPA's evaluation of the study's results and the EPA has placed greater emphasis on studies reporting statistically significant results. However, in the broader evaluation of the evidence from many epidemiological studies, and subsequently during the process of forming causality determinations in the Integrated Science Assessment by integrating evidence from across epidemiological, controlled human exposure, and toxicological studies, the EPA has emphasized the *pattern of results* across epidemiological studies and whether the effects observed were *coherent* across the scientific disciplines for drawing conclusions on the relationship between $PM_{2.5}$ and different health outcomes.

As noted in section III.B.1.a of the proposal, with regard to respiratory effects, the Integrated Science Assessment concluded that extended analyses of studies available in the last review as well as new epidemiological studies conducted in the U.S. and abroad provided stronger evidence of respiratory-related morbidity associated with long-term $PM_{2.5}$ exposure (77 FR 38918). The strongest evidence for respiratory-related effects available in this review was from epidemiological studies that evaluated decrements in lung function growth in children and increased respiratory symptoms and disease incidence in adults (U.S. EPA, 2009a, sections 2.3.1.2, 7.3.1.1, and 7.3.2.1).

In considering the collective evidence from epidemiological, toxicological, and controlled human exposure studies, including the studies discussed above, the EPA recognizes that the Integrated Science Assessment concluded that a causal relationship is likely to exist between long-term $PM_{2.5}$ exposures and respiratory effects (U.S. EPA, 2009a, p. 2–12, pp. 7–42 to 7–43). CASAC concurred with this causality determination (Samet, 2009f, p.9).

pollutants did not provide a significantly better fit to the data than the corresponding single-pollutant models.''

[99] The 24-City study conducted by Dockery *et al.* (1996) included 18 sites in the U.S. and 6 sites in Canada. The Raizenne *et al.* (1996) study considered 22 of these 24 study areas. Athens, OH and South Brunswick, NJ were not included in this study.

The commenter's assertion that the EPA should adhere to its assessment of these studies as it did in the review completed in 2006 is significantly mistaken. Most obviously, the EPA's final decision in the last review was held to be deficient by the DC Circuit in remanding the 2006 primary annual $PM_{2.5}$ standard. As discussed in section III.A.2 above, the DC Circuit specifically held that the EPA did not provide a reasonable explanation of why certain morbidity studies, including an earlier study from the Southern California Children's Health Study (Gauderman *et al.,* 2000, long-term mean $PM_{2.5}$ concentration approximately 15 μg/m³) and the 24-Cities Study (Raizenne *et al.,* 1996, long-term mean concentrations approximately 14.5 μg/m³) did not warrant a more stringent annual $PM_{2.5}$ standard when the long-term mean $PM_{2.5}$ concentrations reported in those studies were at or lower than the level of the annual standard. *American Farm Bureau Federation* v. *EPA.* 559 F. 3d at 525. Indeed, the court found that, viewed together, the Gauderman *et al.* (2000) and Raizenne *et al.,* (1996) studies ''are related and together indicate a significant public health risk * * * On this record, therefore, it appears the EPA too hastily discounted the Gauderman and 24-Cities studies as lacking in significance.'' *Id.*

In this review, the EPA recognizes a significant amount of evidence beyond these two studies that expands our understanding of respiratory effects associated with long-term $PM_{2.5}$ exposures. This body of scientific evidence includes an extended and new analyses from the Southern California Children's Health Study (Gauderman *et al.,* 2004; Islam *et al.,* 2007; Stanojevic *et al.,* 2008) as well as additional studies that examined these health effects (Kim *et al.,* 2004; Goss *et al.,* 2004). Thus, even more so than in the last review, the evidence indicates a ''significant public health risk'' to children from long-term $PM_{2.5}$ exposures at concentrations below the level of the current annual standard. A standard that does not reflect appropriate consideration of this evidence would not be requisite to protect public health with an adequate margin of safety.

(5) With regard to the use of studies of health effects for which the EPA finds the evidence to be ''suggestive'' of a causal relationship, some commenters argued that such studies ''do not merit any weight in the setting of the annual NAAQS'' (e.g., UARG, 2012, Appendix 1, p. 3).

The EPA disagrees with the commenter's view that studies of health effects for which the evidence is suggestive of a causal relationship, rather than studies of health effects for which the evidence supports a causal or likely causal relationship, merit no weight at all in setting the NAAQS. To place no weight at all on such evidence would in essence treat such evidence as though it had been categorized as ''not likely to be a causal relationship.'' To do so would ignore the important distinctions in the nature of the evidence supporting these different causality determinations in the Integrated Science Assessment. It would also ignore the CAA requirement that primary standards are to be set to provide protection with an adequate margin of safety, including providing protection for at-risk populations. Thus, ignoring this information in making decisions on the appropriate standard level would not be appropriate.[100] Nonetheless, in considering studies of health effects for which the evidence is suggestive of a causal relationship, the EPA does believe that it is appropriate to place less weight on such studies than on studies of health effects for which there is evidence of a causal or likely causal relationship.

A second group of commenters supported revising the suite of primary $PM_{2.5}$ standards to provide increased public health protection. These commenters found the available scientific information and technical analyses to be stronger and more compelling than in the last review. These commenters generally placed substantial weight on CASAC advice and on the EPA staff analyses presented in the final Policy Assessment, which concluded that the evidence most strongly supported an annual standard level within a range of 11 to 12 μg/m³ (U.S. EPA, 2011a, p. 2–206). While some of these commenters felt that the level should be set within the proposed range (12 to 13 μg/m³), most of these commenters advocated a level of 11 μg/m³.[101] For example, ALA *et al.,* asserted:

> The EPA's proposed $PM_{2.5}$ standards, while a step in the right direction are insufficient to protect public health, including the health of susceptible populations, with an adequate margin of safety as required by the Clean Air Act * * *we will discuss the enormous gap in public health protection afforded by an annual standard of 13 μg/m³, at the upper end of the proposed range, compared to the more protective 11 μg/m³, as advocated by our organizations (ALA *et al.,* 2012, p. 6).

In general, these commenters expressed the view that given the strength of the available scientific evidence, the serious nature of the health effects associated with $PM_{2.5}$ exposures, the large size of the at-risk populations, the risks associated with long- and short-term $PM_{2.5}$ exposures, and the important uncertainties inherently present in the evidence, the EPA should follow a highly precautionary policy response by selecting an annual standard level that incorporates a large margin of safety.

More specifically, these commenters offered a range of comments related to the general approach used by the EPA to select standard levels, including: (1) The EPA's approach for setting a generally controlling annual standard; (2) the importance of the greatly expanded and stronger overall scientific data base; (3) consideration of the distributional statistical analysis conducted by the EPA and other approaches for translating the air quality information from specific epidemiological studies into standard levels; and (4) the significance of the $PM_{2.5}$-related public health impacts, especially potential impacts on at-risk populations, including children, in reaching judgments on setting standards that provide protection with an adequate margin of safety. These comments are discussed in turn below.

(1) Some of these commenters disagreed with the EPA's approach for setting a ''generally controlling'' annual standard in conjunction with a 24-hour standard providing supplemental protection particularly for areas with high peak-to-mean ratios. These commenters argued this approach would lead to ''regional inequities'' as demonstrated in the EPA's analyses contained in Appendix C of the Policy Assessment (ALA *et al.,* pp. 26 to 27). Specifically, these commenters argued:

> There is no basis in the Clean Air Act for such a determination. The Clean Air Act requires only that the NAAQS achieve public health protection with an adequate margin of safety. It is well-documented that both long- and short-term exposures to $PM_{2.5}$ have serious and sometimes irreversible health impacts. There is no health protection reason to argue that one standard should be ''controlling'' as a matter of policy without regard to the health consequences of such a policy. To adopt such a policy ignores the obligation to provide equal protection under

[100] As discussed in section II.A above, 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. I was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. This certainly encompasses consideration of effects for which there is evidence suggestive of a causal relationship.

[101] As discussed in section III.E.4.c.ii, many of these commenters also supported lowering the level of the primary 24-hour $PM_{2.5}$ standard.

the law to all Americans because it would result in uneven protection from air pollution in different localities and regions of the country (ALA *et al.,* 2012, p. 26).

The EPA believes these commenters misunderstood the basis for the EPA's policy goal of setting a ''generally controlling'' annual standard. This approach relates exclusively to setting standards that will provide requisite protection against effects associated with both long- and short-term $PM_{2.5}$ exposures. It does so by lowering the overall air quality distributions across an area, recognizing that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in lower annual mean $PM_{2.5}$ concentrations but also in fewer and lower peak 24-hour $PM_{2.5}$ concentrations. As discussed in section III.A.3 in the proposal and above, the EPA recognizes that there are various ways to combine the two primary $PM_{2.5}$ standards to achieve an appropriate degree of public health protection. Furthermore, the extent to which these two standards are interrelated in any given area depends in large part on the relative levels of the standards, the peak-to-mean ratios that characterize air quality patterns in an area, and whether changes in air quality designed to meet a given suite of standards are likely to be of a more regional or more localized nature.

In focusing on an approach of setting a generally controlling annual standard, the EPA's intent is in fact to avoid the potential ''regional inequities'' that are of concern to the commenters. The EPA judges that the most appropriate way to set standards that provide more consistent public health protection is by using the approach of setting a generally controlling annual standard. This judgment builds upon information presented in the Policy Assessment as discussed in section III.A.3 above. More specifically, the Policy Assessment recognized that the short-term exposure studies primarily evaluated daily variations in health effects with monitor(s) that measured the variation in daily $PM_{2.5}$ concentrations over the course of several years. The strength of the associations observed in these epidemiological studies was demonstrably in the numerous ''typical'' days within the air quality distribution, not in the peak days (U.S. EPA, 2011a, p. 2–9). In addition, the quantitative risk assessments conducted for this and previous reviews demonstrated the same point, that is, much, if not most, of the aggregate risk associated with short-term $PM_{2.5}$ exposures results from the large number of days during which the 24-hour average concentrations are in the low-to mid-range, below the peak 24-hour concentrations (U.S. EPA, 2011a, section 2.2.2; U.S. EPA, 2010a, section 3.1.2.2). In addition, there was no evidence suggesting that risks associated with long-term exposures were likely to be disproportionately driven by peak 24-hour concentrations.[102]

For these reasons, the Policy Assessment concluded that strategies that focused primarily on reducing peak days were less likely to achieve reductions in the $PM_{2.5}$ concentrations that were most strongly associated with the observed health effects. Furthermore, the Policy Assessment concluded that an approach that focused on reducing peak exposures would most likely result in more uneven public health protection across the U.S. by either providing inadequate protection in some areas or overprotecting in other areas (U.S. EPA, 2011a, p. 2–9; U.S. EPA, 2010a, section 5.2.3). This is because reductions based on control of peak days are less likely to control the bulk of the air quality distribution.

As a result, the EPA believes an approach that focuses on a generally controlling annual standard would likely reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and, therefore, would be the most effective and efficient way to reduce total $PM_{2.5}$-related population risk. The CASAC agreed with this approach and considered it was ''appropriate to return to the strategy used in 1997 that considers the annual and the short-term standards together, with the annual standard as the controlling standard, and the short-term standard supplementing the protection afforded by the annual standard'' (Samet, 2010d, p. 1). For the reasons discussed above, the EPA disagrees with the comments that this approach will result in the concerns raised by the commenters; rather the EPA concludes that this approach will help to address these concerns.

(2) Many of these commenters asserted that the currently available scientific information is greatly expanded and stronger compared to the last review. Some of these commenters highlighted the availability of multiple, multi-city long- and short-term exposure studies providing ''repeated, consistent evidence of effects below the current annual standard level'' (ALA *et al.,* 2012, pp. 39 to 49) and, more specifically, ''significant evidence of harm with strong confidence well below EPA's proposed annual standard range of 12–13 μg/m³'' (AHA *et al.,* 2012, pp. 10 to 12).

The EPA recognizes that in setting standards that are requisite to protect public health with an adequate margin of safety, the Administrator must weigh the various types of available scientific information in reaching public health policy judgments that neither overstate nor understate the strength and limitations of this information or the appropriate inferences to be drawn from the available science.

In general, the EPA agrees with these commenters' views that the currently available scientific evidence is stronger ''because of its breadth and the substantiation of previously observed health effects'' (77 FR 38906/2) and provides ''greater confidence in the reported associations than in the last review'' (77 FR 38940/1). The EPA also agrees with the commenters' position that it is appropriate to consider the regions within the broader air quality distributions where we have the strongest confidence in the associations reported in epidemiological studies in setting the level of the annual standard. However, as discussed in section III.E.4.d below, in weighing the available evidence and technical analyses, as well as the associated uncertainties and limitations in that information, the EPA disagrees with the commenters' views regarding the extent to which the available scientific information provides support for considering an annual standard level below the proposed range (i.e., below 12 to 13 μg/m³). In particular, the EPA disagrees with the degree to which these commenters place more weight on the relatively more uncertain evidence that is suggestive of a causal relationship (e.g., low birth weight). Consistent with CASAC advice (Samet, 2010d, p. 1), the Agency concludes it is appropriate and reasonable to place the greatest emphasis on health effects for which the Integrated Science Assessment concluded there is evidence of a causal or likely causal relationship and to place less weight on the health effects that provide evidence that is only suggestive of a causal relationship.

(3) With regard to using the air quality information from epidemiological studies to inform decisions on standard levels, commenters in this group generally supported the EPA's efforts to explore different statistical metrics from

[102] In confirmation, a number of studies have presented analyses excluding higher PM concentration days and reported a limited effect on the magnitude of the effect estimates or statistical significance of the association (e.g., Dominici, 2006b; Schwartz *et al.,* 1996; Pope and Dockery, 1992).

epidemiological studies to inform the Administrator's decisions. These commenters argued that by considering different analytic measures—either concentrations one standard deviation below the long-term means reported in the epidemiological studies or the EPA's distributional statistical analysis of population-level data that extends the approach used in previous PM NAAQS reviews to consider information beyond a single statistical metric—''the annual standard must be significantly lower than EPA has proposed'' (ALA *et al.,* 2012, pp. 50 to 61). Furthermore, with regard to characterizing the $PM_{2.5}$ air quality at which associations have been observed, some of these commenters highlighted CASAC's recommendation that ''[f]urther consideration should be given to using the 10th percentile as a level for assessing various scenarios of levels for the PM NAAQS'' (Samet, 2010c, p. 11) (ALA *et al.,* 2012, p. 55). Other commenters urged that the EPA extend the distributional analysis to include additional studies. For example, CHPAC urged the EPA to also conduct distributional analysis for children's health studies to better inform standards that would protect both children and adults from adverse health outcomes (CHPAC, 2012, p. 3).

The EPA agrees with these commenters' views that it is appropriate to take into account different statistical metrics from epidemiological studies to inform the decisions on standard levels that are appropriate to consider in setting a standard that will protect public health with an adequate margin of safety. In the development of the Policy Assessment, the EPA staff explored various approaches for using information from epidemiological studies in setting the standards. The general approach used in the final Policy Assessment, discussed in sections III.A.3 and III.E.4.a above, reflects consideration of CASAC advice (Samet, 2010c, d) and public comments on multiple drafts of the Policy Assessment.

With regard to using the distributional statistical analysis to characterize the confidence in the associations, the EPA emphasizes that there is no clear dividing line provided by the scientific evidence, and that choosing how far below the long-term mean concentrations from the epidemiological studies is appropriate to identify a standard level that will provide protection for the public health with an adequate margin of safety is largely a public health policy judgment. The EPA considers the region from approximately the 25th to 10th percentiles to be a reasonable range for providing a general frame of reference as to the part of the distribution over which our confidence in the magnitude and significance of the associations observed in epidemiological studies is appreciably lower. Based on these considerations, the EPA concludes that it is not appropriate to place as much confidence in the magnitude and significance of the associations over the lower percentiles of the distributions in each study as at and around the long-term mean concentrations. Thus, the EPA disagrees with the commenters' views that this analysis compels placing more emphasis on the lower part of this range in selecting a level for an annual standard that will protect public health with an adequate margin of safety. The EPA recognizes that this information comes primarily from two short-term exposure studies, a relatively modest data set. In light of the limited nature of this information, and in recognition of more general uncertainties inherent in the epidemiological evidence, the Administrator deems it reasonable not to place more emphasis on concentrations in the lower part of this range, as discussed below in section III.E.4.d.

With regard to the scope of the distributional statistical analysis, the EPA requested additional population-level data from the study authors for a group of six multi-city studies for which previous air quality analyses had been conducted (Hassett-Sipple *et al.,* 2010; Schmidt *et al.,* 2010, Analysis 2). These six studies were originally selected because they considered multiple locations representing varying geographic regions across multiple years. Thus, these studies provided evidence on the influence of different particle mixtures on health effects associated with long- and short-term $PM_{2.5}$ exposures. In addition, these multi-city studies considered relatively more recent health events and air quality conditions (1999 to 2005). As discussed in section III.E.4.b.i above, the EPA received and analyzed population-level data for four of the six studies (Rajan *et al.,* 2011). Three of these four studies (Krewski *et al.,* 2009; Bell *et al.,* 2008; Zanobetti and Schwartz, 2009) served as the basis for the concentration-response functions used to develop the core risk estimates (U.S. EPA, 2010a, section 3.3.3). While, the EPA agrees that it would be useful to have such data from more studies, the Agency believes that the additional data that was requested and received from study authors provide useful information to help inform the Administrator's selection of the annual standard level.

(4) Many commenters in this group highlighted $PM_{2.5}$-related impacts on at-risk populations, including potential impacts on children, older adults, persons with pre-existing heart and lung disease, and low-income populations, to support their views that the annual standard should be revised to a level of 11 μg/m³ or lower (CHPAC, 2012; AHA *et al.,* 2012; ALA, 2012, pp. 29 to 38; Rom *et al.,* 2012; Air Alliance Houston, *et al.,* 2012). These commenters urged the EPA to adopt a policy approach that placed less weight on the remaining uncertainties and limitations in the evidence and placed more emphasis on margin of safety considerations, including providing protection against effects for which there is more limited scientific evidence. For example, CHPAC urged the EPA ''to place the same weight on studies examining impacts on children's health as that of adult studies. * * * The fact that there may be stronger evidence from adult studies does not mean that standards based on adult studies will be protective for children and consequently will meet the standard requisite to protect public health with an adequate margin of safety'' (CHPAC, 2012 p. 3). Furthermore, with regard to the EPA's approach for weighing uncertainties, some of these commenters stated that ''we find no justification in the preamble for an annual standard level as high as 13 μg/m³, other than the vague assertion that uncertainties increase at lower concentrations. Further, the final proposal completely failed to address the Policy Assessment recommendations that if 13 μg/m³ was proposed, the 24-hour standard should be strengthened as well'' (ALA *et al.,* p. 7).

The EPA has carefully evaluated and considered evidence of effects in at-risk populations. With regard to effects classified as having evidence of a causal or likely causal relationship with long- or short-term $PM_{2.5}$ exposures (i.e., premature mortality, cardiovascular effects, and respiratory effects), the Agency takes note that it considered the full range of studies evaluating these effects, including studies of at-risk populations, to inform its review of the primary $PM_{2.5}$ standards. Specific multi-city studies summarized in Figures 1, 2, and 3 above highlight evidence of effects observed in two different lifestages—children and older adults—that have been identified as at-risk populations. Thus, the EPA places as much weight on studies that explored effects in children for which the evidence is causal or likely causal in

nature as on studies of such effects in adults, including older adults. As discussed above in responses to commenters supporting the retention of the current standards, in setting the standard, the EPA has focused on considering $PM_{2.5}$ concentrations somewhat *below* the lowest long-term mean concentrations from *each* of the key studies of both long- and short-term exposures of effects for which the evidence supports a causal or likely causal relationship (i.e., the first two sets of studies shown in Figure 4). Absent some reason to ignore or discount these studies, which the commenter does not provide (and of which the EPA is unaware), the EPA considers the available evidence of effects in children as well as other at-risk populations.

With respect to the EPA's consideration of more limited studies providing evidence suggestive of a causal relationship (e.g., developmental and reproductive effects), as noted above in responding to comments from the first group of commenters, the Agency agrees that it is important to place some weight on this body of evidence in setting standards that provide protection for at-risk populations, as required by the CAA. However, the Agency does not agree that the same weight must be placed on this information as on the body of scientific information for which there is evidence of a causal or likely causal relationship. To do so would ignore the difference in the breadth and strength of the evidence supporting the different causality determinations reached in the Integrated Science Assessment.

With regard to weighing the uncertainties and limitations remaining in the evidence and technical analyses, as discussed in section II.A above, the EPA recognizes that in setting a primary NAAQS that provides an adequate margin of safety, the Administrator must consider a number of factors including the nature and severity of the health effects involved, the size of sensitive population(s) at risk, and the kind and degree of the uncertainties that remain. As discussed in section III.E.4.d below, the Agency agrees with these commenters that, in weighing the available evidence and technical analyses including the uncertainties and limitations in this scientific information, there is no justification for setting a primary $PM_{2.5}$ annual standard level as high as 13 μg/m³.

Finally, some commenters in both groups also identified ''new'' studies that were not included in the Integrated Science Assessment as providing further support for their views on the level of the annual standard. As discussed in section II.B.3 above, the EPA completed a provisional review and assessment of ''new'' studies published since the close of the Integrated Science Assessment, including ''new'' studies submitted by commenters (U.S. EPA, 2012b). The provisional assessment found that the ''new'' studies expand the scientific information considered in the Integrated Science Assessment and provide important insights on the relationship between $PM_{2.5}$ exposure and health effects of PM (U.S. EPA, 2012b). However, the EPA notes that the provisional assessment found that the ''new'' science did not materially change the conclusions reached in the Integrated Science Assessment. The EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the Integrated Science Assessment that have undergone CASAC and public review, and will consider newly published studies for purposes of decision making in the next PM NAAQS review.

ii. 24-Hour Standard Level

With respect to the level of the 24-hour standard, the EPA received comments on the proposal from two distinct groups of commenters. One group that included virtually all commenters representing industry associations, businesses, and many States agreed with the Agency's proposed decision to retain the level of the 24-hour $PM_{2.5}$ standard. The other group of commenters included many medical groups, numerous physicians and academic researchers, many public health organizations, some State and local agencies, five State Attorneys General, and a large number of individual commenters. These commenters disagreed with the Agency's proposed decision and argued that EPA should lower the level of the 24-hour standard to 30 or 25 μg/m³. Comments from these groups on the level of the 24-hour $PM_{2.5}$ standard are addressed below and in the Response to Comments Document.

As noted above, of the public commenters who addressed the level of the 24-hour $PM_{2.5}$ standard, all industry commenters and most State and local commenters supported the proposed decision to retain the current level of 35 μg/m³. In many cases, these groups agreed with the rationale supporting the Administrator's proposed decision to retain the current 24-hour $PM_{2.5}$ standard, including her emphasis on the annual standard as the generally controlling standard with the 24-hour standard providing supplementary protection, and her conclusion that multi-city, short-term exposure studies provide the strongest data set for informing decisions on the appropriate 24-hour standard level. Many of these commenters agreed with the Administrator's view that the single-city, short-term studies provided a much more limited data set (e.g., limited statistical power, limited exposure data) and more equivocal results (e.g., mixed results within the same study area), making them an unsuitable basis for setting the level of the 24-hour standard.

While these commenters agreed with the EPA's proposed decision to retain the current 24-hour $PM_{2.5}$ standard, some did not agree with the EPA's approach to considering the evidence from short-term multi-city studies. For example, a commenter representing UARG pointed out that the 98th percentile concentrations reported in the proposal for multi-city studies reflect the averages of 98th percentile concentrations across the cities included in those studies (UARG, 2012; Attachment 1; p. 25). This commenter contended that such averaged 98th percentile $PM_{2.5}$ concentrations do not provide information that can appropriately inform a decision on the adequacy of the public health protection provided by the current or alternative 24-hour standards.

While the EPA agrees that there is uncertainty in linking effects reported in multi-city studies to specific air quality concentrations (U.S. EPA, 2011a, section 2.3.4.1), the EPA disagrees with this commenter's view that such uncertainty precludes the use of averaged 98th percentile $PM_{2.5}$ concentrations to inform a decision on the appropriateness of the protection provided by the 24-hour $PM_{2.5}$ standard. In particular, the EPA notes that averaged 98th percentile concentrations do provide information on the extent to which study cities contributing to reported associations would likely have met or violated the current 24-hour $PM_{2.5}$ standard during the study period. As evidence of this, the EPA notes the three multi-city studies specifically highlighted by this commenter as having averaged 98th percentile 24-hour $PM_{2.5}$ concentrations below 35 μg/m³ (Dominici *et al.,* 2006a; Bell *et al.,* 2008; Zanobetti and Schwartz, 2009). Based on the 98th percentiles of 24-hour $PM_{2.5}$ concentrations in the individual cities evaluated in these studies, the EPA notes that the majority of these study cities would likely have met the current standard during the study periods (Hassett-Sipple *et al.,* 2010). Therefore, regardless of whether the averaged 98th percentile concentrations or the 98th

percentile concentrations in each city are considered, these studies provide evidence for associations between short-term $PM_{2.5}$ and mortality or morbidity across a large number of U.S. cities, the majority of which would likely have met the current 24-hour $PM_{2.5}$ standard during study periods. In their review of the PM Policy Assessment, CASAC endorsed the conclusions drawn from analyses of averaged 98th percentile 24-hour $PM_{2.5}$ concentrations, and the EPA continues to conclude that this type of information can appropriately inform the Administrator's decision on the current 24-hour $PM_{2.5}$ standard.[103]

Another group of commenters argued that the 24-hour standard level should be lowered. Many of these commenters supported setting the level of the 24-hour $PM_{2.5}$ standard at either 25 or 30 μg/m³. In support of their position, the ALA *et al.,* AHA *et al.,* five state Attorneys General, and a number of additional groups pointed to 98th percentile $PM_{2.5}$ concentrations in locations of multi-city and single-city epidemiological studies. For example, the ALA and others pointed to multi-city studies by Dominici *et al.* (2006a), Zanobetti and Schwartz (2009), Burnett *et al.* (2000), and Bell *et al.* (2008) as providing evidence for associations with mortality and morbidity in study locations with averaged (i.e., averaged across cities) 98th percentile 24-hour $PM_{2.5}$ concentrations below 35 μg/m³. These commenters also pointed to several single-city and panel studies reporting associations between short-term $PM_{2.5}$ and mortality or morbidity in locations with relatively low 24-hour $PM_{2.5}$ concentrations. Because some of these multi- and single-city studies have reported associations with health effects in locations with 98th percentile $PM_{2.5}$ concentrations below 35 μg/m³, commenters maintained that the current 24-hour $PM_{2.5}$ standard (i.e., with its level of 35 μg/m³) does not provide an appropriate degree of protection in all areas.

In further support of their position that the level of the current 24-hour standard should be lowered, these commenters pointed out the variability across the U.S. in ratios of 24-hour to annual $PM_{2.5}$ concentrations. They noted that some locations, including parts of the northwestern U.S., experience relatively low annual $PM_{2.5}$ concentrations but can experience relatively high 24-hour concentrations at certain times of the year. In order to provide protection against effects associated with short-term $PM_{2.5}$ exposures, especially in locations with high ratios of 24-hour to annual $PM_{2.5}$ concentrations, these commenters advocated setting a lower level for the 24-hour standard.

The EPA agrees with these commenters that it is appropriate to maintain a 24-hour $PM_{2.5}$ standard in order to supplement the protection provided by the revised annual standard, particularly in locations with relatively high ratios of 24-hour to annual $PM_{2.5}$ concentrations. However, in highlighting 98th percentile $PM_{2.5}$ concentrations in study locations without also considering the impact of a revised annual standard on short-term concentrations, these commenters ignore the fact that many areas would be expected to experience decreasing short- and long-term $PM_{2.5}$ concentrations in response to a revised annual standard.

In considering the specific multi-city studies highlighted by public commenters who advocated a more stringent 24-hour standard, the EPA notes that such studies have reported consistently positive and statistically significant associations with short-term $PM_{2.5}$ exposures in locations with averaged 98th percentile $PM_{2.5}$ concentrations ranging from 45.8 to 34.2 μg/m³ and long-term mean $PM_{2.5}$ concentrations ranging from 13.4 to 12.9 (Burnett and Goldberg, 2003; Burnett *et al.,* 2004; Dominici *et al.,* 2006a; Bell *et al.,* 2008; Franklin *et al.,* 2008; Zanobetti and Schwartz, 2009).[104] The EPA notes that to the extent air quality distributions are reduced to meet the current 24-hour standard with its level of 35 μg/m³ and/or the revised annual standard with its level of 12 μg/m³, additional protection would be anticipated against the effects reported in these short-term, multi-city studies. Put another way, to attain an annual standard with a level below the long-term means in the locations of these short-term studies (as EPA is adopting here), the overall air quality distributions in the majority of study cities will necessarily be reduced, resulting in lower daily $PM_{2.5}$ ambient concentrations. We therefore expect that the revised annual standard will result in 98th percentile $PM_{2.5}$ concentrations in these cities that are lower than those measured in the studies, and that the overall distributions of $PM_{2.5}$ concentrations will be lower than those reported to be associated with health effects. Thus, even for effects reported in multi-city studies with averaged 98th percentile concentrations below 35 μg/m³, additional protection from the risks associated with short-term exposures is anticipated from the revised annual standard, without revising the 24-hour standard, because long-term average $PM_{2.5}$ concentrations in multi-city study locations were above the level of the revised annual standard (i.e., 12 μg/m³).[105] As discussed above, reducing the annual standard is the most efficient way to reduce the risks from short-term exposures identified in these studies, as the bulk of the risk comes from the large number of days across the bulk of the air quality distribution, not the relatively small number of days with peak concentrations.

In considering the single-city studies highlighted by public commenters who advocated a more stringent 24-hour standard, the EPA first notes that, overall, these single-city studies reported mixed results. Specifically, some studies reported positive and statistically significant associations with $PM_{2.5}$, some studies reported positive but non-significant associations, and several studies reported negative associations or a mix of positive and negative associations with $PM_{2.5}$. In light of these inconsistent results, the proposal noted that the overall body of evidence from single-city studies is mixed, particularly in locations with 98th percentiles of 24-hour concentrations below 35 μg/m³. Therefore, although some single-city

[103] This is not to say that the EPA's decision on whether to revise the 24-hour $PM_{2.5}$ standard should be based on or only be informed by considerations of whether studies reported associations with mortality or morbidity in areas with averaged 98th percentile $PM_{2.5}$ concentrations less than 35 mg/m³. As discussed below, in reaching a decision in this final notice on the most appropriate approach to strengthen the suite of $PM_{2.5}$ standards, the Administrator considers the degree of public health protection provided by the combination of the annual and 24-hour standards together.

[104] Commenters also highlighted associations with short-term $PM_{2.5}$ concentrations reported in sub-analyses restricted to days with 24-hour concentrations at or below 35 μg/m³ (Dominici, 2006b). These sub-analyses were not included in the original publication by Dominici *et al.* (2006a). Authors provided results of sub-analyses for the Administrator's consideration in a letter to the docket following publication of the proposed rule in January 2006 (personal communication with Dr. Francesca Dominici, 2006b). As noted in section III.A.3, these sub-analyses are part of the basis for the conclusion that there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations. Because the sub-analyses did not present long-term average $PM_{2.5}$ concentrations, it is not clear whether they reflected $PM_{2.5}$ air quality that would have been allowed by the revised annual $PM_{2.5}$ standard being established in this rule.

[105] It is also the case that additional protection is anticipated in locations with 98th percentile 24-hour $PM_{2.5}$ concentrations above 35 μg/m³, even if long-term concentrations are below 12 μg/m³. As noted in the proposal and in the Policy Assessment (U.S. EPA, 2011a, Figure 2–10), parts of the northwestern U.S. are more likely than other parts of the country to violate the 24-hour standard and meet the revised annual standard.

studies reported effects at appreciably lower $PM_{2.5}$ concentrations than short-term multi-city studies, the uncertainties and limitations associated with the single-city studies were noted to be greater. In light of these greater uncertainties and limitations, the Administrator concluded in the proposal that she had less confidence in using these studies as a basis for setting the level of the standard (77 FR 38943).

Given the considerations and conclusions noted above, in the proposal the Administrator concluded that the short-term multi-city studies provide the strongest evidence to inform decisions on the level of the 24-hour standard. Further, she viewed single-city, short-term exposure studies as a much more limited data set providing mixed results, and she had less confidence in using these studies as a basis for setting the level of a 24-hour standard (77 FR 38942). In highlighting specific single-city studies, public health, environmental, and State and local commenters appear to have selectively focused on studies reporting associations with $PM_{2.5}$ and to have overlooked studies that reported more equivocal results (e.g., Ostro *et al.,* 2003; Rabinovitch *et al.,* 2004; Slaughter *et al.,* 2005; Villeneuve *et al.,* 2006) (U.S. EPA, 2011, Figure 2–9). As such, these commenters have not presented new information that causes the EPA to reconsider its decision to emphasize multi-city studies over single-city studies when identifying the appropriate level of the 24-hour $PM_{2.5}$ standard.

In further considering the single-city studies highlighted by public commenters, the EPA notes that some commenters advocating for a lower level for the 24-hour $PM_{2.5}$ standard also discussed short-term studies that have been published since the close of the Integrated Science Assessment. These recent studies were conducted in single cities or in small panels of volunteers. As in prior NAAQS reviews and as discussed above in more detail (section II.B.3), the EPA is basing its decisions in this review on studies and related information assessed in the Integrated Science Assessment. The studies assessed in the Integrated Science Assessment, and the conclusions based on those studies, have undergone extensive critical review by the EPA, CASAC, and the public. The rigor of that review makes the studies assessed in the Integrated Science Assessment, and the conclusions based on those studies, the most reliable source of scientific information on which to base decisions on the NAAQS.

However, as discussed above (section II.B.3), the EPA recognizes that ''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. 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 made in the air quality criteria regarding the health effects of $PM_{2.5}$ (U.S. EPA, 2012b).

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 completing this review. Accordingly, the EPA is basing its final decisions in this review on the studies and related information included in the PM Integrated Science Assessment (i.e., the air quality criteria) that has undergone CASAC and public review. The EPA will consider the ''new studies'' in the next periodic review of the PM NAAQS, which will provide an opportunity to fully assess these studies through a more rigorous review process involving the EPA, CASAC, and the public.

Some public health, medical, and environmental commenters also criticized the EPA's interpretation of $PM_{2.5}$ risk results. These commenters presented risk estimates for combinations of annual and 24-hour standards using more recent air quality data than that used in the EPA's Risk Assessment (U.S. EPA, 2010a). Based on these additional risk analyses, the ALA and other commenters contended that public health benefits could continue to increase as annual and 24-hour standard levels decrease below 13 μg/m³ and 35 μg/m³, respectively.

The EPA agrees with commenters that important public health benefits are expected as a result of revising the level of the annual standard to 12 μg/m³, as is done in this rule, rather than 13 μg/m³. The Agency also acknowledges that estimated $PM_{2.5}$-associated health risks continue to decrease with annual standard levels below 12 μg/m³ and/or with 24-hour standard levels below 35 μg/m³. However, the EPA disagrees with the commenters' views regarding the extent to which risk estimates support setting standard levels below 12 μg/m³ (annual standard) and 35 μg/m³ (24-hour standard).[106]

The CAA charges the Administrator with setting NAAQS that are ''requisite'' (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. In setting such standards the Administrator must weigh the available scientific evidence and information, including associated uncertainties and limitations. As described above, in reaching her proposed decisions on the $PM_{2.5}$ standards that would provide ''requisite'' protection, the Administrator carefully considered the available scientific evidence and risk information, making public health policy judgments that, in her view, neither overstated nor understated the strengths and limitations of that evidence and information. In contrast, as discussed more fully above, public health, medical, and environmental commenters who recommended levels below 35 μg/m³ for the 24-hour $PM_{2.5}$ standard have not provided new information or analyses to suggest that such standard levels are appropriate, given the uncertainties and limitations in the available health evidence, particularly uncertainties in studies conducted in locations with 98th percentile 24-hour $PM_{2.5}$ concentrations below 35 μg/m³ and long-term average concentrations below 12 μg/m³.

d. Administrator's Final Conclusions on the Primary $PM_{2.5}$ Standard Levels

In reaching her conclusions regarding appropriate standard levels, the Administrator has considered the epidemiological and other scientific evidence, estimates of risk reductions associated with just meeting alternative annual and/or 24-hour standards, air quality analyses, related limitations and uncertainties, the advice of CASAC, and extensive public comments on the proposal. After careful consideration of all of these, the Administrator has decided to revise the level of the primary annual $PM_{2.5}$ standard from 15.0 μg/m³ to 12.0 μg/m³ and to retain the level of the primary 24-hour standard at 35 μg/m³.

As an initial matter, the Administrator agrees with the approach supported by CASAC and discussed in the Policy Assessment as summarized in sections III.A.3 and III.E.4.a above, of considering the annual and 24-hour standards together in determining the protection afforded against mortality and morbidity effects associated with both long- and short-term exposures to $PM_{2.5}$. This approach is consistent with the approach taken in the review

[106] This section focuses on the 24-hour standard. Section III.E.4.c.i above also discusses these commenters' recommendations within the context of the annual $PM_{2.5}$ standard.

completed in 1997, in contrast to the approach used in the review completed in 2006 where each standard was considered independently of the other (i.e., only data from long-term exposure studies were used to inform the level of the annual standard and only data from short-term exposure studies were used to inform the level of the 24-hour standard).[107]

Based on the evidence and quantitative risk assessment, the Administrator concludes that it is appropriate to set an annual standard that is generally controlling, which will lower the broad distribution of 24-hour average concentrations in an area as well as the annual average concentration, so as to provide protection from both long- and short-term $PM_{2.5}$ exposures. In conjunction with this, it is appropriate to set a 24-hour standard focused on providing supplemental protection, particularly for areas with high peak-to-mean ratios of 24-hour concentrations, possibly associated with strong local or seasonal sources, and for $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods. The Administrator concludes this approach will reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and is the most effective and efficient way to reduce total $PM_{2.5}$-related population risk and to protect public health with an adequate margin of safety.

In selecting the level of the annual $PM_{2.5}$ standard, based on the characterization and assessment of the epidemiological and other studies presented and assessed in the Integrated Science Assessment and the Policy Assessment, the Administrator recognizes the substantial increase in the number and diversity of studies available in this review. This expanded body of evidence includes extended analyses of the seminal studies of long-term $PM_{2.5}$ exposures (i.e., ACS and Harvard Six Cities studies) as well as important new long-term exposure studies (as summarized in Figures 1 and 2). Collectively, the Administrator notes that these studies, along with evidence available in the last review, provide consistent and stronger evidence than previously observed of an association between long-term $PM_{2.5}$ exposures and premature mortality in areas with lower long-term ambient concentrations than previously observed, with the strongest evidence related to cardiovascular-related mortality. The Administrator also recognizes the availability of stronger evidence of morbidity effects associated with long-term $PM_{2.5}$ exposures, including evidence of respiratory effects such as decreased lung function growth, from the extended analyses for the Southern California Children's Health Study and evidence of cardiovascular effects from the WHI study. Furthermore, the Administrator recognizes new U.S. multi-city studies that greatly expand and reinforce our understanding of mortality and morbidity effects associated with short-term $PM_{2.5}$ exposures, providing stronger evidence of associations in areas with ambient concentrations similar to those previously observed in short-term exposure studies considered in the previous review (as summarized in Figure 3).

The Administrator recognizes the strength of the scientific evidence for evaluating health effects associated with fine particles, noting that the newly available scientific evidence builds upon the previous scientific data base to provide evidence of generally robust associations and a basis for greater confidence in the reported associations than in the last review. She notes the conclusion of the Integrated Science Assessment that this body of evidence supports a causal relationship between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects and a likely causal relationship between long- and short-term $PM_{2.5}$ exposures and respiratory effects. In addition, the Administrator notes additional, but more limited evidence, for a broader range of health endpoints including evidence suggestive of a causal relationship for developmental and reproductive effects as well as for carcinogenic effects.

Based on information discussed and presented in the Integrated Science Assessment, the Administrator recognizes that health effects may occur over the full range of concentrations observed in the epidemiological studies of both long-term and short-term exposures, since no discernible population-level threshold for any such effects can be identified based on the currently available evidence (U.S. EPA, 2009a, section 2.4.3). To inform her decisions on an appropriate level for the annual standard that will protect public health with an adequate margin of safety, in the absence of any discernible population-level thresholds, the Administrator judges that it is appropriate to consider the relative degree of confidence in the magnitude and significance of the associations observed in epidemiological studies across the range of long-term $PM_{2.5}$ concentrations in such studies. Further, she recognizes, in taking note of CASAC advice and the distributional statistics analysis discussed in the Policy Assessment and in section III.E.4.a above, that there is significantly greater confidence in the magnitude and significance of observed associations for the part of the air quality distribution corresponding to where the bulk of the health events evaluated in each study have been observed, generally at and around the long-term mean concentrations. Conversely, she also recognizes that there is significantly diminished confidence in the magnitude and significance of observed associations in the lower part of the air quality distribution corresponding to where a relatively small proportion of the health events were observed. Further, the Administrator recognizes that the long-term mean concentrations, or any other specific point in the air quality distribution of each study, do not represent a ''bright line'' at and above which effects have been observed and below which effects have not been observed.

In considering the long-term mean concentrations reported in epidemiological studies, the Administrator recognizes that in selecting a level of the annual standard that will protect public health with an adequate margin of safety, it is not sufficient to focus on a concentration generally somewhere within the range of long-term mean concentrations from the key long-term and short-term exposure studies that reported lower concentrations than had been observed in earlier reviews. These key studies provide information for various types of serious health endpoints (including mortality and morbidity effects), different study populations (which may include at-risk populations such as children and older adults), and different air quality distributions that are specific to each study. A level somewhere within the range of long-term mean concentrations of the full set of key studies would be higher than the long-term mean of at least one of the studies being considered and therefore would not provide a sufficient degree of protection against the health effects observed in that study. Absent some reasoned basis to place less weight on the evidence in the epidemiological study with the lowest long-term mean concentration among these key studies, this approach would not be consistent with the requirement to set a standard that will protect public health with an

[107] See 71 FR 61148 and 61168, October 17, 2006.

adequate margin of safety.[108] Thus, the Administrator recognizes it is important to protect against the serious effects observed in *each* of these studies so as to protect public health with an adequate margin of safety. In so doing, she looks to identify the study with the lowest long-term mean concentration within the *full* set of key studies to help inform her decision of the appropriate standard level which will provide protection for the broad array of health outcomes observed in *all* of the studies, including effects observed in at-risk populations.

Further, consistent with the general approach summarized in section III.E.4.a above and supported by CASAC as discussed in section III.E.4.b.ii above, the Administrator recognizes that it is appropriate to consider a level for an annual standard that is not just at but rather is somewhat below the long-term mean $PM_{2.5}$ concentrations reported in each of the key long- and short-term exposure studies. In so doing, she focuses especially on multi-city studies that evaluated health endpoints for which the associations are causal or likely causal (i.e., mortality and cardiovascular and respiratory effects associated with both long- and short-term $PM_{2.5}$ exposures). As discussed above, the importance of considering a level somewhat below the lowest long-term mean concentrations in this set of key studies is to establish a standard that would be protective against the observed effects in *all* of the studies, and that takes into account the relative degree of confidence in the magnitude and significance of observed associations across the air quality distributions in these studies.

The Administrator recognizes that there is no clear way to identify how much below the long-term mean concentrations of key studies to set a standard that would provide requisite protection with an adequate margin of safety. She therefore must use her judgment to weigh the available scientific and technical information, and associated uncertainties, to reach a final decision on the appropriate standard level. In considering the information in Figures 1–4 for effects classified as having evidence of a causal or likely causal relationship with long- or short-term $PM_{2.5}$ exposures, she observes a cluster of short-term exposure studies with long-term mean concentrations within a range of 13.4 μg/m³ down to 12.8 μg/m³ (Dominici *et al.,* 2006a; Burnett and Goldberg, 2003; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008; Burnett *et al.,* 2004). She also observes a cluster of long-term exposure studies with long-term mean concentrations within a range of 14.5 μg/m³ to 13.6 μg/m³ (Dockery *et al.,* 1996; Lipfert *et al.,* 2006a; Zeger *et al.,* 2008; McConnell *et al.,* 2003; Goss *et al.,* 2004; Eftim *et al.,* 2008). For the reasons discussed in response to public comments in section III.E.4.c above, the Administrator is less influenced by the long-term mean $PM_{2.5}$ concentrations from the Miller *et al.* (2007) and Krewski *et al.* (2009) studies with reported long-term mean $PM_{2.5}$ concentrations of 12.9 and 14.0 μg/m³, respectively. In each case, the most relevant exposure periods would likely have had higher mean $PM_{2.5}$ concentrations than those reported in the studies.[109] Thus, the Administrator considers the long-term mean $PM_{2.5}$ concentrations from these two studies to be a highly uncertain basis for informing her selection of the annual standard level.[110]

To help guide her judgment of the appropriate level below the long-term mean concentrations in the epidemiological studies at which to set the standard, the Administrator considered additional information from epidemiological studies concerning the broader distribution of $PM_{2.5}$ concentrations which correspond to the health events observed in these studies (e.g., deaths, hospitalizations). The Administrator observes that the development and use of this information in considering standard levels is consistent with CASAC's advice, as discussed in section III.E.4.b.ii above, to focus on understanding the concentrations that were most influential in generating the health effect estimates in individual studies (Samet, 2010d, p. 2).

In considering this additional population-level information, the Administrator recognizes that, in general, the confidence in the magnitude and significance of an association identified in a study is strongest at and around the long-term mean concentration for the air quality distribution, as this represents the part of the distribution in which the data in any given study are generally most concentrated. She also recognizes that the degree of confidence decreases as one moves towards the lower part of the distribution. Consistent with the approach used in the Policy Assessment, the Administrator believes that the range from approximately the 25th to 10th percentiles is a reasonable range for providing a general frame of reference as to the part of the distribution in which her confidence in the associations observed in epidemiological studies is appreciably lower. However, as noted above, it is important to emphasize that there is no clear dividing line or single percentile within a given distribution provided by the scientific evidence that is most appropriate or 'correct' to use to characterize where the degree of confidence in the associations warrants setting the annual standard level. The decision of the appropriate standard level below the long-term mean concentrations of the key studies, which in conjunction with the other elements of the standard would protect public health with an adequate margin of safety, is largely a public health policy judgment, taking into account all of the evidence and its related uncertainties.

As discussed in section III.E.4.b, the Administrator takes note of additional population-level data that were made available to the EPA by study authors.[111] In considering this information, the Administrator particularly focuses on the analysis of the distributions of the health event data for each area within these studies and the corresponding air quality data for the two short-term exposure studies (Zanobetti and Schwartz, 2009; Bell *et al.,* 2008). These short-term exposure studies evaluate the relationship between daily changes (one or more days) in $PM_{2.5}$ concentrations and daily changes in health events (e.g., deaths, hospitalizations), such that the air quality concentrations that comprise the most relevant exposure periods in these

[108] See *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512, 525–26 (D.C. Cir. 2009).

[109] In the case of Miller *et al.* (2007), the mean concentration is based on a single year of air quality data which post-dated by two years the period for which the health events data were collected. In the case of Krewski *et al.* (2009), the air quality data were based on the last two years of the 18-year period for which the health event data were collected.

[110] Nonetheless, as noted above, the EPA notes that the Krewski *et al.* (2009) and Miller *et al.* (2007) studies provide strong evidence of mortality and cardiovascular-related effects associated with long-term $PM_{2.5}$ exposures to inform causality determinations reached in the Integrated Science Assessment (U.S. EPA, 2009a, sections 7.2.11 and 7.6).

[111] As summarized in section III.E.4.a, population-level data were provided to the EPA for four studies. These four studies represent some of the strongest evidence showing associations between health effects and $PM_{2.5}$ within the overall body of scientific evidence and include three studies (Krewski *et al.,* 2009; Bell *et al.,* 2008; and Zanobetti and Schwartz, 2009) that were used as the basis for concentration-response functions in the quantitative risk assessment (U.S. EPA, 2010a, section 3.3.3). The Administrator recognizes that the additional population-level data available for these four multi-city studies represents a more limited data set compared to the set of long-term mean $PM_{2.5}$ concentrations which were available in the published literature for all studies considered in the Integrated Science Assessment.

studies are contemporaneous with the health event data. In addition, these studies considered more recent air quality data, representing generally lower $PM_{2.5}$ concentrations, in a large number of study areas across the U.S. Thus, such studies provide the most useful evidence for an analysis evaluating the distribution of health event data and the corresponding long-term mean $PM_{2.5}$ concentrations across the areas included in each multi-city study.

The Administrator also considered the additional population-level data that were made available to EPA for two long-term exposure studies (Krewski *et al.,* 2009; Miller *et al.,* 2007). She recognizes that in long-term exposure studies investigators follow a specific group of study participants (i.e., cohort) over time and across urban study areas, and evaluate how $PM_{2.5}$ concentrations averaged over a period of years are associated with specific health endpoints (e.g., deaths) across cities. As discussed in response to public comments in section III.E.4.c, disentangling the effects observed in long-term exposure studies associated with more recent air quality measurements from effects that may have been associated with earlier, and most likely higher, $PM_{2.5}$ exposures introduces some uncertainty with regard to understanding the appropriate exposure window associated with the observed effects. This is in contrast to the short-term exposure studies where the relevant exposure period is contemporaneous to the period for which the health data were collected. In light of these considerations, as noted above, the Administrator considers the analysis of air quality concentrations that correspond to the distribution of population-level data in these two studies to be a highly uncertain basis for informing her selection of the annual standard level.

Based on the above considerations, the Administrator views the additional population-level data for the two short-term exposure studies as appropriate to help inform her judgment of how much below the long-term mean concentrations to set the level of the annual standard. The Administrator notes that the long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25th percentiles of the distribution of deaths and cardiovascular-related hospitalizations in these two short-term exposure studies were 12.5 μg/m^3 and 11.5 μg/m^3, respectively, for Zanobetti and Schwartz (2009) and for Bell *et al.* (2008), with the 10th percentiles being lower by approximately 2 μg/m^3 in each study.

The Administrator recognizes, as summarized in section III.B above and discussed more fully in section III.B.2 of the proposal, that important uncertainties remain in the evidence and information considered in this review of the primary fine particle standards. These uncertainties are generally related to understanding the relative toxicity of the different components in the fine particle mixture, the role of $PM_{2.5}$ in the complex ambient mixture, exposure measurement errors, and the nature and magnitude of estimated risks related to increasingly lower ambient $PM_{2.5}$ concentrations. Furthermore, the Administrator notes that epidemiological studies have reported heterogeneity in responses both within and between cities and geographic regions across the U.S. She recognizes that this heterogeneity may be attributed, in part, to differences in fine particle composition in different regions and cities.[112]

With regard to evidence for reproductive and developmental effects identified as being suggestive of a causal relationship with long-term $PM_{2.5}$ exposures, the Administrator recognizes that there are a number of limitations associated with this body of evidence including: the limited number of studies evaluating such effects; uncertainties related to identifying the relevant exposure time periods of concern; and limited toxicological evidence providing little information on the mode of action(s) or biological plausibility for an association between long-term $PM_{2.5}$ exposures and adverse birth outcomes. Nonetheless, the Administrator believes that this more limited body of evidence provides some support for considering that serious effects may be occurring in a susceptible population at concentrations lower than those associated with effects classified as having a causal or likely causal relationship with long-term $PM_{2.5}$ exposures (i.e., mortality, cardiovascular, and respiratory effects).

Overall, the Administrator believes that the available evidence interpreted in light of the remaining uncertainties, as summarized above and discussed more fully in the Integrated Science Assessment and the Policy Assessment, provides increased confidence relative to information available in the last review and provides a strong basis for informing her final decisions in the current review. The Administrator is mindful that considering what standards are requisite to protect public health with an adequate margin of safety requires public health policy judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. In considering how to translate the available information into appropriate standard levels, the Administrator weighs the available scientific information and associated uncertainties and limitations. For the purpose of determining what annual standard level is appropriate the Administrator recognizes that there is no single factor or criterion that comprises the ''correct'' approach to weighing the various types of available evidence and information.

In considering this information, the Administrator notes the advice of CASAC that ''there are significant public health consequences at the current levels of the standards that justify consideration of lowering the $PM_{2.5}$ NAAQS further'' (Samet, 2010c, p. 12). In addition, she recognizes that CASAC concluded, ''although there is increasing uncertainty at lower levels, there is no evidence of a threshold (i.e., a level below which there is no risk for adverse effects)'' (Samet, 2010d, p.ii) and that the final decisions on standard levels must reflect a judgment of the available scientific information with respect to her interpretation of the CAA's requirement to set primary standards that provide requisite protection to public health with an adequate margin of safety (Samet, 2010d, p. 4). The Administrator recognizes CASAC's advice that the currently available scientific information provided support for considering an annual standard level within a range of 13 to 11 μg/m^3 and a 24-hour standard level within a range of 35 to 30 μg/m^3. In considering how the annual and 24-hour standards work together to provide appropriate public health protection, the Administrator observes that CASAC did not express support for any specific levels or combinations of standards within these ranges. She also notes that CASAC encouraged the EPA staff to consider additional data from epidemiological studies to help quantify the characterization of the $PM_{2.5}$ concentrations that were most influential in generating the health

[112] Nonetheless, as explained in section III.E.1, the currently available evidence is not sufficient to support replacing or supplementing the $PM_{2.5}$ indicator with any other indicator defined in terms of a specific fine particle component or group of components associated with any source categories of fine particles. Furthermore, the evidence is not sufficient to support eliminating any component or group of components associated with any source categories of fine particles from the mix of fine particles included in the $PM_{2.5}$ indicator.

effect estimates in these studies (Samet, 2010d, p. 2).

In response to CASAC's advice, the Administrator recognizes that the EPA staff acquired additional data from authors of key epidemiological studies and analyzed these data to characterize the distribution of $PM_{2.5}$ concentrations in relation to health events data to better understand the degree of confidence in the associations observed in the studies as discussed above. The Administrator recognizes that the final Policy Assessment included consideration of these additional analyses in reaching final staff conclusions with regard to the broadest range of alternative standard levels supported by the science. She takes note that the final Policy Assessment concluded that while alternative standard levels within the range of 13 to 11 μg/m³ were appropriate to consider, the evidence most strongly supported consideration of an annual standard level in the range of 12 to 11 μg/m³. The Administrator is aware that, in transmitting the final Policy Assessment to CASAC, the Agency notified CASAC that the final staff conclusions reflected consideration of CASAC's advice and that those staff conclusions were based, in part, on the specific distributional analysis that CASAC had urged the EPA to conduct (Wegman, 2011). Thus, CASAC had an opportunity to comment on the final Policy Assessment, but chose not to provide any additional comments or advice after receiving it.

In selecting the annual standard level, the Administrator has considered many factors including the nature and severity of the health effects involved, the strength of the overall body of scientific evidence as considered in reaching causality determinations, the size of the at-risk populations, and the estimated public health impacts. She has also considered the kind and degree of the uncertainties that remain in the available scientific information. She recognizes that the association between $PM_{2.5}$ and serious health effects is well established, including at concentrations below those allowed by the current standard. Further, she recognizes the CAA requirement that requires primary standards to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information as well as to provide a reasonable degree of protection against hazards that research has not yet identified. In considering the currently available evidence, as summarized and discussed more broadly above, the information on risk, CASAC advice, the conclusions of the Policy Assessment, and public comments on the proposal, the Administrator strongly believes that a lower annual standard level is needed to protect public health with an adequate margin of safety.

In reaching her final decision on the appropriate annual standard level to set, the Administrator is mindful that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health, including the health of at-risk populations, with an adequate margin of safety. On balance, the Administrator concludes that an annual standard level of 12 μg/m³ would be requisite to protect the public health with an adequate margin of safety from effects associated with long- and short-term $PM_{2.5}$ exposures, while still recognizing that uncertainties remain in the scientific information.

In the Administrator's judgment, an annual standard of 12 μg/m³ appropriately reflects placing greatest weight on evidence of effects for which the Integrated Science Assessment determined there is a causal or likely causal relationship with long- and short-term $PM_{2.5}$ exposures. An annual standard level of 12 μg/m³ is below the long-term mean $PM_{2.5}$ concentrations reported in *each* of the key multi-city, long- and short-term exposures studies providing evidence of an array of serious health effects (e.g., premature mortality, increased hospitalization for cardiovascular and respiratory effects). As noted above, the importance of considering a level somewhat below the lowest long-term mean concentration in the full set of studies considered is to set a standard that would provide appropriate protection against the observed effects in *all* such studies.

In reaching her decision, the Administrator has taken into account that at and around the mean $PM_{2.5}$ concentration in any given study represents a part of the air quality distribution in which the health event data in that study are generally most concentrated. Furthermore, in identifying an appropriate annual standard level below the long-term mean concentrations, she recognizes that there is no evidence to support the existence of any discernible threshold, and, therefore, she has a high degree of confidence that the observed effects are associated with concentrations not just at but extending somewhat below the long-term mean concentration. To further inform her judgment in setting the annual standard level so as to protect public health with an adequate margin of safety, the Administrator has placed weight on additional population-level information available from a subset of these epidemiological studies, consistent with CASAC advice. In particular, she has drawn from two short-term exposure studies, which provide the most relevant information for evaluating the distribution of health events and corresponding long-term $PM_{2.5}$ concentrations. As explained above, this helps inform her judgment as to the degree of confidence in the observed associations in the epidemiological studies. In this regard, the Administrator generally judges the region around the 25th percentile as a reasonable part of the distribution to help guide her decision on the appropriate standard level. Since this evidence comes primarily from two studies, a relatively modest data set, the Administrator deems it reasonable not to draw further inferences from air quality and health event data in the lower part of the distribution for the purpose of setting a standard level. The Administrator notes that the long-term mean $PM_{2.5}$ concentrations around the 25th percentile of the distributions of deaths and cardiovascular-related hospitalizations were approximately around 12 μg/m³ in these two studies. The Administrator views this information as helpful in guiding her determination as to where her confidence in the magnitude and significance of the associations is reduced to such a degree that a standard set at a lower level would not be warranted to provide requisite protection that is neither more nor less than needed to provide an adequate margin of safety.

The Administrator also recognizes that a level of 12 μg/m³ places some weight on studies which provide evidence of reproductive and developmental effects (e.g., infant mortality, low birth weight). These studies were identified in the Integrated Science Assessment as having evidence suggestive of a causal relationship with long-term $PM_{2.5}$ concentrations. A level of 12 μg/m³ is approximately the same level as the lowest long-term mean concentration reported in such studies (Figures 2 and 4; 11.9 μg/m³ for Bell *et al.,* 2007).[113] While the Administrator

[113] With respect to cancer, mutagenic, and genotoxic effects, the Administrator observes that the $PM_{2.5}$ concentrations reported in studies evaluating these effects generally included ambient concentrations that are equal to or greater than ambient concentrations observed in studies that reported mortality and cardiovascular and respiratory effects (U.S. EPA, 2009a, section 7.5). Therefore, the Administrator concludes that in selecting alternative standard levels that provide protection from mortality and cardiovascular and respiratory effects, it is reasonable to anticipate that

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acknowledges that this evidence is limited, she believes it is appropriate to place some weight on these studies in order to set a standard that provides protection with an adequate margin of safety, including providing protection for at-risk populations, as required by the CAA. Due to the limited nature of this evidence, she has determined it is not necessary to set a standard below the lowest long-term mean concentration in these studies.

In reflecting on extensive public comments received on the proposal as discussed in section III.E.4.c above, the Administrator recognizes that some commenters have offered different evaluations of the evidence and other information available in this review and would make different judgments about the weight to place on the relative strengths and limitations of the scientific information and about how such information could be used in making public health policy decisions on the annual standard level. One group of such commenters who supported a higher annual standard level (e.g., above 13 μg/m^3) would place greater weight on the remaining uncertainties in the evidence as a basis for supporting a higher standard level than the Administrator judges to be appropriate. Such an approach is based on these commenters' judgment that the uncertainties remaining in the evidence are too great to warrant setting an annual standard below the current level. The Administrator does not agree.

As an initial matter, an annual standard level of 13 μg/m^3 or higher would be above the long-term mean concentrations reported in two well-conducted, multi-city short-term exposure studies reporting positive and statistically significant associations of serious effects (Burnett *et al.,* 2004 and Bell *et al.,* 2008). These important studies are fully consistent with the pattern of evidence presented by the large body of evidence in this review. As the Administrator recognized in the proposal, and as advised by CASAC, the appropriate focus for selecting the level of the annual $PM_{2.5}$ standard is on concentrations somewhat *below* the lowest long-term mean concentrations from the set of key studies of both long-term and short-term $PM_{2.5}$ exposures considered by the EPA (i.e., as shown in Figure 4). Thus, a standard level set at 13 μg/m^3 or higher would clearly not provide protection for the effects observed in the full set epidemiological studies and, therefore, this standard level could not be judged to be requisite with an adequate margin of safety.[114]

In addition, as noted above, in recognizing that there is no evidence to support the existence of a discernible threshold below which an effect would not occur, the Administrator is mindful that effects occur around and below the long-term mean concentrations reported in both the short-term and long-term the epidemiological studies. A standard level of 13 μg/m^3 or higher would not appropriately take into account evidence from the two well-conducted, multi-city, short-term exposure studies reporting serious effects with long-term mean concentrations below 13 μg/m^3 noted above (Burnett *et al,* 2004; Bell *et al.,* 2008). Such a standard level would also not appropriately take into account additional population-level data from a limited number of epidemiological studies. This approach would ignore CASAC's advice to consider such information in order to better understand the concentrations over which there is a high degree of confidence regarding the magnitude and significance of the associations observed in individual epidemiological studies and where there is appreciably less confidence.

Furthermore, a standard level of 13 μg/m^3 or higher would not appropriately take into account the more limited evidence of effects in some at-risk populations (e.g., low birth weight). In the Administrator's view, a standard set at this level would not provide protection with an adequate margin of safety, including providing protection for at-risk populations. The Administrator is mindful that the CAA requirement that primary standards provide an adequate margin of safety, discussed in section II.A above, was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting as well as to provide a reasonable degree of protection against hazards that research has not yet identified.

In light of the entire body of evidence as discussed above, the Administrator judges that an annual standard level set above 12 μg/m^3 would not be sufficient to protect public health with an adequate margin of safety from the serious health effects associated with long- and short-term exposure to $PM_{2.5}$.

The Administrator also recognizes that a second group of commenters supported a lower annual standard level (e.g., no higher than 11 μg/m^3). Such a standard level would reflect placing essentially as much weight on the relatively more limited data providing evidence suggestive of a causal relationship for effects observed in some at-risk populations (e.g., low birth weight) as on more certain evidence of effects classified as having a causal or likely causal relationship with $PM_{2.5}$ exposures. In the Administrator's view, while it is important to place some weight on such suggestive evidence, it would not be appropriate to place as much weight on it as the commenters would do.

An annual standard level of 11 μg/m^3 would also reflect these commenters' judgment that it is appropriate to focus on a lower part of the distributions of health event data from the small number of epidemiological studies for which this information was made available than the Administrator believes is warranted. In the Administrator's view, using this type of information to set a standard level of 11 μg/m^3 or below would assume too high a degree of confidence in the magnitude and significance of the associations observed in the lower part of the distributions of health events observed in these studies. Given the uncertainties in the evidence and the limited set of studies for which the EPA has information on the distribution of health event data and corresponding air quality data, the Administrator believes it is not appropriate to focus on the lower part of the distributions of health events data.

On balance, the Administrator finds that the available evidence interpreted in light of the remaining uncertainties does not justify a standard level set below 12 μg/m^3 as necessary to protect public health with an adequate margin of safety.

After carefully considering the above considerations and the public comments summarized in section III.E.4.c above, the Administrator has decided to set the level of the primary annual $PM_{2.5}$ standard at 12 μg/m^3. In her judgment, a standard set at this level provides the requisite degree of public health protection, including the health of at-risk populations, with an adequate margin of safety and is neither more nor less stringent than necessary for this purpose.

protection will also be provided for carcinogenic effects.

[114] The Administrator is mindful that, in reviewing the 2006 final PM NAAQS decisions, the D.C. Circuit Court of Appeals concluded that the EPA failed to adequately explain why that annual standard provided requisite protection from effects associated with both long- and short-term exposures or from morbidity effects in children and other at-risk populations when long-term means of important short-term studies were below the level the Administrator selected for the annual standard. See *American Farm Bureau* v. *EPA.* 559 F. 3d 512, 524–26. There is no reasonable basis to discount these two studies for purposes of setting the level of the annual standard.

As discussed above, the Administrator concludes that an approach that focuses on setting a generally controlling annual standard is the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures. Such an approach would result in more uniform protection across the U.S. than the alternative of setting the levels of the 24-hour and annual standard such that the 24-hour standard would generally be the controlling standard in areas across the country (see section III.A.3).

The Administrator recognizes that potential air quality changes associated with meeting an annual standard level of 12.μg/m³ will result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures by lowering the overall air quality distribution. However, the Administrator recognizes that such an annual standard alone would not be expected to offer sufficient protection with an adequate margin of safety against the effects of short-term $PM_{2.5}$ exposures in all parts of the country. As a result, in conjunction with an annual standard level of 12 μg/m³, the Administrator concludes that it is appropriate to continue to provide supplemental protection by means of a 24-hour standard set at the appropriate level, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources and for areas with $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods.

In selecting the level of a 24-hour standard meant to provide such supplemental protection, the Administrator relies upon evidence and air quality information from key short-term exposure studies. In considering these studies, the Administrator notes that to the extent air quality distributions in the study areas considered are reduced to meet the current 24-hour standard (at a level of 35 μg/m³) or to meet the revised annual standard discussed above (at a level of 12 μg/m³), additional protection would be anticipated against the effects observed in these studies. In light of this, when selecting the appropriate level for the 24-hour standard, the Administrator considers both the 98th percentiles of 24-hour $PM_{2.5}$ concentrations and the long-term mean $PM_{2.5}$ concentrations in the locations of the short-term exposure studies. She notes that such consideration of both short- and long-term $PM_{2.5}$ concentrations can inform her decision on the extent to which a given 24-hour standard, in combination with the revised annual standard established in this rule, would provide protection against the health effects reported in short-term studies.

As discussed in section III.E.4.a above, the Administrator concludes that multi-city short-term exposure studies provide the strongest data set for informing her decisions on appropriate 24-hour standard levels. With regard to the limited number of single-city studies that reported positive and statistically significant associations for a range of health endpoints related to short-term $PM_{2.5}$ concentrations in areas that would likely have met the current suite of $PM_{2.5}$ standards, the Administrator recognizes that many of these studies had significant limitations (e.g., limited statistical power, limited exposure data) or equivocal results (mixed results within the same study area) that make them unsuitable to form the basis for setting the level of a 24-hour standard.

With regard to multi-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures, the Administrator observes an overall pattern of positive and statistically significant associations in studies with 98th percentile 24-hour values averaged across study areas within the range of 45.8 to 34.2 μg/m³ (Burnett *et al.,* 2004; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008; Dominici *et al.,* 2006a, Burnett and Goldberg, 2003; Franklin *et al.,* 2008). The Administrator notes that, to the extent air quality distributions are reduced to reflect just meeting the current 24-hour standard, additional protection would be provided for the effects observed in the three multi-city studies with 98th percentile values greater than 35 μg/m³ (Burnett *et al.,* 2004; Burnett and Goldberg, 2003; Franklin *et al.,* 2008). In the three additional multi-city studies with 98th percentile values below 35 μg/m³, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 μg/m³, the Administrator notes that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 μg/m³, respectively (Bell *et al.,* 2008; Zanobetti and Schwartz, 2009; Dominici *et al.,* 2006a). In revising the level of the annual standard to 12 μg/m³, as discussed above, the Administrator recognizes that additional protection would be provided for the short-term effects observed in these multi-city studies such that revision to the 24-hour standard would not be warranted. That is, by lowering the level of the annual standard to 12 μg/m³, the 98th percentile of the distribution would be lowered as well such that additional protection from effects associated with short-term exposures would be afforded. Therefore, the epidemiological evidence supports a conclusion that it is appropriate to retain the level of the 24-hour standard at 35 μg/m³, in conjunction with a revised annual standard level of 12 μg/m³.

In addition to considering the epidemiological evidence, the Administrator also has taken into account air quality information based on county-level 24-hour and annual design values to understand the implications of revising the annual standard level from 15 to 12 μg/m³ in conjunction with retaining the 24-hour standard level at 35 μg/m³. She has considered this information to evaluate the public health protection provided by the two standards in combination and to evaluate the most appropriate means of developing a suite of standards providing requisite public health protection with an adequate margin of safety.

In considering the air quality information, the Administrator observes that a suite of $PM_{2.5}$ standards that includes an annual standard level of 12 μg/m³ and a 24-hour standard level of 35 μg/m³ would result in the annual standard as the generally controlling standard in most regions across the country, except for certain areas in the Northwest, where the annual mean $PM_{2.5}$ concentrations have historically been low but where relatively high 24-hour concentrations occur, often related to seasonal wood smoke emissions (U.S. EPA, 2011a, pp. 2–89 to 2–91, Figure 2–10). In fact, these are the type of areas for which the supplemental protection afforded by the 24-hour standard is intended, such that the two standards together provide the requisite degree of protection. The Administrator concludes the current 24-hour standard at a level of 35 μg/m³, in conjunction with a revised annual standard level of 12 μg/m³, will provide appropriate protection from effects observed in studies in such areas in which the long-term mean concentrations were below 12 μg/m³ and the 98th percentile 24-hour concentrations were above 35 μg/m³ (e.g., areas in the Northwest U.S.).

After carefully taking the public comments and above considerations into account, the Administrator has decided to retain the current level of the primary $PM_{2.5}$ 24-hour standard at 35 μg/m³ in conjunction with revising the annual standard level from 15.0 μg/m³ to 12.0 μg/m³.[115] In the Administrator's

[115] As noted in section II.B.1, Table 1 and section III.E.4.a above, the annual standard level is defined to one decimal place. Throughout this section, the annual standard levels discussed have been

Continued

judgment, this suite of primary $PM_{2.5}$ standards and the rationale supporting these levels appropriately reflects consideration of the strength of the available evidence and other information and its associated uncertainties as well as the advice of CASAC and consideration of public comments. In the Administrator's judgment, this suite of primary $PM_{2.5}$ standards is sufficient but not more protective than necessary to protect the public health, including at-risk populations, with an adequate margin of safety from effects associated with long- and short-term exposures to fine particles. This suite of standards will provide significant protection from serious health effects including premature mortality and cardiovascular and respiratory morbidity effects that are causally or likely causally related to long- and short-term $PM_{2.5}$ exposures. These standards will also provide an appropriate degree of protection against other health effects for which there is more limited evidence of effects and causality, such as reproductive and developmental effects. This judgment by the Administrator appropriately considers the requirement for a standard that is requisite to protect public health but is neither more nor less stringent than necessary.[116]

D. Administrator's Final Decisions on Primary $PM_{2.5}$ Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Integrated Science Assessment, Risk Assessment, and Policy Assessment, the advice and recommendations of CASAC, and public comments to date, the Administrator revises the current suite of primary $PM_{2.5}$ standards. Specifically, the Administrator revises: (1) The level of the primary annual $PM_{2.5}$ standard to 12.0 μg/m³ and (2) the form of the primary annual $PM_{2.5}$ standard to one based on the highest appropriate area-wide monitor in an area, with no option for spatial averaging. In conjunction with revising the primary annual $PM_{2.5}$ standard to provide protection from effects associated with long- and short-term $PM_{2.5}$ exposures, the Administrator retains the level of 35 μg/m³ and the 98th percentile form of the primary 24-hour $PM_{2.5}$ standard to continue to provide supplemental protection for areas with high peak $PM_{2.5}$ concentrations. The Administrator is not revising the current $PM_{2.5}$ indicator or the annual and 24-hour averaging times for the primary $PM_{2.5}$ standards. The Administrator concludes that this suite of standards would be requisite to protect public health with an adequate margin of safety against health effects potentially associated with long- and short-term $PM_{2.5}$ exposures.

IV. Rationale for Final Decision on Primary PM_{10} Standard

This section presents the rationale for the Administrator's final decision to retain the current 24-hour primary PM_{10} standard in order to continue to provide public health protection against short-term exposures to inhalable particles in the size range of 2.5 to 10 μm (i.e., $PM_{10-2.5}$ or thoracic coarse particles). These are particles capable of reaching the most sensitive areas of the lung, including the trachea, bronchi, and deep lungs. The current standard uses PM_{10} as the indicator for thoracic coarse particles, and thus is referred to as a PM_{10} standard.[117]

As discussed more fully in the proposal and below, this rationale is based on a thorough review of the latest scientific evidence, published through mid-2009 and assessed in the Integrated Science Assessment (U.S. EPA, 2009a), evaluating human health effects associated with long- and short-term exposures to thoracic coarse particles. The Administrator's final decision also takes into account: (1) The EPA staff analyses of air quality information and health evidence and staff conclusions regarding the current and potential alternative standards, as presented in the Policy Assessment for the PM NAAQS (U.S. EPA, 2011a); (2) CASAC advice and recommendations, as reflected in discussions at public meetings of drafts of the Integrated Science Assessment and Policy Assessment, and in CASAC's letters to the Administrator; (3) the multiple rounds of public comments received during the development of the Integrated Science Assessment and Policy Assessment, both in connection with CASAC meetings and separately; and (4) public comments (including testimony at the public hearings) received on the proposal.

In presenting the rationale for the final decision to retain the current primary PM_{10} standard, this section discusses the EPA's past reviews of the PM NAAQS and the general approach taken to review the current standard (section IV.A), the health effects associated with exposures to ambient $PM_{10-2.5}$ (section IV.B), the consideration of the current and potential alternative standards in the Policy Assessment (section IV.C), CASAC recommendations regarding the current and potential alternative standards (section IV.D), the Administrator's proposed decision to retain the current primary PM_{10} standard (section IV.E), public comments received in response to the Administrator's proposed decision (section IV.F), and the Administrator's final decision to retain the current primary PM_{10} standard (section IV.G).

A. Background

The following sections discuss previous reviews of the PM NAAQS (section IV.A.1), the litigation of the EPA's 2006 decision on the PM_{10} standards (section IV.A.2), and the general approach taken to review the primary PM_{10} standard in the current review (section IV.A.3).

1. Previous Reviews of the PM NAAQS

a. Reviews Completed in 1987 and 1997

The PM NAAQS have always included some type of a primary standard to protect against effects associated with exposures to thoracic coarse particles. In 1987, when the EPA first revised the PM NAAQS, the EPA changed the indicator for PM from TSP to focus on inhalable particles, those which can penetrate into the trachea, bronchi, and deep lungs (52 FR 24634, July 1, 1987). In that review, the EPA changed the PM indicator to PM_{10} based on evidence that the risk of adverse health effects associated with particles with a nominal mean aerodynamic diameter less than or equal to 10 μm was significantly greater than risks associated with larger particles (52 FR 24639, July 1, 1987).

In the 1997 review, in conjunction with establishing new fine particle (i.e., $PM_{2.5}$) standards (discussed above in sections II.B.1 and III.A.1), the EPA concluded that continued protection was warranted against potential effects associated with thoracic coarse particles in the size range of 2.5 to 10 μm. This conclusion was based on particle dosimetry, toxicological information, and on limited epidemiological evidence from studies that measured PM_{10} in areas where the coarse fraction was likely to dominate PM_{10} mass (62 FR 38677, July 18, 1997). The EPA concluded there that a PM_{10} standard could provide requisite protection against effects associated with particles

denoted as integer values (e.g., 12 μg/m³) for simplicity.

[116] The Administrator also judges that this suite of standards addresses the issues raised by the D.C. Circuit's remand of the 2006 primary annual $PM_{2.5}$ standard by appropriately revising that standard.

[117] Throughout this section of the preamble, we are using the terms ''thoracic coarse particles'', ''inhalable coarse particles'', and ''$PM_{10-2.5}$'' synonymously.

in the size range of 2.5 to 10 μm.[118] Although the EPA considered a more narrowly defined indicator for thoracic coarse particles in that review (i.e., $PM_{10-2.5}$), the EPA concluded that it was more appropriate, based on existing evidence, to continue to use PM_{10} as the indicator. This decision was based, in part, on the recognition that the only studies of clear quantitative relevance to health effects most likely associated with thoracic coarse particles used PM_{10}. These were two studies conducted in areas where the coarse fraction was the dominant fraction of PM_{10}, and which substantially exceeded the 24-hour PM_{10} standard (62 FR 38679). In addition, there were only very limited ambient air quality data then available specifically for $PM_{10-2.5}$, in contrast to the extensive monitoring network already in place for PM_{10}. Therefore, the EPA considered it more administratively feasible to use PM_{10} as an indicator. The EPA also stated that the PM_{10} standards would work in conjunction with the $PM_{2.5}$ standards by regulating the portion of particulate pollution not regulated by the then newly adopted $PM_{2.5}$ standards.

In May 1998, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit found ''ample support'' for the EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that the EPA had failed to adequately explain its choice of PM_{10} as the indicator for thoracic coarse particles *American Trucking Associations* v. *EPA,* 175 F. 3d 1027, 1054–56 (D.C. Cir. 1999). In particular, the court held that the EPA had not explained the use of an indicator under which the allowable level of coarse particles varied according to the amount of $PM_{2.5}$ present, and which, moreover, potentially double regulated $PM_{2.5}$. The court also rejected considerations of administrative feasibility as justification for use of PM_{10} as the indicator for thoracic coarse PM, since NAAQS (and their elements) are to be based exclusively on health and welfare considerations. *Id.* at 1054. Pursuant to the court's decision, the EPA removed the vacated 1997 PM_{10} standards from the CFR (69 FR 45592, July 30, 2004) and deleted the regulatory provision (at 40 CFR 50.6(d)) that controlled the transition from the pre-existing 1987 PM_{10} standards to the 1997 PM_{10} standards (65 FR 80776, December 22, 2000). The pre-existing 1987 PM_{10} standards thus remained in place. Id. at 80777.

b. Review Completed in 2006

In the review of the PM NAAQS that concluded in 2006, the EPA considered the growing, but still limited, body of evidence supporting associations between health effects and thoracic coarse particles measured as $PM_{10-2.5}$.[119] The new studies available in the 2006 review included epidemiological studies that reported associations with health effects using direct measurements of $PM_{10-2.5}$, as well as dosimetric and toxicological studies. In considering this growing body of $PM_{10-2.5}$ evidence, as well as evidence from studies that measured PM_{10} in locations where the majority of PM_{10} was in the $PM_{10-2.5}$ fraction (U.S. EPA, 2005, section 5.4.1), staff concluded that the level of protection afforded by the existing 1987 PM_{10} standard remained appropriate (U.S. EPA, 2005, p. 5–67) but recommended that the indicator for the standard be revised. Specifically, staff recommended replacing the PM_{10} indicator with an indicator of urban thoracic coarse particles in the size range of 10–2.5 μm (U.S. EPA, 2005, pp. 5–70 to 5–71). The agency proposed to retain a standard for a subset of thoracic coarse particles, proposing a qualified $PM_{10-2.5}$ indicator to focus on the mix of thoracic coarse particles generally present in urban environments. More specifically, the proposed revised thoracic coarse particle standard would have applied only to an ambient mix of $PM_{10-2.5}$ dominated by resuspended dust from high-density traffic on paved roads and/or by industrial and construction sources. The proposed revised standard would not have applied to any ambient mix of $PM_{10-2.5}$ dominated by rural windblown dust and soils. In addition, agricultural sources, mining sources, and other similar sources of crustal material would not have been subject to control in meeting the standard (71 FR 2667 to 2668, January 17, 2006).

The Agency received a large number of comments overwhelmingly and persuasively opposed to the proposed qualified $PM_{10-2.5}$ indicator (71 FR 61188 to 61197, October 17, 2006). After careful consideration of the scientific evidence and the recommendations contained in the 2005 Staff Paper, the advice and recommendations from CASAC, and the public comments received regarding the appropriate indicator for coarse particles, and after extensive evaluation of the alternatives available to the Agency, the Administrator decided it would not be appropriate to adopt the proposed qualified $PM_{10-2.5}$ indicator, or any qualified indicator. Underlying this determination was the Administrator's decision that it was requisite to provide protection from exposure to *all* thoracic coarse PM, regardless of its origin. The Administrator thus rejected arguments that there are no health effects from community-level exposures to coarse PM in non-urban areas (71 FR 61189). The EPA concluded that dosimetric, toxicological, occupational and epidemiological evidence supported retention of a primary standard for short-term exposures that included all thoracic coarse particles (i.e., particles of both urban and non-urban origin), consistent with the Act's requirement that primary NAAQS must be requisite to protect the public health and provide an adequate margin of safety. At the same time, the Agency concluded that the standard should target protection toward urban areas, where the evidence of health effects from exposure to $PM_{10-2.5}$ was strongest (71 FR at 61193, 61197). The proposed indicator was not suitable for that purpose. Not only did it inappropriately provide no protection at all to many areas, but it failed to identify many areas where the ambient particle mix was dominated by coarse particles contaminated with urban/industrial types of coarse particles for which evidence of health effects was strongest (71 FR 61193).

The Agency ultimately concluded that the existing indicator, PM_{10}, was most consistent with the evidence. Although PM_{10} includes both coarse and fine PM, the Agency concluded that it remained an appropriate indicator for thoracic coarse particles because, as discussed in the PM Staff Paper (U.S. EPA, 2005, p. 2–54, Figures 2–23 and 2–24), fine particle levels are generally higher in urban areas and, therefore, a PM_{10} standard set at a single unvarying level will generally result in lower allowable concentrations of thoracic coarse particles in urban areas than in non-urban areas (71 FR 61195–96). The EPA considered this to be an appropriate targeting of protection given that the strongest evidence for effects associated with thoracic coarse particles came from epidemiological studies conducted in urban areas and that elevated fine particle concentrations in urban areas could result in increased contamination of coarse fraction particles by $PM_{2.5}$,

[118] With regard to the 24-hour PM_{10} standard, the EPA retained the indicator, averaging time, and level (150 μg/m^3), but revised the form (i.e., from one-expected-exceedance to the 99th percentile).

[119] The PM Staff Paper (U.S. EPA, 2005) also presented results of a quantitative assessment of health risks for $PM_{10-2.5}$. However, staff concluded that the nature and magnitude of the uncertainties and concerns associated with this risk assessment weighed against its use as a basis for recommending specific levels for a thoracic coarse particle standard (U.S. EPA, 2005, p. 5–69).

potentially increasing the toxicity of thoracic coarse particles in urban areas (*id.*). Given the evidence that the existing (i.e., 1987) PM_{10} standard was established at a level and form which afforded requisite protection with an adequate margin of safety, the Agency retained the level and form of the 24-hour PM_{10} standard.[120]

The Agency also revoked the annual PM_{10} standard, in light of the conclusion in the PM Criteria Document (U.S. EPA, 2004, p. 9–79) that the available evidence does not suggest an association with long-term exposure to $PM_{10\text{-}2.5}$ and the conclusion in the Staff Paper (U.S. EPA, 2005, p. 5–61) that there is no quantitative evidence that directly supports retention of an annual standard. This decision was consistent with CASAC advice and recommendations (Henderson, 2005a,b).

In the same rulemaking, the EPA also included a new FRM for the measurement of $PM_{10\text{-}2.5}$ in the ambient air (71 FR 61212 to 61213, October 17, 2006). Although the standard for thoracic coarse particles does not use a $PM_{10\text{-}2.5}$ indicator, the new FRM for $PM_{10\text{-}2.5}$ was established to provide a basis for approving FEMs and to promote the gathering of scientific data to support future reviews of the PM NAAQS (71 FR 61202/3, October 17, 2006).[121]

2. Litigation Related to the 2006 Primary PM_{10} Standards

A number of groups filed suit in response to the final decisions made in the 2006 review. *See American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir. 2009). Among the petitions for review were challenges from industry groups on the decision to retain the PM_{10} indicator and the level of the PM_{10} standard and from environmental and public health groups on the decision to revoke the annual PM_{10} standard. The court upheld both the decision to retain the 24-hour PM_{10} standard and the decision to revoke the annual standard.

First, the court upheld the EPA's decision for a standard to encompass all thoracic coarse PM, both of urban and non-urban origin. The court rejected arguments that the evidence showed there are no risks from exposure to non-urban coarse PM. The court further found that the EPA had a reasonable basis not to set separate standards for urban and non-urban coarse PM, namely the inability to reasonably define what ambient mixes would be included under either 'urban' or 'non-urban;' and the evidence in the record that supported the EPA's appropriately cautious decision to provide ''some protection from exposure to thoracic coarse particles * * * in all areas.'' 559 F. 3d at 532–33. Specifically, the court stated,

> Although the evidence of danger from coarse PM is, as EPA recognizes, ''inconclusive,'' (71 FR 61193, October 17, 2006), the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health. The evidence in the record supports the EPA's cautious decision that ''some protection from exposure to thoracic coarse particles is warranted in all areas.'' *Id.* As the court has consistently reaffirmed, the CAA permits the Administrator to ''err on the side of caution'' in setting NAAQS. 559 F. 3d at 533.

The court also upheld the EPA's decision to retain the level of the standard at 150 $\mu g/m^3$ and to use PM_{10} as the indicator for thoracic coarse particles. In upholding the level of the standard, the court referred to the conclusion in the Staff Paper that there is ''little basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times.'' 559 F. 3d at 534. The court also rejected arguments that a PM_{10} standard established at an unvarying level will result in arbitrarily varying levels of protection given that the level of coarse PM would vary based on the amount of fine PM present. The court agreed that the variation in allowable coarse PM was in accord with the strength of the evidence: Typically less coarse PM would be allowed in urban areas (where levels of fine PM are typically higher), in accord with the strongest evidence of health effects from coarse particles. 559 F. 3d at 535–36. In addition, such regulation would not impermissibly double regulate fine particles, since any additional control of fine particles (beyond that afforded by the primary $PM_{2.5}$ standard) would be for a different purpose: To prevent contamination of coarse particles by fine particles. 559 F. 3d at 535, 536. These same explanations justified the choice of PM_{10} as an indicator and provided the reasoned explanation for that choice lacking in the record for the 1997 standard. 559 F. 3d at 536.

With regard to the challenge from environmental and public health groups, the court upheld the EPA's decision to revoke the annual PM_{10} standard. The court rejected the argument that the EPA is required by law to have an annual PM_{10} standard, holding that section 109(d)(1) of the Act allows the EPA to revoke a standard no longer warranted by the current scientific understanding. 559 F. 3d at 538. The court further held that the EPA's decision to revoke the annual standard was supported by the science:

> The EPA reasonably decided that an annual coarse PM standard is not necessary because, as the Criteria Document and the Staff Paper make clear, the latest scientific data do not indicate that long-term exposure to coarse particles poses a health risk. The CASAC also agreed that an annual coarse PM standard is unnecessary. 559 F. 3d at 538–39.

3. General Approach Used in the Current Review

The approach taken to considering the existing and potential alternative primary PM_{10} standards in the current review builds upon the approaches used in previous PM NAAQS reviews. This approach is based most fundamentally on using information from epidemiological studies and air quality analyses to inform the identification of a range of policy options for consideration by the Administrator. The Administrator considers the appropriateness of the current and potential alternative standards, taking into account the four elements of the NAAQS: Indicator, averaging time, form, and level.

Evidence-based approaches to using information from epidemiological studies to inform decisions on PM standards are complicated by the recognition that no population threshold, below which it can be concluded with confidence that PM-related effects do not occur, can be discerned from the available evidence (U.S. EPA, 2009a, sections 2.4.3 and 6.5.2.7).[122] As a result, any approach to

[120] Thus, the standard is met when a 24-hour average PM_{10} concentration of 150 $\mu g/m^3$ is not exceeded more than one day per year, on average over a three-year period. As noted above, the 1987 PM_{10} standard was not adopted solely to control thoracic coarse particles. However, when reviewing this standard in the 2006 review, EPA determined that the level and form of the standard being reviewed (i.e., the 1987 PM_{10} standard) provided requisite protection with an adequate margin of safety from short-term exposures to thoracic coarse particles.

[121] As noted below, however, with this rule the EPA is revoking the requirement for $PM_{10\text{-}2.5}$ speciation at NCore monitoring sites due to technical issues related to the development of appropriate monitoring methods (section VIII.B.3.c). The requirement for $PM_{10\text{-}2.5}$ mass measurements at NCore sites is being retained.

[122] Studies that have characterized the concentration-response relationships for PM exposures have evaluated PM_{10}, which includes

reaching decisions on what standards are appropriate requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards, which includes consideration of how to weigh the uncertainties in reported associations across the distributions of PM concentrations in the studies. The approach taken to informing these decisions in the current review recognizes that the available health effects evidence reflects a continuum consisting of ambient levels at which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. Such an approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

Because the purpose of the PM_{10} standard is to protect against exposures to $PM_{10\text{-}2.5}$, it is most appropriate to focus on $PM_{10\text{-}2.5}$ health studies when considering the degree of public health protection provided by the current PM_{10} standard. Compared to health studies of PM_{10}, studies that evaluate associations with $PM_{10\text{-}2.5}$ provide clearer evidence for health effects following exposures to thoracic coarse particles. In contrast, it is difficult to interpret PM_{10} studies within the context of a standard meant to protect against exposures to $PM_{10\text{-}2.5}$ because PM_{10} is comprised of both fine and coarse particles, even in locations with the highest concentrations of $PM_{10\text{-}2.5}$ (U.S. EPA, 2011a, Figure 3–4). Therefore, the extent to which PM_{10} effect estimates reflect associations with $PM_{10\text{-}2.5}$ versus $PM_{2.5}$ can be highly uncertain. In light of this uncertainty, it is preferable to consider $PM_{10\text{-}2.5}$ studies when such studies are available. Given the availability in this review of a number of studies that evaluated associations with $PM_{10\text{-}2.5}$, and given that the Integrated Science Assessment weight-of-evidence conclusions for thoracic coarse particles were based on studies of $PM_{10\text{-}2.5}$, in this review the EPA focuses primarily on studies that have specifically evaluated $PM_{10\text{-}2.5}$.[123]

As discussed in more detail in the Risk Assessment (U.S. EPA, 2010a, Appendix H), the EPA did not conduct a quantitative assessment of health risks associated with $PM_{10\text{-}2.5}$. The Risk Assessment concluded that limitations in the monitoring network and in the health studies that rely on that monitoring network, which would be the basis for estimating $PM_{10\text{-}2.5}$ health risks, would introduce significant uncertainty into a $PM_{10\text{-}2.5}$ risk assessment such that the risk estimates generated would be of limited value in informing review of the standard. Therefore, it was judged that a quantitative assessment of $PM_{10\text{-}2.5}$ risks is not supportable at this time (U.S. EPA, 2010a, p. 2-6). This decision does not indicate that health effects are not associated with exposure to thoracic coarse particles. Rather, as noted above, it reflects the conclusion that limitations in the available health studies and air quality information would introduce significant uncertainty into a quantitative assessment of $PM_{10\text{-}2.5}$ risks such that the risk estimates generated would be of limited value in informing review of the standard.

B. Health Effects Related to Exposure to Thoracic Coarse Particles

This section briefly outlines the key information presented in section IV.B of the proposal (77 FR 38947 to 38951, June 29, 2012), and discussed more fully in the Integrated Science Assessment (U.S. EPA, 2009a, Chapters 2, 4, 5, 6, 7, and 8) and the Policy Assessment (U.S. EPA, 2011a, Chapter 3), related to health effects associated with thoracic coarse particle exposures. In looking across the new scientific evidence available in this review, our overall understanding of health effects associated with thoracic coarse particle exposures has been expanded, though important uncertainties remain. Some highlights of the key policy-relevant scientific evidence available in this review include the following:

(1) A number of multi-city and single-city epidemiological studies have evaluated associations between short-term $PM_{10\text{-}2.5}$ and mortality, cardiovascular effects (e.g., including hospital admissions and emergency department visits), and/or respiratory effects. Despite differences in the approaches used to estimate ambient $PM_{10\text{-}2.5}$ concentrations, the majority of these studies have reported positive, though often not statistically significant, associations with short-term $PM_{10\text{-}2.5}$ concentrations. Most $PM_{10\text{-}2.5}$ effect estimates remained positive in co-pollutant models that included either gaseous or particulate co-pollutants. In U.S. study locations likely to have met the current PM_{10} standard during the study period, a few $PM_{10\text{-}2.5}$ effect estimates were statistically significant and remained so in co-pollutant models.[124]

(2) A small number of controlled human exposure studies have reported alterations in heart rate variability or increased pulmonary inflammation following short-term exposure to $PM_{10\text{-}2.5}$, providing some support for the associations reported in epidemiological studies. Toxicological studies that have examined the effects of $PM_{10\text{-}2.5}$ have used intratracheal instillation and, because these studies do not directly mirror any real-world mode of exposure, they provide only limited evidence for the biological plausibility of $PM_{10\text{-}2.5}$-induced effects.

(3) Using a more formal framework for reaching causal determinations than used in previous reviews, the Integrated Science Assessment concluded that the existing evidence is ''suggestive'' of a causal relationship between short-term $PM_{10\text{-}2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects (U.S. EPA, 2009a, section 2.3.3).[125] In contrast, the Integrated Science Assessment concluded that available evidence is ''inadequate'' to infer a causal relationship between long-term $PM_{10\text{-}2.5}$ exposures and various health effects.

(4) There are several at-risk populations that may be especially susceptible or vulnerable to PM-related effects, including effects associated with exposures to coarse particles. These groups include those with preexisting heart and lung diseases, specific genetic differences, and lower socioeconomic status as well as the lifestages of childhood and older adulthood. Evidence for PM-related effects in these at-risk populations has expanded and is stronger than previously observed. There is emerging, though still limited, evidence for additional potentially at-risk populations, such as those with diabetes, people who are obese, pregnant women, and the developing fetus.

(5) The Integrated Science Assessment concludes that currently available evidence is insufficient to draw distinctions in particle toxicity based on composition and notes that recent studies have reported that PM (both $PM_{2.5}$ and $PM_{10\text{-}2.5}$) from a variety of sources,

both coarse and fine particles, and $PM_{2.5}$ (U.S. EPA, 2009a, sections 2.4.3 and 6.5.2.7).

[123] It should also be noted that CASAC endorsed the approach adopted in the Integrated Science Assessment, which draws weight-of-evidence conclusions for $PM_{2.5}$ and $PM_{10\text{-}2.5}$, but not for PM_{10} (Samet, 2009f).

[124] The statistical significance of effect estimates provides important information on their statistical precision. However, when a group of studies report effect estimates that are similar in direction and magnitude, such a pattern of results warrants consideration of those studies even if not all reported statistically significant associations in single- or co-pollutant models (section III.D.2, above). In considering the $PM_{10\text{-}2.5}$ epidemiologic studies below, the Administrator considers both the pattern of results across studies and the statistical significance of those results.

[125] The causal framework draws upon the assessment and integration of evidence from across epidemiological, controlled human exposure, and toxicological studies, and the related uncertainties that ultimately influence our understanding of the evidence. This framework employs a five-level hierarchy that classifies the overall weight-of-evidence using the following categorizations: Causal relationship, likely to be causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (U.S. EPA, 2009a, Table 1–3). In the case of a ''suggestive'' determination, ''the evidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out. For example, at least one high-quality epidemiologic study shows an association with a given health outcome but the results of other studies are inconsistent'' (U.S. EPA, 2009a, Table 1–3).

including sources likely to be present in urban and non-urban locations, is associated with adverse health effects.

Although new $PM_{10-2.5}$ scientific studies have become available since the last review and have expanded our understanding of the association between $PM_{10-2.5}$ and adverse health effects (see above and U.S. EPA, 2009a, Chapter 6), important uncertainties remain. These uncertainties, and their implications for interpreting the scientific evidence, include the following:

(1) The potential for confounding by co-occurring pollutants, especially $PM_{2.5}$, has been addressed with co-pollutant models in only a relatively small number of $PM_{10-2.5}$ epidemiological studies (U.S. EPA, 2009a, section 2.3.3). This is a particularly important limitation given the relatively small body of experimental evidence (i.e., controlled human exposure and animal toxicological studies) available to support the associations between $PM_{10-2.5}$ and adverse health effects. The net impact of such limitations is to increase uncertainty in characterizations of the extent to which $PM_{10-2.5}$ itself, rather than one or more co-occurring pollutants, is responsible for the mortality and morbidity effects reported in epidemiological studies.

(2) There is greater spatial variability in $PM_{10-2.5}$ concentrations than $PM_{2.5}$ concentrations, resulting in increased exposure error for $PM_{10-2.5}$ (U.S. EPA, 2009a, p. 2–8). Available measurements do not provide sufficient information to adequately characterize the spatial distribution of $PM_{10-2.5}$ concentrations (U.S. EPA, 2009a, section 3.5.1.1). The net effect of these uncertainties on $PM_{10-2.5}$ epidemiological studies is to bias the results of such studies toward the null hypothesis. That is, as noted in the Integrated Science Assessment, these limitations in estimates of ambient $PM_{10-2.5}$ concentrations ''would tend to increase uncertainty and make it more difficult to detect effects of $PM_{10-2.5}$ in epidemiologic studies'' (U.S. EPA, 2009a, p. 2–21).

(3) Only a relatively small number of $PM_{10-2.5}$ monitoring sites are currently operating and such sites have been in operation for a relatively short period of time, limiting the spatial and temporal coverage for routine measurement of $PM_{10-2.5}$ concentrations. Given these limitations in routine monitoring, epidemiological studies have employed different approaches for estimating $PM_{10-2.5}$ concentrations. Given the relatively small number of $PM_{10-2.5}$ monitoring sites, the relatively large spatial variability in ambient $PM_{10-2.5}$ concentrations (see above), the use of different approaches to estimating ambient $PM_{10-2.5}$ concentrations across epidemiological studies, and the limitations inherent in such estimates, the distributions of thoracic coarse particle concentrations over which reported health outcomes occur remain highly uncertain (U.S. EPA, 2009a, sections 2.2.3, 2.3.3, 2.3.4, and 3.5.1.1).

(4) There is relatively little information on the chemical and biological composition of $PM_{10-2.5}$ and the effects associated with the various components (U.S. EPA, 2009a, section 2.3.4). Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations with health effects across locations is difficult to characterize (U.S. EPA, 2009a, section 6.5.2.3).

(5) One of the implications of the uncertainties and limitations discussed above is that the Risk Assessment concluded it would not be appropriate to conduct a quantitative assessment of health risks associated with $PM_{10-2.5}$. The lack of a quantitative $PM_{10-2.5}$ risk assessment in the current review adds to the uncertainty in any conclusions about the extent to which revision of the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard.[126]

C. Consideration of the Current and Potential Alternative Standards in the Policy Assessment

The following sections discuss the Policy Assessment's consideration of the current and potential alternative standards to protect against exposures to thoracic coarse particles (U.S. EPA, 2011a, chapter 3). Section IV.C.1 discusses the consideration of the current standard while section IV.C.2 discusses the consideration of potential alternative standards in terms of the basic elements of a standard: Indicator, averaging time, form, and level.

1. Consideration of the Current Standard in the Policy Assessment

As discussed above the 24-hour PM_{10} standard is meant to protect the public health against exposures to thoracic coarse particles (i.e., $PM_{10-2.5}$). In considering the adequacy of the current PM_{10} standard, the Policy Assessment considered the health effects evidence linking short-term $PM_{10-2.5}$ exposures with mortality and morbidity (U.S. EPA, 2009a, chapters 2 and 6), the ambient PM_{10} concentrations in $PM_{10-2.5}$ study locations (U.S. EPA, 2011a, section 3.2.1), the uncertainties and limitations associated with this health evidence (U.S. EPA, 2011a, section 3.2.1), and the consideration of these uncertainties and limitations as part of the weight of evidence conclusions in the Integrated Science Assessment (U.S. EPA, 2009a).

In considering the health evidence, air quality information, and associated uncertainties as they relate to the current PM_{10} standard, the Policy Assessment noted that a decision on the adequacy of the public health protection provided by that standard is a public health policy judgment in which the Administrator weighs the evidence and information, as well as its uncertainties. Therefore, depending on the emphasis placed on different aspects of the evidence, information, and uncertainties, consideration of different conclusions on the adequacy of the current standard could be supported. For example, the Policy Assessment noted that one approach to considering the evidence, information, and its associated uncertainties would be to place emphasis on the following (U.S. EPA, 2011a, section 3.2.3):

(1) While most of $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were positive, many were not statistically significant, even in single-pollutant models. This includes effect estimates reported in study locations with PM_{10} concentrations above those allowed by the current 24-hour PM_{10} standard.

(2) The number of epidemiological studies that have employed co-pollutant models to address the potential for confounding, particularly by $PM_{2.5}$, remains limited. Therefore, the extent to which $PM_{10-2.5}$ itself, rather than one or more co-pollutants, contributes to reported health effects remains uncertain.

(3) Only a limited number of experimental studies provide support for the associations reported in epidemiological studies, resulting in further uncertainty regarding the plausibility of a causal link between $PM_{10-2.5}$ and mortality and morbidity.

(4) Limitations in $PM_{10-2.5}$ monitoring and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiological studies result in uncertainty as to the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur.

(5) The chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components, remains uncertain. Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across locations is difficult to interpret.

(6) In considering the available evidence and its associated uncertainties, the Integrated Science Assessment concluded that the evidence is ''suggestive'' of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. These weight-of-evidence conclusions contrast with those for the relationships between $PM_{2.5}$ exposures and adverse health effects, which were judged in the Integrated Science Assessment to be either ''causal'' or ''likely causal'' for mortality, cardiovascular effects, and respiratory effects.

The Policy Assessment concluded that, to the extent a decision on the adequacy of the current 24-hour PM_{10} standard were to place emphasis on the considerations noted above, it could be judged that, although it remains appropriate to maintain a standard to protect against short-term exposures to

[126] As noted above, the EPA's decision not to conduct a quantitative risk assessment reflects uncertainty regarding the value of such an assessment, but does not indicate that health effects are not associated with exposure to thoracic coarse particles.

thoracic coarse particles, the available evidence suggests that the current 24-hour PM_{10} standard appropriately protects public health and provides an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$ exposures. Although such an approach to considering the adequacy of the current standard would recognize the positive, and in some cases statistically significant, associations between all types of $PM_{10-2.5}$ and mortality and morbidity, it would place relatively greater emphasis on the limitations and uncertainties noted above, which tend to complicate the interpretation of that evidence.

In addition, the Policy Assessment noted the judgment that, given the uncertainties and limitations in the $PM_{10-2.5}$ health evidence and air quality information, it would not have been appropriate to conduct a quantitative assessment of health risks associated with $PM_{10-2.5}$ (U.S. EPA, 2011a, p. 3–6; U.S. EPA, 2010a, pp. 2–6 to 2–7, Appendix H). As discussed above, the lack of a quantitative $PM_{10-2.5}$ risk assessment adds to the uncertainty associated with any characterization of potential public health improvements that would be realized with a revised standard.

The Policy Assessment also noted an alternative approach to considering the evidence and its uncertainties would place emphasis on the following (U.S. EPA, 2011a, section 3.2.3):

(1) Several multi-city epidemiological studies conducted in the U.S., Canada, and Europe, as well as a number of single-city studies, have reported generally positive, and in some cases statistically significant, associations between short-term $PM_{10-2.5}$ concentrations and adverse health endpoints including mortality and cardiovascular-related and respiratory-related hospital admissions and emergency department visits.

(2) Both single-city and multi-city analyses, using different approaches to estimate ambient $PM_{10-2.5}$ concentrations, have reported positive $PM_{10-2.5}$ effect estimates in locations that would likely have met the current 24-hour PM_{10} standard. In a few cases, these $PM_{10-2.5}$ effect estimates were statistically significant.

(3) While limited in number, studies that have evaluated co-pollutant models have generally reported that $PM_{10-2.5}$ effect estimates remain positive, and in a few cases statistically significant, when these models include gaseous pollutants or fine particles.

(4) Support for the plausibility of the associations reported in epidemiological studies is provided by a small number of controlled human exposure studies reporting that short-term (i.e., 2-hour) exposures to $PM_{10-2.5}$ decrease heart rate variability and increase markers of pulmonary inflammation.

This approach to considering the health evidence, air quality information, and the associated uncertainties would place substantial weight on the generally positive $PM_{10-2.5}$ effect estimates that have been reported for mortality and morbidity, even those effect estimates that are not statistically significant. The Policy Assessment concluded that this could be judged appropriate given that consistent results have been reported across multiple studies using different approaches to estimate ambient $PM_{10-2.5}$ concentrations and that exposure measurement error, which is likely to be larger for $PM_{10-2.5}$ than for $PM_{2.5}$, tends to bias the results of epidemiological studies toward the null hypothesis, making it less likely that associations will be detected. Such an approach would place less weight on the uncertainties and limitations in the evidence that resulted in the Integrated Science Assessment conclusions that the evidence is only suggestive of a causal relationship.

Given all of the above, the Policy Assessment concluded that it would be appropriate to consider either retaining or revising the current 24-hour PM_{10} standard, depending on the approach taken to considering the available evidence, air quality information, and the uncertainties and limitations associated with that evidence and information (U.S. EPA, 2011a, section 3.2.3).

2. Consideration of Potential Alternative Standards in the Policy Assessment

Given the conclusion that it would be appropriate to consider either retaining or revising the current PM_{10} standard, the Policy Assessment also considered what potential alternative standards, if any, could be supported by the available scientific evidence in order to increase public health protection against exposures to $PM_{10-2.5}$. The Policy Assessment considered such potential alternative standards defined in terms of the elements of a standard (i.e., indicator, averaging time, form, and level). Key conclusions from the Policy Assessment regarding indicator, averaging time, and form included the following:

(1) A PM_{10} indicator would continue to appropriately target protection against thoracic coarse particle exposures to those locations where the evidence is strongest for associations with adverse health effects (i.e., urban areas).

(2) The available evidence supports the importance of maintaining a standard that protects against short-term exposures to all thoracic coarse particles. Given that the majority of this evidence is based on 24-hour average thoracic coarse particle concentrations, consideration of a 24-hour averaging time remains appropriate.

(3) Given the limited body of evidence supporting $PM_{10-2.5}$-related effects following long-term exposures, which resulted in the Integrated Science Assessment conclusion that the available evidence is ''inadequate'' to infer a causal relationship between long-term $PM_{10-2.5}$ exposures and a variety of health effects, consideration of an annual thoracic coarse particle standard is not supported at this time.

(4) To the extent it is judged appropriate to revise the current 24-hour PM_{10} standard, it would be appropriate to consider revising the form to the 3-year average of the 98th percentile of the annual distribution of 24-hour PM_{10} concentrations.

In considering the available evidence and air quality information within the context of identifying potential alternative standard levels for consideration (assuming a decision were made that it is appropriate to amend the standard), the Policy Assessment first noted that a standard level as high as about 85 $\mu g/m^3$, for a 24-hour PM_{10} standard with a 98th percentile form, could be supported. Based on considering air quality concentrations in study locations, the Policy Assessment noted that such a standard level would be expected to maintain PM_{10} and $PM_{10-2.5}$ concentrations below those present in U.S. locations of single-city studies where $PM_{10-2.5}$ effect estimates have been reported to be positive and statistically significant and below those present in some locations where single-city studies reported $PM_{10-2.5}$ effect estimates that were positive, but not statistically significant. These include some locations likely to have met the current PM_{10} standard during the study periods (U.S. EPA, 2011a, section 3.3.4).

The Policy Assessment also noted that, based on analysis of the number of people living in counties that could violate the current and potential alternative PM_{10} standards, a 24-hour PM_{10} standard with a 98th percentile form and a level between 75 and 80 $\mu g/m^3$ would provide a level of public health protection that is generally equivalent, across the U.S., to that provided by the current standard. Given this, the Policy Assessment concluded that it would be appropriate to consider standard levels in the range of approximately 75 to 80 $\mu g/m^3$ (with a 98th percentile form), to the extent population counts were emphasized in comparing the public health protection provided by the current and potential alternative standards and to the extent it was judged appropriate to set a revised standard providing at least the level of public health protection that is provided by the current standard, based on such population counts (U.S. EPA, 2011a, section 3.3.4).

The Policy Assessment also concluded that alternative approaches to considering the evidence could lead to consideration of standard levels below 75 μg/m³ for a standard with a 98th percentile form. For example, a number of single-city epidemiological studies have reported positive, though not statistically significant, $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations below 75 μg/m³. Given that exposure error is particularly important for $PM_{10-2.5}$ epidemiological studies and can bias the results of these studies toward the null hypothesis (see section IV.B above), the Policy Assessment noted that it could be judged appropriate to place more weight on positive associations reported in these epidemiological studies, even when those associations are not statistically significant. In addition, the Policy Assessment noted that multi-city averages of 98th percentile PM_{10} concentrations in the locations evaluated by U.S. multi-city studies of thoracic coarse particles (Zanobetti and Schwartz, 2009; Peng et al., 2008) were near or below 75 ppb. Despite uncertainties in the extent to which effects reported in multi-city studies are associated with the short-term air quality in any particular location, the Policy Assessment noted that emphasis could be placed on these multi-city averaged concentrations. The Policy Assessment concluded that, to the extent more weight is placed on single-city studies reporting positive, but not statistically significant, $PM_{10-2.5}$ effect estimates and on multi-city studies, it could be appropriate to consider standard levels as low as 65 μg/m³ with a 98th percentile form (U.S. EPA, 2011a, section 3.3.4).

In considering potential alternative standard levels below 65 μg/m³, the Policy Assessment noted that the overall body of $PM_{10-2.5}$ health evidence is relatively uncertain, with somewhat stronger support in U.S. studies for associations with $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations above 85 μg/m³ than in locations with 98th percentile PM_{10} concentrations below 65 μg/m³. In light of the limitations in the evidence for a relationship between $PM_{10-2.5}$ and adverse health effects in locations with relatively low PM_{10} concentrations, along with the overall uncertainties in the body of $PM_{10-2.5}$ health evidence as described above and in the Integrated Science Assessment, the Policy Assessment concluded that consideration of standard levels below 65 μg/m³ was not appropriate (U.S. EPA, 2011a, section 3.3.4).

D. CASAC Advice

Following their review of the first and second draft Policy Assessments, CASAC provided advice and recommendations regarding the current and potential alternative standards for thoracic coarse particles (Samet, 2010c,d). With regard to the existing PM_{10} standard, CASAC concluded that ''the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard'' (Samet, 2010d, p. 7). In drawing this conclusion, CASAC noted the positive associations in multi-city and single-city studies, including in locations with PM_{10} concentrations below those allowed by the current standard. In addition, CASAC gave ''significant weight to studies that have generally reported that $PM_{10-2.5}$ effect estimates remain positive when evaluated in co-pollutant models'' and concluded that ''controlled human exposure $PM_{10-2.5}$ studies showing decreases in heart rate variability and increases in markers of pulmonary inflammation are deemed adequate to support the plausibility of the associations reported in epidemiologic studies'' (Samet, 2010d, p. 7).[127] Given all of the above conclusions CASAC recommended that ''the primary standard for PM_{10} should be revised'' (Samet, 2010d, p. ii and p. 7). In discussing potential revisions, while CASAC noted that the scientific evidence supports adoption of a standard at least as stringent as the current standard, they recommended revising the current standard in order to increase public health protection. In considering potential alternative standards, CASAC drew conclusions and made recommendations in terms of the major elements of a standard: indicator, averaging time, form, and level.

The CASAC agreed with the EPA staff's conclusions that the available evidence supports consideration in the current review of retaining the current PM_{10} indicator and the current 24-hour averaging time (Samet, 2010c, Samet, 2010d). Specifically, with regard to indicator, CASAC concluded that ''[w]hile it would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles'' (Samet, 2010d, p. ii). In addition, CASAC ''vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles'' (Samet, 2010d, p. 7).

The CASAC also agreed that the evidence supports consideration of a potential alternative form. Specifically, CASAC ''felt strongly that it is appropriate to change the statistical form of the PM_{10} standard to a 98th percentile'' (Samet, 2010d, p.7). In reaching this conclusion, CASAC noted that ''[p]ublished work has shown that the percentile form has greater power to identify non-attainment and a smaller probability of misclassification relative to the expected exceedance form of the standard'' (Samet, 2010d. p. 7).

With regard to standard level, in conjunction with a 98th percentile form, CASAC concluded that ''alternative standard levels of 85 and 65 μg/m³ (based on consideration of 98th percentile PM_{10} concentration) could be justified'' (Samet, 2010d, p.8). However, in considering the evidence and uncertainties, CASAC recommended a standard level from the lower part of the range discussed in the Policy Assessment, recommending a level ''somewhere in the range of 75 to 65 μg/m³'' (Samet, 2010d, p. ii).

In making this recommendation, CASAC noted that the number of people living in counties with air quality not meeting the current standard is approximately equal to the number living in counties that would not meet a 98th percentile standard with a level between 75 and 80 μg/m³. CASAC used this information as the basis for their conclusion that a 98th percentile standard between 75 and 80 μg/m³ would be ''comparable to the degree of protection afforded to the current PM_{10} standard'' (Samet, 2010d, p. ii). Given this conclusion regarding the comparability of the current and potential alternative standards, as well as their conclusion on the public health protection provided by the current standard (i.e., that available evidence is sufficient to call it into question), CASAC recommended a level within a range of 75 to 65 μg/m³ in order to increase public health protection, relative to that provided by the current standard (Samet 2010d, p. ii).

[127] Nonetheless, CASAC endorsed the Integrated Science Assessment weight of evidence conclusions for $PM_{10-2.5}$ (i.e., that the evidence is only ''suggestive'' of a causal relationship between short-term exposures and mortality, respiratory effects, and cardiovascular effects) (Samet, 2009e; Samet, 2009f).

E. Administrator's Proposed Conclusions Concerning the Adequacy of the Current Primary PM_{10} Standard

In considering the evidence and information as they relate to the adequacy of the current 24-hour PM_{10} standard, the Administrator first noted in the proposal that this standard is meant to protect the public health against effects associated with short-term exposures to $PM_{10-2.5}$. In the last review, it was judged appropriate to maintain such a standard given the ''growing body of evidence suggesting causal associations between short-term exposure to thoracic coarse particles and morbidity effects, such as respiratory symptoms and hospital admissions for respiratory diseases, and possibly mortality'' (71 FR 61185, October 17, 2006). Given the continued expansion in the body of scientific evidence linking short-term $PM_{10-2.5}$ to health outcomes such as premature death and hospital visits, discussed in detail in the Integrated Science Assessment (U.S. EPA, 2009a, Chapter 6) and summarized in the proposal, the Administrator provisionally concluded that the available evidence continued to support the appropriateness of maintaining a standard to protect the public health against effects associated with short-term (e.g., 24-hour) exposures to all $PM_{10-2.5}$. In drawing provisional conclusions in the proposal as to whether the current PM_{10} standard remains requisite (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety against such exposures, the Administrator considered the following:

(1) The extent to which it is appropriate to maintain a standard that provides some measure of protection against all $PM_{10-2.5}$, regardless of composition or source of origin;

(2) The extent to which it is appropriate to retain a PM_{10} indicator for a standard meant to protect against exposures to ambient $PM_{10-2.5}$; and

(3) The extent to which the current PM_{10} standard provides an appropriate degree of public health protection.

With regard to the first point, the proposal noted the conclusion from the last review that dosimetric, toxicological, occupational, and epidemiological evidence supported retention of a primary standard to provide some measure of protection against short-term exposures to all thoracic coarse particles, regardless of their source of origin or location, consistent with the Act's requirement that primary NAAQS provide requisite protection with an adequate margin of safety (71 FR 61197). In that review, the EPA concluded that PM from a number of source types, including motor vehicle emissions, coal combustion, oil burning, and vegetative burning, are associated with health effects (U.S. EPA, 2004). This information formed part of the basis for the D.C. Circuit's holding that it was appropriate for the thoracic coarse particle standard to provide ''some protection from exposure to thoracic coarse particles * * * in all areas'' (*American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 532–33).

In considering this issue in the proposal, the Administrator judged that the expanded body of scientific evidence in this review provides even more support for a standard that protects against exposures to all thoracic coarse particles, regardless of their location or source of origin. Specifically, the Administrator noted that epidemiological studies have reported positive associations between $PM_{10-2.5}$ and mortality or morbidity in a large number of cities across North America, Europe, and Asia, encompassing a variety of environments where $PM_{10-2.5}$ sources and composition are expected to vary widely. See 77 FR 38959. In considering this evidence, the Integrated Science Assessment concluded that ''many constituents of PM can be linked with differing health effects'' (U.S. EPA, 2009a, p. 2–26). While $PM_{10-2.5}$ in most of these study areas is of largely urban origin, the Administrator noted that some recent studies have also linked mortality and morbidity with relatively high ambient concentrations of thoracic coarse particles of non-urban crustal origin. In considering these studies, she noted the Integrated Science Assessment's conclusion that ''PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from crustal, soil or road dust sources or PM tracers linked to these sources are associated with cardiovascular effects'' (U.S. EPA, 2009a, p. 2–26).

In light of this body of available evidence reporting $PM_{10-2.5}$-associated health effects across different locations with a variety of sources, as well as the Integrated Science Assessment's conclusions regarding the links between adverse health effects and PM sources and composition, the Administrator provisionally concluded in the proposal that it is appropriate to maintain a standard that provides some measure of protection against exposures to all thoracic coarse particles, regardless of their location, source of origin, or composition (77 FR 38959–60).

With regard to the second point, in considering the appropriateness of a PM_{10} indicator for a standard meant to provide such public health protection, the Administrator noted that the rationale used in the last review to support the unqualified PM_{10} indicator (see above) remains relevant in the current review. Specifically, as an initial consideration, she noted that PM_{10} mass includes both coarse PM ($PM_{10-2.5}$) and fine PM ($PM_{2.5}$). As a result, the concentration of $PM_{10-2.5}$ allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. At the same time, the Administrator noted that $PM_{2.5}$ concentrations tend to be higher in urban areas than in rural areas (U.S. EPA, 2005, p. 2–54, and Figures 2–23 and 2–24) and, therefore, a PM_{10} standard will generally allow lower $PM_{10-2.5}$ concentrations in urban areas than in rural areas. 77 FR 38960.

In considering the appropriateness of this variation in allowable $PM_{10-2.5}$ concentrations, the Administrator considered the relative strength of the evidence for health effects associated with $PM_{10-2.5}$ of urban origin versus non-urban origin. She specifically noted that, as described above and similar to the scientific evidence available in the last review, the large majority of the available evidence for thoracic coarse particle health effects comes from studies conducted in locations with sources more typical of urban and industrial areas than of rural areas. Although as just noted, associations with adverse health effects have been reported in some study locations where $PM_{10-2.5}$ is largely non-urban in origin (i.e., in dust storm studies), particle concentrations in these study areas are typically much higher than reported in study locations where the $PM_{10-2.5}$ is of urban origin. Therefore, the Administrator noted that the strongest evidence for a link between $PM_{10-2.5}$ and adverse health impacts, particularly for such a link at relatively low particle concentrations, comes from studies where exposure is to $PM_{10-2.5}$ of urban or industrial origin. 77 FR 38960.

The Administrator also noted that chemical constituents present at higher levels in urban or industrial areas, including byproducts of incomplete combustion (e.g. polycyclic aromatic hydrocarbons) emitted as $PM_{2.5}$ from motor vehicles as well as metals and other contaminants emitted from anthropogenic sources, can contaminate $PM_{10-2.5}$ (U.S. EPA, 2004, p. 8–344; 71 FR 2665). While the Administrator acknowledged the uncertainty expressed in the Integrated Science Assessment regarding the extent to which, based on available evidence, particle composition can be linked to health outcomes, she also considered the possibility that $PM_{10-2.5}$ contaminants typical of urban or industrial areas could increase the

toxicity of thoracic coarse particles in urban locations (77 FR 38960).

Given that the large majority of the evidence for $PM_{10-2.5}$ toxicity, particularly at relatively low particle concentrations, comes from study locations where thoracic coarse particles are of urban origin, and given the possibility that $PM_{10-2.5}$ contaminants in urban areas could increase particle toxicity, the Administrator provisionally concluded in the proposal that it remains appropriate to maintain a standard that targets public health protection to urban locations. Specifically, she concluded at proposal that it is appropriate to maintain a standard that allows lower ambient concentrations of $PM_{10-2.5}$ in urban areas, where the evidence is strongest that thoracic coarse particles are linked to mortality and morbidity, and higher concentrations in non-urban areas, where the public health concerns are less certain. *Id.*

Given all of the above considerations and conclusions, the Administrator judged that the available evidence supported retaining a PM_{10} indicator for a standard that is meant to protect against exposure to thoracic coarse particles. In reaching this initial judgment, she noted that, to the extent a PM_{10} indicator results in lower allowable concentrations of thoracic coarse particles in some areas compared to others, lower concentrations will be allowed in those locations (i.e., urban or industrial areas) where the science has shown the strongest evidence of adverse health effects associated with exposure to thoracic coarse particles and where we have the most concern regarding $PM_{10-2.5}$ toxicity. Therefore, the Administrator provisionally concluded that the varying amounts of coarse particles that are allowed in urban vs. non-urban areas under the 24-hour PM_{10} standard, based on the varying levels of $PM_{2.5}$ present, appropriately reflect the differences in the strength of evidence regarding coarse particle effects in urban and non-urban areas (77 FR 38960).

In reaching this provisional conclusion, the Administrator also noted that, in their review of the second draft Policy Assessment, CASAC concluded that ''[w]hile it would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles'' (Samet, 2010d, p. ii). In addition, CASAC ''vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles'' (Samet, 2010d, p. 7). Given this recommendation, the Administrator further judged that, although current evidence is not sufficient to identify a standard based on an alternative indicator that would be requisite to protect public health with an adequate margin of safety across the United States, consideration of alternative indicators (e.g., $PM_{10-2.5}$) in future reviews is desirable and could be informed by additional research, as described in the Policy Assessment (U.S. EPA, 2011a, section 3.5).

With regard to the third point, in evaluating the degree of public health protection provided by the current PM_{10} standard, the Administrator noted that the Policy Assessment discussed two different approaches to considering the scientific evidence and air quality information (U.S. EPA, 2011a, section 3.2.3). These different approaches, which are described above (section IV.C.1), lead to different conclusions regarding the appropriateness of the degree of public health protection provided by the current PM_{10} standard. The Administrator further noted that the primary difference between the two approaches lies in the extent to which weight is placed on the following (U.S. EPA, 2011a, section 3.2.3):

(1) The $PM_{10-2.5}$ weight-of-evidence classifications presented in the Integrated Science Assessment concluding that the existing evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects (a classification supported by CASAC);

(2) Individual $PM_{10-2.5}$ epidemiological studies reporting associations in locations that meet the current PM_{10} standard, including associations that are not statistically significant;

(3) The limited number of $PM_{10-2.5}$ epidemiological studies that have evaluated co-pollutant models;

(4) The limited number of $PM_{10-2.5}$ controlled human exposure studies;

(5) Uncertainties in the $PM_{10-2.5}$ air quality concentrations reported in epidemiological studies, given limitations in $PM_{10-2.5}$ monitoring data and the different approaches used across studies to estimate ambient $PM_{10-2.5}$ concentrations; and

(6) Uncertainties and limitations in the evidence that tend to call into question the presence of a causal relationship between $PM_{10-2.5}$ exposures and mortality/morbidity.

In evaluating the different possible approaches to considering the public health protection provided by the current PM_{10} standard, the Administrator first noted that when the available $PM_{10-2.5}$ scientific evidence and its associated uncertainties are considered, the Integrated Science Assessment concluded that the evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. As discussed in section IV.B.1 above and in more detail in the Integrated Science Assessment (U.S. EPA, 2009a, section 1.5), a suggestive determination is made when the ''[e]vidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out.'' In contrast, the Administrator noted that she proposed to strengthen the annual fine particle standard based on a body of scientific evidence judged sufficient to conclude that a causal relationship exists (i.e., mortality, cardiovascular effects) or is likely to exist (i.e., respiratory effects) (section III.B). 77 FR 38961. The suggestive judgment for $PM_{10-2.5}$ reflects the greater degree of uncertainty associated with this body of evidence, as discussed above (sections IV.B and IV.C) and summarized below.

In the proposal (77 FR 38961), the Administrator noted that the important uncertainties and limitations associated with the scientific evidence and air quality information raise questions as to whether public health benefits would be achieved by revising the existing PM_{10} standard. Such uncertainties and limitations include the following:

(1) While $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were generally positive, most were not statistically significant, even in single-pollutant models. This includes effect estimates reported in some study locations with PM_{10} concentrations above those allowed by the current 24-hour PM_{10} standard.

(2) The number of epidemiological studies that have employed co-pollutant models to address the potential for confounding, particularly by $PM_{2.5}$, remains limited. Therefore, the extent to which $PM_{10-2.5}$ itself, rather than one or more co-pollutants, contributes to reported health effects is less certain.

(3) Only a limited number of experimental studies (i.e., controlled human exposure and animal toxicological) provide support for the associations reported in epidemiological studies, resulting in further uncertainty regarding the plausibility of the associations between $PM_{10-2.5}$ and mortality and morbidity reported in epidemiological studies.

(4) Limitations in $PM_{10-2.5}$ monitoring data and the different approaches used by epidemiological study researchers to estimate $PM_{10-2.5}$ concentrations across epidemiological studies result in uncertainty in the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur, increasing uncertainty in estimates of the extent to

which changes in ambient $PM_{10-2.5}$ concentrations would likely impact public health.

(5) The lack of a quantitative $PM_{10-2.5}$ risk assessment further contributes to uncertainty regarding the extent to which any revisions to the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard (see section III.B.5 above).

(6) The chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components, remains uncertain. Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across locations is difficult to interpret.

In considering these uncertainties and limitations, the Administrator noted in particular the considerable degree of uncertainty in the extent to which health effects reported in epidemiological studies are due to $PM_{10-2.5}$ itself, as opposed to one or more co-occurring pollutants. As discussed above, this uncertainty reflects the fact that there are a relatively small number of $PM_{10-2.5}$ studies that have utilized co-pollutant models, particularly co-pollutant models that have included $PM_{2.5}$, and a very limited body of controlled human exposure evidence supporting the biological plausibility of a causal relationship between $PM_{10-2.5}$ and mortality and morbidity at ambient concentrations. The Administrator noted that these important limitations in the overall body of health evidence introduce uncertainty into the interpretation of individual epidemiological studies, particularly those studies reporting associations with $PM_{10-2.5}$ that are not statistically significant. Given this, the Administrator reached the provisional conclusion in the proposal that it is appropriate to place relatively little weight on epidemiological studies reporting associations with $PM_{10-2.5}$ that are not statistically significant in single-pollutant and/or co-pollutant models. *Id.*

With regard to this provisional conclusion, the Administrator noted that, for single-city mortality studies conducted in the United States where ambient PM_{10} concentration data were available for comparison to the current standard, positive and statistically significant $PM_{10-2.5}$ effect estimates were only reported in study locations that would likely have violated the current PM_{10} standard during the study period (U.S. EPA, 2011a, Figure 3–2). In U.S. study locations that would likely have met the current standard, $PM_{10-2.5}$ effect estimates for mortality were positive, but not statistically significant (U.S. EPA, 2011a, Figure 3–2). In considering U.S. study loc'ations where single-city morbidity studies were conducted, and which would likely have met the current PM_{10} standard during the study period, the Administrator noted that $PM_{10-2.5}$ effect estimates were both positive and negative, with most not statistically significant (U.S. EPA, 2011a, Figure 3–3).

In addition, in considering single-city analyses for the locations evaluated in a large U.S. multi-city mortality study (Zanobetti and Schwartz, 2009), the Administrator noted that associations in most of the study locations were not statistically significant and that this was the only study to estimate ambient $PM_{10-2.5}$ concentrations as the difference between county-wide PM_{10} and $PM_{2.5}$ mass. As discussed in the Policy Assessment and in the proposal, it is not clear how computed $PM_{10-2.5}$ measurements, such as those used by Zanobetti and Schwartz (2009), compare with the $PM_{10-2.5}$ concentrations obtained in other studies either by direct measurement or by calculating the difference using co-located samplers (U.S. EPA, 2009a, section 6.5.2.3). For these reasons, in the proposal the Administrator noted that ''there is considerable uncertainty in interpreting the associations in these single-city analyses'' (77 FR 38961–62).

The Administrator acknowledged that an approach to considering the available scientific evidence and air quality information that emphasizes the above considerations differs from the approach taken by CASAC. Specifically, in its review of the draft Policy Assessment CASAC placed a substantial amount of weight on individual studies, particularly those reporting positive health effects associations for $PM_{10-2.5}$ in locations that met the current PM_{10} standard during the study period. In emphasizing these studies, as well as the limited number of supporting studies that have evaluated co-pollutant models and the small number of supporting experimental studies, CASAC concluded that ''the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard'' (Samet, 2010d, p. 7) and recommended revising the current PM_{10} standard (Samet, 2010d).

The Administrator carefully considered CASAC's advice and recommendations. She noted that in making its recommendation on the current PM_{10} standard, CASAC did not discuss its approach to considering the important uncertainties and limitations in the health evidence, and did not discuss how these uncertainties and limitations were reflected in its recommendation. Nor did CASAC discuss uncertainties in the reported concentrations of $PM_{10-2.5}$ in the epidemiological studies, or how reported concentrations in the various studies relate to one another when differing measurement methodologies are used. As discussed above, such uncertainties and limitations contributed to the conclusions in the Integrated Science Assessment that the $PM_{10-2.5}$ evidence is only suggestive of a causal relationship, a conclusion that CASAC endorsed (Samet, 2009e,f). Given the importance of these uncertainties and limitations to the interpretation of the evidence, as reflected in the weight of evidence conclusions in the Integrated Science Assessment and as discussed above, the Administrator judged it appropriate to consider and account for them when drawing conclusions about the potential implications of individual $PM_{10-2.5}$ health studies for the current standard.

In light of the above approach to considering the scientific evidence, air quality information, and associated uncertainties, the Administrator reached the following provisional conclusions in the proposal:

(1) When viewed as a whole the available evidence and information suggests that the degree of public health protection provided against short-term exposures to $PM_{10-2.5}$ does not need to be increased beyond that provided by the current PM_{10} standard. This provisional conclusion noted the important uncertainties and limitations associated with the overall body of health evidence and air quality information for $PM_{10-2.5}$, as discussed above and as reflected in the Integrated Science Assessment weight-of-evidence conclusions; that $PM_{10-2.5}$ effect estimates for the most serious health effect, mortality, were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers; and that $PM_{10-2.5}$ effect estimates for morbidity endpoints were both positive and negative in locations that met the current standard, with most not statistically significant.

(2) The degree of public health protection provided by the current standard is not greater than warranted. This provisional conclusion noted that positive and statistically significant associations with mortality were reported in single-city U.S. study locations likely to have violated the current PM_{10} standard.[128]

[128] There are similarities with the conclusions drawn by the Administrator in the last review. There, the Administrator concluded that there was no basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour

Continued

In reaching these provisional conclusions, the Administrator noted that the Policy Assessment also discussed the potential for a revised PM_{10} standard (i.e., with a revised form and level) to be ''generally equivalent'' to the current standard, but to better target public health protection to locations where there is greater concern regarding $PM_{10-2.5}$-associated health effects (U.S. EPA, 2011a, sections 3.3.3 and 3.3.4). In considering such a potential revised standard, the Policy Assessment discussed the large amount of variability in PM_{10} air quality correlations across monitoring locations and over time (U.S. EPA, 2011a, Figure 3–7) and the regional variability in the relative degree of public health protection that could be provided by the current and potential alternative standards (U.S. EPA, 2011a, Table 3–2). In light of this variability, the Administrator noted the Policy Assessment conclusion that no single revised PM_{10} standard (i.e., with a revised form and level) would provide public health protection equivalent to that provided by the current standard, consistently over time and across locations (U.S. EPA, 2011a, section 3.3.4). That is, a revised standard, even one that is meant to be ''generally equivalent'' to the current PM_{10} standard, could increase protection in some locations while decreasing protection in others (77 FR 38962).

In considering the appropriateness of revising the current PM_{10} standard in this way, the Administrator noted the following:

(1) Positive $PM_{10-2.5}$ effect estimates for mortality were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers, while positive and statistically significant associations with mortality were reported in locations likely to have violated the current PM_{10} standard.

(2) Effect estimates for morbidity endpoints in locations that met the current standard were both positive and negative, with most not statistically significant.

(3) Important uncertainties and limitations associated with the overall body of health evidence and air quality information for $PM_{10-2.5}$, as discussed above and as reflected in the Integrated Science Assessment weight-of-evidence conclusions, call into question the extent to which the type of quantified and refined targeting of public health protection envisioned under a revised standard could be reliably accomplished.

Given all of the above considerations, the Administrator noted that there is a large amount of uncertainty in the extent to which public health would be improved by changing the locations to which the PM_{10} standard targets protection. Therefore, she reached the provisional conclusion that the current PM_{10} standard should not be revised in order to change that targeting of protection.

In considering all of the above, including the scientific evidence, the air quality information, the associated uncertainties, and CASAC's advice, the Administrator reached the provisional conclusion that the current 24-hour PM_{10} standard is requisite (i.e., neither more protective nor less protective than necessary) to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. In light of this provisional conclusion, the Administrator proposed to retain the current PM_{10} standard in order to protect against health effects associated with short-term exposures to $PM_{10-2.5}$ (77 FR 38963).

The Administrator recognized that her proposed conclusions and decision to retain the current PM_{10} standard differed from CASAC's recommendations, stemming from the differences in how the Administrator and CASAC considered and accounted for the evidence and its limitations and uncertainties. In light of CASAC's views and recommendation to revise the current PM_{10} standard, the Administrator welcomed the public's views on these different approaches to considering and accounting for the evidence and its limitations and uncertainties, as well as on the appropriateness of revising the primary PM_{10} standard, including revising the form and level of the standard. In doing so, the Administrator solicited comment on all aspects of the proposed decision, including her rationale for reaching the provisional conclusion that the current PM_{10} standard is requisite to protect public health with an adequate margin of safety and the provisional conclusion that it is not appropriate to revise the current PM_{10} standard by setting a ''generally equivalent'' standard with the goal of better targeting public health protection.

F. Public Comments on the Administrator's Proposed Decision To Retain the Primary PM_{10} Standard

This section discusses the major public comments received on the Administrator's proposed decision to retain the primary PM_{10} standard. Additional comments are addressed in the Response to Comments Document (U.S. EPA, 2012a).

Many public commenters agreed with the Administrator's proposed decision to retain the current 24-hour primary PM_{10} standard. Among those expressing a position on this proposed decision, industry groups and most State and Local commenters endorsed the Administrator's proposed rationale for retaining the current primary PM_{10} standard, including her consideration of the available scientific evidence and associated uncertainties and her consideration of CASAC recommendations.

Although industry commenters generally agreed with the Administrator's proposed decision to retain the current primary PM_{10} standard, some also contended that the current standard is ''excessively precautionary'' (NMA and NCBA, 2012, p. 4) and a few expressed support for a less stringent standard for coarse particles that are comprised largely of crustal material. For example, the Coarse Particulate Matter Coalition (CPMC) (2012) and several other industry commenters recommended that the final decision allow application of a 98th percentile form for the current standard (i.e. with its level of 150 $\mu g/m^3$) in cases where coarse particles consist primarily of crustal material. Such an approach would allow more yearly exceedances of the existing standard level than are allowed with the current one-expected-exceedance form. These industry commenters contended that a 98th percentile form applied in this way would provide appropriate regulatory relief for areas where the evidence for coarse particle-related health effects is relatively uncertain.

In reaching her conclusion that the current primary PM_{10} standard is requisite to protect public health with an adequate margin of safety, the Administrator considered the degree of public health protection provided by the current standard as a whole, including all elements of that standard (i.e., indicator, averaging time, form, level). As discussed above and in the following section, this conclusion reflects the Administrator's judgments that (1) the current standard appropriately provides some measure of protection against exposures to all thoracic coarse

standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times (71 FR 61202). In addition, the Administrator concluded that there was a high degree of uncertainty in the relevant population exposures implied by the morbidity studies suggesting that there is little basis for concluding that a greater degree of protection is warranted. *Id.* The D.C. Circuit in *American Farm Bureau Federation* v *EPA* explicitly endorsed this reasoning. 559 F. 3d at 534.

particles, regardless of their location, source of origin, or composition and (2) the current standard appropriately allows lower ambient concentrations of $PM_{10-2.5}$ in urban areas, where the evidence is strongest that thoracic coarse particles are linked to mortality and morbidity, and higher concentrations in non-urban areas, where the public health concerns are less certain.

Because the considerations that led to these judgments, and to the conclusion that the current primary PM_{10} standard is requisite to protect public health, took into account the degree of public health protection provided by the standard as a whole, it would not be appropriate to consider revising one element of the standard (e.g., the form, as suggested by commenters in this case) without considering the extent to which the other elements of the standard should also be revised. The change in form requested by industry commenters, without also lowering the level of the standard, would markedly reduce the public health protection provided against exposures to thoracic coarse particles.[129] However, industry commenters have not presented new evidence or analyses to support their conclusion that an appropriate degree of public health protection could be achieved by allowing the use of an alternative form (i.e., 98th percentile) for some coarse particles, while retaining the other elements of the current standard. Nor have these commenters presented new evidence or analyses challenging the basis for the conclusion in the proposal that the varying amounts of coarse particles allowed in urban versus non-urban areas under the current 24-hour PM_{10} standard, based on the varying levels of $PM_{2.5}$ present, appropriately reflect the differences in the strength of evidence regarding coarse particle effects in urban and non-urban areas. In light of this, EPA does not believe that a reduction in public health protection, such as that requested by industry commenters, is warranted.

In further considering these comments, it is to be remembered that epidemiologic studies have not demonstrated that coarse particles of non-urban origin do not cause health effects, and commenters have not provided additional evidence on this point. While there are fewer studies of non-urban coarse particles than of urban coarse particles, several studies have reported positive and statistically significant associations between coarse particles of crustal, non-urban origin and mortality or morbidity (Ostro *et al.,* 2003; Bell *et al.,* 2008; Chan *et al.,* 2008; Middleton *et al.,* 2008; Perez *et al.,* 2008). These studies formed part of the basis for the PM Integrated Science Assessment conclusion that ''recent studies have suggested that PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from crustal, soil or road dust sources or PM tracers linked to these sources are associated with cardiovascular effects'' (U.S. EPA, 2009a, p. 2–26). Moreover, crustal coarse particles may be contaminated with toxic trace elements and other components from previously deposited fine PM from ubiquitous sources such as mobile source engine exhaust, as well as by toxic metals from smelters or other industrial activities, animal waste, or pesticides (U.S. EPA, 2004, p. 8–344). In the proposal, the Administrator acknowledged the potential for this type of contamination to increase the toxicity of coarse particles of crustal, non-urban origin (77 FR 38960; see also 71 FR 61190).

In suggesting a change in the form of the current standard, industry commenters also did not address the manifold difficulties noted above, and in the last review, associated with developing an indicator that could reliably identify ambient mixes dominated by particular types of sources of coarse particles. See above and 71 FR 61193. Yet such an indicator would be a prerequisite of the type of standard these commenters request.

For all of the reasons discussed above, the EPA does not agree with industry commenters who recommended allowing the application of a 98th percentile form for the current standard in cases where coarse particles consist primarily of crustal material.

Some industry commenters contended that the uncertainties and limitations that precluded a quantitative risk assessment also preclude revising the PM_{10} standard. Although the EPA agrees that there are important uncertainties and limitations in the extent to which the quantitative relationships between ambient $PM_{10-2.5}$ and health outcomes can be characterized in risk models, the Agency does not agree that such limitations alone preclude the option of revising a NAAQS. As noted above, the lack of a quantitative $PM_{10-2.5}$ risk assessment in the current review adds uncertainty to conclusions about the extent to which revision of the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard. However, the EPA does not agree that such uncertainties necessarily preclude revision of a NAAQS. Indeed, with respect to thoracic coarse particles, the DC Circuit noted that ''[a]lthough the evidence of danger from coarse PM is, as the EPA recognizes, 'inconclusive', the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health.'' 559 F. 3d at 533. Thus, the Administrator's conclusion that the current 24-hour PM_{10} standard provides requisite protection of public health relies on her consideration of the broad body of evidence, rather than solely on the uncertainties that led to the decision not to conduct a quantitative assessment of $PM_{10-2.5}$ health risks.

Commenters representing a number of environmental groups and medical organizations disagreed with the Administrator's proposal to retain the current primary PM_{10} standard. These commenters generally requested that the EPA revise the PM_{10} standard to increase public health protection, consistent with the recommendations from CASAC.

As discussed above and in the proposal, in reaching provisional conclusions in the proposal regarding the current standard, the Administrator carefully considered CASAC's advice and recommendations. She specifically noted that in making its recommendation on the current PM_{10} standard, CASAC did not discuss its approach to considering the important uncertainties and limitations in the health evidence, and did not discuss how these uncertainties and limitations were reflected in its recommendations. Such uncertainties and limitations contributed to the conclusions in the Integrated Science Assessment that the $PM_{10-2.5}$ evidence is only suggestive of a causal relationship, a conclusion that CASAC endorsed (Samet, 2009e,f). These commenters also did not address the important uncertainties in the epidemiologic studies on which their comments are based. Given the importance of these uncertainties and limitations to the interpretation of the

[129] Based on regression analyses presented in the PA (U.S. EPA, 2011a, Figures 3–7 and 3–8), PM_{10} one-expected-exceedance concentration-equivalent design values were between approximately 175 and 300 μg/m³ at monitoring locations recording 3-year averages of 98th percentile 24-hour PM_{10} concentrations around 150 μg/m³ (i.e., the level of the current standard). This suggests that, depending on the location, a 24-hour PM_{10} standard with a 98th percentile form in conjunction with the current level (i.e., as recommended by these commenters) could be ''generally equivalent'' to a 24-hour PM_{10} standard with a one-expected-exceedance form and a level as high as approximately 300 μg/m³. Based on this analysis, a 24-hour PM_{10} standard with a 98th percentile form and a level of 150 μg/m³ would be markedly less health protective than the current standard.

evidence, as reflected in the weight of evidence conclusions in the Integrated Science Assessment and as discussed in the proposal, the Administrator judges that it is appropriate to consider and account for them when drawing conclusions about the implications of individual $PM_{10-2.5}$ health studies for the current standard. Commenters have not provided new information that would change the Administrator's views on the evidence and uncertainties.

In recommending that the PM_{10} standard be revised, some commenters supported their conclusions by referencing studies that evaluated PM_{10}, rather than $PM_{10-2.5}$. These commenters contended that ''[t]he most relevant studies to the setting of a PM_{10} standard are the thousands of studies that have reported adverse effects associated with PM_{10} pollution'' (ALA *et al.,* 2012).

As discussed in the Policy Assessment, the proposal, and above, since the establishment of the primary $PM_{2.5}$ standards, the purpose of the primary PM_{10} standard has been to protect against health effects associated with exposures to $PM_{10-2.5}$. PM_{10} is the indicator, not the target pollutant. With regard to the appropriateness of considering PM_{10} health studies for the purpose of reaching conclusions on a standard meant to protect against exposures to $PM_{10-2.5}$, the proposal noted that PM_{10} includes both fine and coarse particles, even in locations with the highest concentrations of $PM_{10-2.5}$. Therefore, the extent to which PM_{10} effect estimates reflect associations with $PM_{10-2.5}$ versus $PM_{2.5}$ can be highly uncertain and it is often unclear how PM_{10} health studies should be interpreted when considering a standard meant to protect against exposures to $PM_{10-2.5}$. Given this uncertainty and the availability of a number of $PM_{10-2.5}$ health studies in this review, the Integrated Science Assessment considered $PM_{10-2.5}$ studies, but not PM_{10} studies, when drawing weight-of-evidence conclusions regarding the coarse fraction.[130] In light of the uncertainty in ascribing PM_{10}-related health effects to the coarse or fine fractions, indicating that the best evidence for effects associated with exposures to $PM_{10-2.5}$ comes from studies evaluating $PM_{10-2.5}$ itself, and given CASAC's support for the approach adopted in the Integrated Science Assessment, which draws weight-of-evidence conclusions for $PM_{2.5}$ and $PM_{10-2.5}$ but not for PM_{10} (Samet, 2009f), the EPA continues to conclude that it is appropriate to focus on $PM_{10-2.5}$ health studies when considering the degree of public health protection provided by the current primary PM_{10} standard, a standard intended exclusively to provide protection against exposures to $PM_{10-2.5}$.

G. Administrator's Final Decision on the Primary PM_{10} Standard

In reaching a final decision on the primary PM_{10} standard, the Administrator takes into account the available scientific evidence, and the assessment of that evidence, in the Integrated Science Assessment; the analyses and staff conclusions presented in the Policy Assessment; the advice and recommendations of CASAC; and public comments on the proposal. In particular, as in the proposal, the Administrator places emphasis on her consideration of the following issues:

(1) The extent to which it is appropriate to maintain a standard that provides some measure of protection against all $PM_{10-2.5}$, regardless of composition or source of origin;

(2) The extent to which it is appropriate to retain a PM_{10} indicator for a standard meant to protect against exposures to ambient $PM_{10-2.5}$; and

(3) The extent to which the current PM_{10} standard provides an appropriate degree of public health protection.

Each of these issues is discussed below.

With regard to the first issue, as in the proposal the Administrator judges that the expanded body of scientific evidence available in this review provides ample support for a standard that protects against exposures to all thoracic coarse particles, regardless of their location or source of origin. There was already ample evidence for this position in the previous review,[131] and that evidence has since increased. Specifically, the Administrator notes that epidemiological studies have reported positive associations between $PM_{10-2.5}$ and mortality or morbidity in a large number of cities across North America, Europe, and Asia, encompassing a variety of environments where $PM_{10-2.5}$ sources and composition are expected to vary widely. In considering this evidence, the Integrated Science Assessment concludes that ''many constituents of PM can be linked with differing health effects'' (U.S. EPA, 2009a, p. 2–26). Although $PM_{10-2.5}$ in most of these study areas is of largely urban origin, the Administrator notes that some recent studies have also linked mortality and morbidity with relatively high ambient concentrations of particles of non-urban crustal origin. In considering these studies, she notes the Integrated Science Assessment's conclusion that ''PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from crustal, soil or road dust sources or PM tracers linked to these sources are associated with cardiovascular effects'' (U.S. EPA, 2009a, p. 2–26). The Administrator likewise notes CASAC's emphatic advice that a standard remains needed for all types of thoracic coarse PM.[132] In light of this body of available evidence reporting $PM_{10-2.5}$-associated health effects across different locations with a variety of sources, the Integrated Science Assessment's conclusions regarding the links between adverse health effects and PM sources and composition, and CASAC's advice, the Administrator concludes in the current review that it is appropriate to maintain a standard that provides some measure of protection against exposures to all thoracic coarse particles, regardless of their location, source of origin, or composition.

With regard to the second issue, in considering the appropriateness of a PM_{10} indicator for a standard meant to provide such public health protection, the Administrator notes that the rationale used in the last review to support the unqualified PM_{10} indicator remains relevant in the current review. Specifically, as an initial consideration, she notes that PM_{10} mass includes both coarse PM ($PM_{10-2.5}$) and fine PM ($PM_{2.5}$). As a result, the concentration of $PM_{10-2.5}$ allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. At the same time, the Administrator notes that $PM_{2.5}$ concentrations tend to be higher in urban areas than rural areas (U.S. EPA, 2005, p. 2–54, and Figures 2–23 and 2–24) and, therefore, a PM_{10} standard will generally allow lower $PM_{10-2.5}$ concentrations in urban areas than in rural areas.

In considering the appropriateness of this variation in allowable $PM_{10-2.5}$ concentrations, the Administrator considers the relative strength of the evidence for health effects associated with $PM_{10-2.5}$ of urban origin versus non-urban origin. She specifically notes that, as discussed in the proposal, the large majority of the available evidence for

[130] Although EPA relied in the 1997 review on evidence from PM_{10} studies, EPA did so out of necessity (i.e., there were as yet no reliable studies measuring $PM_{10-2.5}$). In the 2006 review, EPA placed primary reliance on epidemiologic studies measuring or estimating $PM_{10-2.5}$, although there were comparatively few such studies. In this review, a larger body of $PM_{10-2.5}$ studies are available. EPA regards these studies as the evidence to be given principal weight in reviewing the adequacy of the PM_{10} standard.

[131] The D.C. Circuit agreed. See 559 F. 3d at 532–33.

[132] Indeed, CASAC recommended making the standard for all types of thoracic coarse PM more stringent (Samet, 2010d).

thoracic coarse particle health effects comes from studies conducted in locations with sources more typical of urban and industrial areas than rural areas. While associations with adverse health effects have been reported in some study locations where $PM_{10-2.5}$ is largely non-urban in origin (i.e., in dust storm studies), particle concentrations in these study areas are typically much higher than reported in study locations where the PM is of urban origin. Therefore, the Administrator notes that the strongest evidence for a link between $PM_{10-2.5}$ and adverse health impacts, particularly for such a link at relatively low particle concentrations, comes from studies of urban or industrial $PM_{10-2.5}$.

The Administrator also notes that chemical constituents present at higher levels in urban or industrial areas, including byproducts of incomplete combustion (e.g. polycyclic aromatic hydrocarbons) emitted as $PM_{2.5}$ from motor vehicles as well as metals and other contaminants emitted from anthropogenic sources, can contaminate $PM_{10-2.5}$ (U.S. EPA, 2004, p. 8–344; 71 FR 2665, January 17, 2006). While the Administrator acknowledges the uncertainty expressed in the Integrated Science Assessment regarding the extent to which particle composition can be linked to health outcomes based on available evidence, she also considers the possibility that $PM_{10-2.5}$ contaminants typical of urban or industrial areas could increase the toxicity of thoracic coarse particles in urban locations.

Given that the large majority of the evidence for $PM_{10-2.5}$ toxicity, particularly at relatively low particle concentrations, comes from study locations where thoracic coarse particles are of urban origin, and given the possibility that $PM_{10-2.5}$ contaminants in urban areas could increase particle toxicity, the Administrator concludes that it remains appropriate to maintain a standard that provides some protection in all areas but targets public health protection to urban locations. Specifically, she concludes that it is appropriate to maintain a standard that allows lower ambient concentrations of $PM_{10-2.5}$ in urban areas, where the evidence is strongest that thoracic coarse particles are linked to mortality and morbidity, and higher concentrations in non-urban areas, where the public health concerns are less certain.

Given all of the above considerations and conclusions, the Administrator judges that the available evidence supports retaining a PM_{10} indicator for a standard that is meant to protect against exposures to thoracic coarse particles. In reaching this judgment, she notes that, to the extent a PM_{10} indicator results in lower allowable concentrations of thoracic coarse particles in some areas compared to others, lower concentrations will be allowed in those locations (i.e., urban or industrial areas) where the science has shown the strongest evidence of adverse health effects associated with exposure to thoracic coarse particles and where we have the most concern regarding $PM_{10-2.5}$ toxicity. Therefore, the Administrator concludes that the varying amounts of coarse particles that are allowed in urban vs. non-urban areas under the 24-hour PM_{10} standard, based on the varying levels of $PM_{2.5}$ present, appropriately reflect the differences in the strength of evidence regarding coarse particle effects in urban and non-urban areas.[133] [134]

In reaching this conclusion, the Administrator also notes that, in their review of the second draft Policy Assessment, CASAC concluded that ''[w]hile it would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles'' (Samet, 2010d, p. ii). Thus, consistent the considerations presented above and with CASAC advice, the Administrator concludes that it is appropriate to retain PM_{10} as the indicator for thoracic coarse particles.[135]

With regard to the third issue, in evaluating the degree of public health protection provided by the current PM_{10} standard, the Administrator first notes that when the available $PM_{10-2.5}$ scientific evidence and its associated uncertainties were considered, the Integrated Science Assessment concluded that the evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. As discussed above and in more detail in the Integrated Science Assessment (U.S. EPA, 2009a, section 1.5), a suggestive determination is made when the ''[e]vidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out.'' In contrast, the Administrator notes that she is strengthening the annual fine particle standard based on a body of scientific evidence judged sufficient to conclude that a causal relationship exists (i.e., mortality, cardiovascular effects) or is likely to exist (i.e., respiratory effects). The suggestive judgment for $PM_{10-2.5}$ reflects the greater degree of uncertainty associated with this body of evidence, as discussed above and in more detail in the proposal, and as summarized below.

The Administrator notes that the important uncertainties and limitations associated with the scientific evidence and air quality information raise questions as to whether public health benefits would be achieved by revising the existing PM_{10} standard. Such uncertainties and limitations include the following:

(1) While $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were generally positive, most were not statistically significant, even in single-pollutant models. This includes effect estimates reported in some study locations with PM_{10} concentrations above those allowed by the current 24-hour PM_{10} standard.

(2) The number of epidemiological studies that have employed co-pollutant models to address the potential for confounding, particularly by $PM_{2.5}$, remains limited. Therefore, the extent to which $PM_{10-2.5}$ itself, rather than one or more co-pollutants, contributes to reported health effects remains uncertain.

(3) Only a limited number of experimental studies provide support for the associations reported in epidemiological studies, resulting in further uncertainty regarding the plausibility of the associations between $PM_{10-2.5}$ and mortality and morbidity reported in epidemiological studies.

[133] As discussed in the proposal, the Administrator recognizes that this relationship is qualitative. That is, the varying coarse particle concentrations allowed under the PM_{10} standard do not precisely correspond to the variable toxicity of thoracic coarse particles in different areas (insofar as that variability is understood). Although currently available information does not allow any more precise adjustment for relative toxicity, the Administrator believes the standard will generally ensure that the coarse particle levels allowed will be lower in urban areas and higher in non-urban areas. Addressing this qualitative relationship, the DC Circuit held that ''[i]t is true that the EPA relies on a qualitative analysis to describe the protection the coarse PM NAAQS will provide. But the fact that the EPA's analysis is qualitative rather than quantitative does not undermine its validity as an acceptable rationale for the EPA's decision.'' 559 F. 3d at 535.

[134] The D.C. Circuit agreed with similar conclusions in the last review and held that this rationale reasonably supported use of an unqualified PM_{10} indicator for thoracic coarse particles. *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 535–36.

[135] In addition, CASAC ''vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles'' (Samet, 2010d, p. 7). Consideration of alternative indicators (e.g., $PM_{10-2.5}$) in future reviews could be informed by additional research, as described in the Policy Assessment (U.S. EPA, 2011a, section 3.5).

(4) Limitations in $PM_{10-2.5}$ monitoring data and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiological studies result in uncertainty in the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur, increasing uncertainty in estimates of the extent to which changes in ambient $PM_{10-2.5}$ concentrations would likely impact public health.

(5) The lack of a quantitative $PM_{10-2.5}$ risk assessment further contributes to uncertainty regarding the extent to which any revisions to the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard (see section III.B.5 above).

(6) The chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components, remains uncertain. Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across locations is difficult to characterize.

In considering these uncertainties and limitations, the Administrator notes in particular the considerable degree of uncertainty in the extent to which health effects reported in epidemiological studies are due to $PM_{10-2.5}$ itself, as opposed to one or more co-occurring pollutants. As discussed above, this uncertainty reflects the fact that there are a relatively small number of $PM_{10-2.5}$ studies that have evaluated co-pollutant models, particularly co-pollutant models that have included $PM_{2.5}$, and a very limited body of controlled human exposure evidence supporting the plausibility of a causal relationship between $PM_{10-2.5}$ and mortality and morbidity at ambient concentrations. The Administrator notes that these important limitations in the overall body of health evidence introduce uncertainty into the interpretation of individual epidemiological studies, particularly those studies reporting associations with $PM_{10-2.5}$ that are not statistically significant. Given this, the Administrator reaches the conclusion that it is appropriate to place relatively little weight on epidemiological studies reporting associations with $PM_{10-2.5}$ that are not statistically significant in single-pollutant and/or co-pollutant models.[136]

With regard to this conclusion, the Administrator notes that, for single-city mortality studies conducted in the United States where ambient PM_{10} concentration data were available for comparison to the current standard, positive and statistically significant $PM_{10-2.5}$ effect estimates were only reported in study locations that would likely have violated the current PM_{10} standard during the study period (U.S. EPA, 2011a, Figure 3–2). In U.S. study locations that would likely have met the current standard, $PM_{10-2.5}$ effect estimates for mortality were positive, but not statistically significant (U.S. EPA, 2011a, Figure 3–2). In considering U.S. study locations where single-city morbidity studies were conducted, and which would likely have met the current PM_{10} standard during the study period, the Administrator notes that $PM_{10-2.5}$ effect estimates were both positive and negative, with most not statistically significant (U.S. EPA, 2011a, Figure 3–3).

In addition, in considering single-city analyses for the locations evaluated in a large U.S. multi-city mortality study (Zanobetti and Schwartz, 2009), the Administrator notes that associations in most of the study locations were not statistically significant and that this was the only study to estimate ambient $PM_{10-2.5}$ concentrations as the difference between county-wide PM_{10} and $PM_{2.5}$ mass. As discussed in the proposal, the Administrator notes that it is not clear how computed $PM_{10-2.5}$ measurements, such as those used by Zanobetti and Schwartz (2009), compare with the $PM_{10-2.5}$ concentrations obtained in other studies either by direct measurement by calculating the difference using co-located samplers (U.S. EPA, 2009a, section 6.5.2.3). For these reasons, as in the proposal, the Administrator notes that there is considerable uncertainty in interpreting the associations, and especially the concentrations at which such associations may have occurred, in these single-city analyses.

The Administrator acknowledges that an approach to considering the available scientific evidence and air quality information that emphasizes the above considerations differs from the approach taken by CASAC. Specifically, CASAC placed a substantial amount of weight on individual studies, particularly those reporting positive health effects associations in locations that met the current PM_{10} standard during the study period. In emphasizing these studies, as well as the limited number of supporting studies that have evaluated co-pollutant models and the small number of supporting experimental studies, CASAC concluded that ''the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard'' (Samet, 2010d, p. 7) and recommended revising the current PM_{10} standard (Samet, 2010d).

The Administrator has carefully considered CASAC's advice and recommendations. She notes that in making its recommendation on the current PM_{10} standard, CASAC did not discuss its approach to considering the important uncertainties and limitations in the health evidence, and did not discuss how these uncertainties and limitations are reflected in its recommendation. As discussed above, such uncertainties and limitations contributed to the conclusions in the Integrated Science Assessment that the $PM_{10-2.5}$ evidence is only suggestive of a causal relationship, a conclusion that CASAC endorsed (Samet, 2009e,f). Given the importance of these uncertainties and limitations to the interpretation of the evidence, as reflected in the weight of evidence conclusions in the Integrated Science Assessment and as discussed above, the Administrator judges that it is appropriate to consider and account for them when drawing conclusions about the potential implications of individual $PM_{10-2.5}$ health studies for the current standard.

In light of the above approach to considering the scientific evidence, air quality information, and associated uncertainties, the Administrator reaches the following conclusions:

(1) When viewed as a whole the available evidence and information suggests that the degree of public health protection provided against short-term exposures to $PM_{10-2.5}$ should be maintained but does not need to be increased beyond that provided by the current PM_{10} standard. This conclusion emphasizes the important uncertainties and limitations associated with the overall body

[136] The Administrator acknowledges that this approach to interpreting the evidence differs in emphasis from the approach she has adopted for the evidence relating to $PM_{2.5}$. As discussed above in section III.E.4, for fine particles the Administrator has considered not only whether study results are statistically significant (or remain so after application of co-pollutant models), but she also places emphasis on the overall pattern of results across the epidemiological literature. This includes giving some credence to studies that reported statistically non-significant associations. This difference in emphasis stems from the much stronger overall body of evidence available for fine particles, compared to coarse particles. As discussed above, when the available $PM_{2.5}$ scientific evidence and its associated uncertainties were considered, the Integrated Science Assessment concluded that the evidence was sufficient to conclude that causal relationships exist with mortality and cardiovascular effects, and that a causal relationship is likely to exist with respiratory effects. In contrast, the Integrated Science Assessment concluded that the evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. A suggestive determination is made when the ''[e]vidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out'' (U.S. EPA, 2009a, section 1.5). The suggestive judgment for $PM_{10-2.5}$ reflects the greater degree of uncertainty associated with this body of evidence.

of health evidence and air quality information for $PM_{10-2.5}$, as discussed above and as reflected in the Integrated Science Assessment weight-of-evidence conclusions; that $PM_{10-2.5}$ effect estimates for the most serious health effect, mortality, were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers; and that $PM_{10-2.5}$ effect estimates for morbidity endpoints were both positive and negative in locations that met the current standard, with most not statistically significant.[137]

(2) The degree of public health protection provided by the current standard is not greater than warranted. This conclusion notes that positive and statistically significant associations with mortality were reported in single-city U.S. study locations likely to have violated the current PM_{10} standard.[138]

In reaching these conclusions, the Administrator notes that the Policy Assessment also discussed the potential for a revised PM_{10} standard (i.e., with a revised form and level) to be ''generally equivalent'' to the current standard, but to better target public health protection to locations where there is greater concern regarding $PM_{10-2.5}$-associated health effects (U.S. EPA, 2011a, sections 3.3.3 and 3.3.4).[139] In considering such a potential revised standard, the Policy Assessment discusses the large amount of variability in PM_{10} air quality correlations across monitoring locations and over time (U.S. EPA, 2011a, Figure 3–7) and the regional variability in the relative degree of public health protection that could be provided by the current and potential alternative standards (U.S. EPA, 2011a, Table 3–2). In light of this variability, the Administrator notes the Policy Assessment conclusion that no single revised PM_{10} standard (i.e., with a revised form and level) would provide public health protection equivalent to that provided by the current standard, consistently over time and across locations (U.S. EPA, 2011a, section 3.3.4). That is, a revised standard, even one that is meant to be ''generally equivalent'' to the current PM_{10} standard, could increase protection in some locations while decreasing protection in other locations.

In considering the appropriateness of revising the current PM_{10} standard in this way, the Administrator notes the following:

(1) As discussed above, positive $PM_{10-2.5}$ effect estimates for mortality were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers, while positive and statistically significant associations with mortality were reported in locations likely to have violated the current PM_{10} standard.

(2) Also as discussed above, effect estimates for morbidity endpoints in locations that met the current standard were both positive and negative, with most not statistically significant.

(3) Important uncertainties and limitations associated with the overall body of health evidence and air quality information for $PM_{10-2.5}$, as discussed above and as reflected in the Integrated Science Assessment weight-of-evidence conclusions, call into question the extent to which the type of quantified and refined targeting of public health protection envisioned under a revised standard could be reliably accomplished.

Given all of the above considerations, the Administrator notes that there is a large amount of uncertainty in the extent to which public health would be improved by changing the locations to which the PM_{10} standard targets protection. Therefore, she reaches the conclusion that the current PM_{10} standard should not be revised in order to change that targeting of protection.

In considering all of the above, including the scientific evidence, the air quality information, the associated uncertainties, CASAC's advice, and public comments received on the proposed rule, the Administrator reaches the conclusion in the current review that the existing 24-hour PM_{10} standard, with its one-expected exceedance form and a level of 150 μg/m^3, is requisite (i.e., neither more protective nor less protective than necessary) to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. In light of this conclusion, with this rule the Administrator retains the current PM_{10} standard.

V. Communication of Public Health Information

Sections 319(a)(1) and (3) of the CAA require the EPA to establish a uniform air quality index for reporting of air quality. These sections specifically direct the Administrator to ''promulgate regulations establishing an air quality monitoring system throughout the United States which utilizes uniform air quality monitoring criteria and methodology and measures such air quality according to a uniform air quality index'' and ''provides for daily analysis and reporting of air quality based upon such uniform air quality index * * *'' In 1979, the EPA established requirements for index reporting (44 FR 27598, May 10, 1979). The requirement for State and local agencies to report the AQI appears in 40 CFR 58.50, and the specific requirements (e.g., what to report, how to report, reporting frequency, calculations) are in appendix G to 40 CFR part 58.

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily by AQI reporting through EPA's AIRNow Web site.[140] The current AQI has been in use since its inception in 1999.[141] It provides accurate, timely, and easily understandable information about daily levels of pollution (40 CFR 58.50). The AQI establishes a nationally uniform system of indexing pollution levels for ozone, carbon monoxide, nitrogen

[137] This is not to say that the EPA could not adopt or revise a standard for a pollutant for which the evidence is suggestive of a causal relationship. Indeed, with respect to thoracic coarse particles itself, the DC Circuit noted that ''[a]lthough the evidence of danger from coarse PM is, as the EPA recognizes, 'inconclusive', the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health.'' *American Farm Bureau Federation* v *EPA* 559 F. 3d at 533. As explained in the text above, it is the Administrator's judgment that significant uncertainties presented by the evidence and information before her in this review, both as to causality and as to concentrations at which effects may be occurring, best support a decision to retain rather than revise the current primary 24-hour PM_{10} standard.

[138] There are similarities with the conclusions drawn by the Administrator in the last review. There, the Administrator concluded that there was no basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times. 71 FR 61202. In addition, the Administrator concluded that there was a high degree of uncertainty in the relevant population exposures implied by the morbidity studies suggesting that there is little basis for concluding that a greater degree of protection is warranted. *Id.* The D.C. Circuit in *American Farm Bureau Federation* v *EPA* explicitly endorsed this reasoning. 559 F. 3d at 534.

[139] As discussed in detail above (section IV.C.2.d) and in the Policy Assessment (U.S. EPA, 2011a, sections 3.3.3 and 3.3.4), a revised standard that is generally equivalent to the current PM_{10} standard could provide a degree of public health protection that is similar to the degree of protection provided by the current standard, across the United States as a whole. However, compared to the current PM_{10} standard, such a generally equivalent standard would change the degree of public health protection provided in some specific areas, providing increased protection in some locations and decreased protection in other locations.

[140] See *http://www.airnow.gov/.*

[141] In 1976, the EPA established a nationally uniform air quality index, then called the Pollutant Standard Index (PSI), for use by State and local agencies on a voluntary basis (41 FR 37660, September 7, 1976). In August 1999, the EPA adopted revisions to this air quality index (64 FR 42530, August 4, 1999) and renamed the index the AQI.

dioxide, PM, and sulfur dioxide. The AQI is also recognized internationally as a proven tool to effectively communicate air quality information to the public.

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 levels 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 (e.g., daily or hourly standard) NAAQS for each pollutant. Below an index value of 100, an intermediate value of 50 was defined either as the level of the annual standard if an annual standard has been established (e.g., $PM_{2.5}$, nitrogen dioxide), or as a concentration equal to one-half the value of the short-term standard used to define an index value of 100 (e.g., carbon monoxide). 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). The underlying health information that supports the NAAQS review also supports the selection of the AQI ''breakpoints''—the ambient concentrations that delineate the various AQI categories for each pollutant.

Historically, state and local agencies have primarily used the AQI to provide general information to the public about air quality and its relationship to public health. For more than a decade, many states and local agencies, as well as the EPA and other Federal agencies, have been developing new and innovative programs and initiatives to provide more information to the public in a more timely way. These initiatives, including air quality forecasting, real-time data reporting through the AirNow Web site, and state and local air quality action day programs, can serve to provide useful, up-to-date, and timely information to the public about air pollution and its effects. Such information will help individuals take actions to avoid or to reduce exposures to ambient pollution at levels of concern to them. Thus, these programs have significantly broadened the ways in which state and local agencies can meet the nationally uniform AQI reporting requirements and contribute to state and local efforts to provide community health protection.

With respect to an AQI value of 50, the historical approach is to set it at the same level of the annual primary standard, if there is one. This is consistent with the previous AQI sub-index for $PM_{2.5}$, in which the AQI value of 50 was set at 15 μg/m³ in 1999, consistent with the level of the annual $PM_{2.5}$ standard at that time. In recognition of the proposed change to the annual $PM_{2.5}$ standard summarized in section III.F of the proposal, the EPA proposed a conforming change to the $PM_{2.5}$ sub-index of the AQI to be consistent with the proposed change to the annual standard. As discussed below, no state or local agencies, or their organizations (e.g., NACAA), that commented on the proposed changes to the AQI disagreed with our proposed approach. Based on these comments, the EPA continues to see no basis for deviating from this approach in this review. Thus, the EPA is taking final action to set an AQI value of 50 at 12.0 μg/m³, 24-hour average, consistent with the final decision on the annual $PM_{2.5}$ standard level (section III.F).

With respect to an AQI value of 100, which is the basis for advisories to individuals in sensitive groups, in the proposal we described two general approaches that could be used to select the associated $PM_{2.5}$ level. By far the most common approach, which has been used with all of the other sub-indices, is to set an AQI value of 100 at the same level as the short-term standard. In the proposal, the EPA recognized that some state and local air quality agencies have expressed a strong preference that the Agency set an AQI value of 100 equal to any short-term standard (77 FR 38964). These agencies typically express the view that this linkage is useful for the purpose of communicating with the public about the standard, as well as providing consistent messages about the health impacts associated with daily air quality. The EPA proposed to use this approach to set the AQI value of 100 at 35 μg/m³, 24-hour average, consistent with the proposed decision to retain the current 24-hour $PM_{2.5}$ standard. *Id.*

An alternative approach discussed in the proposal (77 FR 38964), was to directly evaluate the health effects evidence to select the level for an AQI value of 100. This was the approach used in the 1999 rulemaking to set the AQI value of 100 at a level of 40 μg/m³, 24-hour average,[142] when the 24-hour standard level was 65 μg/m³. This alternative approach was used in the case of the $PM_{2.5}$ sub-index, because the annual and 24-hour $PM_{2.5}$ standards set in 1997 were designed to work together, and the intended degree of health protection against short-term risks was not defined by the 24-hour standard alone, but rather by the combination of the two standards working in concert. Indeed, at that time, the 24-hour standard was set to provide supplemental protection relative to the principal protection provided by the annual standard. In the proposal, the EPA solicited comment on this alternative approach in recognition that, as proposed, the 24-hour $PM_{2.5}$ standard is intended to continue to provide supplemental protection against effects associated with short-term exposures of $PM_{2.5}$ by working in conjunction with the annual standard to reduce 24-hour exposures to $PM_{2.5}$. The EPA recognized that in the past, some state and local air quality agencies have expressed support for this alternative approach. Using this alternative approach could have resulted in consideration of a lower level for an AQI value of 100, based on the discussion of the health information pertaining to the level of the 24-hour standard in section III.E.4 of the proposal. The EPA encouraged state and local air quality agencies to comment on both the approach and the level at which to set an AQI value of 100 together with any supporting rationale. Of the state or local agencies, or their organizations (e.g., NACAA), that commented on the proposed changes to the AQI, only one organization, NESCAUM, expressed some support for this approach. In its comments, NESCAUM expressed support for a 24-hour standard set at 30 μg/m³, 24-hour average. NESCAUM also expressed the view that EPA should carefully consider how to set the breakpoint for an AQI value of 100. NESCAUM expressed the view that if the EPA were to keep the 24-hour $PM_{2.5}$ standard at 35 μg/m³, the annual standard would be controlling, and a 24-hour breakpoint at that level (35 μg/m³) would not be very effective for the purposes of public health messaging. However, other agencies, such as Georgia Department of Natural Resources (Georgia DNR), expressed the view that linkage between the short-term standard and the AQI of 100 is useful for the purpose of communicating with the public about the standard as well as providing consistent messages about the health

[142] Currently, we are cautioning members of sensitive groups at the AQI value of 100 at 35 μg/m³, 24-hour average, consistent with more recent guidance from the EPA with regard to the development of State emergency episode contingency plans (Harnett, 2009, Attachment B).

impacts associated with the daily air quality. Based on these comments, the EPA sees no basis for deviating from the approach proposed in this review. Thus, the EPA is taking final action to set an AQI value of 100 at 35 μg/m³, 24-hour average, consistent with the final decision on the 24-hour $PM_{2.5}$ standard level (section III.F).

With respect to an AQI value of 150, this level is based upon the same health effects information that informs the selection of the level of the 24-hour standard and the AQI value of 100. The AQI value of 150 was set in the 1999 rulemaking at a level of 65 μg/m³, 24-hour average. In considering what level to propose for an AQI value of 150, we stated the view that the health effects evidence indicates that the level of 55 μg/m³, 24-hour average, is appropriate to use [143] in conjunction with an AQI value of 100 set at the level of 35 μg/m³. The Agency's approach to selecting the levels at which to set the AQI values of 100 and 150 inherently recognizes that the epidemiological evidence upon which these decisions are based provides no evidence of discernible thresholds, below which effects do not occur in either sensitive groups or in the general population, at which to set these two breakpoints. Therefore, the EPA concluded the use of a proportional adjustment would be appropriate. Commenters did not comment on this proposed approach to revising the AQI value of 150; thus, the EPA is taking final action to set an AQI value of 150 at 55 μg/m³, 24-hour average.

Based on the air quality and health considerations discussed in section V of the proposal, the EPA concluded that it was appropriate to propose to retain the current level of 500 μg/m³, 24-hour average, for the AQI value of 500. In addition, the EPA solicited comment on alternative levels and approaches to setting a level for the AQI value of 500, as well as supporting information and rationales for such alternative levels. The EPA also solicited any additional information, data, research or analyses that may be useful to inform a final decision on the appropriate level to set the AQI value of 500. Receiving no information with which to inform alternative approaches to setting an AQI value of 500, the EPA is taking final action to retain the current level of 500 μg/m³, 24-hour average, for the AQI value of 500.

For the intermediate breakpoints in the AQI between the values of 150 and 500, the EPA proposed $PM_{2.5}$ concentrations that generally reflected a linear relationship between increasing index values and increasing $PM_{2.5}$ values (77 FR 38965). The available scientific evidence of health effects related to population exposures to $PM_{2.5}$ concentrations between the level of the 24-hour standard and an AQI value of 500 suggested a continuum of effects in this range, with increasing $PM_{2.5}$ concentrations being associated with increasingly larger numbers of people likely to experience such effects. The generally linear relationship between AQI values and $PM_{2.5}$ concentrations in this range is consistent with the health evidence. This also is consistent with the Agency's practice of setting breakpoints in symmetrical fashion where health effects information does not suggest particular levels.

Table 2 below summarizes the finalized breakpoints for the $PM_{2.5}$ sub-index.[144] Table 2 shows the intermediate breakpoints for AQI values of 200, 300 and 400 based on a linear interpolation between the proposed levels for AQI values of 150 and 500. If a different level were to be set for an AQI value of 150 or 500, intermediate levels would be calculated based on a linear relationship between the selected levels for AQI values of 150 and 500.

TABLE 2—BREAKPOINTS FOR $PM_{2.5}$ SUB-INDEX

AQI category	Index values	Proposed breakpoints (μg/m³, 24-hour average)
Good	0–50	0.0–(12.0)
Moderate	51–100	(12.1)–35.4
Unhealthy for Sensitive Groups	101–150	35.5–55.4
Unhealthy	151–200	55.5–150.4
Very Unhealthy	201–300	150.5–250.4
Hazardous	301–400	250.5–350.4
	401–500	350.5–500.4

In retaining the 500 level for the AQI as described above, we note that the EPA is not establishing a Significant Harm Level (SHL) for $PM_{2.5}$. The SHL is an important part of air pollution Emergency Episode Plans, which are required for certain areas by CAA section 110(a)(2)(G) and associated regulations at 40 CFR 51.150, under the Prevention of Air Pollution Emergency Episodes program. The Agency believes that air quality responses established through an Emergency Episode Plan should be developed through a collaborative process working with State and Tribal air quality, forestry and agricultural agencies, Federal land management agencies, private land managers and the public. Therefore, if in future rulemaking the EPA proposes revisions to the Prevention of Air Pollution Emergency Episodes program, the proposal will include a SHL for $PM_{2.5}$ that is developed in collaboration with these organizations. As discussed in the 1999 Air Quality Index Reporting Rule (64 FR 42530), if a future rulemaking results in a SHL that is different from the 500 value of the AQI for $PM_{2.5}$, the AQI will be revised accordingly.

The EPA also received more general comments on AQI reporting, comments that did not pertain to setting specific breakpoints. One set of commenters (e.g., API and UARG), expressed the view that changes to the AQI are not appropriate. They noted that air quality is getting better, and in fact is better than when EPA established the AQI. These commenters stated that the proposed changes to the annual standard and the AQI would mean that the public would hear less often that air quality is good, and thereby would receive apparently inconsistent or misleading messages that air quality is

[143] We note that this level is consistent with the level recommended in the more recent EPA guidance (Harnett, 2009, Attachment B), which is in use by many State and local agencies.

[144] As discussed in section VII.C below, the EPA is also updating the data handling procedures for reporting the AQI and corresponding updates for other AQI-sub-indices presented in Table 2 of appendix G of 40 CFR part 58.

worse. The AQI has been revised several times in conjunction with revisions to the standards. State and local air quality agencies and organizations are proficient at communicating with the public about the reasons for changes to the AQI. Therefore, the EPA strongly disagrees with these commenters that the public will receive inconsistent or misleading messages. Recognizing the importance of the AQI as a communication tool that allows the public to take exposure reduction measures when air quality may pose health risks, the EPA agrees with state and local air quality agencies and organizations that favored revising the AQI at the same time as the primary standard.

A few state and local air quality agencies and organizations recommended against using near-roadway $PM_{2.5}$ monitors for AQI reporting. In support of this comment, they expressed the following views, that near-roadway monitors are source-oriented, represent micro-scale conditions, and the agencies don't have experience using them for AQI reporting. The EPA disagrees with the comment in that these monitors will be sited at existing near-road stations sited to be representative of area-wide $PM_{2.5}$ concentrations indicative of general population exposure. Accordingly, data from these near-road monitors should be included in the AQI since they provide information about $PM_{2.5}$ levels that millions of people, who work, live and go to school near busy roadways, are exposed to. The stations are representative of somewhat elevated concentrations in near-road environments, but since these stations represent many such locations throughout a metropolitan area, they are appropriate for characterizing exposure in typical portions of major urban areas. The EPA is committed to helping air quality agencies develop appropriate ways to report $PM_{2.5}$ levels from these monitors using the AQI.

VI. Rationale for Final Decisions on the Secondary PM Standards

This section presents the Administrator's final decisions regarding the need to revise the current suite of secondary $PM_{2.5}$ and PM_{10} standards to address visibility impairment and other welfare effects considered in this review. Specifically, this section describes the Administrator's final decision to retain the current suite of secondary PM standards to address PM-related visibility impairment as well as other PM-related welfare effects, including ecological effects, effects on materials, and climate impacts. This suite of standards includes an annual $PM_{2.5}$ standard of 15 μg/m³, a 24-hour $PM_{2.5}$ standard of 35 μg/m³, and a 24-hour PM_{10} standard of 150 μg/m³. The Administrator is revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. Contrary to what was proposed, the Administrator has decided not to establish a distinct standard to address PM-related visibility impairment. The rationale for this decision is presented below.

The Administrator's final decisions on the secondary standards are based on a thorough review of the latest scientific information published through mid-2009 on welfare effects associated with fine and coarse particles in the ambient air, as presented in the Integrated Science Assessment. The final decisions also take into account: (1) Staff assessments of the most policy-relevant information presented and assessed in the Integrated Science Assessment and staff analyses of air quality and visibility effects presented in the Visibility Assessment and the Policy Assessment, upon which staff conclusions regarding appropriate considerations in this review are based; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the Integrated Science Assessment, Visibility Assessment, and Policy Assessment at public meetings, in separate written comments, and in CASAC's letters to the Administrator; (3) the multiple rounds of public comments received during the development of these documents, both in connection with CASAC meetings and separately; and (4) public comments received on the proposal.

In particular, this section presents background information on the EPA's previous and current reviews of the secondary PM standards (section VI.A), a summary of the proposed decisions regarding the secondary PM standards (section VI.B), a discussion of significant public comments received on those proposed decisions (section VI.C), and the Administrator's final decisions on the secondary PM standards (section VI.D).

A. Background

The current suite of secondary PM standards is identical to the suite of primary PM standards set in 2006, including 24-hour and annual $PM_{2.5}$ standards and a 24-hour PM_{10} standard. The current secondary $PM_{2.5}$ standards are intended to provide protection from PM-related visibility impairment, whereas the entire suite of secondary PM standards is intended to provide protection from other PM-related effects on public welfare, including effects on sensitive ecosystems, materials damage and soiling, and climatic and radiative processes.

The approach used for reviewing the current suite of secondary PM standards built upon and broadened the approaches used in previous PM NAAQS reviews. The following discussion focuses particularly on the current secondary $PM_{2.5}$ standards related to visibility impairment and provides a summary of the approaches used to review and establish secondary $PM_{2.5}$ standards in the last two reviews (section VI.A.1); judicial review of the 2006 standards that resulted in the remand of the secondary annual and 24-hour $PM_{2.5}$ NAAQS to the EPA (section VI.A.2); and the approach used in this review for evaluating the secondary $PM_{2.5}$ standards (section VI.A.3).

1. Approaches Used in Previous Reviews

The original secondary $PM_{2.5}$ standards were established in 1997, and a revision to the 24-hour standard was made in 2006. The approaches used in making final decisions on secondary standards in those reviews, as well as the current review, utilized different ways to consider the underlying body of scientific evidence. They also reflected an evolution in EPA's understanding of the nature of the effect on public welfare from PM-related visibility impairment, from an approach that focused only on Federal Class I area visibility impacts to a more multifaceted approach that also considered PM-related impacts on visibility in non-Federal Class I areas, such as in urban areas. This evolution occurred in conjunction with the expansion of available PM data and information from visibility-related studies of public perception, valuation, and personal comfort and well-being.

In 1997, the EPA revised the PM NAAQS in part by establishing new identical primary and secondary $PM_{2.5}$ standards. In revising the secondary standards, the EPA recognized that PM produces adverse effects on visibility and that impairment of visibility was being experienced throughout the U.S., in multi-state regions, urban areas, and remote mandatory Federal Class I areas alike. However, in considering an appropriate level for a secondary standard to address adverse effects of $PM_{2.5}$ on visibility, the EPA concluded that the determination of a single national level was complicated by important regional differences influenced by factors such as

background and current levels of $PM_{2.5}$, composition of $PM_{2.5}$, and average relative humidity. Variations in these factors across regions could thus result in situations where attaining an appropriately protective concentration of fine particles in one region might or might not provide adequate protection in a different region. The EPA also determined that there was insufficient information at that time to establish a level for a national secondary standard that would represent a threshold above which visibility conditions would always be adverse and below which visibility conditions would always be acceptable.

Based on an assessment of the potential visibility improvements that would result from reaching attainment with the new primary standards for $PM_{2.5}$, the EPA concluded that attainment of the annual and 24-hour $PM_{2.5}$ primary standards would lead to visibility improvements in the eastern U.S. at both urban and regional scales, but little or no change in the western U.S., except in and near certain urban areas.

The EPA also considered the potential effectiveness of a regional haze program, required by sections 169A and 169B of the CAA [145] to address those effects of PM on visibility that would not be addressed through attainment of the primary $PM_{2.5}$ standards. The regional haze program would be designed to address the widespread, regionally uniform type of haze caused by a multitude of sources. The structure and requirements of sections 169A and 169B of the CAA provide for visibility protection programs that can be more responsive to the factors contributing to regional differences in visibility than can programs addressing the kinds of nationally applicable secondary NAAQS considered in the 1997 review. The regional haze visibility goal is more protective than a secondary NAAQS since the goal is to eliminate any anthropogenic impairment rather than to provide a level of protection from visibility impairment that is requisite to protect the public welfare. Thus, an important factor considered in the 1997 review was whether a regional haze program, in conjunction with secondary standards set identical to the suite of $PM_{2.5}$ primary standards, would provide appropriate protection for visibility in non-Federal Class I areas. The EPA concluded that the two programs and associated control strategies should provide such protection due to the regional approaches needed to manage emissions of pollutants that impair visibility in many of these areas.

For these reasons, in 1997 the EPA concluded that a national regional haze program, combined with a nationally applicable level of protection achieved through secondary $PM_{2.5}$ standards set identical to the primary $PM_{2.5}$ standards, would be more effective for addressing regional variations in the adverse effects of $PM_{2.5}$ on visibility than would be national secondary standards for PM with levels lower than the primary $PM_{2.5}$ standards. The EPA further recognized that people living in certain urban areas may place a high value on unique scenic resources in or near these areas and as a result might experience visibility problems attributable to sources that would not necessarily be addressed by the combined effects of a regional haze program and $PM_{2.5}$ secondary standards. The EPA concluded that in such cases, state or local regulatory approaches, such as past action in Colorado to establish a local visibility standard for the City of Denver, would be more appropriate and effective in addressing these special situations because of the localized and unique characteristics of the problems involved. Visibility in an urban area located near a mandatory Federal Class I area could also be improved through state implementation of the then-current visibility regulations, by which emission limitations can be imposed on a source or group of sources found to be contributing to ''reasonably attributable'' impairment in the mandatory Federal Class I area.

Based on these considerations, in 1997 the EPA set secondary $PM_{2.5}$ standards identical to the primary $PM_{2.5}$ standards, that would work in conjunction with the Regional Haze Program to be established under sections 169A and 169B of the CAA, as the most appropriate and effective means of addressing the public welfare effects associated with visibility impairment. Together, the two programs and associated control strategies were expected to provide appropriate protection against PM-related visibility impairment and enable all regions of the country to make reasonable progress toward the national visibility goal.

In 2006, the EPA revised the suite of secondary $PM_{2.5}$ standards to address visibility impairment by making the suite of secondary standards identical to the revised suite of primary $PM_{2.5}$ standards. The EPA's decision regarding the need to revise the suite of secondary $PM_{2.5}$ standards reflected a number of new developments that had occurred and sources of information that had become available following the 1997 review. First, the EPA promulgated a Regional Haze Program in 1999 (65 FR 35713, July 1, 1999) which required states to establish goals for improving visibility in Federal Class I areas and to adopt control strategies to achieve these goals. Second, extensive new information from visibility and fine particle monitoring networks had become available, allowing for updated characterizations of visibility trends and PM concentrations in urban areas, as well as Federal Class I areas. These new data allowed the EPA to better characterize visibility impairment in urban areas and the relationship between visibility and $PM_{2.5}$ concentrations. Finally, additional studies in the U.S. and abroad provided the basis for the establishment of standards and programs to address specific visibility concerns in a number of local areas. These studies (Denver, Phoenix, and British Columbia) utilized photographic representations of visibility impairment and produced reasonably consistent results in terms of the visual ranges found to be generally acceptable by study participants. The EPA considered the information generated by these studies useful in characterizing the nature of particle-induced haze and for informing judgments about the acceptability of various levels of visual air quality in urban areas across the U.S. Based largely on this information, the Administrator concluded that it was appropriate to revise the secondary $PM_{2.5}$ standards to provide increased protection from visibility impairment principally in urban areas, in conjunction with the regional haze program for protection of visual air quality in Federal Class I areas.

In so doing, the Administrator recognized that PM-related visibility impairment is principally related to fine particle concentrations and that perception of visibility impairment is most directly related to short-term, nearly instantaneous levels of visual air quality. Thus, in considering whether the then-current suite of secondary standards would provide the appropriate degree of protection, he concluded that it was appropriate to focus on just the 24-hour secondary $PM_{2.5}$ standard to provide requisite protection.

The Administrator then considered whether $PM_{2.5}$ mass remained the appropriate indicator for a secondary

[145] In 1977, Congress established as a national goal ''the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Federal Class I areas which impairment results from manmade air pollution,'' section 169A(a)(1) of the CAA. The EPA is required by section 169A(a)(4) of the CAA to promulgate regulations to ensure that ''reasonable progress'' is achieved toward meeting the national goal.

standard to protect visibility, primarily in urban areas. The Administrator noted that PM-related visibility impairment is principally related to fine particle levels. Hygroscopic components of fine particles, in particular sulfates and nitrates, contribute disproportionately to visibility impairment under high humidity conditions. Particles in the coarse mode generally contribute only marginally to visibility impairment in urban areas. With the substantial addition to the air quality and visibility data made possible by the national urban $PM_{2.5}$ monitoring networks, an analysis conducted for the 2006 review found that, in urban areas, visibility levels showed far less difference between eastern and western regions on a 24-hour or shorter time basis than implied by the largely non-urban data available in the 1997 review. In analyzing how well $PM_{2.5}$ concentrations correlated with visibility in urban locations across the U.S., the 2005 Staff Paper concluded that clear correlations existed between 24-hour average $PM_{2.5}$ concentrations and calculated (i.e., reconstructed) light extinction, which is directly related to visual range (U.S. EPA, 2005, p. 7–6). These correlations were similar in the eastern and western regions of the U.S. These correlations were less influenced by relative humidity and more consistent across regions when $PM_{2.5}$ concentrations were averaged over shorter, daylight time periods (e.g., 4 to 8 hours) when relative humidity in eastern urban areas was generally lower and thus more similar to relative humidity in western urban areas. The 2005 Staff Paper noted that a standard set at any specific $PM_{2.5}$ concentration would necessarily result in visual ranges that vary somewhat in urban areas across the country, reflecting the variability in the correlations between $PM_{2.5}$ concentrations and light extinction. The 2005 Staff Paper concluded that it was appropriate to use $PM_{2.5}$ as an indicator for standards to address visibility impairment in urban areas, especially when the indicator is defined for a relatively short period (e.g., 4 to 8 hours) of daylight hours (U.S. EPA, 2005, p. 7–6). Based on their review of the Staff Paper, most CASAC Panel members also endorsed such a $PM_{2.5}$ indicator for a secondary standard to address visibility impairment (Henderson, 2005a, p. 9). Based on the above considerations, the Administrator concluded that $PM_{2.5}$ should be retained as the indicator for fine particles as part of a secondary standard to address visibility protection, in conjunction with averaging times from 4 to 24 hours.

In considering what level of protection against PM-related visibility impairment would be appropriate, the Administrator took into account the results of the public perception and attitude surveys regarding the acceptability of various degrees of visibility impairment in the U.S. and Canada, state and local visibility standards within the U.S., and visual inspection of photographic representations of several urban areas across the U.S. In the Administrator's judgment, these sources provided useful but still quite limited information on the range of levels appropriate for consideration in setting a national visibility standard primarily for urban areas, given the generally subjective nature of the public welfare effect involved. Based on photographic representations of varying levels of visual air quality, public perception studies, and local and state visibility standards, the 2005 Staff Paper had concluded that 30 to 20 $\mu g/m^3$ $PM_{2.5}$ represented a reasonable range for a national visibility standard primarily for urban areas, based on a sub-daily averaging time (U.S. EPA, 2005, p. 7–13). The upper end of this range was below the levels at which illustrative scenic views are significantly obscured, and the lower end was around the level at which visual air quality generally appeared to be good based on observation of the illustrative views. This concentration range generally corresponded to median visual ranges in urban areas within regions across the U.S. of approximately 25 to 35 km, a range that was bounded above by the visual range targets selected in specific areas where state or local agencies placed particular emphasis on protecting visual air quality. In considering a reasonable range of forms for a $PM_{2.5}$ standard within this range of levels, the 2005 Staff Paper had concluded that a concentration-based percentile form was appropriate, and that the upper end of the range of concentration percentiles for consideration should be consistent with the 98th percentile used for the primary standard and that the lower end of the range should be the 92nd percentile, which represented the mean of the distribution of the 20 percent most impaired days, as targeted in the regional haze program (U.S. EPA, 2005 pp. 7–11 to 7–13). While recognizing that it was difficult to select any specific level and form based on then-currently available information (Henderson, 2005a, p. 9), the CASAC Panel was generally in agreement with the ranges of levels and forms presented in the 2005 Staff Paper.

The Administrator also considered the level of protection that would be afforded by the proposed suite of primary $PM_{2.5}$ standards (71 FR 2681, January 17, 2006), on the basis that although significantly more information was available than in the 1997 review concerning the relationship between fine PM levels and visibility across the country, there was still little available information for use in making the relatively subjective value judgment needed in selecting the appropriate degree of protection to be afforded by such a standard. In so doing, the Administrator compared the extent to which the proposed suite of primary standards would require areas across the country to improve visual air quality with the extent of increased protection likely to be afforded by a standard based on a sub-daily averaging time. Based on such an analysis, the Administrator observed that the predicted percent of counties with monitors not likely to meet the proposed suite of primary $PM_{2.5}$ standards was actually somewhat greater than the predicted percent of counties with monitors not likely to meet a sub-daily secondary standard with an averaging time of 4 daylight hours, a level toward the upper end of the range recommended in the 2005 Staff Paper, and a form within the recommended range. Based on this comparison, the Administrator tentatively concluded that revising the secondary 24-hour $PM_{2.5}$ standard to be identical to the proposed revised primary $PM_{2.5}$ standard (and retaining the then-current annual secondary $PM_{2.5}$ standard) was a reasonable policy approach to addressing visibility protection primarily in urban areas. In proposing this approach, the Administrator also solicited comment on a sub-daily (4- to 8-hour averaging time) secondary $PM_{2.5}$ standard (71 FR 2675 to 2781, January 17, 2006).

In commenting on the proposed decision, the CASAC requested that a sub-daily standard to protect visibility ''be favorably reconsidered'' (Henderson, 2006a, p.6). The CASAC noted three cautions regarding the proposed reliance on a secondary $PM_{2.5}$ standard identical to the proposed 24-hour primary $PM_{2.5}$ standard: (1) $PM_{2.5}$ mass measurement is a better indicator of visibility impairment during daylight hours, when relative humidity is generally low; the sub-daily standard more clearly matches the nature of visibility impairment, whose adverse effects are most evident during the daylight hours; using a 24-hour $PM_{2.5}$ standard as a proxy introduces error and

uncertainty in protecting visibility; and sub-daily standards are used for other NAAQS and should be the focus for visibility; (2) CASAC and its monitoring subcommittees had repeatedly commended EPA's initiatives promoting the introduction of continuous and near-continuous PM monitoring and recognized that an expanded deployment of continuous $PM_{2.5}$ monitors would be consistent with setting a sub-daily standard to protect visibility; and (3) the analysis showing a similarity between percentages of counties not likely to meet what the CASAC Panel considered to be a lenient 4- to 8-hour secondary standard and a secondary standard identical to the proposed 24-hour primary standard was a numerical coincidence that was not indicative of any fundamental relationship between visibility and health. The CASAC Panel further stated that ''visual air quality is substantially impaired at $PM_{2.5}$ concentrations of 35 $\mu g/m^3$'' and that ''[i]t is not reasonable to have the visibility standard tied to the health standard, which may change in ways that make it even less appropriate for visibility concerns'' (Henderson, 2006a, pp. 5 to 6).

In reaching a final decision, the Administrator focused on the relative protection provided by the proposed primary standards based on the above-mentioned similarities in percentages of counties meeting alternative standards and on the limitations in the information available concerning studies of public perception and attitudes regarding the acceptability of various degrees of visibility impairment in urban areas, as well as on the subjective nature of the judgment required. In so doing, the Administrator concluded that caution was warranted in establishing a distinct secondary standard for visibility impairment and that the available information did not warrant adopting a secondary standard that would provide either more or less protection against visibility impairment in urban areas than would be provided by secondary standards set equal to the proposed primary $PM_{2.5}$ standards.

2. Remand of 2006 Secondary $PM_{2.5}$ Standards

As noted above in section II.B.2 above, several parties filed petitions for review challenging EPA's decision to set the secondary NAAQS for fine PM identical to the primary NAAQS. On judicial review, the D.C. Circuit remanded to the EPA for reconsideration the secondary NAAQS for fine PM because the Agency's decision was unreasonable and contrary to the requirements of section 109(b)(2). *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir., 2009).

The petitioners argued that the EPA's decision lacked a reasoned basis. First, they asserted that the EPA never determined what level of visibility was ''requisite to protect the public welfare.'' They argued that the EPA unreasonably rejected the target level of protection recommended by its staff, while failing to provide a target level of its own. The court agreed, stating that ''the EPA's failure to identify such a level when deciding where to set the level of air quality required by the revised secondary fine PM NAAQS is contrary to the statute and therefore unlawful. Furthermore, the failure to set any target level of visibility protection deprived the EPA's decision-making of a reasoned basis.'' 559 F. 3d at 530.

Second, the petitioners challenged EPA's method of comparing the protection expected from potential standards. They contended that the EPA relied on a meaningless numerical comparison, ignored the effect of humidity on the usefulness of a standard using a daily averaging time, and unreasonably concluded that the primary standards would achieve a level of visibility roughly equivalent to the level the EPA staff and CASAC deemed ''requisite to protect the public welfare.'' The court found that the EPA's equivalency analysis based on the percentages of counties exceeding alternative standards ''failed on its own terms.'' The same table showing the percentages of counties exceeding alternative secondary standards, used for comparison to the percentages of counties exceeding alternative primary standards to show equivalency, also included six other alternative secondary standards within the recommended CASAC range that would be more ''protective'' under EPA's definition than the adopted primary standards. Two-thirds of the potential secondary standards within the CASAC's recommended range would be substantially more protective than the adopted primary standards. The court found that the EPA failed to explain why it looked only at one of the few potential secondary standards that would be less protective, and only slightly less so, than the primary standards. More fundamentally, however, the court found that the EPA's equivalency analysis based on percentages of counties demonstrated nothing about the relative protection offered by the different standards, and that the tables offered no valid information about the relative visibility protection provided by the standards. 559 F. 3d at 530–31.

Finally, the Staff Paper had made clear that a visibility standard using $PM_{2.5}$ mass as the indicator in conjunction with a daily averaging time would be confounded by regional differences in humidity. The court noted that the EPA acknowledged this problem, yet did not address this issue in concluding that the primary standards would be sufficiently protective of visibility. 559 F. 3d at 530. Therefore, the court granted the petition for review and remanded for reconsideration the secondary $PM_{2.5}$ NAAQS.

3. General Approach Used in the Policy Assessment for the Current Review

The approach used in this review broadened the general approaches used in the last two PM NAAQS reviews by utilizing, to the extent available, enhanced tools, methods, and data to more comprehensively characterize visibility impacts. As such, the EPA took into account considerations based on both the scientific evidence (''evidence-based'') and a quantitative analysis of PM-related impacts on visibility (''impact-based'') to inform conclusions related to the adequacy of the current secondary $PM_{2.5}$ standards and alternative standards that were appropriate for consideration in this review. As in past reviews, the EPA also considered that the secondary NAAQS should address PM-related visibility impairment in conjunction with the Regional Haze Program, such that the secondary NAAQS would focus on protection from visibility impairment principally in urban areas in conjunction with the Regional Haze Program that is focused on improving visibility in Federal Class I areas. The EPA again recognized that such an approach remains the most appropriate and effective means of addressing the public welfare effects associated with visibility impairment in areas across the country.

The Policy Assessment drew from the qualitative evaluation of all studies discussed in the Integrated Science Assessment (U.S. EPA, 2009a). Specifically, the Policy Assessment considered the extensive new air quality and source apportionment information available from the regional planning organizations, long-standing evidence of PM effects on visibility, and limited public preference study information from four urban areas (U.S. EPA, 2009a, chapter 9), as well as the integration of evidence across disciplines (U.S. EPA, 2009a, chapter 2). In addition, limited information that had become available regarding the characterization of public preferences in urban areas provided

some new perspectives on the usefulness of this information in informing the selection of target levels of urban visibility protection. On these bases, the Policy Assessment again focused assessments on visibility conditions in urban areas.

The conclusions in the Policy Assessment reflected EPA staff's understanding of both evidence-based and impact-based considerations to inform two overarching questions related to (1) the adequacy of the current suite of $PM_{2.5}$ standards and (2) what potential alternative standards, if any, should be considered in this review to provide appropriate protection from PM-related visibility impairment. In addressing these broad questions, the discussions in the Policy Assessment were organized around a series of more specific questions reflecting different aspects of each overarching question (U.S. EPA, 2011a, Figure 4–1). When evaluating the visibility protection afforded by the current or any alternative standards considered, the Policy Assessment took into account the four basic elements of the NAAQS: indicator, averaging time, level, and form.

B. Proposed Decisions on Secondary PM Standards

At the time of proposal, the Administrator proposed to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment, focused primarily on visibility in urban areas. This proposed standard was to be defined in terms of a $PM_{2.5}$ visibility index, which would use measured $PM_{2.5}$ mass concentration, in combination with speciation and relative humidity data, to calculate $PM_{2.5}$ light extinction, translated into the deciview (dv) scale; a 24-hour averaging time; a 90th percentile form, averaged over 3 years; and a level of 28–30 dv. To address other non-visibility welfare effects, the Administrator proposed to retain the current suite of secondary PM standards generally, while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this proposed change to the primary annual $PM_{2.5}$ standard. Each of these proposed decisions is described in more detail in the proposal and below.

1. PM-Related Visibility Impairment

As discussed in Section VI.B of the proposal, the Administrator's proposed decision regarding a distinct secondary standard to provide protection from visibility impairment reflected careful consideration of the following: (1) The latest scientific information on visibility effects associated with PM as described in the Integrated Science Assessment (U.S. EPA, 2009a); (2) insights gained from assessments of correlations between ambient $PM_{2.5}$ and visibility impairment prepared by EPA staff in the Visibility Assessment (U.S. EPA, 2010b); and (3) specific conclusions regarding the need for revisions to the current standards (i.e., indicator, averaging time, form, and level) that, taken together, would be requisite to protect the public welfare from adverse effects on visual air quality. This section summarizes key information from the proposal regarding the nature of visibility impairment, including the relationship between ambient PM and visibility, temporal variations in light extinction, periods during the day of interest for assessing visibility conditions, and exposure durations of interest (section VI.B.1.a); limited public perceptions and attitudes about visibility impairment and the impacts of visibility impairment on public welfare (section VI.B.1.b); CASAC advice regarding the need for, and design of, secondary standards to protect visibility (section VI.B.1.c); and the Administrator's proposed conclusions regarding setting a distinct standard to address visibility impairment (section VI.B.1.d).

a. Nature of PM-Related Visibility Impairment

As noted at the time of proposal, the fundamental science characterizing the contribution of PM, especially fine particles, to visibility impairment is well understood. This science provides the basis for the Integrated Science Assessment designation of the relationship between PM and visibility impairment as causal. New research available in this review, discussed in chapter 9 of the Integrated Science Assessment, continues to support and refine EPA's understanding of the effect of PM on visibility and the source contributions to that effect in rural and remote locations. This research provides new insights regarding the regional source contributions to urban visibility impairment and better characterization of the increment in PM concentrations and visibility impairment that occur in many cities (i.e., the urban excess) relative to conditions in the surrounding rural areas (i.e., regional background). Ongoing urban $PM_{2.5}$ speciated and aggregated mass monitoring has produced new information that has allowed for updated characterization of current visibility levels in urban areas.

i. Relationship Between Ambient PM and Visibility

Visibility impairment is caused by the scattering and absorption of light by suspended particles and gases in the atmosphere. When PM is present in the air, its contribution to light extinction typically greatly exceeds that of gases. The combined effect of light scattering and absorption by both particles and gases is characterized as light extinction, i.e., the fraction of light that is scattered or absorbed in the atmosphere. Light extinction can be quantified by a light extinction coefficient with units of 1/distance, which is often expressed as 1/(1 million meters) or inverse megameters (abbreviated Mm^{-1}) or in terms of an alternative scale known as the deciview scale, defined by the following equation: [146]

$$\text{Deciview (dv)} = 10 \ln (b_{ext} / 10\ Mm^{-1})$$

The deciview scale is frequently used in the scientific literature on visibility, as well as in the Regional Haze Program. In particular, the deciview scale is used in the public perception studies that were considered in the past and current reviews to inform judgments about an appropriate degree of protection to be provided by a secondary NAAQS.

The amount of light extinction contributed by PM depends on the particle concentration as well as on the particle size distribution and composition and also on the relative humidity. As described in detail in section VI.B.1.a of the proposal, visibility scientists have developed an algorithm, known as the IMPROVE algorithm,[147] to estimate light extinction using routinely monitored fine particle ($PM_{2.5}$) speciation and coarse particle mass ($PM_{10-2.5}$) data, as well as data on relative humidity. There is both an original and a revised version of the IMPROVE algorithm (Pitchford *et al.,* 2007). The revised version was developed to address observed biases in the predictions using the original algorithm under very low and very high

[146] As used in the Regional Haze Program, the term b_{ext} refers to light extinction due to $PM_{2.5}$, $PM_{10-2.5}$, and ''clean'' atmospheric gases. In the Policy Assessment, in focusing on light extinction due to $PM_{2.5}$, the deciview values include only the effects of $PM_{2.5}$ and the gases. The ''Rayleigh'' term associated with clean atmospheric gases is represented by the constant value of 10 Mm^{-1}. Omission of the Rayleigh term would create the possibility of negative deciview values when the $PM_{2.5}$ concentration is very low.

[147] The algorithm is referred to as the IMPROVE algorithm because it was developed specifically to use the aerosol monitoring data generated at network sites and with equipment specifically designed to support the IMPROVE program and was evaluated using IMPROVE optical measurements at the subset of sites that make those measurements (Malm *et al.,* 1994).

light extinction conditions.[148] These IMPROVE algorithms are routinely used to calculate light extinction levels on a 24-hour basis in Federal Class I areas under the Regional Haze Program.

In either version of the IMPROVE algorithm, the concentration of each of the major aerosol components is multiplied by a dry extinction efficiency value and, for the hygroscopic components (i.e., ammoniated sulfate and ammonium nitrate), also multiplied by an additional factor to account for the water growth to estimate these components' contribution to light extinction. Summing the contribution of each component gives the estimate of total light extinction per unit distance denoted as the light extinction coefficient (b_{ext}), as shown below for the original IMPROVE algorithm.

$$b_{ext} \approx 3 \times f(\mathrm{RH}) \times [\mathrm{Sulfate}] + 3 \times f(\mathrm{RH}) \times [\mathrm{Nitrate}] + 4 \times [\mathrm{Organic\ Mass}] + 10 \times [\mathrm{Elemental\ Carbon}] + 1 \times [\mathrm{Fine\ Soil}] + 0.6 \times [\mathrm{Coarse\ Mass}] + 10$$

Light extinction (b_{ext}) is in units of Mm^{-1}, the mass concentrations of the components indicated in brackets are in units of $\mu g/m^3$, and f(RH) is the unitless water growth term that depends on relative humidity. The final term of 10 Mm^{-1} is known as the Rayleigh scattering term and accounts for light scattering by the natural gases in unpolluted air. Despite the simplicity of this algorithm, it performs reasonably well and permits the contributions to light extinction from each of the major components (including the water associated with the sulfate and nitrate compounds) to be separately approximated. Inspection of the PM component-specific terms in the simple original IMPROVE algorithm shows that most of the $PM_{2.5}$ components contribute 5 times or more light extinction than a similar concentration of $PM_{10\text{-}2.5}$.

The f(RH) term in the original algorithm reflects the increase in light scattering caused by particulate sulfate and nitrate under conditions of high relative humidity. Particles with hygroscopic components (e.g., particulate sulfate and nitrate) contribute more light extinction at higher relative humidity than at lower relative humidity because they change size in the atmosphere in response to ambient relative humidity conditions. For relative humidity below 40 percent the f(RH) value is 1, but it increases to 2 at approximately 66 percent, 3 at approximately 83 percent, 4 at approximately 90 percent, 5 at approximately 93 percent, and 6 at approximately 95 percent relative humidity. The result is that both particulate sulfate and nitrate are more efficient per unit mass in light extinction than any other aerosol component for relative humidity above approximately 85 percent where their total light extinction efficiency exceeds the 10 m^2/g associated with elemental carbon (EC). PM containing elemental or black carbon (BC) absorbs light as well as scattering it, making it the component with the greatest light extinction contributions per unit of mass concentration, except for the hygroscopic components under these high relative humidity conditions.[149]

As noted above, subsequent to the development of the original IMPROVE algorithm, an alternative algorithm (variously referred to as the ''revised algorithm'' or the ''new algorithm'' in the literature) was developed. The revised IMPROVE algorithm is different from the original algorithm in several important ways. First, the revised algorithm employs a more complex split-component mass extinction efficiency to correct biases believed to be related to particle size distributions.[150] Specifically, the revised algorithm incorporates terms to account for particles representing the different dry extinction and water uptake from two size modes of sulfate, nitrate and organic mass.[151] Second, the revised algorithm uses a different multiplier for organic carbon for purposes of estimating organic carbonaceous material to better represent aged aerosol found in remote areas.[152] In addition, the revised algorithm includes a term for hygroscopic sea salt that can be important for remote coastal areas, and site-specific Rayleigh light scattering terms in place of a universal Rayleigh light scattering value. As noted in section VI.B.1.a of the proposal, the revised IMPROVE algorithm can yield higher estimates of current light extinction levels in urban areas on days with relatively poor visibility as compared to the original algorithm (Pitchford, 2010). This difference is primarily attributable to the split-component mass extinction efficiency treatment in the revised algorithm. This revised algorithm was evaluated at 21 *remote* locations and is generally used by RPOs and States for implementation of the Regional Haze Rule.

ii. Temporal Variations of Light Extinction

Particulate matter concentrations and light extinction in urban environments vary from hour to hour throughout the 24-hour day due to a combination of diurnal changes in meteorological conditions and systematic changes in emissions activity (e.g., rush hour traffic). Various factors combine to make early morning the most likely time for peak urban light extinction; although the net effects of the systematic urban- and larger-scale variations mean that peak daytime PM light extinction levels can occur any time of day, in many areas they occur most often in early morning hours (U.S. EPA, 2010b, sections 3.4.2 and 3.4.3; Figures 3–9, 3–10, and 3–12). This temporal pattern in urban areas contrasts with the general lack of a strong diurnal pattern in PM concentrations and light extinction in most Federal Class I areas, reflective of a relative lack of local sources as compared to urban areas. The use in the Regional Haze Program of 24-hour average concentrations in the IMPROVE algorithm is consistent with this general lack of a strong diurnal pattern in Federal Class I areas.

iii. Periods During the Day of Interest for Assessment of Visibility

As noted in sections VI.B.1.b and VI.B.1.c of the proposal, daytime visibility has dominated the attention of

[148] These biases were detected by comparing light extinction estimates generated from the IMPROVE algorithm to direct optical measurements in a number of rural Federal Class I areas.

[149] The IMPROVE algorithm does not explicitly separate the light-scattering and light-absorbing effects of elemental carbon.

[150] In either version of the IMPROVE algorithm, the concentration of each of the major aerosol components is multiplied by a dry extinction efficiency value and, for the hygroscopic components (i.e., ammoniated sulfate and ammonium nitrate), also multiplied by an additional factor to account for the water growth to estimate these components' contribution to light extinction. Both the dry extinction efficiency and water growth terms have been developed by a combination of empirical assessment and theoretical calculation using typical particle size distributions associated with each of the major aerosol components.

[151] The relative contributions of sulfate, nitrate, and organic mass concentrations to visibility impairment with the revised algorithm are different than with the original algorithm due to the combination of the dry extinction coefficient and f(RH) functions for derived concentrations of small and large particles. The apportionment of the total fine particle concentration of each of the three $PM_{2.5}$ components into the concentrations of the small and large size fractions was empirically developed for remote areas. The fraction of the fine particle component that is in the large mode is estimated by dividing the total concentration of the component by 20 $\mu g/m^3$. If the total concentration of a component exceeds 20 $\mu g/m^3$, all of it is assumed to be in the large mode.

[152] The revised IMPROVE algorithm uses a multiplier of 1.8 for rural areas instead of 1.4 as used in the original algorithm for the mean ratio of organic mass to organic carbon.

those who have studied the visibility effects of air pollution, particularly in urban areas. The EPA recognizes, however, that physically PM light extinction behaves the same at night as during the day and can contribute to nighttime visibility effects by enhancing the scattering of anthropogenic light, contributing to the ''skyglow'' within and over populated areas, adding to the total sky brightness, and contributing to the reduction in contrast of stars against the background. However, little research has been conducted on nighttime visibility, and the state of the science is not comparable to that associated with daytime visibility impairment, particularly in terms of the impact on human welfare. The Policy Assessment notes that the science is not available at this time to support adequate characterization specifically of nighttime PM light extinction conditions and the related effects on public welfare (U.S. EPA, 2011a, p. 4–18). Therefore the EPA has focused its assessments of PM visibility impacts in urban areas on daylight hours during this review.

iv. Exposure Durations of Interest

As noted in section VI.B.1.d of the proposal, the roles that exposure duration and variations in visual air quality within any given exposure period play in determining the acceptability or unacceptability of a given level of visual air quality have not been investigated via preference studies. In the preference studies available for this review, subjects were simply asked to rate the acceptability or unacceptability of each image of a haze-obscured scene, without being provided any suggestion of assumed duration or of assumed conditions before or after the occurrence of the scene presented. Preference and/or valuation studies show that atmospheric visibility conditions can be quickly assessed and preferences determined. The EPA is unaware of any studies that characterize the extent to which different frequencies and durations of exposure to visibility conditions contribute to the degree of public welfare impact that occurs.

The Policy Assessment considered a variety of circumstances that are commonly expected to occur in evaluating the potential impact of visibility impairment on the public welfare based on available information (U.S. EPA, 2011a, pp. 4–19 to 4–20). In some circumstances, such as infrequent visits to scenic vistas in natural or urban environments, people are motivated specifically to take the opportunity to view a valued scene and are likely to do so for many minutes to hours to appreciate various aspects of the vista they choose to view. However, the public has many more opportunities to notice visibility conditions on a daily basis in settings associated with performing daily routines (e.g., during commutes and while working, exercising, or recreating outdoors). As noted in the Policy Assessment, information regarding the fraction of the public that has only one or a few opportunities to experience visibility during the day, or on the role the duration of the observed visibility conditions has on wellbeing effects associated with those visibility conditions, is not available (U.S. EPA, 2011a, p. 4–20). However, it is possible that people with limited opportunities to experience visibility conditions on a daily basis would receive the entire impact of the day's visual air quality based on the visibility conditions that occur during the short time period when they can see it. Since this group could be affected on the basis of observing visual air quality conditions for periods as short as one hour or less, and because during each daylight hour there are some people outdoors, commuting, or near windows, the Policy Assessment judged that it would be appropriate to use the maximum hourly value of PM light extinction during daylight hours for each day for purposes of evaluating the adequacy of the current suite of secondary standards. Other observers may have access to visibility conditions throughout the day. For this group, it might be that an hour with poor or ''unacceptable'' visibility can be offset by one or more other hours with clearer conditions. Therefore, the proposal acknowledged that it might also be appropriate to consider a multi-hour daylight exposure period.

v. Periods of Fog and Rain

As discussed in section VI.C of the proposal, the EPA also recognized that it is appropriate to give special treatment to periods of fog and rain when considering whether current $PM_{2.5}$ standards adequately protect public welfare from PM-related visibility impairment. Visibility impairment occurs during periods with fog or precipitation irrespective of the presence or absence of PM. Therefore, it is logical that periods with naturally impaired visibility due to fog or precipitation should not be treated as having PM-impaired visibility. There are multiple ways to adjust visibility data to reduce the effects of fog and precipitation. In the Visibility Assessment, following the advice of CASAC, the EPA evaluated the effect of excluding daylight hours for which relative humidity was greater than 90 percent from analyses in order to avoid precipitation and fog confounding estimates of PM visibility impairment. For the 15 urban areas included in the Visibility Assessment, the EPA found that a 90 percent relative humidity cutoff criterion was effective in that on average less than 6 percent of the daylight hours were removed from consideration, yet those hours had on average ten times the likelihood of rain, six times the likelihood of snow/sleet, and 34 times the likelihood of fog compared with hours with 90 percent or lower relative humidity. In the Regional Haze program, the EPA utilizes monthly average relative humidity values based on 10 years of climatological data to reduce the effect of fog and precipitation. This approach focuses on longer-term averages for each monitoring site and thereby eliminates the effect of very high humidity conditions on visibility at those locations.

b. Public Perception of Visibility Impairment

As described in section VI.B.2 of the proposal, there are two main types of studies that evaluate the public perception of urban visibility impairment: urban visibility preference studies and urban visibility valuation studies. As noted in the Integrated Science Assessment, ''[b]oth types of studies are designed to evaluate individuals' desire (or demand) for good visual air quality (VAQ) where they live, using different metrics to evaluate demand. Urban visibility preference studies examine individuals' demand by investigating what amount of visibility degradation is unacceptable while economic studies examine demand by investigating how much one would be willing to pay to improve visibility'' (U.S. EPA, 2009a, p. 9–66). Because of the limited number of new studies on urban visibility valuation, the Integrated Science Assessment cites to the discussion in the 2004 Criteria Document of the various methods one can use to determine the economic valuation of changes in visibility, which include hedonic valuation, contingent valuation and contingent choice, and travel cost.

Contingent valuation studies are a type of stated preference study that measures the strength of preferences and expresses that preference in dollar values. Contingent valuation studies often include payment vehicles that require respondents to consider implementation costs and their ability to pay for visibility improvements in their responses. This study design

aspect is critical because the EPA cannot consider implementations costs in setting either primary or secondary NAAQS. Therefore in considering the information available to help inform the standard-setting process, the EPA has focused on the public perception studies that do not embed consideration of implementation costs. Nonetheless, the EPA recognizes that valuation studies do provide additional evidence that the public is experiencing losses in welfare due to visibility impairment.[153] The public perception studies are described in detail below.

In order to identify levels of visibility impairment appropriate for consideration in setting secondary PM NAAQS to protect the public welfare, the Visibility Assessment comprehensively examined information that was available in this review regarding people's stated preferences regarding acceptable and unacceptable visual air quality.

Light extinction is an atmospheric property that by itself does not directly translate into a public welfare effect. Instead, light extinction becomes meaningful in the context of the impact of differences in visibility on the human observer. This has been studied in terms of the acceptability or unacceptability expressed for the visibility impact of a given level of light extinction by a human observer. The perception of the visibility impact of a given level of light extinction occurs in conjunction with the associated characteristics and lighting conditions of the viewed scene.[154] Thus, a given level of light extinction may be perceived differently by observers looking at different scenes or the same scene with different lighting characteristics. Likewise, different observers looking at the same scene with the same lighting may have different preferences regarding the associated visual air quality. When scene and lighting characteristics are held constant, the perceived appearance of a scene (i.e., how well the scenic features can be seen and the amount of visible haze) depends only on changes in light extinction. This has been demonstrated using the WinHaze model (Molenar *et al.,* 1994) that uses image processing technology to apply user-specified changes in light extinction values to the same base photograph with set scene and lighting characteristics.

Much of what is known about the acceptability of levels of visibility comes from survey studies in which participants were asked questions about their preference or the value they place on various visibility levels as displayed to them in scenic photographs and/or WinHaze images with a range of known light extinction levels. The Visibility Assessment (U.S. EPA, 2010b, chapter 2) reviewed the limited number of urban visibility preference studies currently available (i.e., four studies) to assess the light extinction levels judged by the participant to have acceptable visibility for those particular scenes.

The reanalysis of urban preference studies conducted in the Visibility Assessment for this review included three completed western urban visibility preference survey studies plus a pair of smaller focus studies designed to explore and further develop urban visibility survey instruments. The three western studies included one in Denver, Colorado (Ely *et al.,* 1991), one in the lower Fraser River valley near Vancouver, British Columbia (BC), Canada (Pryor, 1996), and one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group study was also conducted for Washington, DC (Abt Associates Inc., 2001). In response to an EPA request for public comment on the Scope and Methods Plan (74 FR 11580, March 18, 2009), comments were received (Smith, 2009) about the results of a new focus group study of scenes from Washington, DC, that had been conducted on subjects from both Houston, Texas, and Washington, DC, using scenes, methods and approaches similar to the method and approach employed in the EPA pilot study (Smith and Howell, 2009). When taken together, these studies from the four different urban areas included a total of 852 individuals, with each individual responding to a series of questions while viewing a set of images of various urban visual air quality conditions.

The approaches used in the four studies were similar and were all derived from the method first developed for the Denver urban visibility study. In particular, the studies all used a similar group interview type of survey to investigate the level of visibility impairment that participants described as ''acceptable.'' In each preference study, participants were initially given a set of ''warm up'' exercises to familiarize them with how the scene in the photograph or image appears under different VAQ conditions. The participants next were shown 25 randomly ordered photographs (images), and asked to rate each one based on a scale of 1 (poor) to 7 (excellent). They were then shown the same photographs or images again, in the same order, and asked to judge whether each of the photographs (images) would violate what they would consider to be an appropriate urban visibility standard (i.e. whether the level of impairment was ''acceptable'' or ''unacceptable''). The term ''acceptable'' was not defined, so that each person's response was based on his/her own values and preferences for VAQ. However, when answering this question, participants were instructed to consider the following three factors: (1) The standard would be for their own urban area, not a pristine national park area where the standards might be stricter; (2) The level of an urban visibility standard violation should be set at a VAQ level considered to be unreasonable, objectionable, and unacceptable visually; and (3) Judgments of standards violations should be based on visibility only, not on health effects. While the results differed among the four urban areas, results from a rating exercise show that within each preference study, individual survey participants consistently distinguish between photos or images representing different levels of light extinction, and that more participants rate as acceptable images representing lower levels of light extinction than they do images representing higher levels.

Given the similarities in the approaches used, the EPA staff concluded that it was reasonable to compare the results to identify overall trends in the study findings and to conclude that this comparison can usefully inform the selection of a range of levels for use in further analyses. However, the staff also noted that variations in the specific materials and methods used in each study introduce uncertainties that should also be considered when interpreting the results

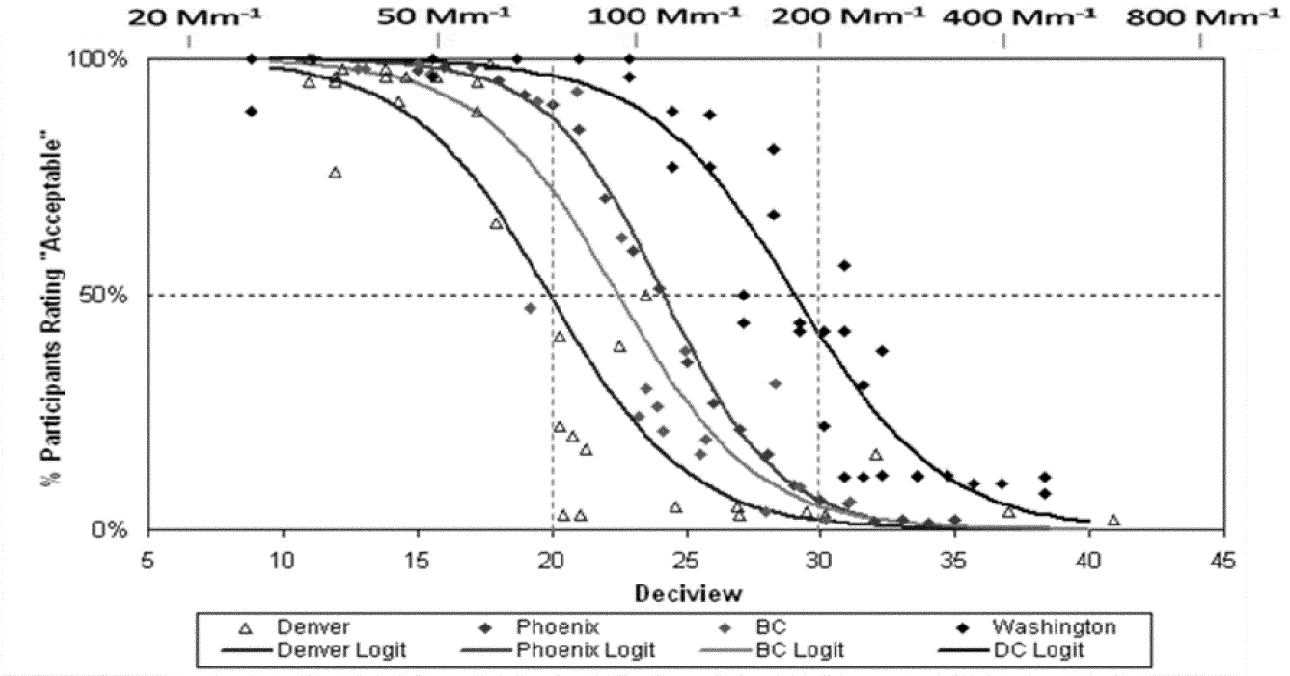
[153] In the regulatory impact analysis (RIA) accompanying this rulemaking, the EPA describes a revised approach to estimate urban residential visibility benefits that applies the results of several contingent valuation studies. The EPA is unable to apply the public perception studies to estimate benefits because they do not provide sufficient information on which to develop monetized benefits estimates. Specifically, the public perception studies do not provide preferences expressed in dollar values, even though they do provide additional evidence that the benefits associated with improving residential visibility are not zero. As previously noted in this preamble, the RIA is done for informational purposes only, and the proposed decisions on the NAAQS in this rulemaking are not in any way based on consideration of the information or analyses in the RIA.

[154] By ''characteristics of the scene'' the EPA means the distance(s) between the viewer and the object(s) of interest, the shapes and colors of the objects, the contrast between objects and the sky or other background, and the inherent interest of the objects to the viewer. Distance is particularly important because at a given value of light extinction, which is a property of air at a given point(s) in space, more light is actually absorbed and scattered when light passes through more air between the object and the viewer.

of these comparisons. Key differences between the studies include the following: (1) Scene characteristics; (2) image presentation methods (e.g., projected slides of actual photos, projected images generated using WinHaze (a significant technical advance in the method of presenting visual air quality conditions), or use of a computer monitor screen; (3) number of participants in each study; (4) participant representativeness of the general population of the relevant metropolitan area; and (5) specific wording used to frame the questions used in the group interview process.

In the Visibility Assessment, each study was evaluated separately and figures developed to display the percentage of participants that rated the visual air quality depicted in each photograph as ''acceptable.'' Ely *et al.* (1991) introduced a ''50% acceptability'' criterion analysis of the Denver preference study results. The 50 percent acceptability criterion is designed to identify the visual air quality level (defined in terms of deciviews or light extinction) that best divides the photographs into two groups: Those with a visual air quality rated as acceptable by the majority of the participants, and those rated not acceptable by the majority of participants. The Visibility Assessment adopted this criterion as a useful index for comparison between studies. The results of each analysis were then combined graphically to allow for visual comparison. This information was then carried forward into the Policy Assessment. Figure 5 presents the graphical summary of the results of the studies in the four cities and draws on results previously presented in Figures 2–3, 2–5, 2–7, and 2–11 of chapter 2 in the Visibility Assessment. Figure 5 also contains lines at 20 dv and 30 dv that generally identify a range where the 50 percent acceptance criteria occur across all four of the urban preference studies (U.S. EPA, 2011a, p. 4–24). Out of the 114 data points shown in Figure 5, only one photograph (or image) with a visual air quality below 20 dv was rated as acceptable by less than 50 percent of the participants who rated that photograph.[155] Similarly, only one image with a visual air quality above 30 dv was rated acceptable by more than 50 percent of the participants who viewed it.[156]

Figure 5. Summary of Results of Urban Visibility Studies in Four Cities, Showing the Identified Range of the 50% Acceptance Criteria[157]



Source: U.S. EPA, 2011a, Figure 4-2; U.S. EPA 2010b, Figure 2-16

As Figure 5 above shows, each urban area has a separate and unique response curve that appears to indicate that it is distinct from the others.[158] These curves are the result of a logistical regression analysis using a logit model of the greater than 19,000 ratings of haze images as acceptable or unacceptable. The model results can be used to estimate the visual air quality in terms of dv values where the estimated response functions cross the 50 percent acceptability level, as well as any alternative criteria levels. Selected examples of these are shown in Table 4–

[155] Only 47 percent of the British Columbia participants rated a 19.2 dv photograph as acceptable.

[156] In the 2001 Washington, DC study, a 30.9 dv image was used as a repeated slide. The first time it was shown 56 percent of the participants rated it as acceptable, but only 11 percent rated it as acceptable the second time it was shown. The same visual air quality level was rated as acceptable by 4 percent of the participants in the 2009 study (Test 1). All three points are shown in Figure 5.

[157] Top scale shows light extinction in inverse megameter units; bottom scale in deciviews. Logit analysis estimated response functions are shown as the color-coded curved lines for each of the four urban areas.

[158] At present, data is only available for four urban areas, as presented in Figure 5 and discussed throughout this section. Additional research could help inform whether the range identified by combining the results of the studies depicted in Figure 5 is more broadly representative.

1 of the Policy Assessment (U.S. EPA, 2011a; U.S. EPA, 2010b, Table 2–4). This table shows that the logit model results also support the upper and lower ends of the range of 50th percentile acceptability values (e.g., near 20 dv for Denver and near 30 dv for Washington, DC) already identified in Figure 5.

Based on the composite results and the effective range of 50th percentile acceptability across the four urban preference studies shown in Figure 5 and Table 4–1 of the Policy Assessment, benchmark levels of (total) light extinction were selected in a range from 20 dv to 30 dv (75 to 200 Mm^{-1})[159] for the purpose of provisionally assessing whether visibility conditions would be considered acceptable (i.e., less than the low end of the range), unacceptable (i.e., greater than the high end of the range), or potentially acceptable (within the range) based on the very limited public preference information. A midpoint of 25 dv (120 Mm^{-1}) was also selected for use in the assessment. This level is also very near to the 50th percentile criterion value from the Phoenix study (i.e., 24.2 dv), which is by far the best of the four studies in terms of the fit of the data to the response curve and the representativeness of study participants. Based on the currently available information, the Policy Assessment concluded that the use of 25 dv to represent the middle of the distribution of results seemed well supported (U.S. EPA, 2011a, p. 4–25).

These three benchmark values provide a low, middle, and high set of light extinction conditions that are used to provisionally define daylight hours with urban haze conditions that have been judged unacceptable by at least 50 percent of the participants in one or more of these preference studies. As discussed above, PM light extinction is taken to be (total) light extinction minus the Rayleigh scatter,[160] such that the low, middle, and high levels correspond to PM light extinction levels of about 65 Mm^{-1}, 110 Mm^{-1}, and 190 Mm^{-1}. In the Visibility Assessment, these three light extinction levels were called Candidate Protection Levels (CPLs). This term was also used in the Policy Assessment and in the proposal notice. It is important to note, however, that the degree of protection provided by a secondary NAAQS is not determined solely by any one component of the standard but by all the components (i.e., indicator, averaging time, form, and level) being applied together. Therefore, the Policy Assessment noted that the term CPL is meant only to indicate target levels of visibility within a range that the EPA staff felt appropriate for consideration that could, in conjunction with other elements of the standard, including indicator, averaging time, and form, potentially provide an appropriate degree of visibility protection.

In characterizing the Policy Assessment's confidence in each CPL and across the range, a number of issues were considered (U.S. EPA, 2011a, p. 4–26). Looking first at the two studies that define the upper and lower bounds of the range, the Policy Assessment considered whether they represent a true regional distinction in preferences for urban visibility conditions between western and eastern U.S. There was little information available to help evaluate the possibility of a regional distinction especially given that there have been preference studies in only one eastern urban area. Smith and Howell (2009) found little difference in preference response to Washington, DC, haze photographs between the study participants from Washington, DC, and those from Houston, Texas.[161] This provides some limited evidence that the value judgment of the public in different areas of the country may not be an important factor in explaining the differences in these study results.

In further considering what factors could explain the observed differences in preferences across the four urban areas, the Policy Assessment noted that the urban scenes used in each study had different characteristics (U.S. EPA, 2011a, p. 4–26). For example, each of the western urban visibility preference study scenes included mountains in the background while the single eastern urban study did not. It is also true that each of the western scenes included objects at greater distances from the camera location than in the eastern study. There is no question that objects at a greater distance have a greater sensitivity to perceived visibility changes as light extinction is changed compared to otherwise similar scenes with objects at a shorter range. This alone might explain the difference between the results of the eastern study and those from the western urban studies. Having scenes with the object of greatest intrinsic value nearer and hence less sensitive in the eastern urban area compared with more distant objects of greatest intrinsic value in the western urban areas could further explain the difference in preference results.

Another question considered was whether the high CPL value that is based on the eastern preference results is likely to be generally representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. Such areas would include the middle of the country, many areas in the eastern U.S., and possibly some areas in the western U.S. as well.[162] Based on the currently available information, the Policy Assessment concluded that the high end of the CPL range (30 dv) is an appropriate level to consider (U.S. EPA, 2011a, p. 4–27).

With respect to the low end of the range, the Policy Assessment considered factors that might further refine its understanding of the robustness of this level. The Policy Assessment concluded that additional urban preference studies, especially with a greater variety in types of scenes, could help evaluate whether the lower CPL value of 20 dv is generally supportable (U.S. EPA, 2011a, p. 4–27). Further, the reason for the noisiness in data points around the curves apparent in both the Denver and British Columbia results compared to the smoother curve fit of Phoenix study results could be explored. One possible explanation discussed in the Policy Assessment is that these older studies use photographs taken at different times of day and on different days to capture the range of light extinction levels needed for the preference studies. In contrast, the use of WinHaze in the Phoenix (and Washington, DC) study reduced variations that affect scene appearance preference rating and avoided the uncertainty inherent in using ambient measurements to

[159] These values were rounded from 74 Mm^{-1} and 201 Mm^{-1} to avoid an implication of greater precision than is warranted. Note that the middle value of 25 dv when converted to light extinction is 122 Mm^{-1} is rounded to 120 Mm^{-1} for the same reason. Assessments conducted for the Visibility Assessment and the first and second drafts of the Policy Assessment used the unrounded values. The Policy Assessment considered the results of assessment using unrounded values to be sufficiently representative of what would result if the rounded values were used that it was unnecessary to redo the assessments. That is why some tables and figures in the Policy Assessment reflected the unrounded values.

[160] Rayleigh scatter is light scattering by atmospheric gases which is on average about 10 Mm^{-1}.

[161] The first preference study using WinHaze images of a scenic vista from Washington, DC was conducted in 2001 using subjects who were residents of Washington, DC. More recently, Smith and Howell (2009) interviewed additional subjects using the same images and interview procedure. The additional subjects included some residents of the Washington, DC area and some residents of the Houston, Texas area.

[162] In order to examine this issue, an effort would have to be made to see if scenes in such areas could be found that would be generally comparable to the western scenes (e.g., scenes that contain valued scenic elements at more sensitive distances than that used in the eastern study). This is only one of a family of issues concerning how exposure to urban scenes of varying sensitivity affects public perception for which no preference study information is currently available.

represent sight path-averaged light extinction values. Reducing these sources of noisiness and uncertainty in the results of future studies of sensitive urban scenes could provide more confidence in the selection of a low CPL value.

Based on the above considerations, and recognizing the limitations in the currently available information, the Policy Assessment concluded that it is reasonable to consider a range of CPL values including a high value of 30 dv, a mid-range value of 25 dv, and a low value of 20 dv (U.S. EPA, 2011a, p. 4–27). Based on its review of the second draft Policy Assessment, CASAC also supported this set of CPLs for consideration by the EPA in this review. CASAC noted that these CPL values were based on all available visibility preference data and that they bound the study results as represented by the 50 percent acceptability criteria. While recommending that further visibility preference studies be conducted to reduce remaining uncertainties,[163] CASAC concluded that this range of levels was ''adequately supported by the evidence presented'' (Samet, 2010d, p. iii).

c. Summary of Proposed Conclusions

i. Adequacy of the Current Standards for PM-Related Visibility Impairment

At the time of proposal, the Administrator provisionally concluded that the current suite of secondary PM standards is not sufficiently protective of visual air quality, and that consideration should be given to an alternative secondary standard that would provide additional protection against PM-related visibility impairment, with a focus primarily in urban areas. This proposed conclusion was based on the information presented in the proposal with regard to the nature of PM-related visibility impairment, the results of public perception surveys on the acceptability of varying degrees of visibility impairment in urban areas, analyses of the number of days that are estimated to exceed a range of candidate protection levels under conditions simulated to just meet the current standards, and the advice of CASAC. This section summarizes key points from section VI.C of the proposal regarding visibility under current conditions, the degree of protection afforded by the current standards, and CASAC's advice regarding the adequacy of the current standards.

As discussed in section VI.C.1 of the proposal, to evaluate visibility under current conditions the Visibility Assessment and Policy Assessment estimated PM-related light extinction[164] levels for 15 urban areas[165] in the United States. Consistent with the emphasis in this review on the hourly or multi-hour time periods that might reasonably characterize the visibility effects experienced by various segments of the population, these analyses focused on using maximum 1-hour and 4-hour values of PM light extinction during daylight hours for purposes of evaluating the degree of visibility impairment. Hourly average PM-related light extinction was analyzed in terms of both PM_{10} and $PM_{2.5}$ light extinction. For reasons discussed above, hours with relative humidity greater than 90 percent were excluded from consideration. Recent visibility conditions in these urban areas were then compared to the CPLs identified above. The Visibility Assessment, which focused on PM_{10} light extinction in 14 of the 15 urban areas during the 2005 to 2007 time period,[166] found that all 14 areas had daily maximum hourly PM_{10} light extinction values estimated to exceed even the highest CPL some of the days. Except for the two Texas areas and the non-California western urban areas, all of the other urban areas were estimated to have maximum hourly PM_{10} concentrations that exceeded the high CPL on about 20 percent to over 60 percent of the days. All 14 of the urban areas were estimated to have maximum hourly PM_{10} concentrations that exceeded the low CPL on about 40 percent to over 90 percent of the days. In general, areas in the East and in California tend to have a higher frequency of hourly visibility conditions estimated to be above the high CPL compared with those in the western U.S.

The Policy Assessment repeated the Visibility Assessment-type modeling based on $PM_{2.5}$ light extinction and data from the more recent 2007 to 2009 time period for the same 15 study areas (including St. Louis). While the estimates of the percentage of daily maximum hourly $PM_{2.5}$ light extinction values exceeding the CPLs were somewhat lower than for PM_{10} light extinction, the patterns of these estimates across the study areas was found to be similar. More specifically, except for the two Texas and the non-California western urban areas, all of the other urban areas were estimated to have maximum hourly $PM_{2.5}$ concentrations that exceeded the high CPL on about 10 percent up to about 50 percent of the days based on $PM_{2.5}$ light extinction, while all 15 areas were estimated to have maximum hourly $PM_{2.5}$ concentrations that exceeded the low CPL on over 10 percent to over 90 percent of the days.

To evaluate how PM-related visibility would be affected by just meeting the current suite of $PM_{2.5}$ secondary standards, the Policy Assessment applied the proportional rollback approach described in section VI.C.2 of the proposal to all the $PM_{2.5}$ monitoring sites in each study area.[167] After adjusting for composition, the Policy Assessment applied the original IMPROVE algorithm to calculate the PM_{10} light extinction, using ''rolled back'' $PM_{2.5}$ component concentrations, the current conditions $PM_{10\text{-}2.5}$ concentration for the day and hour, and relative humidity for the day and hour.

In these analyses, the Policy Assessment estimated both $PM_{2.5}$ and PM_{10} light extinction in terms of both daily maximum 1-hour average values and multi-hour (i.e., 4-hour) average values for daylight hours. Figure 4–7 and Table 4–6 of the Policy Assessment displayed the results of the rollback procedures as a box and whisker plot of daily maximum daylight 1-hour $PM_{2.5}$ light extinction and the percentage of daily maximum hourly $PM_{2.5}$ light extinction values estimated to exceed the CPLs when just meeting the current

[163] ''CASAC has also identified needs for the next review cycle in terms of further research on a number of topics related to urban visibility; * * *. In particular, there is a need for the Agency to conduct additional urban visibility preference studies over a broad range of urban areas and viewing conditions, to further evaluate and refine the range of visibility levels considered to be acceptable in the current assessment.'' (Samet, 2010a)

[164] PM-related light extinction is used here to refer to the light extinction caused by PM regardless of particle size; PM_{10} light extinction refers to the contribution by particles sampled through an inlet with a particle size 50 percent cutpoint of 10 μm diameter; and $PM_{2.5}$ light extinction refers to the contribution by particles sampled through an inlet with a particle size 50 percent cutpoint of 2.5 μm diameter.

[165] The 15 urban areas are Tacoma, Fresno, Los Angeles, Phoenix, Salt Lake City, Dallas, Houston, St. Louis, Birmingham, Atlanta, Detroit, Pittsburgh, Baltimore, Philadelphia, and New York.

[166] Comments on the second draft Visibility Assessment from those familiar with the monitoring sites in St. Louis indicated that the site selected to provide continuous PM_{10} monitoring, although less than a mile from the site of the $PM_{2.5}$ data, was not representative of the urban area and resulted in unrealistically large $PM_{10\text{-}2.5}$ values. The EPA staff considered these comments credible and set aside the St. Louis assessment results for PM_{10} light extinction. Thus, results and statements in the Policy Assessment regarding PM_{10} light extinction applied to only the other 14 areas. However, results regarding $PM_{2.5}$ light extinction in most cases applied to all 15 study areas because the St. Louis estimates for $PM_{2.5}$ light extinction were not affected by the PM_{10} monitoring issue.

[167] Phoenix and Salt Lake City met the current $PM_{2.5}$ NAAQS under current conditions and required no reduction.

suite of $PM_{2.5}$ secondary standards for all 15 areas considered in the Visibility Assessment (including St. Louis) (excluding hours with relative humidity greater than 90 percent). These displays showed that the daily maximum 1-hour average $PM_{2.5}$ light extinction values in all of the study areas other than the three western non-California areas were estimated to exceed the high CPL on about 8 percent up to over 30 percent of the days and to exceed the middle CPL on about 30 percent up to about 70 percent of the days, while all areas except Phoenix were estimated to have daily maximum 1-hour average $PM_{2.5}$ light extinction values that exceeded the low CPL on over 15 percent to about 90 percent of the days. Figure 4–8 and Table 4–7 of the Policy Assessment present results based on daily maximum 4-hour average values. These displays show that the daily maximum 4-hour average $PM_{2.5}$ light extinction values in all of the study areas other than the three western non-California areas and the two areas in Texas were estimated to exceed the high CPL on about 4 percent up to over 15 percent of the days and to exceed the middle CPL on about 15 percent up to about 45 percent of the days, while all areas except Phoenix were estimated to have daily maximum 4-hour average $PM_{2.5}$ light extinction values that exceeded the low CPL on over 10 percent to about 75 percent of the days. A similar set of figures and tables were developed in terms of PM_{10} light extinction (U.S. EPA, 2011a, Figures 4–5 and 4–6, Tables 4–4 and 4–5).

Taking the results of these analyses focusing on 1-hour and 4-hour maximum light extinction values into account, the Policy Assessment concluded that the available information in this review clearly called into question the adequacy of the current suite of $PM_{2.5}$ standards in the context of public welfare protection from visibility impairment, primarily in urban areas, and supported consideration of alternative standards to provide appropriate protection (U.S. EPA, 2011a, p. 4–39). This conclusion was based in part on the large percentage of days, in many urban areas, that were estimated to have maximum 1-hour or 4-hour light extinction values that exceed the range of CPLs identified for consideration under simulations of conditions that would just meet the current suite of $PM_{2.5}$ secondary standards. In particular, for air quality that was simulated to just meet the current $PM_{2.5}$ standards, greater than 10 percent of the days were estimated to have peak light extinction values that exceed the highest, least protective CPL of 30 dv in terms of $PM_{2.5}$ light extinction for 9 of the 15 urban areas, based on 1-hour average values, and would thus likely fail to meet a 90th percentile-based standard at that level. For these areas, the percent of days estimated to have maximum 1-hour values that exceed the highest CPL ranged from over 10 percent to over 30 percent. Similarly, when the middle CPL of 25 dv was considered, greater than 30 percent up to approximately 70 percent of the days were estimated to have peak light extinction that exceeded that CPL in terms of $PM_{2.5}$ light extinction, for 11 of the 15 urban areas, based on 1-hour average values. Based on a 4-hour averaging time, 5 of the areas were estimated to have at least 10 percent of the days with peak light extinction exceeding the highest CPL in terms of $PM_{2.5}$ light extinction, and 8 of the areas were estimated to have at least 30 percent of the days with peak light extinction exceeding the middle CPL in terms of $PM_{2.5}$ light extinction. For the lowest CPL of 20 dv, the percentages of days with 4-hour maximum light extinction estimated to exceed that CPL are even higher for all cases considered. Based on all of the above, the Policy Assessment concluded that PM light extinction estimated to be associated with just meeting the current suite of $PM_{2.5}$ secondary standards in many areas across the country exceeded levels and percentages of days that could reasonably be considered to be important from a public welfare perspective (U.S. EPA, 2011a, p. 4–40).

Further, the Policy Assessment concluded that use of the current indicator of $PM_{2.5}$ mass, in conjunction with the current 24-hour and annual averaging times, is clearly called into question for a national standard intended to protect public welfare from PM-related visibility impairment (U.S. EPA, 2011a, p. 4–40). This is because such a standard is inherently variable in the degree of protection provided because of regional differences in relative humidity and species composition of $PM_{2.5}$, which are critical factors in the relationship between the mix of fine particles in the ambient air and the associated impairment of visibility. The Policy Assessment noted that this concern was one of the important elements in the court's decision to remand the $PM_{2.5}$ secondary standards set in 2006 to the Agency.

Thus, in addition to concluding that the available information clearly calls into question the adequacy of the protection against PM-related visibility impairment afforded by the current suite of $PM_{2.5}$ standards, the Policy Assessment also concluded that it clearly calls into question the appropriateness of each of the current standard elements: indicator, averaging time, form, and level (U.S. EPA, 2011a, p. 4–40).

After reviewing the information and analysis in the second draft Policy Assessment, CASAC concluded that the ''currently available information clearly calls into question the adequacy of the current standards and that consideration should be given to revising the suite of standards to provide increased public welfare protection'' (Samet, 2010d, p. iii). CASAC noted that the detailed estimates of hourly PM light extinction associated with just meeting the current standards ''clearly demonstrate that current standards do not protect against levels of visual air quality which have been judged to be unacceptable in all of the available urban visibility preference studies.'' Further, CASAC stated, with respect to the current suite of secondary $PM_{2.5}$ standards, that ''[T]he levels are too high, the averaging times are too long, and the $PM_{2.5}$ mass indicator could be improved to correspond more closely to the light scattering and absorption properties of suspended particles in the ambient air'' (Samet, 2010d, p. 9).

After considering the available evidence and the advice of CASAC, the Administrator concluded at the time of proposal that such information did provide an appropriate basis to inform a conclusion as to whether the current standards afford adequate protection against PM-related visibility impairment in urban areas. The Administrator took into account the information discussed above with regard to the nature of PM-related visibility impairment, the results of public perception surveys on the acceptability of varying degrees of visibility impairment in urban areas, analyses of the number of days on which peak 1-hour or 4-hour light extinction values are estimated to exceed a range of candidate protection levels under conditions simulated to just meet the current standards, and the advice of CASAC. She noted the clear causal relationship between PM in the ambient air and impairment of visibility, the evidence from the visibility preference studies, and the rationale for determining a range of candidate protection levels based on those studies. She also noted the relatively large number of days when maximum 1-hour or 4-hour light extinction values were estimated to exceed the three candidate protection levels, including the highest level of 30 dv, under the current standards. While recognizing the limitations in the available information on public

perceptions of the acceptability of varying degree of visibility impairment and the information on the number of days estimated to exceed the CPLs, she concluded that such information provided an appropriate basis to inform a conclusion as to whether the current standards provide adequate protection against PM-related visibility impairment in urban areas. Based on these considerations, and placing great importance on the advice of CASAC, the Administrator provisionally concluded that the current standards are not sufficiently protective of visual air quality, and that consideration should be given to an alternative secondary standard that would provide additional protection against PM-related visibility impairment, with a focus primarily in urban areas.

Having reached this conclusion, the Administrator also stated at the time of proposal that the current indicator of $PM_{2.5}$ mass, in conjunction with the current 24-hour and annual averaging times, is not well suited for a national standard intended to protect public welfare from PM-related visibility impairment. As noted in the proposal, the current standards do not incorporate information on the concentrations of various species within the mix of ambient particles, nor do they incorporate information on relative humidity, both of which play a central role in determining the relationship between the mix of PM in the ambient air and impairment of visibility. Such considerations were reflected both in CASAC's advice to set a distinct secondary standard that would more directly reflect the relationship between ambient PM and visibility impairment and in the court's remand of the current secondary $PM_{2.5}$ standards. Based on the above considerations, at the time of proposal the Administrator provisionally concluded that the current secondary $PM_{2.5}$ standards, taken together, are neither sufficiently protective nor suitably structured to provide an appropriate degree of public welfare protection from PM-related visibility impairment, primarily in urban areas. This led the EPA to consider alternative standards by looking at each of the elements of the standards—indicator, averaging time, form, and level—as discussed below.

ii. Indicator

At the time of proposal, the EPA considered three alternative indicators for a $PM_{2.5}$ standard designed to protect against visibility impairment: The current $PM_{2.5}$ mass indicator; directly measured $PM_{2.5}$ light extinction; and calculated $PM_{2.5}$ light extinction. Directly measured $PM_{2.5}$ light extinction is a measurement (or combination of measurements) of the light absorption and scattering caused by $PM_{2.5}$ under ambient conditions. Calculated $PM_{2.5}$ light extinction uses the IMPROVE algorithm to calculate $PM_{2.5}$ light extinction using measured $PM_{2.5}$ mass, speciated $PM_{2.5}$ mass, and measured relative humidity. The Policy Assessment evaluated each of these alternatives, finally concluding that consideration should be given to establishing a new calculated $PM_{2.5}$ light extinction indicator (U.S. EPA, 2011a, p. 4–51).

As discussed in section VI.D.1 of the proposal, the Policy Assessment concluded that consideration of the use of either directly measured $PM_{2.5}$ light extinction or calculated $PM_{2.5}$ light extinction as an indicator is justified because light extinction is a physically meaningful measure of the characteristic of ambient $PM_{2.5}$ that is most relevant and directly related to PM-related visibility effects (U.S. EPA, 2011a, p. 4–41). Further, as noted above, $PM_{2.5}$ is the component of PM responsible for most of the visibility impairment in most urban areas. In these areas, the contribution of $PM_{10\text{-}2.5}$ is a minor contributor to visibility impairment most of the time. The Policy Assessment also indicated that the available evidence demonstrated a strong correspondence between calculated $PM_{2.5}$ light extinction and PM-related visibility impairment, as well as the significant degree of variability in visibility protection across the U.S. allowed by a $PM_{2.5}$ mass indicator. The Policy Assessment recognized that while in the future it would be appropriate to consider a direct measurement of $PM_{2.5}$ light extinction it was not an appropriate option in this review because a suitable specification of the equipment and associated performance verification procedures cannot be developed in the time frame for this review.

(a) $PM_{2.5}$ Mass

In terms of utilizing a $PM_{2.5}$ mass indicator, the proposal noted that $PM_{2.5}$ mass monitoring methods are in widespread use, including the FRM involving the collection of periodic (usually 1-day-in-6 or 1-day-in-3) 24-hour filter samples. However, these routine monitoring activities do not include measurement of the full water content of the ambient $PM_{2.5}$ that contributes, often significantly, to visibility impacts. Further, the $PM_{2.5}$ mass concentration monitors do not provide information on the composition of the ambient $PM_{2.5}$, which plays a central role in the relationship between PM-related visibility impairment and ambient $PM_{2.5}$ mass concentrations. Additional analyses discussed in the proposal that looked at the contribution of $PM_{2.5}$ to total PM-related light extinction (defined in terms of hourly PM_{10} calculated light extinction) indicate that there is a poor correlation between hourly PM_{10} light extinction and hourly $PM_{2.5}$ mass principally due to the impact of the water content of the particles on light extinction, which depends on both the composition of the $PM_{2.5}$ and the ambient relative humidity. Both composition and especially relative humidity vary during a single day, as well as from day-to-day, at any site and time of year. Also, there are systematic regional and seasonal differences in the distribution of ambient humidity and $PM_{2.5}$ composition conditions that make it impossible to select a $PM_{2.5}$ concentration that generally would correspond to the same PM-related light extinction levels across all areas of the nation. Analyses discussed in the proposal quantify the projected uneven protection that would result from the use of 1-hour average $PM_{2.5}$ mass as the indicator.

(b) Directly Measured $PM_{2.5}$ Light Extinction

PM light extinction has a nearly one-to-one relationship to light extinction, unlike $PM_{2.5}$ mass concentration. As explained above, $PM_{2.5}$ is the component responsible for the large majority of PM light extinction in most places and times. $PM_{2.5}$ light extinction can be directly measured using several instrumental methods, some of which have been used for decades to routinely monitor the two components of $PM_{2.5}$ light extinction (light scattering and absorption) or to jointly measure both as total light extinction (from which Rayleigh scattering is subtracted to get $PM_{2.5}$ light extinction). As noted at the time of proposal, there are a number of advantages to direct measurements of light extinction for use in a secondary standard relative to estimates of $PM_{2.5}$ light extinction calculated using $PM_{2.5}$ mass and speciation data. These include greater accuracy of direct measurements with shorter averaging times and overall greater simplicity when compared to the need for measurements of multiple parameters to calculate PM light extinction.

In evaluating whether direct measurement of $PM_{2.5}$ or PM_{10} light extinction is appropriate to consider in the context of this PM NAAQS review, the EPA solicited comment from the Ambient Air Monitoring and Methods

Subcommittee (AAMMS) of CASAC. The CASAC AAMMS recommended that consideration of direct measurement should be limited to $PM_{2.5}$ light extinction, and that although instruments suitable for this purpose are commercially available at present, research is expected to produce even better instruments in the near term. The CASAC AAMMS advised against choosing any currently available commercial instrument, or even a general measurement approach, as an FRM because to do so could discourage development of other potentially superior approaches. Instead, the CASAC AAMMS recommended that the EPA develop performance-based approval criteria for direct measurement methods in order to put all approaches on a level playing field.

At the present time, the EPA has not undertaken to develop and test such performance-base approval criteria. The EPA anticipates that if an effort were begun it would take at least several years before such criteria would be ready for regulatory use. Thus, the Policy Assessment concluded that while in the future it would be appropriate to consider a direct measurement of $PM_{2.5}$ light extinction, or the sum of separate measurements of light scattering and light absorption, as the indicator for the secondary $PM_{2.5}$ standard, this is not an appropriate option in this review because a suitable specification of the equipment or appropriate performance-based verification procedures cannot be developed in the time frame for this review (U.S. EPA, 2011a, p. 4–51, –52).

(c) Calculated $PM_{2.5}$ Light Extinction

For the reasons discussed above, the Policy Assessment concluded that a calculated $PM_{2.5}$ light extinction indicator would be the preferred approach. $PM_{2.5}$ light extinction can be calculated from $PM_{2.5}$ mass, combined with speciated $PM_{2.5}$ mass concentration data plus relative humidity data, as is presently routinely done on a 24-hour average basis under the Regional Haze Program using data from the rural IMPROVE monitoring network. This same calculation procedure, using a 24-hour average basis, could be used for a NAAQS focused on protecting against PM-related visibility impairment primarily in urban areas. This approach would use the type of data that is routinely collected from the urban CSN [168] in combination with monthly average relative humidity data based on long-term climatological means as used in the Regional Haze Program (U.S. EPA, 2011a, Appendix G, section G.2). The proposal discussed the complex approach utilized in the Visibility Assessment for calculating hourly $PM_{2.5}$ light extinction [169] and discussed various simplified approaches for calculating these hourly values that were analyzed in the Policy Assessment. The Policy Assessment concluded that each of these simplified approaches provided reasonably good estimates of $PM_{2.5}$ light extinction and each would be appropriate to consider as the indicator for a distinct hourly or multi-hour secondary standard (U.S. EPA, 2011a, p. 4–48). The proposal also recognized that the Policy Assessment identified a number of variations on these simplified approaches that it would be appropriate to consider, including:

(1) The use of the split-component mass extinction efficiency approach from the revised IMPROVE algorithm [170]

(2) The use of more refined value(s) for the organic carbon multiplier [171]

(3) The use of the reconstructed 24-hour $PM_{2.5}$ mass (i.e., the sum of the five $PM_{2.5}$ components from speciated monitoring) as a normalization value for the hourly measurements from the $PM_{2.5}$ instrument as a way of better reflecting ambient nitrate concentrations

(4) The use of historical monthly or seasonal, or regional, speciation averages

Overall, the analyses conducted for the Visibility Assessment and Policy Assessment indicated that the use of a calculated $PM_{2.5}$ light extinction indicator would provide a much higher degree of uniformity in terms of the degree of protection from visibility impairment across the country than a $PM_{2.5}$ mass indicator, because a calculated $PM_{2.5}$ light extinction indicator would directly incorporate the effects of humidity and $PM_{2.5}$ composition differences between various regions. Further, the proposal noted that the Policy Assessment concluded that consideration could be given to defining a calculated $PM_{2.5}$ light extinction indicator on either a 24-hour or a sub-daily basis (U.S. EPA, 2011a, p. 4–52). However, the Policy Assessment noted that approval of continuous FEM monitors has been based only on 24-hour average, not hourly, $PM_{2.5}$ mass. In addition, there are mixed results of data quality assessments on a 24-hour basis for these monitors, as well as the near absence of performance data for sub-daily averaging periods. Thus, while it is possible to utilize data from $PM_{2.5}$ continuous FEMs on a 1-hour or multi-hour (e.g., 4-hour) basis, these factors increase the uncertainty of utilizing continuous methods to support 1-hour or 4-hour $PM_{2.5}$ mass measurements as an input to the light extinction calculation. Therefore, as noted at the time of proposal, until issues regarding the comparability of 24-hour $PM_{2.5}$ mass values derived from continuous FEMs and filter-based FRMs [172] are resolved, there is reason to be cautious about relying on a calculation procedure that uses hourly $PM_{2.5}$ mass values reported by continuous FEMs in combination with speciated $PM_{2.5}$ mass values from 24-hour filter-based samplers.

(d) CASAC Advice

In reviewing the second draft Policy Assessment, CASAC stated that it ''overwhelmingly * * * would prefer the direct measurement of light extinction,'' recognizing it as the property of the atmosphere that most directly relates to visibility effects (Samet, 2010d, p. iii). CASAC noted that ''[I]t has the advantage of relating directly to the demonstrated harmful welfare effect of ambient PM on human visual perception.'' However, CASAC also concluded that the calculated $PM_{2.5}$ light extinction indicator ''appears to be a reasonable approach for estimating hourly light extinction'' (Samet, 2010d, p. 11). Further, based on CASAC's understanding of the time that would be required to develop an FRM for this indicator, CASAC agreed with the staff preference presented in the second draft Policy Assessment for a calculated $PM_{2.5}$ light extinction indicator. CASAC noted that ''[I]ts reliance on procedures that

[168] About 200 sites in the CSN routinely measure 24-hour average $PM_{2.5}$ chemical components using filter-based samplers and chemical analysis in a laboratory, on either a 1-day-in-3 or 1-day-in-6 schedule (U.S. EPA, 2011a, Appendix B, section B.1.3).

[169] As noted at the time of proposal, the sheer size of the ambient air quality, meteorological, and chemical transport modeling data files involved with the Visibility Assessment approach would make it very difficult for state agencies or any interested party to consistently apply such an approach on a routine basis for the purpose of implementing a national standard defined in terms of the Visibility Assessment approach.

[170] If the revised IMPROVE algorithm were used to define the calculated $PM_{2.5}$ mass-based indicator, it would not be possible to algebraically reduce the revised algorithm to a two-factor version as described above and in Appendix F of the Policy Assessment for the simplified approaches. Instead, five component fractions would be determined from each day of speciated sampling, and then either applied to hourly measurements of $PM_{2.5}$ mass on the same day or averaged across a month and then applied to measurements of $PM_{2.5}$ mass on each day of the month.

[171] An organic carbon (OC)-to-organic mass (OM) multiplier of 1.6 was used for the assessment, which was found to produce a value of OM comparable to the one derived with the original, albeit more complex, Visibility Assessment method.

[172] Filter-based FRMs are designed to adequately quantify the amount of $PM_{2.5}$ collected over 24-hours. They cannot be presumed to be appropriate for quantifying average concentrations over 1-hour or 4-hour periods.

have already been implemented in the CSN and routinely collected continuous $PM_{2.5}$ data suggest that it could be implemented much sooner than a directly measured indicator'' (Samet, 2010d, p. iii).[173]

(e) Administrator's Proposed Conclusions on Indicator

At the time of proposal, while agreeing with CASAC that a directly measured PM light extinction indicator would provide the most direct link between PM in the ambient air and PM-related light extinction, the Administrator provisionally concluded that this was not an appropriate option in this review because a suitable specification of currently available equipment or performance-based verification procedures cannot be developed in the time frame of this review. Taking all of the above considerations and CASAC advice into account, the Administrator provisionally concluded that a new calculated $PM_{2.5}$ light extinction indicator, similar to that used in the Regional Haze Program (i.e., using an IMPROVE algorithm as translated into the deciview scale), was the appropriate indicator to replace the current $PM_{2.5}$ mass indicator. Such an indicator, referred to as a $PM_{2.5}$ visibility index, would appropriately reflect the relationship between ambient PM and PM-related light extinction, based on the analyses discussed in the proposal and incorporation of factors based on measured $PM_{2.5}$ speciation concentrations and relative humidity data. In addition, selection of this type of indicator would address, in part, the issues raised in the court's remand of the 2006 p.m.$_{2.5}$ standards. The Administrator also noted that such a $PM_{2.5}$ visibility index would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by virtue of directly incorporating the effects of differences in $PM_{2.5}$ composition and relative humidity across the country.

Based on these above considerations, the Administrator proposed to set a distinct secondary standard for $PM_{2.5}$ defined in terms of a $PM_{2.5}$ visibility index (i.e., a calculated $PM_{2.5}$ light extinction indicator, translated into the deciview scale) to protect against PM-related visibility impairment primarily in urban areas. The Administrator proposed that such an index be based on the original IMPROVE algorithm in conjunction with monthly average relative humidity data based on long-term climatological means as used in the Regional Haze Program. The EPA solicited comment on all aspects of the proposed indicator, especially:

(1) The proposed use of a $PM_{2.5}$ visibility index rather than a PM_{10} visibility index which would include an additional term for coarse particles;

(2) Using the revised IMPROVE algorithm rather than the original IMPROVE algorithm;

(3) The use of alternative values for the organic carbon multiplier in conjunction with either the original or revised IMPROVE algorithm;

(4) The use of historical monthly, seasonal, or regional speciation averages;

(5) Alternative approaches to determining relative humidity; and

(6) Simplified approaches to generating hourly $PM_{2.5}$ light extinction values for purposes of calculating an hourly or multi-hour indicator.

iii. Averaging Times

In this review, as discussed in section VI.D.2 of the proposal, consideration of appropriate averaging times for use in conjunction with a $PM_{2.5}$ visibility index was informed by information related to the nature of PM visibility effects and the nature of inputs to the calculation of $PM_{2.5}$ light extinction, as discussed above. The EPA considered both sub-daily (1- and 4-hour averaging times) and 24-hour averaging times. In considering sub-daily averaging times, the EPA has also considered what diurnal periods and ambient relative humidity conditions would be appropriate to consider in conjunction with such an averaging time.

As an initial matter, the Policy Assessment considered sub-daily averaging times. Taking into account what is known from available studies concerning how quickly people experience and judge visibility conditions, the possibility that some fraction of the public experiences infrequent or short periods of exposure to ambient visibility conditions, and the typical rate of change of the path-averaged PM light extinction over urban areas, the initial analyses conducted as part of the Visibility Assessment focused on a 1-hour averaging time. In its review of the first draft Policy Assessment, CASAC agreed that a 1-hour averaging time would be appropriate to consider, noting that PM effects on visibility can vary widely and rapidly over the course of a day and such changes are almost instantaneously perceptible to human observers (Samet, 2010c, p. 19). The Policy Assessment noted that this view related specifically to a standard defined in terms of a directly measured PM light extinction indicator, in that CASAC also noted that a 1-hour averaging time is well within the instrument response times of the various currently available and developing optical monitoring methods.

However, CASAC also advised that if a $PM_{2.5}$ mass indicator were to be used, it would be appropriate to consider ''somewhat longer averaging times—2 to 4 hours—to assure a more stable instrumental response'' (Samet, 2010c, p. 19). In considering this advice, the Policy Assessment concluded that since a calculated $PM_{2.5}$ light extinction indicator relies in part on measured $PM_{2.5}$ mass, it would be appropriate to consider a multi-hour averaging time on the order of a few hours (e.g. 4-hours). A multi-hour averaging time might reasonably characterize the visibility effects experienced by the segment of the population who have access to visibility conditions often or continuously throughout the day. For this segment of the population, it may be that their perception of visual air quality reflects some degree of offsetting an hour with poor visual air quality with one or more hours of clearer visual conditions. Further, the Policy Assessment recognized that a multi-hour averaging time would have the effect of averaging away peak hourly visibility impairment, which can change significantly from one hour to the next (U.S. EPA, 2011a, p. 4–53; U.S. EPA, 2010b, Figure 3–12).

In considering either 1-hour or multi-hour averaging times, the Policy Assessment recognized that no data are available with regard to how the duration and variation of time a person spends outdoors during the daytime impacts his or her judgment of the acceptability of different degrees of visibility impairment. As a consequence, it is not clear to what degree, if at all, the protection levels found to be acceptable in the public preference studies would change for a multi-hour averaging time as compared to a 1-hour averaging time. Thus, the Policy Assessment concluded that it is appropriate to consider a 1-hour or multi-hour (e.g., 4-hour) averaging time as the basis for a sub-daily standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator (U.S. EPA, 2011a, p. 4–53).

In addition, as discussed above, some data quality uncertainties have been observed with regard to hourly data collected by FEMs. Specifically, as part of the review of data from all continuous FEM $PM_{2.5}$ instruments operating at state/local monitoring sites, the Policy Assessment noted that the occurrence of questionable outliers in 1-

[173] In commenting on the second draft Policy Assessment, CASAC did not have an opportunity to review the assessment of continuous $PM_{2.5}$ FEMs compared to collocated FRMs (Hanley and Reff, 2011) as presented and discussed in the final Policy Assessment (U.S. EPA, 2011a, p. 4–50).

hour data submitted to AQS from continuous FEM $PM_{2.5}$ instruments had been observed at some of these sites (Evangelista, 2011). Some of these outliers were questionable simply by virtue of their extreme magnitude, as high as 985 μg/m^3, whereas other values were questionable because they were isolated to single hours with much lower values before and after, a pattern that is much less plausible than if the high concentrations were more sustained.[174] The Policy Assessment noted that any current data quality problems might be resolved in the normal course of monitoring program evolution as operators become more adept at instrument operation and maintenance and data validation or by improving the approval criteria and testing requirements for continuous instruments. Regardless, the Policy Assessment noted that multi-hour averaging of FEM data could serve to reduce the effects of such outliers relative to the use of a 1-hour averaging time.

The Policy Assessment noted that there are significant reasons to consider using $PM_{2.5}$ light extinction calculated on a 24-hour basis to reduce the various data quality concerns described above with respect to relying on continuous $PM_{2.5}$ monitoring data. However, the Policy Assessment recognized that 24 hours is far longer than the hourly or multi-hour time periods that might reasonably characterize the visibility effects experienced by various segments of the population, including both those who do and do not have access to visibility conditions often or continuously throughout the day. Thus, the Policy Assessment concluded that the appropriateness of considering a 24-hour averaging time would depend upon the extent to which PM-related light extinction calculated on a 24-hour average basis would be a reasonable and appropriate *surrogate* for PM-related light extinction calculated on a sub-daily basis.

To examine this relationship, the EPA conducted comparative analyses of 24-hour and 4-hour averaging times in conjunction with a calculated $PM_{2.5}$ indicator. For these analyses, 4-hour average $PM_{2.5}$ light extinction was calculated based on using the Visibility Assessment approach. The 24-hour average $PM_{2.5}$ light extinction was calculated using the original IMPROVE algorithm and long-term relative humidity conditions to calculate $PM_{2.5}$ light extinction. Based on these analyses,[175] which are presented and discussed in Appendix G of the Policy Assessment, scatter plots comparing 24-hour and 4-hour calculated $PM_{2.5}$ light extinction were constructed for each of the 15 cities included in the Visibility Assessment and for all 15 cities pooled together (U.S. EPA, 2011a, Figures G–4 and G–5). Though there was some scatter around the regression line for each city because the calculated 4-hour light extinction values included day-specific and hour-specific influences that are not captured by the simpler 24-hour approach, these analyses generally showed good correlation between 24-hour and 4-hour average $PM_{2.5}$ light extinction, as evidenced by reasonably high city-specific and pooled R^2 values, generally in the range of over 0.6 to over 0.8.[176] This suggested that $PM_{2.5}$ light extinction calculated on a 24-hour basis is a reasonable and appropriate surrogate to $PM_{2.5}$ light extinction calculated on a sub-daily basis.

Taking the above considerations and CASAC's advice into account, the Policy Assessment concluded that it would be appropriate to consider a 24-hour averaging time, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and an appropriately specified standard level, as discussed below. By using site-specific daily data on $PM_{2.5}$ composition and site-specific long-term relative humidity conditions, this 24-hour average indicator would provide more consistent protection from $PM_{2.5}$-related visibility impairment than would a secondary $PM_{2.5}$ NAAQS based only on 24-hour or annual average $PM_{2.5}$ mass. In particular, this approach would account for the systematic difference in humidity conditions between most eastern states and most western states. The Policy Assessment also concluded that it would also be appropriate to consider a multi-hour, sub-daily averaging time, for example a period of 4 hours, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and with further consideration of the data quality issues discussed above. Such an averaging time, to the extent that data quality issues can be appropriately addressed, would be more directly related to the short-term nature of the perception of visibility impairment, short-term variability in PM-related visual air quality, and the short-term nature (hourly to multiple hours) of relevant exposure periods for segments of the viewing public. Such an averaging time would still result in an indicator that is less sensitive than a 1-hour averaging time to short-term instrument variability with respect to $PM_{2.5}$ mass measurement. In conjunction with consideration of a multi-hour, sub-daily averaging time, the Policy Assessment concluded that consideration should be given to including daylight hours only and to applying a relative humidity screen of approximately 90 percent to remove hours in which fog or precipitation is much more likely to contribute to the observed visibility impairment (U.S. EPA, 2011a, p. 4–58). Recognizing that a 1-hour averaging time would be even more sensitive to data quality issues, including short-term variability in hourly data from currently available continuous monitoring methods, the Policy Assessment concluded that it would not be appropriate to consider a 1-hour averaging time in conjunction with a calculated $PM_{2.5}$ light extinction indicator in this review (U.S. EPA, 2011a, p. 4–58).

As noted above, in its review of the first draft Policy Assessment, CASAC concluded that PM effects on visibility can vary widely and rapidly over the course of a day and such changes are almost instantaneously perceptible to human observers (Samet, 2010c, p. 19). Based in part on this consideration, CASAC agreed that a 1-hour averaging time would be appropriate to consider in conjunction with a directly measured PM light extinction indicator, noting that a 1-hour averaging time is well within the instrument response times of the various currently available and developing optical monitoring methods. At that time, CASAC also advised that if a $PM_{2.5}$ mass indicator were to be used, it would be appropriate to consider ''somewhat longer averaging times—2- to 4-hours—to assure a more stable instrumental response'' (Samet, 2010c, p. 19). Thus, CASAC's advice on averaging times that would be appropriate for consideration was predicated in part on the capabilities of monitoring methods that were available for the alternative indicators discussed in the draft Policy Assessment. CASAC's views on a multi-hour averaging time would also apply to the calculated $PM_{2.5}$ light extinction indicator since hourly $PM_{2.5}$ mass measurements are also required for this

[174] Similarly questionable hourly data were not observed in the 2005 to 2007 continuous $PM_{2.5}$ data used in the Visibility Assessment, all of which came from early-generation continuous instruments that had not been approved as FEMs. However, only 15 sites and instruments were involved in the Visibility Assessment analyses, versus about 180 currently operating FEM instruments submitting data to AQS. Therefore, there were more opportunities for very infrequent measurement errors to be observed in the larger FEM data set.

[175] These analyses are also based on the use of a 90th percentile form, averaged over 3 years, as discussed below in section VI.D.3 and in section 4.3.3 of the Policy Assessment (U.S. EPA, 2011a).

[176] The EPA staff noted that the R^2 value (0.44) for Houston was notably lower than for the other cities.

indicator when calculated on a sub-daily basis.

It is important to note that at the time it provided advice on suitable averaging times, CASAC did not have the benefit of EPA's subsequent assessment of the data quality issues associated with the use of continuous FEMs as the basis for hourly $PM_{2.5}$ mass measurements. Furthermore, since CASAC only commented on the first and second drafts of the Policy Assessment, neither of which included discussion of a calculated $PM_{2.5}$ indicator based on a 24-hour averaging time, CASAC did not have a basis to offer advice regarding a 24-hour averaging time. In addition, the 24-hour averaging time is not based on consideration of 24-hours as a relevant exposure period, but rather as a surrogate for a sub-daily period of 4 hours, which is consistent with CASAC's advice concerning an averaging time associated with the use of a $PM_{2.5}$ mass indicator.

Taking into account the information discussed above with regard to analyses and conclusions presented in the final Policy Assessment the Administrator recognized that hourly or sub-daily, multi-hour averaging times, within daylight hours and excluding hours with relative humidity above approximately 90 percent, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. On the other hand, she recognized that data quality uncertainties have recently been associated with currently available instruments that would be used to provide the hourly $PM_{2.5}$ mass measurements that would be needed in conjunction with an averaging time shorter than 24-hours. As a result, while the Administrator recognized the desirability of a sub-daily averaging time, she had strong reservations about proposing to set a standard at this time in terms of a sub-daily averaging time.

In considering the information and analyses related to consideration of a 24-hour averaging time, the Administrator recognized that the Policy Assessment concluded that $PM_{2.5}$ light extinction calculated on a 24-hour averaging basis is a reasonable and appropriate surrogate for sub-daily $PM_{2.5}$ light extinction calculated on a 4-hour average basis. In light of this finding and the views of CASAC based on its reviews of the first and second drafts of the Policy Assessment, the Administrator proposed to set a distinct secondary standard with a 24-hour averaging time in conjunction with a $PM_{2.5}$ visibility index.

iv. Form

As discussed in section VI.D.3 of the proposal, the ''form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether the standard is achieved. The form of the current 24-hour $PM_{2.5}$ NAAQS is such that the level of the standard is compared to the 3-year average of the annual 98th percentile value of the measured indicator. The purpose in averaging for three years is to provide stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year. The use of a multi-year percentile form, among other things, makes the standard less subject to the possibility of transient violations caused by statistically unusual indicator values, thereby providing more stability to the air quality management process that may enhance the practical effectiveness of efforts to implement the NAAQS. Also, a percentile form can be used to take into account the number of times an exposure might occur as part of the judgment on protectiveness in setting a NAAQS. For all of these reasons, the Policy Assessment concluded it would be appropriate to consider defining the form of a distinct secondary standard in terms of a 3-year average of a specified percentile air quality statistic (U.S. EPA, 2011a, p. 4–58).

The urban visibility preference studies that provided results leading to the range of CPLs being considered in this review offer no information that addresses the frequency of time that visibility levels should be below those values. Given this lack of information, and recognizing that the nature of the public welfare effect is one of aesthetics and/or feelings of well-being, the Policy Assessment concluded that it would not be appropriate to consider eliminating all exposures above the level of the standard and that allowing some number of hours/days with reduced visibility can reasonably be considered (U.S. EPA, 2011a, p. 4–59). In the Visibility Assessment, 90th, 95th, and 98th percentile forms were assessed for alternative PM light extinction standards (U.S. EPA, 2010b, section 4.3.3). In considering these alternative percentiles, the Policy Assessment noted that the Regional Haze Program targets the 20 percent most impaired days for improvements in visual air quality in Federal Class I areas. If improvement in the 20 percent most impaired days were similarly judged to be appropriate for protecting visual air quality in urban areas, a percentile well above the 80th percentile would be appropriate to increase the likelihood that all days in this range would be improved by control strategies intended to attain the standard. A focus on improving the 20 percent most impaired days suggests that the 90th percentile, which represents the median of the distribution of the 20 percent worst days, would be an appropriate form to consider. Strategies that are implemented so that 90 percent of days have visual air quality that is at or below the level of the standard would reasonably be expected to lead to improvements in visual air quality for the 20 percent most impaired days. Higher percentile values within the range assessed could have the effect of limiting the occurrence of days with peak PM-related light extinction in urban areas to a greater degree. In considering the limited information available from the public preference studies, the Policy Assessment found no basis to conclude that it would be appropriate to consider limiting the occurrence of days with peak PM-related light extinction in urban areas to a greater degree.

Another aspect of the form discussed in the proposal for a sub-daily averaging time was whether to include all daylight hours or only the maximum daily daylight hour(s). The maximum daily daylight 1-hour or multi-hour form would be most directly protective of the welfare of people who have limited, infrequent or intermittent exposure to visibility during the day (e.g., during commutes), but spend most of their time without an outdoor view. For such people a view of poor visibility during their morning commute may represent their perception of the day's visibility conditions until the next time they venture outside during daylight, which may be hours later or perhaps the next day. Other people have exposure to visibility conditions throughout the day. For those people, it might be more appropriate to include every daylight hour in assessing compliance with a standard, since it is more likely that each daylight hour could affect their welfare.

The Policy Assessment did not have information regarding the fraction of the public that has only one or a few opportunities to experience visibility during the day, nor did it have information on the role the duration of the observed visibility conditions has on wellbeing effects associated with those visibility conditions. However, it is logical to conclude that people with limited opportunities to experience visibility conditions on a daily basis

would experience the entire impact associated with visibility based on their short-term exposure. The impact of visibility for those who have access to visibility conditions often or continuously during the day may be based on varying conditions throughout the day.

In light of these considerations, the analyses conducted as part of the Visibility Assessment analyses included both the maximum daily hour and the all daylight hours forms. The Policy Assessment noted that there is a close correspondence between the level of protection afforded for all 15 urban areas by a maximum daily daylight 1-hour approach using the 90th percentile form and an all daylight hours approach combined with the 98th percentile form (U.S. EPA, 2010b, section 4.1.4). This suggested that reductions in visibility impairment required to meet either form of the standard would provide protection to both fractions of the public (i.e., those with limited opportunities and those with greater opportunities to view PM-related visibility conditions). CASAC generally supported consideration of both types of forms without expressing a preference based on its review of information presented in the second draft Policy Assessment (Samet, 2010d, p. 11).

In conjunction with a calculated $PM_{2.5}$ light extinction indicator and alternative 24-hour or sub-daily (e.g., 4-hour) averaging times, based on the above considerations, and given the lack of information on and the high degree of uncertainty over the impact on public welfare of the number of days with visibility impairment over a year, the Policy Assessment concluded that it would be appropriate to give primary consideration to a 90th percentile form, averaged over three years (U.S. EPA, 2011a, p. 4–60). Further, in the case of a multi-hour, sub-daily alternative standard, the Policy Assessment concluded that it would be appropriate to give primary consideration to a form based on the maximum daily multi-hour period in conjunction with the 90th percentile form (U.S. EPA, 2011a, p. 4–60). This sub-daily form would be expected to provide appropriate protection for various segments of the population, including those with limited opportunities during a day and those with more extended opportunities over the daylight hours to experience PM-related visual air quality.

Though CASAC did not provide advice as to a specific form that would be appropriate, it took note of the alternative forms considered in that document and encouraged further analyses in the final Policy Assessment that might help to clarify a basis for selecting from within the range of forms identified. In considering the available information and the conclusions in the final Policy Assessment in light of CASAC's comments, at the time of proposal the Administrator concluded that a 90th percentile form, averaged over 3 years, is appropriate, and proposed such a form in conjunction with a $PM_{2.5}$ visibility index and a 24-hour averaging time.

v. Level

As discussed in section VI.D.4 of the proposal, in considering appropriate levels for a 24-hour standard defined in terms of a $PM_{2.5}$ visibility index and an 90th percentile form, averaged over 3 years, the Policy Assessment took into account the evidence- and impact-based considerations discussed above, with a focus on the results of public perception and attitude surveys related to the acceptability of various levels of visual air quality and on the important limitations in the design and scope of such available studies. The Policy Assessment considered a variety of approaches for identifying appropriate levels for such a standard, including utilizing both adjusted and unadjusted CPLs derived from the visibility preference studies.

The Policy Assessment interpreted the results from the visibility preferences studies conducted in four urban areas to define a range of low, middle, and high CPLs for a sub-daily standard (e.g., 1- to 4-hour averaging time) of 20, 25, and 30 dv, which are approximately equivalent to $PM_{2.5}$ light extinction of values of 65, 110, and 190 Mm^{-1}. The CASAC generally supported this approach, noting that the ''EPA staff's approach for translating and presenting the technical evidence and assessment results is logically conceived and clearly presented. The 20–30 deciview range of levels chosen by EPA staff as 'Candidate Protection Levels' is adequately supported by the evidence presented'' (Samet, 2010d, p. 11).[177] The Policy Assessment also recognized that to define a range of alternative levels that would be appropriate to consider for a 24-hour calculated $PM_{2.5}$ light extinction standard, it would be appropriate to consider whether some adjustment to these CPLs is warranted since these preference studies cannot be directly interpreted as applying to a 24-hour exposure period (as noted above and in Policy Assessment section 4.3.1). Considerations related to such adjustments are more specifically discussed below.

In considering alternative levels for a sub-daily standard based directly on the four preference study results, the Policy Assessment noted that the individual low and high CPLs are in fact generally reflective of the results from the Denver and Washington, DC studies respectively, and the middle CPL is very near to the 50th percentile criteria result from the Phoenix study, which was by far the best of the studies, providing somewhat more support for the middle CPL.

In considering the results from the four visibility preference studies, the Policy Assessment recognized that currently available studies are limited in that they were conducted in only four areas, three in the U.S. and one in Canada. Further, the Policy Assessment recognized that available studies provide no information on how the duration and variation of time a person spends outdoors during the daytime may impact their judgment of the acceptability of different degrees of visibility impairment. As such, there is a relatively high degree of uncertainty associated with using the results of these studies to inform consideration of a national standard for any specific averaging time. Nonetheless, the Policy Assessment concluded, as did CASAC, that these studies are appropriate to use for this purpose (U.S. EPA, 2011a, p. 4–61).

Using approaches described in section VI.C.4 of the proposal, the Policy Assessment explored various approaches to adjusting the CPLs derived from the preference studies to inform alternative levels for a 24-hour standard. These various approaches, based on analyses of 2007–2009 data from the 15 urban areas assessed in the Visibility Assessment, focused on estimating CPLs for a 24-hour standard that would provide generally equivalent protection as that provided by a 4-hour standard with CPLs of 20, 25, and 30 dv. In conducting these analyses, staff initially expected that the values of 24-hour average $PM_{2.5}$ light extinction and daily maximum daylight 4-hour average $PM_{2.5}$ light extinction would differ on any given day, with the shorter term peak value generally being larger. This would mean that, in concept, the level of a 24-hour standard should include a

[177] In 2009, the DC Circuit remanded the secondary $PM_{2.5}$ standards to the EPA in part because the Agency failed to identify a target level of protection, even though EPA staff and CASAC had identified a range of target levels of protection that were appropriate for consideration. The court determined that the Agency's failure to identify a target level of protection as part of its final decision was contrary to the statute and therefore unlawful, and that it deprived EPA's decision-making of a reasoned basis. See 559F. 3d at 528–31; see also section VI.A.2 above and the Policy Assessment, section 4.1.2.

downward adjustment compared to the level of a 4-hour standard to provide generally equivalent protection. As discussed more fully in section G.5 of Appendix G and summarized below, this initial expectation was not found to be the case across the range of CPLs considered. In fact, as shown in Tables G–7 and G–8 of Appendix G and in the corrected version of Table G–6 found in Frank *et al.* (2012b),[178] in considering estimates aggregated or averaged over all 15 cities as well as the range of city-specific estimates for the various approaches considered, these analyses indicated that the generally equivalent 24-hour levels ranged from somewhat below the 4-hour level to just above the 4-hour level for each of the CPLs.[179] In all cases, the range of city-specific estimates of generally equivalent 24-hour levels included the 4-hour level for each of the CPLs of 20, 25, and 30 dv. As noted in the proposal, looking more broadly at these results could support consideration of using the same CPL for a 24-hour standard as for a 4-hour standard, recognizing that there is no one approach that can most closely identify a generally equivalent 24-hour standard level in each urban area for each CPL. The use of such an unadjusted CPL for a 24-hour standard would place more emphasis on the relatively high degree of spatial and temporal variability in relative humidity and fine particle composition observed in urban areas across the country, so as to reduce the potential of setting a 24-hour standard level that would require more than the intended degree of protection in some areas.

In considering the appropriate level of a secondary standard focused on protection from PM-related urban visibility impairment based on either a 24-hour or a multi-hour, sub-daily (e.g., 4-hour) averaging time, the EPA has been mindful of the important limitations in the available evidence from public preference studies. These uncertainties and limitations are due in part to the small number of stated preference studies available for this review; the relatively small number of study participants and the extent to which the study participants may not be representative of the broader study area population in some of the studies; and the variations in the specific materials and methods used in each study such as scene characteristics, the range of VAQ levels presented to study participants, image presentation methods and specific wording used to frame the questions used in the group interviews. In addition the EPA has noted that the scenic vistas available on a daily basis in many urban areas across the country generally may not have the inherent visual interest or the distance between viewer and object of greatest intrinsic value as in the Denver and Phoenix preference studies, and that there is the possibility that there could be regional differences in individual preferences for VAQ.

It is also important to note that as in past reviews, the EPA is considering a national visibility standard in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in urban, non-urban, and Federal Class I areas across the country. The EPA recognizes that programs implemented to meet a national standard focused primarily on the visibility problems in urban areas can be expected to improve visual air quality in surrounding non-urban areas as well, as would programs now being developed to address the requirements of the Regional Haze Program established for protection of visual air quality in Federal Class I areas. The EPA also believes that the development of local programs, such as those in Denver and Phoenix, can continue to be an effective and appropriate approach to provide additional protection, beyond that afforded by a national standard, for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas.

The Policy Assessment concluded that it is appropriate to give primary consideration to alternative standard levels toward the upper end of the ranges identified above for 24-hour and sub-daily standards, respectively (U.S. EPA, 2011a, p. 4–63). Thus, the Policy Assessment concluded it is appropriate to consider the following alternative levels: A level of 28 dv or somewhat below, down to 25 dv, for a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, a 90th percentile form, and a 24-hour averaging time; and a standard level of 30 dv or somewhat below, down to 25 dv, for a similar standard but with a 4-hour averaging time (U.S. EPA, 2011a, p. 4–63). The Policy Assessment judged that such standards would provide appropriate protection against PM-related visibility impairment primarily in urban areas. The Policy Assessment noted that CASAC generally supported consideration of the 20–30 dv range as CPLs and, more specifically, that support for consideration of the upper part of the range of the CPLs derived from the public preference studies was expressed by some CASAC Panel members during the public meeting on the second draft Policy Assessment. The Policy Assessment concluded that such a standard would be appropriate in conjunction with the Regional Haze Program to achieve appropriate levels of protection against PM-related visibility impairment in areas across the country (U.S. EPA, 2011a, p. 4–63).

Based on the considerations discussed above and in section VI.D.4 of the proposal, and taking into account the advice of CASAC, at the time of proposal the Administrator concluded that it would be appropriate to establish a target level of protection—for a standard defined in terms of a $PM_{2.5}$ visibility index; a 90th percentile form averaged over 3 years; and a 24-hour averaging time—equivalent to the protection afforded by such a sub-daily (i.e., 4-hour) standard at a level of 30 dv, which is the upper end of the range of CPLs identified in the Policy Assessment and generally supported by CASAC. More specifically, the Administrator provisionally concluded that a 24-hour level of either 30 dv or 28 dv could be construed as providing such a degree of protection, and that either level was supported by the available information and was generally consistent with the advice of CASAC. Thus, the EPA proposed two options for the level of a new 24-hour standard (defined in terms of a $PM_{2.5}$ visibility index and a 90th percentile form, averaged over 3 years) to provide appropriate protection from PM-related visibility impairment: Either 30 dv or 28 dv. As noted in the proposal, the option of setting such a 24-hour standard at a level of 30 dv would reflect recognition that there is considerable spatial and

[178] Note that the city-specific ranges shown in Table G–6, Appendix G of the Policy Assessment are incorrectly stated for Approaches C and E. Drawing from the more detailed and correct results for Approaches C and E presented in Tables G–7 and G–8, respectively, the city-specific ranges in Table G–6 for Approach C should be 17–21 dv for the CPL of 20 dv; 21–25 dv for the CPL of 25 dv; and 24–30 dv for the CPL of 30 dv; the city-specific ranges in Table G–6 for Approach E should be 17–21 dv for the CPL of 20 dv; 21–26 dv for the CPL of 25 dv; and 25–31 dv for the CPL of 30 dv. In the EPA's reanalysis comparing 4- vs. 24-hour values, Frank et al. (2012b) recreated Table G–6 using the correct values from Tables G–7 and G–8.

[179] As discussed in more detail in Appendix G of the Policy Assessment, some days have higher values for 24-hour average light extinction than for daily maximum 4-hour daylight light extinction, and consequently an adjusted ''equivalent'' 24-hour CPL can be greater than the original 4-hour CPL. This can happen for two reasons. First, the use of monthly average historical RH data will lead to cases in which the *f*(RH) values used for the calculation of 24-hour average light extinction are higher than all or some of the four hourly values of *f*(RH) used to determine daily maximum 4-hour daylight light extinction on the same day. Second, $PM_{2.5}$ concentrations may be greater during non-daylight periods than during daylight hours.

temporal variability in the key factors that determine the value of the $PM_{2.5}$ visibility index in any given urban area, such that there is a relatively high degree of uncertainty as to the most appropriate approach to use in selecting a 24-hour standard level that would be generally equivalent to a specific 4-hour standard level. Selecting a 24-hour standard level of 30 dv would reflect a judgment that such substantial degrees of variability and uncertainty should be reflected in a higher standard level than would be appropriate if the underlying information were more consistent and certain. Alternatively, the option of setting such a 24-hour standard at a level of 28 dv would reflect placing more weight on statistical analyses of aggregated data from across the study cities and not placing as much emphasis on the city-to-city variability as a basis for determining an appropriate degree of protection on a national scale.

The information available for the Administrator to consider when setting the secondary PM standard raises a number of uncertainties. While CASAC supported moving forward with a new standard on the basis of the available information, CASAC also recognized these uncertainties, referencing the discussion of key uncertainties and areas for future research in the second draft of the Policy Assessment. In discussing areas of future research, CASAC stated that: ''The range of 50% acceptability values discussed as possible standards are based on just four studies (Figure 4–2), which, given the large spread in values, provide only limited confidence that the benchmark candidate protection levels cover the appropriate range of preference values. Studies using a range of urban scenes (including, but not limited to, iconic scenes—''valued scenic elements'' such as those in the Washington, DC study), should also be considered'' (Samet, 2010d, p. 12). The EPA solicited comment on how the Administrator should weigh those uncertainties as well as any additional comments and information to inform her consideration of these uncertainties.

In addition, the EPA solicited comment on a number of other issues related to the level of the standard, including:

(1) Both of the proposed levels and the various approaches to identifying generally equivalent levels upon which the alternative proposed levels are based.

(2) A broader range of levels down to 25 dv in conjunction with a 24-hour averaging time.

(3) A range of alternative levels from 30 to 25 dv in conjunction with a sub-daily (e.g., 4-hour) averaging time.

(4) The strengths and limitations associated with the public preference studies and the use of these studies to inform the selection of a range of levels that could be used to provide an appropriate degree of public welfare protection when combined with the other elements of the standard (i.e. indicator, form and averaging time).

(5) Specific aspects of the public preference studies, including the extent to which the 50 percent acceptability criterion is an appropriate basis for establishing target protection levels in the context of establishing a distinct secondary NAAQS to address PM-related visibility impairment in urban areas; how the variability among preference studies in the extent to which study participants may be representative of the broader study area population should be weighed in the context of considering these studies in reaching proposed conclusions on a distinct secondary NAAQS; and the extent to which the ranges of VAQ levels presented to participants in each of the studies may have influenced study results and on how this aspect of the study designs should appropriately be weighed in the context of considering these studies in the context of this review.

vi. Administrator's Proposed Conclusions Regarding PM Standards To Protect Visibility

At the time of proposal, based on the considerations described above, the Administrator proposed to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment, focused primarily on visibility in urban areas. This proposed visibility standard was to be defined in terms of a $PM_{2.5}$ visibility index, which would use measured $PM_{2.5}$ mass, combined with $PM_{2.5}$ speciation data and relative humidity data, to calculate $PM_{2.5}$ light extinction, translated into the deciview (dv) scale; a 24-hour averaging time; a 90th percentile form, averaged over 3 years; and a level of 28–30 dv.

vii. Related Technical Analysis

At the time of proposal, the EPA conducted a two-pronged technical analysis of the relationships between the proposed $PM_{2.5}$ visibility index standard and the current 24-hour $PM_{2.5}$ mass-based standard (Kelly, *et al.,* 2012a). This analysis was designed to provide technical information to inform key issues related to implementing a distinct secondary standard for visibility as proposed. Specifically, the EPA recognized that significant technical issues were likely to arise for new or modified emissions sources conducting air quality analyses for purposes of demonstrating that they would not cause or contribute to a violation of the visibility standard under the Prevention of Significant Deterioration (PSD) program. Such a demonstration for the proposed secondary $PM_{2.5}$ visibility index standard could require each PSD applicant to predict, via air quality modeling, the increase in visibility impairment, in terms of the proposed $PM_{2.5}$ visibility index, that would result from the proposed source's emissions in conjunction with an assessment of existing air quality (visibility impairment) conditions in terms of the proposed $PM_{2.5}$ visibility index. The EPA noted that if this demonstration were to be attempted using the six-step procedure that the EPA proposed to use for calculating $PM_{2.5}$ visibility index design values from monitored air concentrations of $PM_{2.5}$ components, significant technical issues with the modeling procedures could arise.

To address these technical issues, the EPA sought to explore whether sources that met the requirements pertaining to the 24-hour mass-based standard of 35 $\mu g/m^3$ would also meet the requirements pertaining to the proposed visibility index standard. As described in Kelly *et al.* (2012a), the first prong of the analysis addressed aspects of a PSD significant impact analysis by evaluating whether an individual source's impact resulting in a small increase in the ambient $PM_{2.5}$ concentration would produce a comparably small increase in visibility impairment. This analysis included estimates of $PM_{2.5}$ speciation profiles based on direct $PM_{2.5}$ emission profiles for a broad range of source categories and for theoretical upper and lower bound scenarios.

The second prong of the analysis addressed aspects of a PSD cumulative impact analysis by exploring the relationship between the three-year design values for the existing 24-hour $PM_{2.5}$ standard and coincident design values for the proposed $PM_{2.5}$ visibility index standard based on recent air quality data. This aspect of the analysis indicated that increases in 24-hour $PM_{2.5}$ design values generally correspond to increases in visibility index design values, and vice-versa. The analysis further explored the appropriateness of using a demonstration that a source does not cause or contribute to a violation of the 24-hour $PM_{2.5}$ standard as a surrogate for a demonstration that a source does not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index standard. This analysis was based on 2008 to 2010 air quality data, and compared the proposed level of 35 $\mu g/m^3$ for the 24-hour $PM_{2.5}$ standard and for illustrative purposes an alternative standard level of 12 $\mu g/m^3$ for the annual $PM_{2.5}$ standard with the

proposed levels of 28 or 30 dv for the secondary $PM_{2.5}$ visibility index standard with a 24-hour averaging time and a 90th percentile form. The results indicated that all (for the 30 dv level) or nearly all (for the 28 dv level) areas in attainment of the 24-hour $PM_{2.5}$ standard would also have been in attainment of the proposed secondary $PM_{2.5}$ visibility index standard.

Based on this technical analysis, the EPA proposed that there is sufficient evidence that a demonstration that a source does not cause or contribute to a violation of the mass-based 24-hour $PM_{2.5}$ standard serves as a suitable surrogate for demonstrating that a source does not cause or contribute to a violation of the proposed secondary 24-hour $PM_{2.5}$ visibility index standard under the PSD program. As such, the EPA proposed to conclude that many or all sources undergoing PSD review for $PM_{2.5}$ could rely upon their analysis for demonstrating that they do not cause or contribute to a violation of the mass-based 24-hour $PM_{2.5}$ standard to also show that they do not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index standard, if a distinct visibility standard were finalized.

Although this proposed ''surrogacy policy'' was designed to address an implementation-related issue, the second prong of the technical analysis addresses the broader technical question of the relationship between the existing 24-hour $PM_{2.5}$ standard and the proposed $PM_{2.5}$ visibility index standard in terms of the degree of protection likely to be afforded by each standard. Specifically, the analysis indicated that depending on the level of the proposed $PM_{2.5}$ visibility index standard, the existing 24-hour $PM_{2.5}$ mass-based standard would be as protective or in some areas *more* protective of visibility than a distinct secondary standard set within the range of levels proposed. Commenters on the proposed $PM_{2.5}$ visibility index explored the implications of this analysis at length, as discussed further below in section VI.C.1.f. For this reason, the analysis is described in some detail here.

Kelly *et al.* (2012a) noted that the relationship between design values for the 24-hour $PM_{2.5}$ standard and the proposed secondary visibility index standard is not obvious *a priori* because of differences in design value calculations for the standards. However, closer examination of this relationship indicated that increases or decreases in 24-hour $PM_{2.5}$ design values correspond, respectively, to increases or decreases in visibility index values. Specifically, based on measurements from 102 sites with complete data from 2008–2010, Kelly *et al.* (2012a) found linear correlations between the 24-hour $PM_{2.5}$ design values and the visibility index design values with r^2 values ranging from 0.65 to 0.98 across these sites, with an average r^2 value of 0.75 across all U.S. sites. Moreover, the data indicated that no design value existed where the visibility index design value exceeded 30 dv, but the 24-hour $PM_{2.5}$ standard level of 35 $\mu g/m^3$ was attained. Visibility index design values for certain sites in the Industrial Midwest were shown to exceed 28 dv despite the fact that the 24-hour $PM_{2.5}$ design values for these sites were below 35 $\mu g/m^3$. This was attributed to the combination of high nitrate and sulfate fractions, substantial RH adjustment factors, and $PM_{2.5}$ distribution characteristics that led to relatively high visibility index design values for a given 24-hour $PM_{2.5}$ design value for counties in the Industrial Midwest.[180] Kelly *et al.* (2012a) concluded that the ''overall, design values based on 2008–2010 data suggest that counties that attain 24-hour $PM_{2.5}$ NAAQS level of 35 $\mu g/m^3$ would attain the proposed secondary $PM_{2.5}$ visibility index NAAQS level of 30 dv and generally attain the level of 28 dv'' (pp. 17–18). In addition, the Kelly *et al.* analysis indicated that at sites that violated both the 24-hour $PM_{2.5}$ level and the proposed visibility index 30 dv level, the proposed level of 30 dv would likely be attained if $PM_{2.5}$ concentrations were reduced such that the 24-hour $PM_{2.5}$ level of 35 $\mu g/m^3$ was attained (Kelly *et al.,* 2012a, p.15).[181] A key implication of this analysis, therefore, was that within the range of levels proposed by the EPA for a visibility index standard (28–30 dv), the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would be controlling in almost all (at 28 dv) or all (at 30 dv) instances.

2. Other (Non-Visibility) PM-related Welfare Effects

In the 2006 review, the EPA concluded that there was insufficient information to consider a distinct secondary standard based on PM-related impacts to ecosystems, materials damage and soiling, and climatic and radiative processes (71 FR 61144, October 17, 2006). Specifically, there was a lack of evidence linking various non-visibility welfare effects to specific levels of ambient PM. In that review, to provide a level of protection for these welfare-related effects, the secondary standards were set equal to the revised primary standards to directionally improve the level of protection afforded vegetation, ecosystems, and materials (71 FR 61210, October 17, 2006).

This section briefly outlines key conclusions discussed more fully in section VI.E of the proposal regarding the non-visibility welfare effects of PM. These conclusions relate to the climate, ecological (including effects on plants, soil and nutrient cycling, wildlife and water) and materials damage effects of PM. For all of these effects, the Policy Assessment concluded that there is insufficient information at this time to revise the current suite of secondary standards. It is important to note that the Policy Assessment explicitly excluded discussion of the effects associated with deposited particulate matter components of NO_X and SO_x and their transformation products which are addressed fully in the joint review of the secondary NO_2 and SO_2 NAAQS.

a. Evidence of Other Welfare Effects Related to PM

With regard to the role of PM in climate, the proposal noted that there is considerable ongoing research focused on understanding aerosol contributions to changes in global mean temperature and precipitation patterns. The Integrated Science Assessment concluded ''that a causal relationship exists between PM and effects on climate, including both direct effects on radiative forcing and indirect effects that involve cloud feedbacks that influence precipitation formation and cloud lifetimes'' (U.S. EPA, 2009a, section 9.3.10). These effects are discussed in more detail in section VI.E.1 of the proposal, which provides information on the major aerosol components of interest for climate processes, including black carbon (BC), organic carbon (OC), sulfates, nitrates, and mineral dusts, and the nature, magnitude, and direction (e.g., cooling vs. warming) of various aerosol impacts on climate.[182] The Policy Assessment concluded that aerosols alter climate processes directly through radiative forcing and by indirect effects on cloud brightness, changes in precipitation, and

[180] Kelly *et al.* (2012a) also noted that ''Regional reductions in sulfate $PM_{2.5}$ due to emission controls planned as part of national rules as well as emission reductions associated with potential annual standard violations are expected to improve visibility in this region'' (p. 17).

[181] The analysis also showed that attaining the 24-hour $PM_{2.5}$ standard level of 35 $\mu g/m^3$ would result in achieving a lower $PM_{2.5}$ visibility index level in certain areas of the country, largely western areas, than would be achieved in other areas of the country. This is due to differences in the composition of ambient $PM_{2.5}$ and the lower relative humidity in those areas.

[182] Atmospheric PM is referred to as aerosols in the remainder of this section to be consistent with the Integrated Science Assessment.

possible changes in cloud lifetimes (U.S. EPA, 2011a, p. 5–10). Further, the Policy Assessment noted that the major aerosol components that contribute to climate processes (i.e. BC, OC, sulfate, nitrate and mineral dusts) vary in their reflectivity, forcing efficiencies and even in the direction of climate forcing, though there is an overall net climate cooling associated with aerosols in the global atmosphere (U.S. EPA, 2009a, section 9.2.10). The Policy Assessment concluded that the current mass-based $PM_{2.5}$ and PM_{10} secondary standards were not an appropriate or effective means of focusing protection against PM-associated climate effects due to these differences in components (U.S. EPA, 2011a, p. 5–11). In addition, in light of the significant uncertainties in current scientific information and the lack of sufficient data, the Policy Assessment concluded it is not currently feasible to conduct a quantitative analysis for the purpose of informing revisions of the current secondary PM standards based on climate (U.S. EPA, 2011a, p. 5–11). Overall the Policy Assessment concluded that there is insufficient information at this time to base a national ambient standard on climate impacts associated with current ambient concentrations of PM or its constituents (U.S. EPA, 2011a, p. 5–11, –12).[183]

With regard to ecological effects, the proposal noted that several ecosystem components (e.g., plants, soils and nutrient cycling, wildlife and water) are impacted by PM air pollution, which may alter the services provided by affected ecosystems. Ecological effects include both direct effects due to deposition (e.g., wet, dry or occult) to vegetation surfaces and indirect effects occurring via deposition to ecosystem soils or surface waters where the deposited constituents of PM then interact with biological organisms. Some of the ecological effects considered in this review include direct effects to metabolic processes of plant foliage; contribution to total metal loading resulting in alteration of soil biogeochemistry and microbiology, and plant and animal growth and reproduction; and contribution to total organics loading resulting in bioaccumulation and biomagnification across trophic levels. Section VI.E.2 of the proposal summarizes key findings related to:

(1) Impacts on plants and the ecosystem services they provide due to deposition of PM to vegetative surfaces, which alters the radiation received by the plant, and uptake of deposited PM components by plants from soil or foliage, which can lead to stress and decreased photosynthesis;

(2) Impacts on ecosystem support services such as nutrient cycling, products such as crops and the regulation of flooding and water quality;

(3) Impacts on wildlife, especially due to biomagnification of heavy metals (especially Hg) up the food chain and bioconcentration of POPs and PBDEs; and

(4) Impacts of deposited PM, especially metals and organics, on the ecosystem services provided by water bodies, including primary production, provision of fresh water, regulation of climate and floods, recreational fishing and water purification.

The proposal noted that the Integrated Science Assessment had concluded that ecological evidence is sufficient to conclude that a causal relationship is likely to exist between deposition of PM and a variety of effects on individual organisms and ecosystems (U.S. EPA, 2009a, sections 2.5.3 and 9.4.7), and also noted that vegetation and other ecosystem components are affected more by particulate chemistry than size fraction. However, the proposal also pointed to the Integrated Science Assessment conclusion that it is generally difficult to characterize the nature and magnitude of effects and to quantify relationships between ambient concentrations of PM and ecosystem response due to significant data gaps and uncertainties as well as considerable variability that exists in the components of PM and their various ecological effects. There are few studies that link ambient PM concentrations to observed effect. Most direct ecosystem effects associated with particulate pollution occur in severely polluted areas near industrial point sources (quarries, cement kilns, metal smelting) (U.S. EPA, 2009a, sections 9.4.3 and 9.4.5.7).

Based on the evidence available at this time, the proposal noted the following key conclusions in the Policy Assessment:

(1) A number of significant environmental effects that either have already occurred or are currently occurring are linked to deposition of chemical constituents found in ambient PM.

(2) Ecosystem services can be adversely impacted by PM in the environment, including supporting, provisioning, regulating and cultural services.

(3) The lack of sufficient information to relate specific ambient concentrations of particulate metals and organics to a degree of impairment of a specific ecological endpoint hinders the identification of a range of appropriate indicators, levels, forms and averaging times of a distinct secondary standard to protect against associated effects.

(4) Data from regionally-based ecological studies can be used to establish probable local, regional and/or global sources of deposited PM components and their concurrent effects on ecological receptors.

The proposal noted that the Policy Assessment had concluded that the currently available information is insufficient for purposes of assessing the adequacy of the protection for ecosystems afforded by the current suite of PM secondary standards or establishing a distinct national standard for ambient PM based on ecosystem effects of particulates not addressed in the NO_X/SO_X secondary review (e.g., metals, organics) (U.S. EPA, 2011a, p. 5–24). Furthermore, the Policy Assessment had concluded that in the absence of information providing a basis for specific standards in terms of particle composition, the observations continue to support retaining an appropriate degree of control on both fine and coarse particles to help address effects to ecosystems and ecosystem components associated with PM (U.S. EPA, 2011a, p. 5–24).

With regard to materials damage, the proposal discussed effects associated with deposition of PM, including both physical damage (materials damage effects) and impaired aesthetic qualities (soiling effects). As with the other categories of welfare effects discussed above, the Integrated Science Assessment concluded that evidence is sufficient to support a causal relationship between PM and effects on materials (U.S. EPA, 2009a, sections 2.5.4 and 9.5.4). The deposition of PM can physically affect materials, adding to the effects of natural weathering processes, by potentially promoting or accelerating the corrosion of metals, by degrading paints and by deteriorating building materials such as stone, concrete and marble (U.S. EPA, 2009a, section 9.5). In addition, the deposition of ambient PM can reduce the aesthetic appeal of buildings and objects through soiling. The Policy Assessment made the following observations:

(1) Materials damage and soiling that occur through natural weathering processes are enhanced by exposure to atmospheric pollutants, most notably sulfur dioxide and particulate sulfates.

(2) While ambient particles play a role in the corrosion of metals and in the weathering of materials, no quantitative relationships between ambient particle concentrations and rates of damage have been established.

(3) While soiling associated with fine and course particles can result in increased cleaning frequency and repainting of surfaces, no quantitative relationships between particle characteristics and the frequency of cleaning or repainting have been established.

(4) Limited new data on the role of microbial colonizers in biodeterioration

[183] This conclusion would apply for both the secondary (welfare-based) and the primary (health-based) standards.

processes and contributions of black crust to soiling are not sufficient for quantitative analysis.

(5) While several studies in the PM Integrated Science Assessment and NO_X/SO_X Integrated Science Assessment suggest that particles can promote corrosion of metals there remains insufficient evidence to relate corrosive effects to specific particulate levels or to establish a quantitative relationship between ambient PM and metal degradation. With respect to damage to calcareous stone, numerous studies suggest that wet or dry deposition of particles and dry deposition of gypsum particles can enhance natural weathering processes.

The Policy Assessment concluded that none of the new evidence in this review called into question the adequacy of the current standards for protecting against material damage effects, that such effects could play no quantitative role in determining whether revisions to the secondary PM NAAQS are appropriate at this time, and that observations continue to support retaining an appropriate degree of control on both fine and coarse particles to help address materials damage and soiling associated with PM (U.S. EPA, 2011a, p. 5–29).

b. CASAC Advice

In advising the EPA regarding the non-visibility welfare effects, CASAC stated that it ''concurs with the Policy Assessment's conclusions that while these effects are important, and should be the focus of future research efforts, there is not currently a strong technical basis to support revisions of the current standards to protect against these other welfare effects'' (Samet, 2010c). More specifically, with regard to climate impacts, CASAC concluded that while there is insufficient information on which to base a national standard, the causal relationship is established and the risk of impacts is high, so further research on a regional basis is urgently needed (Samet, 2010c, p. 5). CASAC also noted that reducing certain aerosol components could lead to increased radiative forcing and regional climate warming while having a beneficial effect on PM-related visibility. As a consequence, CASAC noted that a secondary standard directed toward reducing PM-related visibility impairment has the potential to be accompanied by regional warming if light scattering aerosols are preferentially targeted.

With regard to ecological effects, CASAC concluded that the published literature is insufficient to support a national standard for PM effects on ecosystem services (Samet, 2010c, p.23). CASAC noted that the best-established effects are related to particles containing nitrogen and sulfur, which are being considered in the EPA's ongoing review of the secondary NAAQS for NO_X/SO_X. With regard to PM-related effects on materials, CASAC concluded that the published literature, including literature published since the last review, is insufficient either to call into question the current level of the standard or to support any specific national standard for PM effects on materials (Samet, 2010c, p.23). Nonetheless, with regard to both types of effects, CASAC noted the importance of maintaining an appropriate degree of control of both fine and coarse particles to address such effects, even in the current absence of sufficient information to develop a standard.

c. Summary of Proposed Decisions Regarding Other Welfare Effects

Based on the above considerations and the advice of CASAC, at the time of proposal the Administrator provisionally concluded that it would not be appropriate to establish any distinct secondary PM standards to address other non-visibility PM-related welfare effects, including ecological effects, effects on materials, and climate impacts. Nonetheless, the Administrator concurred with the conclusions of the Policy Assessment and CASAC advice that it is important to maintain an appropriate degree of control of both fine and coarse particles to address such effects. Noting that there is an absence of information that would support any different standards, the Administrator proposed generally to retain the current suite of secondary PM standards [184] to address non-visibility welfare effects. Specifically, the Administrator proposed to retain all aspects of the current secondary 24-hour $PM_{2.5}$ and PM_{10} standards. With regard to the secondary annual $PM_{2.5}$ standard, the Administrator proposed to retain the level of the current standard and to revise the form of the standard by removing the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard.

C. Public Comments on Proposed Decisions Regarding Secondary PM Standards

The EPA received a large number of comments on its proposed decisions with regard to secondary PM standards, with the large majority of those comments focusing on the proposal to set a distinct standard to protect against visibility impairment, discussed below in section VI.C.1. Very few commenters addressed the proposal to retain the existing secondary standards for non-visibility welfare effects, discussed below in section VI.C.2. As discussed in section VI.D. below, the Administrator has decided to retain the current suite of secondary PM standards generally, while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. The Administrator has also decided, contrary to what was proposed, not to establish a distinct secondary standard to address PM-related visibility impairment. This section discusses EPA's responses to the comments EPA received on its proposal, and the rationale behind the Administrator's final decisions is discussed in section VI.D. below.

1. Comments on Proposed Secondary Standard for Visibility Protection

a. Overview of Comments

Among those commenting on the proposal to set a distinct secondary $PM_{2.5}$ visibility index standard, a large majority of commenters, including more than 25 state and local agencies; regional organizations such as NACAA, NESCAUM, and WESTAR; and industry commenters, such as ACC, API, BP, EPRI, NCBA, NEDA–CAP, NMA, NSSGA, and UARG, opposed setting a distinct secondary standard for visibility at this time. Many commenters in this group expressed the view that such a standard was not needed, primarily on the basis that adequate protection was provided by the existing 24-hour secondary $PM_{2.5}$ standard. Some of these commenters also expressed legal concerns with the nature of the proposed standard. Other commenters in this group supported a distinct secondary standard for visibility in concept, but expressed the view that it was premature to set such a standard pending collection of additional visibility preference study data and the resolution of a number of key technical issues. Support for setting such a distinct secondary standard for visibility at this time came from a second group of commenters, including the Department of the Interior (National Park Service), several states, the Mid-Atlantic/Northeast Visibility Union (MANE–VU), the National Tribal Air Association (NTAA), environmental organizations such as the Appalachian Mountain Club, National Parks Conservation Association, Earthjustice (AMC, *et al.*) and the League of Women

[184] As summarized in section VI.A and Table 1 above, the current suite of secondary PM standards includes annual and 24-hour $PM_{2.5}$ standards and a 24-hour PM_{10} standard.

Voters of Texas. These commenters argued that the existing secondary standards are not sufficiently protective of visual air quality, and that a distinct secondary standard similar to the proposed visibility index standard is both necessary and appropriate to ensure adequate protection of visibility.

Commenters in both groups expressed concerns about various aspects of the proposed distinct secondary standard, including the indicator, averaging time, level, and form. In addition, a large number of commenters, including commenters from both groups, expressed concern and/or confusion over the relationship between the Regional Haze Program and the proposed distinct secondary standard for visibility, raising issues such as analytical differences in methods between the programs, monitoring issues, and other implementation challenges.

A discussion of the significant comments outlined above, including EPA's responses to the comments, is presented here, with more detailed discussion in the Response to Comments document. Comments relating to the specific elements of the proposed standard—indicator, averaging time, form and level—are discussed in sections VI.C.1.b-e, respectively. Comments related to the need for a distinct secondary standard at this time are discussed in section VI.C.f. Legal issues raised by commenters opposed to setting a secondary standard based on the proposed visibility index are discussed in section VI.C.g. Finally, comments related to the relationship between a distinct secondary standard and the Regional Haze Program are discussed in section VI.C.h.[185] While the EPA concludes in section VI.D below to retain the current suite of secondary $PM_{2.5}$ standards, the appropriateness of the protection that would be provided by the proposed $PM_{2.5}$ visibility index standard, and the relationship between this degree of protection and that provided by the current secondary 24-hour secondary $PM_{2.5}$ standard, are key elements in the Administrator's decision, and are discussed below.

b. Indicator

Numerous commenters, both those supporting a distinct secondary standard and those opposed to setting such a standard, expressed views on the suitability of utilizing a $PM_{2.5}$ calculated light extinction indicator for the standard as proposed. While these groups of commenters differed in terms of their views on the appropriateness of using calculated $PM_{2.5}$ light extinction as the basis for the indicator rather than relying on direct measurements of $PM_{2.5}$ light extinction, commenters from both groups expressed concern over specific elements of the proposed method of calculating $PM_{2.5}$ light extinction. In particular, commenters expressed differing views on which IMPROVE algorithm should be utilized; whether it is appropriate to exclude coarse particles from the indicator; and whether the proposed protocols for incorporating data on relative humidity and $PM_{2.5}$ species are appropriate.[186]

i. Comments on Calculated vs. Directly Measured Light Extinction

The majority of commenters in both groups noted the uncertainties associated with relying on a calculated light extinction indicator and stated a preference for utilizing direct light extinction measurements. However, recognizing the limitations on applying direct measurements at present, commenters supporting the proposal to set a distinct standard argued that relying on ''calculated light extinction is a reasonable first approach'' (DOI, p. 2). These commenters pointed to the advice of CASAC, which had acknowledged that it was not possible for the EPA to develop an FRM for direct measurement of light extinction within the time frame of this review and had concluded that relying on a calculated $PM_{2.5}$ light extinction indicator represented a reasonable approach that could be implemented sooner than a directly measured indicator. These commenters generally supported the proposal to adopt a calculated $PM_{2.5}$ light extinction indicator, at least as an interim approach.

Commenters opposed to setting a distinct standard generally argued that it was inappropriate to rely on a calculated light extinction indicator rather than direct measurements. Some of these commenters argued that the proposed calculated light extinction indictor is ill suited for a bright line standard because the method uses average humidity and a reconstructed visibility measurement calculated from $PM_{2.5}$ speciation filter analysis, rather than measuring what is actually observed by individuals. A number of commenters advocated postponing setting a distinct standard until an approach based on direct light extinction measurements can be adopted. Many of these commenters stated that relying on direct light extinction measurements would enable a standard to be based on a shorter averaging time, either 1-hour or sub-daily (4 to 6 hours), consistent with the more instantaneous nature of perceptions of visual air quality and the advice of CASAC in this review.

The EPA generally agrees with commenters that an indicator based on directly measured light extinction would provide the most direct link between PM in the ambient air and PM-related light extinction. However, as noted at the time of proposal and in accordance with the advice of CASAC, the EPA has concluded that this is not an appropriate option in this review because a suitable specification of currently available equipment or performance-based verification procedures could not be developed in the time frame of this review. Moreover, CASAC concluded that relying on a calculated $PM_{2.5}$ light extinction indicator based on $PM_{2.5}$ chemical speciation and relative humidity data represented a reasonable approach. The inputs that are necessary include measurements that are available through existing monitoring networks and approved protocols. Thus, the EPA remains confident that the available evidence demonstrates that a strong correspondence exists between calculated $PM_{2.5}$ light extinction and PM-related visibility impairment. Furthermore, CASAC agreed, noting that the proposed calculated $PM_{2.5}$ light extinction indicator based on the original IMPROVE algorithm ''appears to be a reasonable approach for estimating hourly light extinction'' (Samet, 2010d, p. 11) and ''its reliance on procedures that have already been implemented in the CSN and routinely collected continuous $PM_{2.5}$ data suggest that it could be implemented much sooner than a directly measured indicator'' (Samet, 2010d, p. iii). Thus it would not be appropriate to postpone setting a distinct secondary standard until an approach based on direct light extinction measurements could be adopted.

ii. Comments on Specific Aspects of Calculated Light Extinction Indicator

Some commenters, even those supporting the adoption of a calculated light extinction indicator, also expressed concern over specific aspects of the proposed indicator. First, a

[185] Comments pertaining to implementation issues, which the Administrator may not consider in making decisions about setting national ambient air quality standards, are discussed in the Response to Comments document, as are comments regarding monitoring issues related to the proposed distinct visibility index standard.

[186] Some commenters expressed concern about the omission of other contributors to visibility impairment from the visibility index, as discussed in the Response to Comments document.

number of commenters expressed concern over the proposal to use the original IMPROVE algorithm as the basis for the calculated light extinction indicator. These commenters noted that the original IMPROVE algorithm has been shown to have consistent biases at both low and high levels of light extinction. In particular, these commenters expressed concern with the algorithm's bias at higher levels of light extinction, which they pointed out were the conditions that might be encountered on hazier days in urban areas.

Some commenters supported use of the revised IMPROVE algorithm. These commenters noted that the revised equation has been through a peer review which confirmed that it is based on the best science and corrects the biases inherent in the original algorithm. Commenters also noted that this revised algorithm has been widely incorporated into Regional Haze plans, and urged the EPA to use this same equation in the visibility index for the sake of consistency: ''EPA approved this approach for regional haze and does not dispute its greater accuracy. Therefore, a national secondary ambient air quality standard based on criteria that accurately reflect the latest scientific knowledge logically should not revert to the original IMPROVE algorithm'' (Oklahoma DEQ, p. 2). Other commenters noted that both the original and the revised IMPROVE algorithms were designed in support of the Regional Haze Program which is focused on largely rural Class I areas, and that neither algorithm is necessarily suitable for urban areas. Noting that the EPA has not thoroughly evaluated the applicability of either IMPROVE algorithm in urban areas, these commenters urged additional research to evaluate the suitability of either algorithm (or an alternative approach) in urban areas.

Second, a number of commenters argued that exclusion of coarse PM from the calculated light extinction indicator was inappropriate. These commenters noted that coarse particulate matter is an important contributor to visibility impairment in many areas, particularly in the western U.S., and that the levels of ''acceptable'' visual air quality derived from the visibility preference studies reflected total light extinction due to the full mix of particles (including coarse PM) in ambient air. A few commenters noted that due to the exclusion of coarse particles, a ''deciview'' calculated for purposes of the proposed $PM_{2.5}$ visibility index is inconsistent with the unit as conventionally defined under the Regional Haze Program. Other commenters, however, supported the proposal to exclude coarse PM from the calculated light extinction indicator, noting the important role that $PM_{2.5}$ plays in urban visibility and arguing it would be more difficult to control the contribution of coarse particle sources such as wind-blown dust to urban visibility impairment.

Third, some commenters questioned why the EPA was proposing to rely on monthly average relative humidity (f(RH)) values when hourly humidity data are widely available, particularly in urban areas. One commenter argued that the EPA's proposed approach involves ''guessing relative humidity'' rather than relying on accurate, readily available measurements (Oklahoma DEQ, p. 1). The commenter stated that since relative humidity is highly variable and weather dependent, the proposed approach ''effectively undermines the capacity of the prescribed monitoring regime to identify periods when $PM_{2.5}$ adversely affects visibility.'' Other commenters supported this view, noting that relative humidity can vary substantially even within a 24-hour period, and that light extinction can be very sensitive to these changes. These commenters recommended that hourly or daily humidity measurements should be utilized in place of the proposed monthly average f(RH) values.

Some commenters also recommended that the EPA should utilize a 90 percent relative humidity screen rather than 95 percent cap for purposes of eliminating periods in which visibility impairment is due to rain or fog. These commenters claimed that under a 95 percent cap, both the average f(RH) values and the $PM_{2.5}$ visibility index values could be inflated in locations frequently affected by fog and/or precipitation. These commenters preferred the approach of excluding hours with relative humidity above 90 percent on the grounds that this approach would eliminate foggy/rainy hours irrespective of the frequency of occurrence.

The EPA does not agree with commenters who advocated using the revised IMPROVE algorithm. Both the original and the revised IMPROVE algorithms have been evaluated by comparing the calculated estimates of light extinction with coincident optical measurements. As discussed above in section VI.B.1.a.i, the revised algorithm was developed to address observed biases in the predictions using the original algorithm under very low and very high light extinction conditions, with further modifications and additions to better account for differences in particle composition and aging in remote areas.[187] However, the EPA does not believe that these same modifications and additions would necessarily be appropriate for calculating light extinction in urban areas. Instead, the EPA considers the original algorithm to be suitable for purposes of calculating urban light-extinction, although some adjustments may be appropriate for urban environments as well. The reasons why the original algorithm is suited to urban environments are discussed further below, along with adjustments that the EPA believes are likely appropriate based on the current (limited) state of knowledge.

First, the EPA considers that the multiplier of 1.8 used to convert OC to OM in the revised IMPROVE algorithm is too high for urban environments. The EPA is aware that there has been considerable debate within the research community about the appropriate multiplier to use to best represent urban environments. As discussed in Appendix F of the Policy Assessment (U.S. EPA, 2011a), the EPA used the SANDWICH mass closure approach (Frank, 2006) in the Urban Focused Visibility Assessment (U.S. EPA, 2010b) for purposes of calculating maximum daylight hourly $PM_{2.5}$ light extinction and evaluated which multiplier would produce 24-hour results most similar to the SANDWICH approach using 24-hour $PM_{2.5}$ organic carbon derived from the new Chemical Speciation Network (CSN) carbon monitoring protocol established in 2007.[188] Analyses presented in Appendix F of the Policy Assessment indicate that a multiplier of 1.6 is most appropriate for purposes of comparing the hourly $PM_{2.5}$ light extinction with calculated 24-hour extinction (see Appendix F, section F.6 for a full explanation). The EPA also considers this higher multiplier to be a better approach for urban CSN monitoring sites where the new measurements of organic carbon tend to be lower than those produced by the older NIOSH-type monitoring protocol

[187] Specifically, the revised IMPROVE algorithm incorporates additional terms to account for particles representing the different dry extinction and water uptake (f(RH)) from two size modes of sulfate, nitrate and organic mass, as well as adding a term for hygroscopic sea salt. There are also adjustments for the calculation of OM as 1.8*OC compared to 1.4*OC in the original algorithm to better account for the more aged PM organic components found in remote areas.

[188] Starting in 2007, the CSN adopted the IMPROVE monitoring protocol for the measurement of organic and elemental carbon using the IMPROVE analytical method and an IMPROVE-like sampler. The transition was completed in 2009. (See ''Modification of Carbon Procedures in the Speciation Network,'' *http://www.epa.gov/ttn/amtic/files/ambient/pm25/spec/faqcarbon.pdf.*)

(Malm, 2011). A multiplier of 1.6 is now used to calculate OM from OC measurements at CSN sites.

At the time of proposal, the EPA proposed to use the original IMPROVE algorithm with its 1.4 multiplier for converting OC to OM, but requested comment on whether this value was appropriate. Comments received by the Agency generally indicate that the OC-to-OM multiplier of 1.4 used in the original IMPROVE algorithm is too low for urban areas. Based on the analyses presented in Appendix F of the Policy Assessment, the EPA agrees with these commenters. However, the EPA also believes that it would be inappropriate to use a multiplier as high as 1.8 to convert OC to OM in urban areas. As noted by commenters, the organic mass contribution to visibility impairment can be large, and generally OM is significantly larger in urban areas compared to surrounding rural areas.[189] Because a large portion of the organic component of urban PM results from nearby emissions sources, the total OM mass is generally closer to the measured OC from which it is derived. This means it is appropriate to use a smaller multiplier to convert OC to OM in urban areas as compared to the value of 1.8 used in the revised algorithm, which is tailored to remote areas. The CASAC noted that urban OM includes fresh emissions and the EPA concluded in the Visibility Assessment that ''the original version is considered more representative of urban situations when emissions are still fresh rather than aged as at remote IMPROVE sites'' (U.S. EPA, 2010b, p. 3–19). Although the revised algorithm represents the best science of estimating extinction in *remote* areas with its aged aerosol, the commenters did not address how the EPA should modify the revised algorithm to best represent the more complex and different urban aerosol, particularly for OM. In light of all of these considerations, in particular the analyses the EPA conducted for Appendix F of the Policy Assessment and the fact that the monitoring method for organic carbon has recently changed in the CSN network, the EPA judges that a multiplier of 1.6 for urban areas would be most appropriate for purposes of calculating $PM_{2.5}$ light extinction in urban areas.[190] In formulating this judgment, the EPA recognizes that neither the original nor the revised IMPROVE algorithm has been tested for suitability in urban areas and that additional research is necessary to reduce the uncertainties about the most appropriate value for the OC to OM multiplier in urban environments. With regard to other changes between the original and revised IMPROVE algorithms, the EPA also does not believe that it would be appropriate to include a term for hygroscopic sea salt for urban light extinction, or to differentiate between different size modes of sulfate, nitrate, and organic mass as empirically defined by the revised IMPROVE algorithm. Unlike in some remote coastal locations, sea salt is not major contributor to light extinction in urban areas. Moreover, urban sources of salt include sanding of roads during the winter and those re-entrained particles are mostly in the coarse size range.

Like in remote areas, small and large size modes of sulfate, nitrate and organic mass would exist in the urban environment. However, the apportionment of the total fine particle concentration of each of the three $PM_{2.5}$ components into the concentrations of the small and large size fractions would likely need a different approach than that used for remote areas. This is because of the closer proximity of urban sources to their emissions. This is a particular concern not only for organic mass, which as explained previously has a large contribution from nearby urban emission sources, but also for $PM_{2.5}$ nitrate whose concentrations are also higher in urban areas compared to the surrounding regions. Thus, a higher portion of the total urban concentration may be in the small mode compared to remote areas and thus a different apportionment algorithm would be needed.

Finally, the EPA does not consider it necessary to employ site-specific Rayleigh light scattering terms in place of a universal Rayleigh light scattering value for purposes of calculating light extinction in urban areas for purposes of calculating the 90th percentile values. The site-specific Rayleigh value is most important to accurately estimate extinction on the best visibility days which is an essential metric for the regional haze program.

For all of these reasons, the EPA considers the original IMPROVE algorithm better suited to the task of calculating urban light extinction than the revised IMPROVE algorithm. However, the EPA does consider it appropriate to make certain adjustments to the original algorithm for purposes of calculating urban light extinction. As discussed above, the EPA believes it is appropriate to use a 1.6 multiplier to convert OC to OM in urban areas. In addition, the EPA believes it is appropriate to exclude the term for coarse particles from the equation. The EPA does not agree with commenters who suggested that coarse particles should be included in the calculated light extinction indicator. As noted in the proposal, $PM_{2.5}$ is the component of PM responsible for most of the visibility impairment in most urban areas. Currently available data suggest that $PM_{10\text{-}2.5}$ is a minor contributor to visibility impairment most of the time, although at some locations (U.S. EPA, 2010b, Figure 3–13 for Phoenix) $PM_{10\text{-}2.5}$ can be a major contributor to urban visibility effects. While it is reasonable to assume that other urban areas in the desert southwestern region of the country may have conditions similar to the conditions shown for Phoenix, in fact few urban areas conduct continuous $PM_{10\text{-}2.5}$ monitoring. This significantly increases the difficulty of assessing the role of coarse particles in urban visibility impairment. For example, among the 15 urban areas assessed in this review, only four areas had collocated continuous PM_{10} data allowing calculation of hourly $PM_{10\text{-}2.5}$ data for 2005 to 2007. In addition, $PM_{10\text{-}2.5}$ is generally less homogenous in urban areas than $PM_{2.5}$ in that coarse particle concentrations exhibit greater temporal variability and a steeper gradient across urban areas than fine particles (U.S. EPA, 2009a, p. 3–72). This makes it more challenging to select sites that would adequately represent urban visibility conditions. Thus, while it would be possible to include a $PM_{10\text{-}2.5}$ light extinction term in a calculated light extinction indicator, as was done in the Visibility Assessment, there is insufficient information available at this time to assess the impact and effectiveness of such a refinement in providing public welfare protection in areas across the country (U.S. EPA, 2011a, pp. 4–41 to 4–42). Therefore, the EPA concludes that it is not appropriate to set a standard based on a calculated light extinction indicator that includes coarse particles at this time, and the calculated indicator should be based on $PM_{2.5}$ light extinction.

With regard to the suggestion by some commenters that the calculated light extinction indicator should be calculated using hourly humidity data,

[189] The difference between higher $PM_{2.5}$ mass in urban areas compared to surrounding regions, known as the urban excess, is largely attributed to organic mass (U.S. EPA, 2004b).

[190] The implications of this shift to a 1.6 multiplier for OC in urban areas for decisions about averaging time, level, and need for a distinct secondary standard are discussed further below in sections VI.C.1.c, VI.C.1.e, and VI.C.1.f, respectively.

the EPA disagrees that concurrent humidity measurements should be used. The use of longer-term averages for each monitoring site adequately captures the seasonal variability of relative humidity and its effects of visibility impairment, and this approach focuses more on the underlying aerosol contributions to visibility impairment and less on the day-to-day variations in humidity. This provides a more stable indicator for comparison to the NAAQS and one that is more directly related to the underlying emissions that contribute to visibility impairment.

With regard to the comments advocating the use of a 90 percent humidity screen as opposed to a 95 percent humidity cap, the EPA believes that relying on monthly average relative humidity values based on 10 years of climatological data appropriately reduces the effect of fog and precipitation. Although the approach of using a 95 percent humidity cap, as in the Regional Haze Program, includes some hours with relative humidity between 90–95 percent, the general approach of using a longer-term average for each monitoring site effectively eliminates the effect of very high humidity conditions on visibility at those locations.

Therefore, taking all of the above considerations and CASAC advice into account, the EPA continues to conclude that a calculated $PM_{2.5}$ light extinction indicator, similar to that used in the Regional Haze Program (i.e., using an IMPROVE algorithm as translated into the deciview scale), would be the most appropriate indicator to replace the current $PM_{2.5}$ mass indicator for a distinct secondary standard. Moreover, the EPA continues to conclude that this calculated indicator should based on the original IMPROVE algorithm, adjusted to use a 1.6 OC multiplier and exclude the term for coarse particles, in conjunction with monthly average relative humidity data (i.e., f(RH) values) based on long-term climatological means as used in the Regional Haze Program. A $PM_{2.5}$ visibility index defined in this way would appropriately reflect the relationship between ambient PM and PM-related light extinction, based on the analyses discussed in the proposal and reflecting the aerosol and relative humidity contributions to visibility impairment by incorporation of factors based on measured $PM_{2.5}$ speciation concentrations and climatological average relative humidity data. In addition, this type of indicator would address, in part, the issues raised in the court's remand of the 2006 $PM_{2.5}$ standards. Such a $PM_{2.5}$ visibility index would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by virtue of directly incorporating the effects of differences in $PM_{2.5}$ composition and relative humidity across the country.

c. Averaging Time

Few commenters specifically addressed the issue of averaging time. Those who did generally expressed the view that an hourly or sub-daily averaging time would be the most appropriate approach, as supported by CASAC and the EPA's own analyses in this review. These comments were generally consistent with the emphasis among all commenters on the desirability of adopting a directly measured light extinction indicator that could be measured on an hourly or sub-daily time scale. Some commenters noted that a standard based on a 4–6 hour averaging time would better capture peak daily light extinction while allowing stable signal quality; others urged EPA to adopt a 1-hour averaging time in conjunction with direct measurements. Commenters pointed to significant limitations associated with using a 24-hour averaging time, including the uncertainties in translating hourly or sub-daily visibility index values into 24-hour equivalent values. Some commenters criticized the analysis presented in the Policy Assessment comparing the 24-hour calculated light extinction values to the maximum daylight 4-hour calculated light extinction values. These commenters stated that the scatter plots and regressions presented in the Policy Assessment indicate there is considerable variation in the 24-hour vs. 4-hour relationship, and interpreted this to mean that 24-hour light extinction values are a poor surrogate for 4-hour values. For example, several industry commenters cited an analysis which noted that the correlation coefficient between the 24-hour and 4-hour values was as low as $r^2 = 0.42$ in Houston, and stated that the EPA was being overly ''optimistic'' in concluding that city-specific and pooled r^2 values in the range of 0.6 to 0.8 showed good correlation (UARG, Attachment 2, p. 27).

In addition, some commenters expressed concern over potential bias and greater uncertainty introduced by the inclusion of nighttime hours, noting that because relative humidity tends to be higher at night, inclusion of these hours could cause areas to ''record NAAQS exceedances that have no corresponding visibility impairment value'' (UARG, p. 36). Commenters also emphasized the poor fit of a 24-hour averaging time with the near instantaneous judgments about visibility impairment reflected in the visibility preference studies. Commenters also noted that there is greater hourly variation in PM concentrations and resulting visibility conditions in urban areas than in Class I areas; thus, while the Regional Haze Program uses 24-hour IMPROVE data, the commenters stated that a shorter averaging time is needed for an urban-focused $PM_{2.5}$ visibility standard. Some commenters objected to a 24-hour averaging time as unsupported by the record in this review: ''Because the science the Administrator relies on for the other elements of the proposed visibility standard is tied to short-term exposures to visibility impairment, the EPA has no basis for promulgating a standard that uses a 24-hour averaging time'' (API, p. 43). These commenters claimed that while the EPA may not have the information or infrastructure in place to allow the Agency to set a standard based on a 1-hour or other sub-daily averaging time, this does not justify moving to a 24-hour averaging time.

Among commenters supporting the proposed distinct secondary standard for visibility, many commenters recognized the limitations on monitoring methods and currently available data that led to the EPA's proposal to adopt a standard based on a 24-hour averaging time. Most of these commenters acknowledged that the lack of reliable hourly speciation data means that a 24-hour averaging time is the only workable approach for a standard based on calculated light extinction. Commenters advocating a distinct secondary standard for visibility therefore generally supported the proposal to adopt a 24-hour averaging time, at least as an interim approach until a directly measured light extinction indicator could be adopted in the future. This approach was also supported by a few industry commenters who noted that since a visibility index standard would be based on data from the IMPROVE and CSN monitors, which operate on a 24-hour basis with 1-in-3 (or 1-in-6) day sampling, ''it is imperative that EPA retain a 24-hour averaging time if a secondary visibility standard is promulgated'' (API, Attachment 2, p. 9).

In response to comments supporting a 1-hour or sub-daily (4- to 6- hour) averaging time in conjunction with a direct light extinction measurements, the EPA notes that, as discussed above in the response to comments on indicator, the Agency has concluded

that a directly measured light extinction indicator is not an appropriate option in this review, independent of the decision on averaging time. Having reached the conclusion that a calculated $PM_{2.5}$ light extinction indicator would be most appropriate, the EPA has next considered what averaging time would be most desirable for such an indicator. As noted in the proposal, the EPA has recognized that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. Thus, the Agency agrees with commenters' general point that, as a starting premise, a sub-daily averaging time would generally be preferable.

However, as noted at the time of proposal and discussed above in section VI.B.1.c, important data quality uncertainties have recently been identified in association with currently available instruments that would be used to provide the hourly $PM_{2.5}$ mass measurements that would be needed in conjunction with an averaging time shorter than 24 hours. As a result, at this time the Agency has strong technical reservations about a secondary standard that would be defined in terms of a sub-daily averaging time. The data quality issues which have been identified, including short-term variability in hourly data from currently available continuous monitoring methods, effectively preclude adoption of a 1-hour averaging time in this review, given the sensitivity of a 1-hour averaging time to these data quality limitations. Even with regard to multi-hour averaging times, the EPA continues to conclude that the data quality concerns preclude adoption of a sub-daily averaging time.

Moreover, analyses conducted for the Policy Assessment indicate that $PM_{2.5}$ light extinction calculated on a 24-hour average basis would be a reasonable and appropriate surrogate for $PM_{2.5}$ light extinction calculated on a 4-hour basis. The scatter plots comparing 24-hour and 4-hour calculated $PM_{2.5}$ light extinction in the Policy Assessment (U.S. EPA, 2011a, Figures G–4 and G–5) do show some scatter around the regression line for each city. This was to be expected, since the calculated 4-hour light extinction includes day-specific and hour-specific influences that are not captured by the simpler 24-hour approach. Overall, however, in the EPA's view, both the city-specific and pooled 15-city 24-hour vs. 4-hour comparisons show strong correlation between the two averaging times. Moreover, the 90th percentile design values calculated for 4-hour vs. 24-hour light extinction are much more closely correlated than are the values for individual days in particular urban areas calculated using these two approaches. Thus, while the EPA agrees with commenters who pointed out the relatively low correlation between 4- and 24-hour values in cities such as Houston, the Agency points out that the correlations of 90th percentile values are much higher, particularly when one considers the average values across urban areas. In general, the 90th percentile values line up better and demonstrate closer to a one-to-one relationship.

The EPA has conducted a reanalysis (Frank *et al.,* 2012b) of the relationships between estimated 24-hour and 4-hour visibility impairment based on the variety of metrics discussed in Appendix G of the Policy Assessment that further supports this finding. The reanalysis more appropriately considered the uncertainty of the calculated 4-hour values. It also considered the effect of changing the OC to OM multiplier used in urban areas with the new CSN monitoring protocol from 1.4 to 1.6. The revised analysis shows that the 24-hour values are generally closer to the 4-hour values than originally estimated.

Since conclusions in the proposal about the relationship between 4-hour and 24-hour values were drawn not just on the basis of the city-specific results but also on the more robust 90th percentile values, the EPA disagrees with commenters who state that the Agency was overly optimistic in considering 24-hour values an appropriate surrogate for 4-hour values. Also, it is appropriate to focus on the 90th percentile design value comparison since the design values would determine attainment status and the degree of improvement in air quality that could be expected in areas instituting controls to meet the NAAQS. Therefore the EPA does not agree with commenters who state that a 24-hour averaging time cannot serve as an appropriate surrogate for sub-daily periods of visibility impairment. On the contrary, the EPA continues to conclude, on the basis of this analysis, that $PM_{2.5}$ light extinction calculated on a 24-hour basis is a reasonable and appropriate surrogate for sub-daily $PM_{2.5}$ light extinction calculated on a 4-hour basis.

The EPA recognizes that the effect of adopting a 24-hour averaging time may be to smooth out some of the hour-by-hour variability in visibility index values. (Indeed, this is true if we compare a 4-hour averaging time to a 1-hour averaging time as well.) Hour-specific influences which would be evident if an hourly or sub-daily averaging time were to be used will be masked to some extent when those hours are averaged together with other hours. This means, in part, that a 24-hour averaging time may effectively reduce peak values by means of averaging them together with other hours, which may have lower values. However, given the well documented variability in hourly visibility conditions, especially in urban areas, as noted by commenters, it is reasonable to assume that in some cases peak hours may be significantly influenced by atypical conditions, making it appropriate to adopt an averaging time that is sufficiently long to ensure that hour-specific influences are balanced against more typical conditions. Perhaps even more important is the concern that many peak hourly measurements may be significantly influenced by atypical instrument performance; this reinforces the conclusion that it is appropriate to adopt a longer averaging time, to ensure that hour-specific uncertainties are balanced against more robust measurements.

Thus, in agreement with commenters who supported a daily averaging time, the EPA concludes that a 24-hour averaging time would be appropriate for a distinct secondary standard based on a calculated $PM_{2.5}$ light extinction indicator.

d. Form

The EPA received very few comments with regard to the proposal to adopt a 90th percentile form, averaged over 3-years, in conjunction with a $PM_{2.5}$ visibility index and a 24-hour averaging time. One commenter stated that it was inappropriate to use a 90th percentile form, noting that this would result in the exclusion of a minimum of 36 days of data annually. The commenter expressed particular concern that this proposed approach, in combination with a 24-hour standard based on an unadjusted CPL, would not capture the worst visibility impairment and that this would undermine ''the intent of setting a meaningful secondary visibility standard'' (AMC, *et al.,* p. 2). Another commenter argued that the EPA had provided no scientific basis for why the 90th percentile form was suitable, and claimed that the Agency was making ''a somewhat arbitrary judgment that people's welfare would be affected only if adverse urban visibility were to occur

more than 10 percent of the time'' (API, Attachment 2, p. 4).

On other hand, a few commenters who appeared to generally support the proposal to use a 90th percentile form advocated averaging the 90th percentile values over longer time periods, arguing that averaging over only 3 years would not provide a stable assessment of visual air quality in the West because this time period is insufficient to properly account for western drought and fire cycles. These commenters pointed to the approach in the Regional Haze Program of averaging visibility impairment over 5 years, and noted that even within this longer time period data can be significantly influenced by high emissions during significant fire years.

The EPA disagrees with all of these comments. With regard to the comment opposing the 90th percentile form as inappropriately excluding the worst visibility days, the EPA notes that there is a significant lack of information on, and a high degree of uncertainty regarding, the impact on public welfare of the number of days with visibility impairment over the course of a year. For example, the visibility preference studies used to derive the range of CPLs considered in this review offered no information regarding the frequency of time that visibility levels should be below those values. Based on this limitation, the EPA concluded in the Policy Assessment that it would not be appropriate to consider eliminating all exposures above the level of the standard and that it was reasonable to consider allowing some number of days with reduced visibility. Recognizing that the Regional Haze Program focuses attention on the 20 percent worst visibility days (i.e., those at or above the 80th percentile of visibility impairment), the EPA continues to believe, as noted in the proposal, that a percentile well above the 80th percentile would be appropriate to increase the likelihood that all days in this range would be improved by control strategies intended to help areas attain the standard. Focusing on the 90th percentile, which represents the median of the distribution of the 20 percent worst visibility days, could be reasonably expected to lead to improvements in visual air quality on the 20 percent most impaired days. Thus, the EPA has made a reasoned judgment based on a full consideration of the upper end of the distribution of visibility impairment conditions and continues to conclude that it is appropriate to focus on the 90th percentile of visibility impairment values.

With regard to comments requesting the EPA adopt a longer multi-year averaging period for the 90th percentile values, the EPA disagrees that it would be appropriate to average the 90th percentile values over periods longer than 3 years. The EPA recognizes that a multi-year percentile form offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. Utilizing a 3-year average form provides stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year. The Agency has adopted this approach in other NAAQS, including the current secondary 24-hour $PM_{2.5}$ NAAQS, which has a 98th percentile form averaged over 3 years. However, adopting a multi-year averaging period longer than 3 years would increase the number of days with visibility impairment above the target level of protection and would therefore reduce the protectiveness of the standard. Based on this the EPA does not believe it would be appropriate to average 90th percentile values over a period as long as five years. Therefore, the EPA continues to conclude that a 90th percentile form, averaged over 3 years, would be appropriate, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and a 24-hour averaging time.

e. Level

With regard to level, commenters focused on two main themes. First, a large number of commenters addressed the information available from the public preference studies with regard to the acceptability of various levels of visual air quality. These comments, which are discussed in subsection VI.C.1.e.i below, address the EPA's use of visibility preference studies as the basis for the selection of a range of appropriate levels for the Administrator to consider. Many commenters challenged the use of these studies as the basis for setting a distinct secondary standard, arguing that limitations in these studies rendered them an unsuitable and insufficient basis on which to establish such a standard. Second, commenters expressed different views as to what level(s) of a distinct secondary standard would be appropriate, if the EPA were to set such a standard. These comments reflected consideration of the results of the public preference studies as well as analyses conducted in the Visibility Assessment and the Policy Assessment, as discussed in the proposal. Comments addressing the appropriateness of specific levels are discussed in subsection VI.C.1.e.ii below.

i. Comments on Visibility Preference Studies

A majority of commenters expressed the view that the existing preference studies provide an insufficient basis for selection by the Administrator of an appropriate level of public welfare visibility protection for a national standard. These commenters highlighted a number of limitations and uncertainties (enumerated below) associated with these studies as support for this view. In contrast, other commenters felt that despite certain limitations, these studies do provide a sufficient basis on which the Administrator can select an appropriate level of a standard to provide national public welfare visibility protection. The remainder of this section organizes and discusses these comments under four broad topic areas, including: (a) Limitations and uncertainties associated with the visibility preference studies; (b) preference study methods and design; (c) use of preference study results for determining adversity; (d) the appropriateness of using regionally varying preference study results to select a single level for a national standard.

(a) Preference Study Limitations and Uncertainties

A large and diverse number of limitations and uncertainties associated with the visibility preference studies have been identified and discussed in the public comments. Many of these same limitations and uncertainties were also identified and discussed by the EPA in the various documents developed throughout this review. The most important and fundamental limitations and uncertainties will be discussed here in the preamble, while more specific, unique or detailed comments will be addressed in the Response to Comments document.

The primary or most frequent limitation cited by many commenters relates to the small number of preference studies that are available in this review. In particular, some commenters note that these preference studies cover just four locations, only three of which occur in the U.S., that the two studies conducted in Washington, DC were pilot studies, not full preference studies, and/or that three of the preference studies were conducted in the West, while only one was conducted in the East, providing only limited geographic coverage. Typically, these same commenters also pointed out that taken together, these

limited studies only included a total of 852 participants, which they claimed was too small a sample size and unrepresentative nationally. These commenters thus concluded that there is insufficient information, both geographically and demographically, upon which to select a national level of a visibility index for purposes of visibility protection.

In contrast, several commenters stated support for using the preference studies, concluding they provide an adequate basis, in spite of their limited nature. In particular, AMC *et al.* state:

> We believe that these studies provide sufficient results to inform setting a national visibility standard. While the number of studies is small, they do incorporate spatial variation and, in the case of Denver and Phoenix, varied populations* * *. EPA should have confidence, rather than uncertainty, in the fact that these studies used different methods and respondents and yield a range of 20–24 dv, with one outlier of 29. (AMC, *et al.,* pp. 6–7)

Regarding the first group of commenters, the EPA notes that it is well aware of the limited nature of the information, which it has described in great detail in the Integrated Science Assessment, Visibility Assessment, and Policy Assessment, as well as in section VI.B.2 of the proposed rule (77 FR 38973). The EPA further notes, however, that limited information does not preclude the Administrator from making judgments based on the best available science, taking into account the existing uncertainties and limitations associated with that available science. Thus, in reaching judgments based on the science, the Administrator appropriately weighs the associated uncertainties. The CASAC supported this view and concluded that the available information provided a sufficient basis on which the Administrator could form a judgment about requisite PM-related public welfare visibility protection. Specifically, CASAC stated ''[t]he 20–30 deciview range of levels chosen by EPA staff as 'Candidate Protection Levels' is adequately supported by the evidence presented'' (Samet, 2010b, p. iii). As discussed in the proposed rule (77 FR 38990), the Administrator recognized and explicitly took into account the uncertainties and limitations in the science in determining an appropriate degree of protection when she proposed a level at the upper end of the recommended range. As discussed below, the Administrator continues to be mindful of these uncertainties and limitations in reaching her final determination regarding what constitutes an appropriate degree of protection with respect to PM-related visibility impairment.

With respect to the comments of AMC *et al.,* the EPA agrees that these studies provide a sufficient basis to inform the Administrator's judgments regarding an appropriate level of protection from PM-related visibility impairment, but she recognizes that these studies, which are the only studies before her, are a limited source of information. However, the EPA does not agree that the Washington, DC, results represent an outlier, and thus the EPA believes these results are appropriately included in the range identified for the Administrator to consider.

Some commenters made the point that the EPA relied on much of this same evidence to reach the conclusion in 2006 that the information was too limited to allow selection of a national standard. For example, API stated:

> [T]he bulk of the VAQ preference studies were available during the previous PM NAAQS review and were considered by the Agency in its establishment of the 2006 p.m. secondary NAAQS * * *. The Proposed Rule does not mention this fact and does not explain why many of these same studies now compel EPA to propose this new secondary NAAQS * * *. The Proposed Rule notes in passing that, since the last review of the PM NAAQS, 'limited information that has become available regarding the characterization of public preferences in urban areas has provided some new perspectives on the usefulness of this information in informing the selection of target levels of urban visibility protection.' 77 Fed. Reg. at 38969/2. It is a serious oversight that the Proposed Rule makes no attempt to explain what that information is or how it affects the interpretation of the VAQ preference studies. This 'limited information' is an apparent reference to information provided by Dr. Anne Smith. (API, p. 37)

The EPA disagrees with these commenters. First, the EPA disagrees that it failed to distinguish between studies that were available in the previous review and the current review. The discussion in section VI.A.1 of the proposal specifically identifies the studies from Denver, Phoenix and British Columbia (77 FR 38967/2) as being considered in the last review. The EPA further disagrees with the implication that it is being circumspect about identifying the ''limited information that has become available regarding the characterization of public preferences in urban areas.'' Beginning in section VI.A.3 of the proposed rule (77 FR 38969), the EPA was clear about what information, both preexisting and new, it relied upon in this review to inform its views and provide the basis for its proposal. In section VI.B.2, the EPA elaborates on the specific information, tools, methods and data which are considered in relation to the public preference studies, including the new information available since the last review.

As noted above and in the proposal, in addition to the substantial PM urban air quality information and analyses new to this review, there are three other sources of information that have specifically ''provided some new perspectives on the usefulness of'' the preference studies ''in informing the selection of target levels of urban visibility protection'' (77 FR 38969). They include: (1) Results from additional urban visibility preference study experiments conducted for Washington, DC by Smith and Howell (2009) which added to the preference data for that location and shed light on the role of location in preference responses; (2) a review and reanalysis (Stratus Consulting, 2009) of the urban visibility public preference studies from the four urban areas, including the newly available Smith and Howell (2009) experiments which examined the similarities and differences between the studies and evaluated the potential significance of those differences on the study results; and (3) additional analyses, including most importantly a logit analysis (Deck and Lawson, 2010, as discussed in Chapter 2 and Appendix J of the Visibility Assessment), which was requested and reviewed by CASAC, which showed that each city's responses represented unique and statistically different curves. Taken together, these sources contributed to the EPA's current knowledge and understanding of each survey study's results, the appropriateness of comparing each study's results to the others, and the key uncertainties relevant to data interpretation. In addition, in the last review the decision to not adopt a distinct secondary standard was remanded as contrary to law and failing to provide a reasoned explanation for the decision. As such it is not appropriate for purposes of comparison with the Administrator's judgment and reasoning in this review.

(b) Preference Study Methods and Design

In addition to the limitations and uncertainties noted above, many comments also asserted the methodologies used in the preference studies are fundamentally flawed. Many commenters cited some of the same issues that have already been identified by the EPA as sources of uncertainty and potential factors in producing the statistically different study results (see section VI.B.1.b above). As noted above,

the EPA is well aware of the issues raised regarding the adequacy of the preference studies to serve as a basis for a secondary NAAQS (see 77 FR 38975) and solicited comment on how these uncertainties should be considered (see 77 FR 38990). Most of these same commenters also pointed to an assessment of the preference studies methodology provided by Smith and Howell (2009) as the basis for their views, as indicated by the following comments:

> Smith and Howell (2009) show that VAQ preference study outcomes are malleable and depend entirely on the design of the study. Accordingly, such studies do not identify any meaningful threshold of acceptable visibility conditions. Despite Smith and Howell's conclusions, EPA continues to assert that the VAQ preference studies can be used to identify minimally acceptable visibility conditions even though the Agency has never provided any valid scientific basis for discounting the Smith and Howell (2009) results. (API, p. 38)

> Well-controlled preference studies discussed by Anne Smith of Charles River Associates at the March 2010 CASAC meeting demonstrated that the judgment of panel members was affected by the order in which photographs were presented and tendency to identify the middle of the range of visibility degredation as a threshold of acceptability. This points to a potential flaw in these studies and that artifacts caused by these tendencies may have influenced study results. Dismissing these inherent flaws in the existing preference studies and then using these studies to set a secondary NAAQS is arbitrary and capricious. (API, Attachment 2, p. 12)

> EPA also fails to acknowledge that the only study conducted since the last review rebuts the validity of the VAQ preference studies previously conducted. (UARG, Attachment 2, p. 28)

As is explained in a more detailed discussion in the Response to Comments document, the EPA disagrees that the study conducted by Smith and Howell (2009) supports the conclusion that the preference study methodologies were fundamentally flawed; however, the EPA notes that their experiments do identify areas where additional research would be useful to further inform our limited understanding of public preferences in urban areas. The EPA views the Smith and Howell experiments as increasing the EPA's knowledge and understanding of the findings of the 2001 Washington, DC focus group pilot study (Abt, 2001) in several important ways, although this information still remains limited overall. Specifically, the Smith and Howell results suggest: (1) The 2001 results, while based on a small sample size of 9, were consistent with results from a larger sample of the general Washington, DC population; (2) an individual's preferences for visibility in one location may not depend on whether they live in that location; and (3) presentation method (i.e., changing from slide projection to computer monitor) did not appear to affect the reported preferences.

(c) Preference Study Results and Adversity

A number of comments were received regarding the EPA's use of preference study results to make the determination that adverse $PM_{2.5}$-related visibility effects on the public welfare are occurring. In this context, several commenters questioned whether the EPA had made the case that unacceptable levels of visual air quality based on preference study results alone can be equated with an adverse public welfare effect. These commenters suggested that unless preference study information is linked to personal comfort and well-being or other associated welfare effects, it cannot form the basis of a determination of adversity. For example, Kennecott Utah Copper LLC stated that:

> Thus, EPA seemingly was building the foundation for a determination of what constitutes an adverse effect on visibility in the context of public welfare. However * * * EPA subsequently veered toward an oversimplified focus on public acceptance of visibility conditions * * *. EPA's discussion of visibility in the Policy Assessment and its proposed rule in the Federal Register focuses entirely on ''acceptable'' and ''unacceptable'' visual air quality and make no mention of an ''adverse effect'' in the context of visibility. EPA's reliance on only 3 urban preference studies represents a paucity of data and a wholesale abandonment of any effort to seek a scientifically measurable adverse effect. (Kennecott Utah Copper LLC, p. 26)

In response, the EPA first notes that the definition of effects on welfare included in section 302(h) of the CAA identifies both visibility and the broader category of effects on personal comfort and well-being as effects on welfare. In setting a secondary standard to address visibility impairment, the EPA considers the effect on the public from impairment of visibility as a separate and distinct welfare effect in its own right. The EPA is not required to translate this into terms of personal comfort and well-being, as visibility impairment is designated explicitly by Congress as an effect on welfare. While there may be a large degree of overlap among these different welfare effects, the EPA properly focuses on evaluating all of the information before the Agency on the effect visibility impairment has on the public, whether or not this impairment would also be categorized as having an adverse effect on personal comfort and well-being. It is in the context of all of this information that the EPA makes the judgment as to the appropriate degree of protection from known and anticipated adverse effects on the public from visibility impairment. The EPA recognizes that there is uncertainty about the degree of adversity to the public welfare associated with PM-related visibility impairment. However a secondary standard is designed to provide protection from ''known or anticipated'' adverse effects, and a bright line determination of adversity is not required in judging the requisite degree of protection under section 109(b)(2). Furthermore, the EPA disagrees that it has abandoned its consideration of visibility-related impacts on the welfare effect of personal comfort and well-being, as is made clear in the following quote:

> Research has demonstrated that people are emotionally affected by low visual air quality, that perception of pollution is correlated with stress, annoyance, and symptoms of depression, and that visual air quality is deeply intertwined with a ''sense of place,'' affecting people's sense of the desirability of a neighborhood (U.S. EPA, 2009a, section 9.2.4). *Though it is not known to what extent these emotional effects are linked to different periods of exposure to poor visual air quality, providing additional protection against short-term exposures to levels of visual air quality considered unacceptable by subjects in the context of the preference studies would be expected to provide some degree of protection against the risk of loss in the public's ''sense of well-being.''* (77 FR 38973/1, emphasis added)

The approach taken to address such qualitative, but policy-relevant, information in this review is the same as in other NAAQS reviews. The review is initiated with a comprehensive assessment of all possible public health and welfare effects associated with PM in the Integrated Science Assessment. Then policy-relevant effects for which there is sufficient quantitative information to allow a determination of the change in risks associated with incremental changes in air quality are assessed (in this review, in the Visibility Assessment) and used to provide a quantitative basis to inform the selection of an appropriate range of levels for further consideration in the Policy Assessment. In the Policy Assessment, the EPA considers all important policy-relevant evidence and information, both quantitative and qualitative, in making recommendations regarding the range of policy options appropriate for the Administrator to consider. It is in the context of all of this information that the Administrator

makes her final judgment as to the appropriate degree of protection from known and anticipated adverse effects on the public from visibility impairment.

Another issue raised in the comments regarding adversity is the EPA's decision to use the 50 percent acceptability criterion from the public preference studies in determining candidate protection levels of visibility impairment for the selection of a national level of visibility protection. For example, AMC *et al.* recommended ''a 75% acceptability criterion as a target that is in line with protecting the broader public from the negative effects of visibility impairment'' (AMC, *et al.,* p. 9).

In the Visibility Assessment, the EPA noted that the use of the 50 percent acceptance level for urban visibility was first presented in Ely *et al.* (1991) (U.S. EPA, 2010b, p. 2–5). Ely discussed the use of the 50 percent acceptability criterion as a reasonable basis for setting an urban visibility standard.

> The standard was determined based on a 50% acceptability criterion, that is, the standard was set at the level of extinction that would divide the slides into two groups: those judged acceptable and those judged unacceptable by a majority of the people in the study. The criterion is politically reasonable because it defines the point where a majority of the study participants begin to judge slides as representing unacceptable visibility. It is also consistent with psychological scaling theory which indicates that a ''true score'' exceeds a standard when more than 50% of the ''observed scores'' exceed that standard. (Ely *et al.,* 1991, p. 11)

As Ely described, the 50 percent acceptability criterion and the preference study conducted by Ely were used as the basis for setting the level of the Denver Visibility Standard in 1990. That same criterion was judged appropriate and selected for use in the Phoenix preference study (BBC research, 2003) and as the basis for setting the level of the Phoenix Visibility Standard in 2003. Most recently, the 50 percent acceptability criterion has been recommended by the British Columbia Visibility Coordinating Committee as the basis for the visibility standard currently under consideration by British Columbia, Canada. Furthermore, CASAC supported this approach, while recognizing the uncertainty associated with this issue. Specifically, CASAC agreed that ''the 50th percentile for the acceptability criteria is logical, given the noted similarities in methodologies employed in the 4 study areas. * * * In terms of choosing a specific percentile from the preference studies, we note that there may not be a ''preferred'' one, but in assessing preference studies to propose a PM secondary NAAQS, the 50th percentile is sufficient, as it is the basis for existing visibility indexes used in the Denver/Colorado Front Range and Phoenix metropolitan areas'' (Samet, 2009c, pp. 8–9). Therefore, after considering the information that served as the original basis for its selection as described in Ely *et al.,* 1991, and given its acceptance and use in existing visibility programs, the EPA continues to conclude, consistent with the advice of CASAC, that it is reasonable to use the 50 percent acceptability criterion in determining target levels of protection from visibility impairment.

(d) Appropriateness of using regionally varying preference study results to select a single level for a national standard.

A number of commenters raised concerns regarding the bases for and implications of the differences observed in the preference study results, concluding that these results were due to regionally varying factors and thus could not be used to set a national standard. For example, some commenters asserted that because the confidence intervals around the four 50 percent acceptability levels do not overlap at all, and because there are variations in preference study designs and inherent differences in the visual setting among cities and panels, the four preference curves and their associated 50 percent dv values are city-specific and statistically different. The commenters concluded, therefore, that it was inappropriate to aggregate the 50th percentile dv values from multiple studies and that they should instead be evaluated individually.

Other commenters expressed the related view that the preference study results cannot be used to set a national standard for visibility impairment because the results show that visibility preferences vary regionally. For example, API stated that:

> The 'one-size-fits-all' approach * * * is not viable because it does not account for regional and city-specific factors that have been made evident in the disparity of preference study data * * *. It is well known, for example, that the level of light extinction to which people in different areas of the country are accustomed, as well as the urban setting, are the primary factors that affect a person's visual perception of an urban vista. Thus, the degree to which extinction threshold can be related to human welfare is inevitably regionally-dependent. (API, Attachment 2, p. 4)

Some of these commenters argued that because acceptable visual air quality is regionally dependent, it would be more appropriate to develop distinct visibility standards at the state or local level. Others pointed out that areas which lack ''important visibility vistas'' might not need standards at all, since flat areas without significant terrain have a limited maximum visual range (NEDA/CAP, p. 3).

Other commenters stated that due to regionally varying factors, such as relative humidity, it is not possible to select a single level for a national standard to protect visibility across the United States. In particular, these commenters pointed to differences between Eastern and Western areas, arguing that a single national standard could not offer the appropriate degree of protection in locations with distinct characteristics. For example:

> [T]he proposed method falls short because it is not temporally or geographically representative enough to have any meaning * * *. The uncertainty evidenced in these studies and the non-uniformity between the western and eastern vistas makes it impossible at this time to set an acceptable light extinction value that would appropriately address visibility concerns in non-Class I areas. (New York DOH/DEC, pp. 5–6)

The EPA agrees that the preference curves and the 50 percent dv levels are separate and distinct data points representing four different VAQ preference curves for four unique urban scenes. However, the EPA does not consider the fact that the four curves are distinct as a weakness of the approach or a reason that the results cannot be compared. In addition, the EPA does not agree that the study results necessarily support a conclusion that preferences are regionally dependent. In particular, the EPA notes that the results of Smith and Howell (2009) which show that participants in Houston and Washington, DC did not have significantly different views on acceptable air quality in Washington, DC, provide limited support for the conclusion that people's preferences differ less because of where they live and more because of the scene they are viewing.

On the other hand, the existing literature indicates that people's preferences for VAQ depend in large part on the characteristics and sensitivity of the scene being viewed. The EPA understands there is a wide variety or range of urban scenes within the United States. These sensitive urban scenes include those with natural vistas such as the Colorado Rocky Mountains as well as those with iconic man-made urban structures like the Washington Monument. The EPA believes that the scenes presented in the four urban areas

include important types of sensitive valued urban scenes and therefore, when considered together, can inform the selection of a level of acceptable urban VAQ at the national scale, taking into account the variation across the country evidenced in the studies. This is discussed further in the next section, below.

The EPA does agree with commenters that there are regionally varying factors that are important to take into account when setting a national standard for visibility protection. Section VI.A above regarding the history of the secondary PM NAAQS review discusses the evolution of the EPA's understanding regarding the regional differences in PM concentrations, relative humidity and other factors. As a result, the current review has gone to great lengths to address these factors, leading to the EPA's proposal to use the IMPROVE algorithm to calculate light extinction in order to take into account the varying effects of relative humidity and speciated PM. While this approach does not result in a uniform level of ambient $PM_{2.5}$, it does ensure a nationally uniform level of visibility protection. The EPA refers the reader to other sections of the final rule, including sections VI.B.1.a, VI.B.1.c, VI.C.1.b and VI.C.1.f, and the Response to Comments document for a more detailed response as to how it is taking these variables into account.

ii. Specific Comments on Level

The EPA received relatively few comments endorsing a specific level for a distinct secondary standard for visibility. In general, commenters who opposed setting a distinct secondary standard at this time did not address the question of what level would be appropriate if the EPA were to set a distinct secondary standard for visibility; similarly, commenters who supported adopting a distinct secondary standard at this time generally did not recommend a specific level. However, a few commenters did provide comments in support of a specific level or range of levels, with some commenters advocating standards at the upper end of the range of proposed levels (i.e., 30 dv), while others supported levels below the lower end of the proposed range (i.e., below 28 dv).

As discussed above, a large number of commenters argued that the currently available data are insufficient to determine what constitutes a standard that would be neither more nor less protective than necessary and that no standard should be set at this time. These commenters pointed to the limitations and uncertainties in the preference studies discussed above as the basis for this claim. These commenters pointed to significant variation in the results of the preference studies in support of their arguments that the studies should not be used to derive a level for a distinct secondary standard for visibility. For example, one consultant cited by several industry commenters argued that the proposed level of 28 or 30 dv did not reflect the substantial difference in visibility preferences between the East and the West reflected in the preference studies (UARG, Attachment 2, p. 11), and that it did not reflect the full range of preferences (i.e., potential 50 percent acceptability levels) likely to exist nationwide (UARG, Attachment 2, p. 19). This commenter further objected to the EPA's proposal for a level of 28 or 30 dv on the grounds that the EPA had inaccurately adjusted 4-hour values into 24-hour values. Based on his analysis, the consultant concluded that ''a range of adjusted values from 28 to 32 dv is needed'' to account for the majority of the spread between the 4-hour vs. 24-hour equivalent values at the upper end of the distribution of values.

A number of commenters questioned whether the proposed range of levels was appropriate. One industry commenter claimed that the EPA had not explicitly justified why a standard within the proposed range was requisite, stating that ''EPA makes no attempt to explain how the proposed level of the standard is neither lower nor higher than necessary to protect public welfare'' (NSSGA, p. 15). Arizona DEQ noted that since the proposed calculated light extinction indicator excluded coarse particles and Rayleigh scattering, the proposed levels of 28 or 30 dv were inconsistent with the visibility preference studies, which considered total light extinction. Noting these perceived problems with the proposed range of levels, a few commenters noted that if the EPA were to set a distinct secondary standard, the level should be set no lower than 30 dv, ''to account for inconsistent value judgments, a great deal of spatial and temporal variability, and a very high level of uncertainty'' (Texas CEQ, p. 7).

In contrast, some commenters supporting the EPA's proposal for a distinct secondary standard for visibility stated that the proposed range of levels from 28–30 dv was insufficiently protective based on a 24-hour averaging time, and recommended a lower level for the visibility index standard. These commenters expressed the view that the proposed levels of 28 or 30 dv represented neither adequate surrogates for equivalent 4-hour values, as the EPA claimed, nor sufficiently protective levels based on recent air quality data. Several commenters stated that the EPA's own analyses suggested that a standard set at a level of 28 or 30 dv was insufficiently protective based on a 24-hour averaging time. One commenter emphasized that the Policy Assessment had indicated a level between 25–28 dv was appropriate for a standard calculated on a 24-hour average, and encouraged the EPA to adopt a standard level of 25 dv. Several environmental groups provided comments stating that a 24-hour average would underestimate a 4-hour value by 13–42 percent and certain areas of the country—particularly the Northeast—would be affected disproportionately. These commenters suggested that a 24-hour $PM_{2.5}$ visibility index standard should be set at a level of 18.6–20 dv. The Department of the Interior pointed to recent air quality data indicating that visibility on the 20% worst days in several large metropolitan areas, including Birmingham, Fresno, New York City, Phoenix, and Washington, DC was below 29 dv. While noting that these calculations were based on IMPROVE calculations which include contributions from coarse PM mass, DOI expressed the view that the proposed level of 28 to 30 dv would not provide adequate visibility protection compared to the current 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ and recommended that the standard be set at a level of 25 dv consistent with the results of the Phoenix visibility preference study.

In contrast, the states of Arizona and Colorado submitted comments arguing that the visibility preference studies conducted in Phoenix and Denver, respectively, were designed to address a specific local problem and that the results of these studies were not an appropriate basis for selecting the level of a national standard. For example, Arizona DEQ noted:

> The cited studies were conducted considering total light extinction; including extinction resulting from particulate matter and Rayleigh scattering. Visibility impairment due to coarse particulate matter can be an important contributor in Arizona, specifically in the Phoenix area where ongoing measurements have been made. Therefore, ADEQ believes that the proposed levels of the secondary visibility standard are inconsistent with applicable urban studies. (Arizona DEQ, p. 2)

Similarly, the Colorado Department of Public Health and the Environment noted that the Denver visibility standard was designed to address ''brown clouds'', i.e., strong inversions that occur in the Denver metropolitan area, and that this standard ''is based on a

specific view of Denver'' associated with particular sight paths and direct measurement methods. The commenter stated that this standard ''is applicable only to this location,'' and that these limitations make it potentially unsuitable for application as ''a national secondary standard, particularly a proposed standard that does not use a direct measurement method'' (Colorado DPHE, p. 2).

While acknowledging the uncertainties and limitations associated with the visibility preference studies as discussed above, the EPA continues to conclude, as did CASAC, that the preference studies are appropriate to use as the basis for selecting a target level of protection from visibility impairment. However, the EPA agrees with commenters who emphasize the high degree of variability in visibility conditions and the potential variability in visibility preferences across different parts of the country. In light of the associated uncertainty, as noted in the proposal, the Administrator judged it appropriate to establish a target level of protection equivalent to the upper end of the range of Candidate Protection Levels (CPLs) identified in the Policy Assessment and generally supported by CASAC. Thus, the EPA proposed to set a 24-hour visibility index standard that would provide protection equivalent to the protection afforded by a 4-hour standard set at a level of 30 dv. In light of the comments received on the proposal, in particular comments emphasizing the uncertainty and variability in the results of the public preference studies, the EPA continues to conclude that this approach is warranted, and that it is appropriate to set a target level of protection equivalent to the protection that would be afforded by a 4-hour, 30 dv visibility index standard.

Moreover, the EPA disagrees with commenters who argued that the EPA's approach for translating 4-hour CPLs into equivalent 24-hour values was inappropriate. In adjusting 4-hour values for purposes of defining an appropriate level for a 24-hour standard, the EPA noted at the time of proposal that there were multiple approaches for estimating generally equivalent levels on a city-specific or national basis. While expressing the view that it was appropriate to consider the two approaches with the highest r^2 values (Approaches A and B in Appendix G of the Policy Assessment),[191] which used regressions of 90th percentile light extinction values, the EPA determined it would also be appropriate to consider the city-specific estimates resulting from Approaches C and E which showed greater variability than the aggregated estimates. Approaches C and E generated a range of city-specific estimates of generally equivalent 24-hour levels that encompassed the range of levels considered appropriate for 4-hour CPLs, including the CPL of 30 dv at the upper end of that range. This information provided support for using the same CPL for a 24-hour standard as for a 4-hour standard, since no single approach could generate an equivalent 24-hour standard level in each urban area for each CPL. The EPA continues to conclude, as it did at the time of proposal, that using an unadjusted 4-hour CPL for purposes of establishing a target level of protection for a 24-hour standard is appropriate because this approach places more emphasis on the relatively high degree of spatial and temporal variability in relative humidity and fine particle composition observed in urban areas across the country, consistent with EPA's reanalysis discussed below.

The EPA has conducted a reanalysis (Frank *et al.,* 2012b) of the relationships between estimated 24-hour and 4-hour visibility impairment based on the variety of metrics discussed in Appendix G of the Policy Assessment. The reanalysis has more appropriately considered the uncertainty of the calculated 4-hour values. The revised analysis shows that the 24-hour equivalent level is generally closer to the 4-hour value at the upper end of the range of CPLs than originally estimated, as can be seen in the results for Approaches B, C, and D.[192] For example, the reanalysis indicates that Approach B yields an adjusted 24-hour CPL of 29 dv[193] as generally being equivalent to a 4-hour CPL of 30 dv, while Approach C yields a 24-hour equivalent CPL of 29 dv averaged across cities and a range of city-specific values from 25–36 dv.[194] [195] Not only are the 90th percentile and pooled average values closer to the 4-hour CPL of 30 dv, the range of city-specific results shows a wider spread that clearly encompasses the unadjusted 4-hour value of 30 dv near the midpoint of the city-specific range. This provides support for concluding that the EPA's approach to translating of 4-hour CPLs into equivalent 24-hour values was appropriate, and that it is appropriate to use unadjusted 4-hour values for purposes of selecting a level for a standard based on a 24-hour averaging time.[196]

Moreover, the EPA disagrees with commenters who argue that the currently available evidence is sufficient to justify establishing a target level of protection at 25 dv or below. The EPA recognizes that 25 dv represents the middle of the range of 50 percent acceptability levels from the 4 cities studied, and represents the 50 percent acceptability level from the Phoenix study, which the Agency has acknowledged as the best of the four studies in terms of having the least noise in the preference study results and the most representative selection of participants. The EPA also notes the caveats discussed in the proposal regarding whether it would be appropriate to interpret results from the western studies as generally representative of a broader range of scenic vistas in urban areas across the country. The Policy Assessment noted significant differences in the

[191] In particular, EPA staff expressed a preference for Approach B in the Policy Assessment. However, in light of the additional information provided by the other approaches explored in Appendix G of the Policy Assessment and the reanalysis in Frank, *et al.* (2012b), the EPA judges it more appropriate to consider the range of values resulting from all five analytical approaches for purposes of informing decisions about the equivalent level of a 24-hour standard.

[192] Approach E as presented in the Policy Assessment is based on the median values for each city; these results are not affected by the regression analyses. Therefore, Approach E was not included in the reanalysis, and the results remain unchanged from those reported in the corrected Table G–6 as reported in Frank, *et al.,* 2012b.

[193] In Appendix G of the Policy Assessment, a 24-hour adjusted CPL of 28 dv was estimated to be equivalent to a 4-hour value of 30 dv under Approach B (annual 90th percentile values regression).

[194] In Appendix G of the Policy Assessment, under Approach C (all-days city-specific regression), a 24-hour adjusted CPL of 27 dv was estimated to be equivalent to a 4-hour CPL of 30 dv when averaged across cities, while city-specific values were estimated to range from 24–30 dv.

[195] In the reanalysis, Approach D (all days pooled regression) generated results of 28 dv for the 24-hour CPL equivalent to a 4-hour value of 30 dv as compared to a value of 27 dv in the original analysis described in Appendix G.

[196] The analysis in Appendix G of the Policy Assessment used the 4-hour light extinction value treated as the independent (x-axis) variable in an ordinary least squares regression. The EPA now concludes that this regression approach was not the most appropriate approach because that variable has error and in fact may be more uncertain than the calculated 24-hour extinction values. The Frank et al. (2012b) reanalysis uses an orthogonal regression instead of ordinary least squares regression and results in slopes closer to the 1:1 line for all the results, particularly for Dallas, TX. Furthermore, consistent with the EPA's conclusion that a higher multiplier for converting OC to OM would be appropriate (see section VI.C.1.b.ii above), the reanalysis substitutes a 1.6 multiplier for converting OC to OM in the calculation of 24-hour values instead of the value of 1.4 that was used in calculating 24-hour values for Appendix G. The higher multiplier is more consistent with the SANDWICH approach used to calculate the 4-hour values found in Appendix G. See Frank et al. (2012b) for a more detailed explanation.

characteristics of the urban scenes used in each study, with western urban visibility preference study scenes including mountains in the background and objects at greater distances, while scenes in the eastern study did not. Since objects at a greater distance have a greater sensitivity to perceived visibility changes as light extinction changes compared to otherwise similar scenes with objects at a shorter range, this likely explains part of the difference between the results of the eastern study and results of the western studies. In the proposal, the EPA noted that the scenic vistas available on a daily basis in many urban areas across the country generally do not have the inherent visual interest or the distance between viewer and object of greatest intrinsic value as in the Denver and Phoenix preference studies. Also, the Agency takes note of the caution expressed by Colorado and Arizona about using the results of the Denver and Phoenix preference studies, which were aimed at addressing specific local visibility problems, to inform the choice of level for a national standard. Therefore, the Agency considers it reasonable to conclude, especially in light of the significant uncertainties, that it is appropriate to place less weight on the western preference results and that the high CPL value (30 dv) that is based on the eastern preference results is likely to be more representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. These areas would include the middle of the country and many areas in the eastern U.S., as well as some western areas. As a result, the EPA concludes that it is more appropriate to establish a target level of protection at the upper end of the range of 24-hour CPLs considered, recognizing that no one level will be ''correct'' for every urban area in the country.

In considering the upper end of this range, the EPA must identify a target level of protection that is considered requisite to protect public welfare from a national perspective, recognizing that the same target level would apply in all locations. Making this judgment requires a balancing of the risks to the public welfare and the substantial uncertainties surrounding appropriate levels of visibility protection. As acknowledged in the proposal, the EPA recognizes that setting a target level of protection for a 24-hour standard at 30 dv would reflect a judgment that the current substantial degrees of variability and uncertainty inherent in the public preference studies should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain. Also, a 24-hour visibility index at a level of 30 dv would reflect recognition that there is considerable spatial and temporal variability in the key factors that determine the value of the $PM_{2.5}$ visibility index in any given urban area, such that there is a relatively high degree of uncertainty as to the most appropriate approach to use in selecting a 24-hour standard level that would be generally equivalent to a specific 4-hour standard level. In light of these uncertainties, the EPA continues to believe that it is appropriate to establish a target level of protection for visual air quality of 30 dv, averaged over 24-hours, with a form as discussed above.

In reaching this conclusion, the EPA notes that any national ambient air quality standard for visibility would be designed to work in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in all areas of the country, including urban, non-urban, and Federal Class I areas. While the Regional Haze Program is focused on improving visibility in Federal Class I areas and a secondary visibility index NAAQS would focus on protecting visual air quality principally in urban areas, both programs could be expected to provide benefits in surrounding areas. In addition, the development of local programs, such as those in Denver and Phoenix, can continue to be an effective and appropriate approach to provide additional protection, beyond that afforded by a national standard, for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas. With regard to comments from the Department of Interior noting that many large metropolitan areas have 24-hour IMPROVE values below 30 dv on the worst 20 percent of days already, the EPA notes that the purpose of establishing NAAQS is to ensure adequate protection of public welfare everywhere, not to mandate continuous improvements in areas that may already be relatively clean. In fact, the evidence from the IMPROVE program that many urban areas have total 24-hour PM-related light extinction below 29 dv on the 20 percent worst visibility days suggests that many areas have relatively good visual air quality already.

f. Need for a Distinct Secondary Standard To Protect Visibility

Numerous commenters questioned whether a distinct secondary standard for visibility is necessary in light of the analysis described in section VI.B.1.c.vii above (Kelly *et al.,* 2012a) which indicated that a 24-hour mass-based $PM_{2.5}$ standard of 35 μg/m³ would protect against visibility impacts exceeding the range of levels considered in the proposal (28–30 dv). While this analysis was conducted in support of proposed implementation requirements for a distinct secondary standard (specifically, the modeling demonstrations that would be required under the PSD program), the second prong of the analysis showed that within the range of levels proposed by the EPA for the visibility index NAAQS (28–30 dv), the 24-hour $PM_{2.5}$ standard of 35 μg/m³ would generally be controlling. Kelly *et al.* (2012a) concluded that ''overall, design values based on 2008–2010 data suggest that counties that attain 24-hour $PM_{2.5}$ NAAQS level of 35 μg/m³ would attain the proposed secondary $PM_{2.5}$ visibility index NAAQS level of 30 dv and generally attain the level of 28 dv'' (pp. 17–18).

Citing this conclusion, many state and local agencies and industry commenters argued that a visibility index standard in the range proposed (28–30 dv) would provide no additional protection beyond that afforded by the existing secondary 24-hour $PM_{2.5}$ NAAQS, and therefore no distinct visibility standard was necessary. These commenters advocated retaining the current 24-hour $PM_{2.5}$ mass-based standard to protect against visibility effects. ''Since the 24-hour $PM_{2.5}$ standard already protects the welfare the 24-hour $PM_{2.5}$ visibility standard is designed to protect, the new standard is duplicative and unnecessary'' (South Dakota DENR, p. 2). Furthermore, a number of state commenters objected to the additional resource burden associated with implementing a standard which had, in their view, no practical effect: ''If the 24-hour $PM_{2.5}$ mass standard has the same effect as the visibility standard, crafting complex regulations to implement another standard seems redundant'' (South Carolina DHEC, p. 3). Other states agreed: ''A $PM_{2.5}$-related Visibility Index appears redundant since the benefits achieved from the current primary and secondary annual and 24-hour $PM_{2.5}$ standards already provide reductions that would improve visibility. Establishing a new $PM_{2.5}$ secondary standard for visibility would be an additional complication and burden to the states that is not warranted'' (Indiana DEM, p. 5).

In addition, several commenters submitted additional analyses supporting their position that a 35 μg/m³ 24-hour $PM_{2.5}$ standard would provide at least equivalent protection to

a distinct 24-hour visibility standard within the range of levels proposed (API, Attachment 2, p. 8 and Attachment 3, p. 1).

In responding to these comments stating that a distinct visibility standard is not needed, the EPA notes as an initial matter that the Administrator provisionally concluded at the time of proposal that the current PM standards were not sufficiently protective of visual air quality, and that consideration should be given to an alternative secondary standard that would provide additional protection against PM-related visibility impairment, especially in urban areas. This provisional conclusion was based on the results of public preference surveys on the acceptability of varying degrees of visibility impairment in urban areas, analyses of the number of days on which peak 1-hour or 4-hour light extinction values were estimated to exceed a range of CPLs under conditions simulated to just meet the current standards, and the advice of CASAC. The Administrator also noted that the current indicator of $PM_{2.5}$ mass, in conjunction with the current 24-hour and annual averaging times, was not well suited for purposes of protecting visibility, since it does not incorporate species composition or relative humidity, both of which play a central role in determining the impact of ambient PM on visibility. Taking into account the advice of CASAC and the court's remand of the current secondary $PM_{2.5}$ standards, the Administrator provisionally concluded that the current secondary standards were neither sufficiently protective nor suitably structured to provide an appropriate degree of public welfare protection from PM-related visibility impairment. As a result, the EPA proposed a new, distinct secondary standard that was designed to address these deficiencies.

The EPA notes that in critiquing the proposed secondary standard, commenters generally did not advocate that the form of the existing mass-based $PM_{2.5}$ standards was better suited *scientifically* to the task of protecting against visibility impairment. Rather, the commenters' position that a distinct secondary standard was not needed for purposes of protecting visibility was based almost entirely on the relative *degree of protection* likely to be afforded by the existing standards (in particular, the existing 24-hour $PM_{2.5}$ standard) as compared to the proposed visibility index, along with the relatively large uncertainties associated with the latter. Thus, for all the reasons discussed in the proposal with regard to the scientific appropriateness of an indicator that takes into account both species composition and relative humidity, the EPA continues to conclude that the proposed standard based on a visibility index would be appropriate scientifically to provide targeted protection of visibility, since it would provide a measure of PM-related light extinction that directly takes into account the factors (i.e., species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in the ambient air and PM-related visibility impairment.

Furthermore, the EPA disagrees with commenters who stated that implementation concerns, in particular the additional resource burden associated with implementing a distinct secondary standard, should alter the Agency's decision making with regard to a standard to protect visibility. The EPA may not take the costs of implementation into account in setting or revising the NAAQS.

However, in light of the results of the Kelly *et al.* (2012a) analysis and the views expressed by commenters on the implications of this analysis for conclusions regarding the adequacy of the current secondary 24-hour $PM_{2.5}$ standard, the EPA has reconsidered some of the conclusions drawn at the time of proposal, in particular with regard to the degree of protection that would be provided by the current secondary standard. Based on a review of comments related to indicator, averaging time, form and level, the Agency has concluded that (as described in sections VI.C.1b-e above) a standard defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction), a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, and a level of 30 dv, would provide sufficient but not more than necessary protection of the public welfare with regard to visual air quality. Having identified this target level of protection, the EPA is now in a position to compare it specifically to the existing secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ for purposes of determining whether it would provide more, the same, or less protection from visibility impairment. The EPA must consider both whether the existing secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ is sufficient (i.e. not under-protective) and whether it is more stringent than necessary (i.e. over-protective).

With regard to the degree to which the existing secondary 24-hour $PM_{2.5}$ standard provides sufficient but not more than necessary protection for visibility, the EPA first notes that the kind of area-specific analysis conducted in Kelly *et al.* (2012a) is essential for addressing the court remand of the 2006 secondary standards. In the case of the 2006 secondary standards, the EPA had argued that the 35 $\mu g/m^3$ 24-hour $PM_{2.5}$ standard was requisite because one part of the proposed range for a distinct secondary standard the Agency had considered would affect the attainment status of a somewhat fewer counties than the 35 $\mu g/m^3$ 24-hour $PM_{2.5}$ standard. The court rejected this kind of rough balancing, finding that the EPA's equivalency analysis based on percentages of counties demonstrated nothing about the relative protection offered by the different standards. Based on this, an area-by-area evaluation of the relative degree of protection offered by different standards should be conducted to the extent air quality data is available.

Kelly *et al.* (2012a) performed such an evaluation. Based on 2008–2010 data, there are no areas that would have exceeded a 30 dv, 24-hour visibility index standard that would not also have exceeded a 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$. Stated another way, all areas that met the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would have had visual air quality at least as good as 30 dv (24-hour average, based on 90th percentile form averaged over 3 years). The Kelly (2012a) analysis also showed that for some areas, particularly in the West, areas that would have met a 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would have had visual air quality better than 30 dv for the $PM_{2.5}$ visibility index standard, and that at sites that violated both the 24-hour level and the visibility index 30 dv level, the visibility index level of 30 dv would likely be attained if $PM_{2.5}$ concentrations were reduced such that the 24-hour $PM_{2.5}$ level of 35 $\mu g/m^3$ was attained.

The EPA has conducted a reanalysis (Kelly *et al.,* 2012b) to update the area-by-area analysis in the original Kelly *et al.* (2012a) analysis in three respects. First, noting that the original Kelly *at al.* (2012a) analysis used a 1.4 multiplier to convert OC to OM at those monitors not using the new CSN monitoring protocol, the EPA recalculated the visibility index design values for 2008–2010 using a higher multiplier for converting OC to OM at monitors not already using the new CSN monitoring protocol SANDWICH approach, consistent with the Agency's view that it is more appropriate to use a multiplier of 1.6 at such monitors as compared to 1.4, as described in section VI.C.1.a.ii,

above.[197] The recomputed visibility design index values for 2008–2010 show the same overall relationship to 24-hour $PM_{2.5}$ design values as presented in Kelly *et al.,* 2012a.

Second, the EPA repeated the calculations comparing visibility index design values with 24-hour $PM_{2.5}$ design values using 2009–2011 data, the most recent three years of air quality information currently available.[198] Third, the EPA modified the area-by-area evaluation to ensure consistency with the data completeness criteria of 40 CFR part 50, Appendix N, including the removal of data approved by EPA as exceptional events, for the current 24-hour $PM_{2.5}$ standard and the proposed visibility index standard.

The results of this reanalysis, as presented in Kelly *et al.* (2012b), show a similar pattern to that described in the original Kelly memo. Specifically, the analysis indicates that there were no areas with visibility impairment above 30 dv that did not also exceed the 24-hour $PM_{2.5}$ standard of 35 μg/m^3. The updated memo concludes that the results for 2009–2011 corroborate the findings for 2008–2010.

Based on these analyses (Kelly *et al.,* 2012a; 2012b), the EPA concludes with a high degree of confidence that having air quality that meets the 24-hour $PM_{2.5}$ standard of 35 μg/m^3 would be sufficient to ensure areas would not exceed 30 dv. The EPA notes that this conclusion from Kelly *et al.* (2012a) is supported by two analyses submitted by industry commenters (API, Attachments 2 and 3).

At the time of proposal, the EPA had reached a different conclusion, specifically that the 35 μg/m^3 24-hour $PM_{2.5}$ standard was not sufficiently protective. This conclusion was based, in part, on the analyses conducted for the Visibility Assessment and Policy Assessment regarding 1- to 4-hour peak light extinction values based on 2007–2009 data. For the reasons outlined above in sections VI.B.1.c and VI.C.1.c, the EPA originally focused on hourly or sub-daily timeframes for evaluating visibility conditions. However, data quality concerns effectively precluded adoption of a 1-hour or sub-daily averaging time in this review, and ultimately the EPA has concluded that a 24-hour averaging time can serve as an appropriate surrogate. In reaching this conclusion, the EPA has recognized that adopting a 24-hour averaging time will likely smooth out some of the hour-by-hour variability in visibility index values, and will effectively reduce peak values by averaging them together with other hours. In concluding it is appropriate to adopt a 24-hour averaging time, which limits the impact of hour-specific influences, the Agency is now placing less weight on the results of the 1-hour and 4-hour analyses presented in the Visibility Assessment and the Policy Assessment which focused on identifying the percent of days with peak hourly light extinction above various CPLs. In light of the Agency's conclusion that a 24-hour averaging time would be appropriate, the Agency has determined to place more weight on analyses of visibility conditions over a 24-hour time period, especially the results in Kelly *et al.* (2012a and 2012b). In addition, the EPA notes that the Kelly *et al.* analyses reflects updated air quality information from more recent years of data (2008–2010 for Kelly *et al.,* 2012a; 2009–2011 for Kelly *et al.* 2012b) as compared to the air quality information used in the Visibility Assessment and Policy Assessment.

In light of all of these considerations, including the results of the Kelly *et al.* (2012a; 2012b) analyses, and the supporting comments provided by a broad range of public commenters, the EPA now concludes that the 24-hour $PM_{2.5}$ standard of 35 μg/m^3 provides sufficient protection in all areas against the effects of visibility impairment. The EPA concludes that the existing 24-hour $PM_{2.5}$ standard would provide *at least* the target level of protection for visual air quality defined by a visibility index set at 30 dv, as described above, which the EPA judges appropriate.

However, the EPA also recognizes that it is important to evaluate whether such a standard would be over-protective (i.e. more stringent than necessary to protect public welfare). The analyses presented in Kelly *et al.* (2012a; 2012b) indicates that the 24-hour $PM_{2.5}$ standard of 35 μg/m^3 would achieve *more than* the target level of protection of visual air quality (30 dv) in some areas. That is, when meeting a mass-based standard of 35 μg/m^3, some areas would have levels of PM-related visibility impairment far below 30 dv. Thus, when considered by itself and without consideration of the secondary standards adopted for purposes of non-visibility welfare effects, the 24-hour $PM_{2.5}$ standard of 35 μg/m^3 would be over-protective of visibility in some areas. However, it is important to note that as long as the current secondary 24-hour $PM_{2.5}$ standard of 35 μg/m^3 remains in effect, this overprotection for visibility would occur, regardless of whether a distinct secondary standard based on a visibility index set at 30 dv were adopted. These issues are discussed more fully in section VI.D, which outlines the Administrator's final conclusions on the secondary PM standards, below.

g. Legal Issues

Some commenters opposed the proposal to establish a distinct secondary standard that would be defined in terms of a $PM_{2.5}$ visibility index. The proposed standard would use measured $PM_{2.5}$ mass concentration, in combination with speciated $PM_{2.5}$ mass concentration and relative humidity data, to calculate $PM_{2.5}$ light extinction, translated to the deciview (dv) scale. The standard would also be defined in terms of a specified averaging time and form, and a level for the $PM_{2.5}$ visibility index set at one of two options—either 30 dv or 28 dv. The commenters argued that the entire approach proposed by the EPA is inconsistent with the requirements of CAA section 109(b). They pointed to a number of different aspects of the proposal which in their view made it incompatible with the CAA. For example, the Utility Air Resources Group (UARG) stated:

> In the past, EPA has always used a measure of PM mass as the indicator for both primary and secondary PM NAAQS. Such a standard is, as a general matter, consistent with the directive in the CAA that the NAAQS ''specify a level of air quality'' and targets for control the listed criteria air pollutant. CAA § 109(b)(2). The standard contained in EPA's proposed rule does neither of these things. Instead, it would (1) regulate relative humidity, which is not a criteria pollutant; (2) fail to ''specify a level of air quality'' as required by section 109(b)(2) of the CAA; and (3) result in a standard necessitating nationally variable PM concentrations instead of a standard establishing a nationally uniform, minimally acceptable PM concentration. (UARG, p. 22–23)

Other commenters raised similar or related issues, arguing that the EPA improperly set a visibility standard, and not a $PM_{2.5}$ standard, and that NAAQS can only be set in terms of a level or concentration of the air pollutant. Commenters also argued that an endangerment finding and air quality criteria would be needed before the EPA could set a standard based on PM components. Each of these comments is discussed below.

As an initial matter, the commenters argued that the proposed standard is unlawful because it is ''not a $PM_{2.5}$ standard at all, but rather a visibility standard, and visibility is neither an air pollutant nor a criteria pollutant for which a NAAQS may be promulgated''

[197] Some of the OC measurements were produced with CSN's newer monitoring protocol and did not require a change in the computed OM.

[198] The 2011 air quality data were not yet available at the time of proposal.

(NMA/NCBA, p. 21). According to these commenters, the CAA requires that NAAQS be established as limits on the concentration of an air pollutant in ambient air, not limits on the ''identifiable effects'' caused by that air pollutant. These commenters claimed that reduced visibility due to light extinction is not an air pollutant but instead is an effect, noting that ''the Act's definition of 'air pollutant' speaks in terms of specific substances or matter in the ambient air'' (NSSGA, p. 8). The commenters pointed to the use of the term ''air pollutant'' in sections 109(a)(1)(A) and (b)(2) as support for their argument, as these provisions refer to setting standards for the ''air pollutant'' to address the effects associated with the presence of the air pollutant in the ambient air. They likewise pointed to section 108(a)(2)'s reference to the presence of the air pollutant in the ambient air. Since reduced visibility is not an air pollutant, they argue the EPA cannot set a NAAQS that is a standard for visibility. They argue that the proposed secondary standard it is not a $PM_{2.5}$ standard as it does not limit the concentration of $PM_{2.5}$ or any other fraction of particulate matter in the ambient air and therefore is not an ''ambient air quality standard'' for any pollutant.

One commenter argued that the EPA is required to ''specify a level of air quality'' under section 109(b)(2), which Congress intended as an acceptable concentration level of the air pollutant in the ambient air, noting that specification of acceptable visibility conditions is not the same as an acceptable air pollution concentration level. Citing *American Farm Bureau* v. *EPA,* 559 F.3d at 516, one commenter claimed that the court had affirmed that ''the NAAQS—whether primary or secondary—is a mass-based standard'' (Nevada DEP, p. 5). Commenters also refer to the legislative history of the 1970 amendments, referring to NAAQS as setting the ''maximum permissible ambient air level'' for an air pollutant. The commenters argue that the proposed standard is improper because it does not limit the concentration of $PM_{2.5}$ or any fraction of PM in ambient air, but improperly sets a limit on visibility effects.

With regard to humidity, these commenters argued that the proposed standard improperly regulates relative humidity because it is included in the calculation to determine the value of the visibility index. According to these commenters, the CAA allows the EPA to control criteria air pollutants through the NAAQS program, but not other various substances. The commenters stated that the EPA recognized this in the last review, treating humidity as a confounding factor and considering addressing it by measuring $PM_{2.5}$ mass-based concentration over the midday hours, when humidity would have the least effect. This would target the effects caused by PM, and not by humidity. Referring to *American Farm Bureau* v. *EPA,* 559 F.3d 512, 528 (DC Cir. 2009) and 77 FR at 38979 n.153. UARG contested the proposed calculated visibility index as it does not approach relative humidity as a confounding factor but instead ''embraces it and treats it as if it were a PM effect'' (UARG p. 24).

The commenters also stated that the use of a calculated visibility index, and the failure to exclude the effects of humidity, would result in acceptable PM concentrations that vary across the nation. These commenters claimed that such a standard is inconsistent with the requirements of the CAA because the proposed approach fails to establish a nationally uniform PM concentration standard. For example, API argued that the proposed visibility index approach is ''essentially specifying levels—not a level—of air quality'' (API, p. 29). UARG agreed, and stated that the Act ''requires that criteria pollutant concentrations *throughout the nation* reach, at the least, a *single,* specified ambient concentration level'' (UARG, p. 25, emphasis in original). The commenters argue that a $PM_{2.5}$ visibility index standard cannot provide equal protection nationwide due to geographic variation in key factors such as relative humidity that affect level of particles allowed in different areas. The commenters noted that establishing a single national level for the $PM_{2.5}$ visibility index would necessarily result in unequal acceptable $PM_{2.5}$ levels in different areas of the country, with lowest allowable $PM_{2.5}$ levels in urban areas in the Southeast and highest allowable levels in the arid West. UARG recognized that under section 108 the air quality criteria are to ''address those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant,'' but stated that while section 108 ''allows'' this, it has no bearing on this issue. Instead, the commenter stated that the EPA may take such information into account in setting a permissible concentration of the pollutant that is uniform and national (UARG, p. 25).

In addition, some commenters opposed to the proposed distinct secondary standard argued that in order to base a standard on measured levels of several speciated substances, the EPA must first make an endangerment finding and issue air quality criteria for each of the speciated substances included in the calculation of $PM_{2.5}$ light extinction. According to these commenters, ''EPA cannot use NAAQS to indirectly regulate multiple substances which are not criteria pollutants under the guise of establishing a visibility standard'' (NMA/NCBA, p. 21). Noting that air quality criteria for particulate matter were issued in 1969, NMA/NCBA argued that the 1969 Criteria Document ''did not establish air quality criteria for individual constituents that occur in particle form, instead it established criteria for particulate matter as a whole'' (p. 27). In light of the fact that criteria have never been issued for ''individual speciated components of particulate matter,'' these commenters argued, ''if EPA wishes to promulgate a rule such as its secondary visibility NAAQS, it first must make a finding that the speciated components listed in Appendix N endanger public health or welfare and then issue an air quality criteria document for those components'' (NMA/NCBA, p. 29). According to these commenters, the approach the EPA adopted in promulgating a NAAQS for lead supports this view:

> When EPA promulgated a NAAQS for lead, an individual substance in particle form, it did not assert that an endangerment finding or criteria document for lead was unnecessary because lead was already covered by the PM Criteria Document. Instead, EPA complied with the Section 108 and 109 NAAQS prerequisites for lead, just as it must do for Appendix N substances if it intends to promulgate a NAAQS for those substances. * * * [In 1976], EPA listed lead as an air pollutant that adversely affected public health or welfare, issued an air quality criteria document for lead, and promulgated a NAAQS for lead. 43 FR 46246 (Oct. 5, 1976). (NMA/NCBA, p. 29)

Finally, UARG argued that the EPA has in the past recognized that the secondary NAAQS is an inappropriate vehicle for regulating PM-related visibility, referring to 62 FR at 38680, including fn 49. UARG claimed the same situation continues, and the EPA has not provided a valid basis for changing this conclusion.

The EPA disagrees with the points raised by these commenters. While the EPA is not adopting the proposed secondary standard, as explained below, this decision is not based on concern over the EPA's authority to adopt a secondary standard such as the one proposed.

The proposed distinct secondary standard is a standard for $PM_{2.5}$, and is

not a ''visibility standard.'' The proposed secondary standard is based on the mass concentration of $PM_{2.5}$ in the ambient air. The standard is defined in terms of calculated $PM_{2.5}$ light extinction which is based on the measurement of the mass concentration of ambient $PM_{2.5}$ over a 24-hour period. The measured mass concentration is adjusted based on information on the speciated mass components of the $PM_{2.5}$ and the relative humidity, resulting in a calculated visibility index. The level of the visibility index, combined with the form of the standard and averaging time, identifies whether a level of ambient mass concentration of $PM_{2.5}$ achieves the standard or not. Given any specific mass concentration of ambient $PM_{2.5}$, combined with information on speciation and relative humidity, it can be determined whether the specific mass concentration of ambient $PM_{2.5}$ achieved the NAAQS. Hence, the proposed secondary NAAQS specifies acceptable levels of ambient mass concentration of $PM_{2.5}$.

The combination of indicator, averaging time, form, and level of the proposed NAAQS is designed to provide the appropriate degree of protection from visibility impairment caused by ambient levels of $PM_{2.5}$. It does this by calculating the light extinction associated with ambient concentrations of $PM_{2.5}$ and specifying the level of acceptable $PM_{2.5}$ mass concentration in terms of this calculation. However this does not change the fact that the standard is for the air pollutant $PM_{2.5}$, and defines acceptable ambient levels of this air pollutant. It does not transform the standard into a ''visibility standard'' and not a standard for $PM_{2.5}$. While the commenters had additional concerns over the use of relative humidity in the calculation, and the variation around the country of acceptable mass concentrations, those issues are separate and do not change the fact that the proposed standard defined in terms of calculated $PM_{2.5}$ light extinction is based on measurement of $PM_{2.5}$ concentration in the ambient air, and is a NAAQS for $PM_{2.5}$.

With regard to the contention that section 109(b) limits the EPA to setting a standard that is based on the concentration of the pollutant in the ambient air, we note that the term ''concentration'' typically means some measure of relative content. For example, this would include relative measures such as mass per unit of volume or parts per million. The EPA has often used such metrics to define the NAAQS, largely because the scientific evidence of health or welfare effects supporting the NAAQS typically use such metrics in air pollution studies. For example, the current secondary standards for PM are defined in terms of the concentration of $PM_{2.5}$ and PM_{10} in the ambient air, measured as the dried mass of the particulate matter per unit of air. However section 109(b) does not require that a NAAQS be defined this way.

Sections 109(a) and (b) both use the general term ''air quality'' when discussing the EPA's obligation to set NAAQS. The NAAQS are clearly national ambient ''air quality'' standards under section 109(b), which specifies that the primary NAAQS ''shall be ambient air quality standards'' and the secondary NAAQS ''shall specify a level of air quality.'' Both the primary and secondary NAAQS are to be based on the ''air quality criteria,'' which are to accurately reflect the latest scientific knowledge on the effects on public health and welfare associated with ''the presence of such air pollutant in the ambient air, in varying quantities.'' Section 109(b), 108(a)(2). Congress spoke in broad terms, tasking the EPA with assessing the latest scientific knowledge about the public health and welfare associated with the presence of the pollutant in the air, without limiting this to consideration of only those effects associated with one or more measures of concentration of the air pollutant. Congress referred to any and all effects associated with the presence of the pollutant in the ambient air, not just the effects associated with the concentration of the pollutant in the ambient air. Based on this knowledge, the EPA is required to set standards for the quality of the air that will provide the appropriate degree of protection from these health and welfare effects, without limitation on how to measure or define air quality. While concentration in the air has typically been an appropriate way to set a standard to achieve these requirements, the more general terms used in section 108(a) and 109(b) do not limit the EPA to using concentration as the only way to measure air quality for purposes of setting a NAAQS. The EPA is charged with setting air quality standards, and has the discretion under section 109(b) to choose the metric for defining air quality that is appropriate to address the health or welfare effect at issue.

Congress did refer to ''concentration'' in certain situations. In section 109(c) Congress required the EPA to set a primary NAAQS for NO_2 concentration over 3 hours. This addressed Congress' concern over whether the then current NO_2 standard, which used concentration as a metric, provided adequate protection. Congress also called on CASAC to advise the Administrator on the relative contribution to ''air pollution concentrations'' of natural and anthropogenic sources, under section 109(d)(2)(C)(iii). This information is in addition to the advice CASAC is required to provide concerning appropriate revisions to the ''air quality criteria'' and to the NAAQS under section 109(d)(2)(B).[199] While these provisions refer to ambient concentrations of pollutants, this reflects the EPA's standard practice to date in setting NAAQS, and none of them change or limit the range of discretion provided under section 109(b) in setting NAAQS. They do not change the fact that the EPA is to set ''air quality'' standards, and is not limited to ''air concentration'' standards. The reference in the legislative history to a maximum permissible ambient air level for the pollutant also does not limit the EPA to a level of air pollutant concentration, as compared to a different metric for specifying the level of air quality, if that is judged to be appropriate.

The text of sections 108 and 109 does not support the limited interpretation commenters suggest. Instead these provisions provide the EPA with significant discretion in determining the metric for air quality that is appropriate to achieve the required degree of protection of public welfare. The commenters' interpretation would improperly limit this discretion, interfering with achieving the goals of section 109(b).

For example, in this review the EPA considered whether it would be appropriate to base a secondary NAAQS on direct measurement of the light extinction caused by $PM_{2.5}$. See 77 FR 38890, 38980–1 (June 29, 2012). There are several instrumental methods that directly measure $PM_{2.5}$ light extinction—the amount of light extinction caused by the presence of $PM_{2.5}$ in the ambient air. This is not a measure of the concentration of $PM_{2.5}$ in the air, but a measure of the light extinction caused by $PM_{2.5}$. This is clearly an effect associated with the presence of $PM_{2.5}$ in the ambient air,

[199] In a provision that is not part of the CAA, in 1990 Congress required EPA to request a report from the National Academy of Sciences on the role of secondary national ambient air quality standards, including information on the ''effects on welfare and the environment which are caused by ambient concentrations of pollutants'' listed under section 108, and the ''ambient concentrations of each such pollutant which would be adequate to protect welfare and the environment from such effects.'' Section 817(a) of the CAA Amendments of 1990, Pub. L. 101–549.

and this atmospheric property is directly related to visibility effects. Unlike $PM_{2.5}$ mass concentration, there is a close scientific relationship between directly measured $PM_{2.5}$ light extinction and visibility effects.

It would appear straightforward to say that $PM_{2.5}$ light extinction is a quality of the ambient air, and a secondary NAAQS that specified an acceptable level of $PM_{2.5}$ based on directly measured $PM_{2.5}$ light extinction would be an ''ambient air quality standard'' for the air pollutant that specifies a ''level of air quality'' designed to provide protection against visibility impairment. Unlike directly measured $PM_{2.5}$ light extinction, the mass concentration of $PM_{2.5}$ does not have the same direct relationship to light extinction, and specifying an acceptable level of mass concentration of $PM_{2.5}$ would be a more indirect and less effective way to provide protection from visibility impairment caused by the presence of $PM_{2.5}$ in the ambient air. Under the commenters' interpretation, the EPA would be precluded from specifying a level of air quality in terms of directly measured $PM_{2.5}$ light extinction, the more scientifically appropriate and direct measure of the effect $PM_{2.5}$ has on visibility. Instead the EPA would be limited to the more indirect and less effective specification of a level of concentration of $PM_{2.5}$.

The commenters also objected to the inclusion of relative humidity as an adjustment factor in the calculation of $PM_{2.5}$ light extinction. Contrary to the claims of these commenters, the use of calculated $PM_{2.5}$ light extinction does not regulate relative humidity. The proposed secondary standard would define acceptable levels of ambient $PM_{2.5}$, not acceptable levels of relative humidity. In addition, section 108 explicitly requires that the air quality criteria include information on the atmospheric conditions that can alter the effects of the air pollutant on public health or welfare, and relative humidity certainly has this kind of impact. Section 109(b) requires that the standard be based on the air quality criteria, indicating that this information can and should be taken into account in setting the standard. Including relative humidity as an adjustment factor in the calculation of $PM_{2.5}$ light extinction is a reasonable and straightforward way to use the scientific information in the air quality criteria in establishing a standard to provide protection from visibility impairment.[200]

Some commenters pointed to the EPA's position in the last review, stating that the EPA properly treated relative humidity as a confounding factor, and in this review improperly moves away from that position. See 77 FR at 38979, 71 FR 61144, 61205 (October 17, 2006). In the last review the EPA considered a distinct $PM_{2.5}$ mass-based secondary standard. In that context, limiting the measurement of $PM_{2.5}$ mass concentration to the mid-day hours when relative humidity had the least impact would promote the correlation between measured $PM_{2.5}$ mass concentration and light extinction, which would promote achievement of a relatively consistent degree of visibility protection across the country. However in this rulemaking the proposed calculated $PM_{2.5}$ light extinction standard achieves a consistent degree of visibility protection by directly accounting for humidity, in a scientifically defensible manner. The goal has not changed—achieving the desired degree of protection across the country. What has changed is that calculated $PM_{2.5}$ light extinction is a more direct and scientifically appropriate way to achieve that result.

Finally, it should be made clear that water is not a separate compound from $PM_{2.5}$ that confounds the impact $PM_{2.5}$ has on light extinction. As described in the Integrated Science Assessment, ''PM is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes'' (U.S. EPA, 2009a, p. 1–4). ''Particles composed of water soluble inorganic salts (i.e., ammoniated sulfate, ammonium nitrate, sodium chloride, etc.) are hygroscopic in that they absorb water as a function of relative humidity to form a liquid solution droplet. Aside from the chemical consequences of this water growth, the droplets become larger when relative humidity increases, resulting in increased light scattering. Hence, the same PM dry concentration produces more haze'' (U.S. EPA, 2009a, p. 9–6). Thus water is not a compound that is separate and apart from the particle that acts as an extraneous confounding factor.[201] The effect of relative humidity occurs after the water becomes part of the particle. Certain water soluble salts absorb water and the resulting particle is larger in size and scatters more light, increasing the visibility impact of the particle. But the particle is still a $PM_{2.5}$ particle. The fact that the PM NAAQS traditionally uses a measurement of the dried mass of the particles as the metric for the standard does not change the fact that the particles in the air include liquid droplets and particles that have increased in size because of absorption of water. These ambient $PM_{2.5}$ particles are what is in the air and impacting visibility, not just the dried mass of $PM_{2.5}$ that is measured in the laboratory and is currently used as the indicator for the PM NAAQS. Thus the commenters improperly claimed that the proposed secondary standard regulates water or relative humidity, and not $PM_{2.5}$, when in fact the proposed secondary standard accounts in a scientific manner for the fact that some $PM_{2.5}$ particles are larger in size and have a greater impact on light extinction when the relative humidity increases.

The commenters also raised concerns that a standard based on calculated $PM_{2.5}$ light extinction, compared to a standard based on just $PM_{2.5}$ mass concentration, improperly results in variable levels of acceptable $PM_{2.5}$ mass concentrations across the country. This stems from the adjustments in the calculation for speciated components of $PM_{2.5}$ and relative humidity. According to commenters, this is improper as section 109(b) requires that the NAAQS set a single, specified ambient concentration that is nationally uniform across the country.

As discussed above, the text of section 109(b) does not specify this limitation of a single national acceptable concentration. Instead the secondary NAAQS is to specify a level of air quality that achieves the appropriate degree of protection. The proposed secondary standard would do just that—specify a level of air quality, defined in terms of calculated $PM_{2.5}$ light extinction, that would achieve the desired degree of protection. The fact that this results in varying allowable levels of $PM_{2.5}$ mass concentrations is not inconsistent with the Act. The DC Circuit recently approved such a result. In the last review of the PM_{10} primary NAAQS, the court approved the EPA's choice of an indicator that was designed to allow varying levels of acceptable coarse PM. The court stated that:

> The industry petitioners next argue that the 150 μg/m³ standard for PM_{10} will result in arbitrarily varying levels of coarse PM, and that the agency should instead have used a $PM_{10-2.5}$ indicator. The EPA does not dispute

[200] UARG recognizes these provisions, but argues, as above, that this is limited by the requirement that the EPA set a NAAQS based solely on ambient concentration.

[201] According to the Integrated Science Assessment, ''Confounding is '* * * a confusion of effects. Specifically, the apparent effect of the exposure of interest is distorted because the effect of an extraneous factor is mistaken for or mixed with the actual exposure effect (which may be null)' (Rothman and Greenland, 1998, 086599)'' (U.S. EPA, 2009a, p. 1–16).

that using the PM_{10} indicator will result in coarse PM levels that vary within the limit of 150 μg/m³. As the EPA explains: ''Because the PM_{10} indicator includes both coarse PM ($PM_{10-2.5}$) and fine PM ($PM_{2.5}$), the concentration of $PM_{10-2.5}$ allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. Thus, the level of coarse particles allowed varies depending on the level of fine particles present.'' *Id. at 61,195.*

Although the EPA acknowledges that a PM_{10} indicator will result in varying coarse PM levels, it does not agree that the variance will be arbitrary. The EPA agrees with the industry petitioners that protection from coarse particles should be targeted at urban areas, where coarse particles have been shown to pose the greatest danger. *Id. at 61,194.* But the agency argues that targeting of urban areas is effectively accomplished by using an indicator that permits the varying levels that the industry petitioners challenge. * * * *Id. at 61,195–96* (citations omitted). In other words: ''The varying levels of coarse particles allowed by a PM_{10} indicator will therefore target protection in urban and industrial areas where the evidence of adverse health effects associated with exposure to coarse particles is strongest.'' *Id.*

The EPA also offers a further rationale for tying the stringency of coarse PM regulation to increases in the level of $PM_{2.5}$.* * * EPA argues that it is ''logical to allow lower levels of coarse particles when fine particle concentrations are high.* * * [I]nclusion of $PM_{2.5}$ in the PM_{10} indicator for purposes of coarse particle protection would appropriately reflect the contribution that contaminants emitted in fine particle form can make to the overall health risk posed by coarse particles.'' *Id.*

In sum, we find that the EPA has provided a reasonable explanation for its decision[ ] * * * to utilize a standard that allows targeted variance in coarse PM levels in an inverse relationship to the amount of fine PM in the air. *American Farm Bureau* v. *EPA,* 559 F.3d 512, 534–5 (D.C. Cir. 2009).

A similar result applies here. Under the proposed secondary standard there would be a single level of air quality specified for the NAAQS. The standard would apply across the nation; it would not be a regional standard. The proposed standard would be the same standard everywhere—the acceptable level of mass concentration of $PM_{2.5}$ would be defined the same way across the nation, using the same method of calculating the allowable concentration of $PM_{2.5}$. The same degree of protection from visibility impairment would apply across the country. While the allowable amount of $PM_{2.5}$ could vary, this would be a reasoned way to achieve the desired degree of protection from visibility impairment. The requirements of section 109(b) would be satisfied.

Commenters also objected that the EPA could not set a NAAQS for the separate components of $PM_{2.5}$ without listing the components of $PM_{2.5}$ under section 108, based on an endangerment finding, and issuing air quality criteria for these components. They argued that the issuance of air quality criteria for particulate matter starting in 1969 did not provide a lawful basis for a proposed secondary standard that is based on components of PM, as the 1969 air quality was for particulate matter ''as a whole,'' defining PM as particles smaller than 500 micrometers (NMA/NCBA, p. 27). However, as discussed above, the proposed standard sets the allowable limit on ambient concentrations of $PM_{2.5}$. Information on both the speciated components of $PM_{2.5}$ and the relative humidity affect how much light extinction is associated with any specific level of $PM_{2.5}$, but the standard is for $PM_{2.5}$. The D.C. Circuit has made it clear that $PM_{2.5}$, just like PM_{10} and TSP before that, is an appropriate subset of PM for the EPA to focus on in setting the NAAQS based on the scientific evidence before the EPA. This focus of the NAAQS does not make the subset a new pollutant that requires listing and new air quality criteria under section 108 before setting a NAAQS. *American Trucking Association et al.* v. *EPA,* 175 F.3d 1027, 1055 (D.C. Cir. 1999). Commenters' interpretation would apply to $PM_{2.5}$ as well as to components of $PM_{2.5}$, and is inconsistent with the ATA decision. In addition, it is clear that the current air quality criteria do address the scientific basis for calculating $PM_{2.5}$ light extinction as the EPA proposed (U.S. EPA, 2009a, pp. 9–5 to 9–8).

Finally, at least one commenter argued that the EPA has concluded in prior reviews that the secondary NAAQS program is an inappropriate vehicle for regulating PM related visibility impairment (UARG, p. 26). UARG mischaracterized the EPA's past decision-making. In past reviews the EPA has been clear that the EPA should take into account the existence of the visibility program under section 169A, the regional haze program, when considering a secondary NAAQS and should not treat the secondary NAAQS as the sole mechanism to address visibility impairment across the country. That is the approach the EPA has taken in this and prior reviews. See 77 FR at 38990.

h. Relationship With Regional Haze Program

A large number of commenters expressed confusion and concern over differences between the proposed visibility index standard and the Regional Haze Program. This included commenters who supported setting a distinct secondary standard to protect visibility as well as those opposed to setting such a standard. A number of these commenters noted that visibility impairment would be assessed differently under the two approaches due to differences in the way light extinction is calculated, including different IMPROVE equations and differences in the inclusion and weighting of specific species and components. The commenters argued it would be inappropriate to have two different regimes for managing visibility impairment in the exact same location. These commenters claimed that since data from the IMPROVE monitoring network would inform nonattainment designations, as well as an area's obligations under the Regional Haze Program, there could be considerable confusion over how to draw nonattainment boundaries and what requirements would affect large sources in rural areas. These commenters also noted the resource burden associated with maintaining two different programs aimed at protecting visibility in the same geographic area. Some commenters argued that a visibility NAAQS should not apply to rural areas. The Department of the Interior requested that the EPA clearly define the geographic area to which the visibility index standard would be applicable, and suggested that Class I and Class II areas should generally be excluded from the standard. As discussed above, commenters questioned the need for a distinct visibility standard, arguing that the existing primary PM standards combined with the Regional Haze Program ensured adequate protection of visibility, even in urban areas.

In response to these comments relating to the overlap between the Regional Haze program and a distinct secondary standard designed to protect visibility principally in urban areas, the EPA notes that the objectives of each program are distinct. While the Regional Haze program is designed to eliminate man-made impairment of visibility in Federal Class I areas over the course of several decades, a distinct secondary standard for PM-related visibility impairment would be focused on providing a nationally applicable level of protection for all areas, particularly urban areas which do not receive targeted protection under the Regional Haze Program. Moreover, the metric used to assess visibility impairment differs between the two programs precisely because each program is aimed at a different aspect of the problem. Recognizing the importance of fresh emissions for urban visibility, the

Visibility Assessment focused on visibility impairment as measured by the original IMPROVE equation because ''the original version is considered more representative of urban situations when emissions are still fresh rather than aged as at remote IMPROVE sites'' (U.S. EPA, 2010b, p. 3–19). The Regional Haze Program, on the other hand, has shifted to a revised IMPROVE algorithm more suited to remote locations. While this difference is discussed in more detail in section VI.C.1.b above, the result is that each program would appropriately measure those aspects of visibility impairment most closely related to the problem the program is trying to prevent. Since the same data can be used to calculate both visibility impairment under the Regional Haze approach and the proposed visibility index, the additional calculation burden for state and local agencies would be light. Also, to the extent that there is any difference in terms of the emissions control obligations the two different programs would impose upon state and local areas, this is likely appropriate given the extent and nature of visibility impairment in those areas. The EPA notes that in general, there is likely to be substantial overlap in the control strategies a state or local area would pursue under either program. Thus, the EPA disagrees with commenters who stated that a distinct visibility standard as proposed would inherently conflict with the Regional Haze Program or that it would be appropriate to draw geographical distinctions that would explicitly exclude some areas (e.g., Class I areas) from the NAAQS. The EPA notes that the CAA requires that NAAQS be national in scope, and that the specific requirements laid out in the proposal for the distinct secondary standard would ensure that the protection it afforded would be appropriately targeted toward urban areas so that it could work in conjunction with—not be in conflict with—the Regional Haze Program under sections 169A and 169B of the CAA.

2. Comments on the Proposed Decision Regarding Non-Visibility Welfare Effects

Relatively few commenters addressed the proposal to retain the existing suite of secondary PM standards to address non-visibility welfare effects. A couple of states, including Mississippi and South Dakota, offered brief endorsements of the proposal. A few other commenters offered more extensive comments on the proposal to retain the existing secondary standards, and these commenters opposed this aspect of the proposal for one of two reasons. First, some commenters opposed the proposal to retain the current secondary annual $PM_{2.5}$ standard of 15 μg/m³ in light of the proposal to revise the level of the primary annual $PM_{2.5}$ standard to a level between 12–13 μg/m³. Expressing concern over the implications of this decision for the air quality planning obligations of states, these commenters argued that the EPA should revise the secondary $PM_{2.5}$ standards to be equivalent in all respects to the primary $PM_{2.5}$ standards. For example, the American Association of State Highway and Transportation Officials (AASHTO) supported ''retaining secondary standards that are consistent with the primary standards in order to reduce the complexity of the transportation and air quality planning processes, as well as the transportation conformity process'' (AASHTO, p. 3). Thus, if the EPA were to adopt a lower level for the primary annual $PM_{2.5}$ standard, the commenters recommended that the EPA adopt this same lower level for the primary secondary $PM_{2.5}$ standard as well.

In response to these comments, the EPA notes that the Agency lacks an appropriate scientific basis for revising the level of the secondary annual $PM_{2.5}$ standard. As noted above in section VI.B.2, there is an absence of information that would support any different secondary standards for PM. Comments related to the implementation challenges associated with distinct primary and secondary standards are not relevant to the Administrator's final decisions regarding what standards are requisite to protect the public welfare. Therefore, the EPA continues to conclude that it would be appropriate to retain the current suite of secondary PM standards [202] to address non-visibility welfare effects, while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard, as proposed.

Other commenters focused on the impacts of particulate matter on climate. One commenter cited a number of recent studies that considered mobile source black carbon emissions and associated climate impacts, and urged the EPA to protect the public welfare by setting ''higher standards for gasoline quality'' (Urban Air Initiative, p. 4). This commenter did not, however, advocate specific secondary NAAQS to address climate impacts of PM. More extensive comments on this same subject were provided by the Center for Biological Diversity (CBD), which urged the EPA to ''set a separate limit for black carbon within the overall $PM_{2.5}$ standard'' to ensure that public welfare is fully protected ''from the serious climate impacts of black carbon'' (CBD, p. 2). This commenter argued that ''[p]recaution is required for secondary NAAQS,'' citing *American Trucking Associations, Inc.* v. *EPA,* 283 F.3d 355, 369 (D.C. Cir. 2002):

> [N]othing in the Clean Air Act requires EPA to wait until it has perfect information before adopting a protective secondary NAAQS. Rather, the Act mandates promulgation of secondary standards requisite to protect public welfare from any ''*anticipated* adverse effects associated with'' regulated pollutants, 42 U.S.C. 7409(b)(2) (emphasis added), suggesting that EPA must act as soon as it has enough information (even if crude) to ''anticipate[]'' such effects[.]

The commenter stressed the growing scientific evidence regarding the impacts of black carbon on climate, and argued that the EPA's proposal ignores important research studies published within the last five years which provide improved estimates of the radiative forcing associated with black carbon, and the effects of black carbon on snow and ice, the Arctic climate, water availability and climate ''tipping points.'' The commenter also noted that reductions in cooling aerosol species, particularly sulfate, due to pollution control programs are leading to an ''unmasking'' of the true extent of warming due to the accumulation of greenhouse gases in the atmosphere. The commenter argued that this unmasking effect can be offset by ensuring ''that sufficient black carbon reductions accompany reductions in overall aerosol pollution'' (CBD, p. 10). The commenter also argued that the EPA did not consider the negative impacts of climate change on public health adequately in the proposal.

The commenter stated that the EPA had an obligation to address the impacts of black carbon in the PM NAAQS, despite the remaining uncertainties. The commenter pointed to the EPA's report to Congress on Black Carbon (U.S. EPA, 2012c), stating that the ''report shows that EPA is aware of the climate science and public health information that point to the importance of addressing black carbon pollution. EPA must use this information in its relevant decisionmaking'' (CBD, p. 13). The commenter also noted that the U.S. participates in a number of international forums that have recognized the need to take action on black carbon, and argued

[202] As summarized in section VI.A and Table 1 above, the current suite of secondary PM standards includes annual and 24-hour $PM_{2.5}$ standards and a 24-hour PM_{10} standard.

that the U.S. has ''an obligation under the Gothenburg Protocol to address black carbon pollution.'' The commenter challenged the uncertainties cited by EPA with regard to the climate impacts of aerosols generally, arguing that they ''do not apply to the regulation of black carbon'' (CBD, p. 14). Specifically, the commenter stated that ''there are significant anthropogenic sources of black carbon that contribute a large proportion of total black carbon emissions''; that ''there is enough information related to black carbon's impact to know that global temperatures will rise due to black carbon emissions''; that spatial and temporal heterogeneity in black carbon emissions do not matter for estimating likely climate effects; that ''[b]lack carbon's negative climate impacts do not depend upon details of cloud interactions with aerosols''; and that the EPA does not need to be able to quantify the health or climate benefits precisely to know that it is appropriate to control black carbon as a specific component of PM under the CAA (CBD, pp. 14–15).

As a result, the commenter concluded that the current size-based PM mass standard ''is insufficient to fully protect health and welfare,'' and that the EPA was obligated to establish a specific limit on black carbon as a component of PM. The commenter argued that ''Black carbon must be regulated separately and in addition to $PM_{2.5}$ because absent separate standards sulfates and nitrates may be more likely to be mitigated than the black carbon component of PM'' (CBD, p. 17). To support this point, the commenter cited the conclusion in the Policy Assessment that:

> The current standards that are defined in terms of aggregate size mass cannot be expected to appropriately target controls on components of fine and coarse particles that are related to climate forcing effects. Thus, the current mass-based $PM_{2.5}$ and PM_{10} secondary standards are not an appropriate or effective means of focusing protection against PM-associated climate effects due to these differences in components. (U.S. EPA, 2011a, p. 5–11)

The commenter also noted that existing regulations on diesel engines, which are the largest source of black carbon in the United States, do not affect existing engines and vehicles, and stated that ''The NAAQS program is one of the few opportunities to reduce black carbon from existing engines, industrial and biofuel sources within the United States and rapidly reduce emissions from this pollutant'' (CBD, p. 18).

The EPA agrees with the commenters' assertion that the scientific information about the impacts of aerosol species on climate is developing rapidly, and that understanding of the magnitude of aerosol effects on climate and the contribution of individual aerosol components to those effects has improved substantially over the past decade. The EPA also agrees that certain species, in particular black carbon, play a significant role in multiple aspects of climate. The Policy Assessment recognized that ''Aerosols can impact glaciers, snowpack, regional water supplies, precipitation and climate patterns,'' and may contribute to the melting of ice and snow, a decrease in surface albedo, and climate impacts in the Arctic and other locations (U.S. EPA, 2011a, p. 5–9). The contribution of black carbon to these effects is discussed in detail in the EPA's recent *Report to Congress on Black Carbon* (U.S. EPA, 2012c). In particular, black carbon plays an important role in heating the lower atmosphere by absorbing incoming solar radiation and outgoing terrestrial radiation, i.e. via ''direct'' radiative forcing.

However, the EPA disagrees that there is sufficient information available at this time to establish a NAAQS to protect against the climate impacts associated with current ambient concentrations of black carbon or other PM constituents. While the Integrated Science Assessment concluded that ''a causal relationship exists between PM and effects on climate, including both direct effects on radiative forcing and indirect effects that involve cloud feedbacks that influence precipitation formation and cloud lifetime'' (U.S. EPA, 2009a, section 9.3.10), it also identified substantial remaining uncertainties with regard to the contribution of individual aerosol species to these climate effects. The contribution of individual aerosol components to total aerosol direct radiative forcing is more uncertain than the global average (U.S. EPA, 2009a, section 9.3.6.6), and the indirect effects of aerosols and aerosol components remain highly uncertain, in particular with regard to their complex interactions with clouds.

With regard to black carbon, for example, the EPA disagrees with CBD's claims that ''black carbon's negative climate impacts do not depend upon details of cloud interactions with aerosols'' and that the uncertainties associated with climate impacts of aerosols generally do not apply to black carbon. In fact, the EPA has pointed to cloud interactions as the area of greatest uncertainty with regard to black carbon: recognizing that black carbon affects cloud reflectivity (albedo), lifetime, and stability as well as precipitation, the *Report to Congress on Black Carbon* noted that ''few quantitative estimates of these effects are available, and significant uncertainty remains. Due to all of the remaining gaps in scientific knowledge, it is difficult to place quantitative bounds on the forcing attributable to [black carbon] impacts on clouds at present'' (U.S. EPA, 2012c, p. 4). The Report acknowledged that ''most estimates of the forcing from aerosol indirect effects are based on all aerosol species (e.g. total PM) and are not estimated for individual species (e.g, BC alone)'' (U.S. EPA, 2012c, p. 40). The Report concluded that it remains unclear the extent to which black carbon contributes to the overall aerosol indirect effect, and did not assign any central estimate or even a range of possible values to the role of black carbon in the overall aerosol indirect effect. With regard to black carbon's net contribution to climate, therefore, the Report concluded:

> The direct and snow/ice albedo effects of BC are widely understood to lead to climate warming. However, the globally averaged net climate effect of BC also includes the effects associated with cloud interactions, which are not well quantified and may cause either warming or cooling. Therefore, though most estimates indicate that BC has a net warming influence, a net cooling effect cannot be ruled out. It is also important to note that the net radiative effect of all aerosols combined (including sulfates, nitrates, BC and OC) is widely understood to be negative (cooling) on a global average basis. (U.S. EPA, 2012c, p. 3)

Given the remaining uncertainties about the impact of aerosols on climate, there is even greater uncertainty with regard to how aerosol-induced climate change will affect public health. At this time, it is not possible to estimate the extent to which aerosols in general, let alone particular aerosol components, contribute to the occurrence or exacerbation of adverse health outcomes due to climate change. The EPA therefore disagrees with CBD's claim that the EPA should pursue black carbon reductions for purposes of reducing the impacts of climate change on public health.

The *Report to Congress on Black Carbon* also stressed the importance of considering co-emitted PM species, such as SO_2 and NO_X, in evaluating the benefits of black carbon mitigation options. Noting that many of these co-emitted particles and gases have a cooling influence on climate, the Report noted the difficulty of estimating the net effect of various mitigation measures on net radiative forcing or other climate variables. The EPA concluded that the location and timing of emissions reductions would be critically important for achieving climate benefits, and that

''more research is needed on the benefits of individual control measures in specific locations to support policy decisions made at the national level'' (U.S. EPA, 2012c, p. 140). Thus, the EPA disagrees with CBD's claim that spatial and temporal heterogeneity in black carbon emissions do not matter for estimating likely climate effects, and continues to believe that being able to quantify the climate impacts of various aerosol species, alone and in combination, is essential for informing any possible revisions to the current secondary PM standards based on climate.

Furthermore, while the EPA agrees with the commenter that a large percentage of black carbon emissions come from anthropogenic sources, including diesel engines and vehicles, the EPA notes that existing regulations on mobile diesel engines are already reducing these emissions substantially. Between 1990 and 2005, new engine requirements resulted in a 32 percent reduction in black carbon emissions from mobile sources, and a further 86 percent reduction from 2005 levels is projected to occur by 2030 as vehicles and engines meeting existing regulations are phased into the fleet (U.S. EPA, 2012c, p. 175). Long-term historic data indicate that there has been a dramatic overall decline in black carbon emissions over the past century, due to changes in fuel use, more efficient combustion practices, and implementation of PM controls. Therefore, the EPA disagrees with CBD's claim that a distinct black carbon NAAQS is necessary to achieve reductions in black carbon emissions. Clearly, U.S. emissions of black carbon are already declining substantially, suggesting that the existing mass-based PM standards, though not targeting black carbon specifically, have been effective in achieving black carbon emissions reductions in practice. As acknowledged in the *Report to Congress on Black Carbon,* ''While [black carbon] is not the direct target of existing programs, it has been reduced through controls aimed at reducing ambient $PM_{2.5}$ concentrations and/or direct particle emissions'' (U.S. EPA, 2012c, p. 161). The EPA has acknowledged the need to encourage PM mitigation strategies that focus on reducing directly emitted $PM_{2.5}$ for purposes of reducing black carbon, and this is reflected in U.S. commitments under the Gothenburg Protocol: the new provisions in the Protocol pertaining to PM encourage parties to develop national inventories and projections for black carbon, and to ''give priority'' to black carbon when implementing measures to control PM. However, the EPA notes that the U.S. has not yet ratified the PM amendments to the Gothenburg Protocol, and furthermore, these amendments do not require action specifically to reduce black carbon, but rather encourage countries to take such actions voluntarily within the context of their broader PM reduction strategies. Thus the EPA disagrees with the commenter that the U.S. has an ''obligation'' to reduce black carbon under the Gothenburg Protocol, or that it has ''agree[d] to choose mitigation options for particulate matter that focus on black carbon reductions'' under the Protocol (CBD, p. 13).

In sum, the EPA notes the substantial remaining the uncertainties and gaps with regard to the climate impacts of PM components, including black carbon. These include the uncertainties associated with the spatial and temporal heterogeneity of PM components that contribute to climate forcing; the uncertainties associated with measurement of aerosol components; the inadequate consideration of aerosol impacts in climate modeling; and the currently insufficient data on local and regional microclimate variations and the heterogeneity of cloud formations. As a result, the EPA continues to conclude that it is not currently feasible to conduct a quantitative analysis for the purpose of informing revisions of the current secondary PM standards based on climate, and that there is insufficient information at this time to base a national ambient standard on climate impacts associated with current ambient concentrations of PM or any of its constituents.[203]

D. Conclusions on Secondary PM Standards

This section describes the Administrator's conclusions regarding the secondary PM standards and the rationale leading to the Administrator's final decision to retain the current suite of secondary PM standards, including an annual $PM_{2.5}$ standard of 15 μg/m^3 a 24-hour $PM_{2.5}$ standard of 35 μg/m^3, and a 24-hour PM_{10} standard of 150 μg/m^3, to address PM-related visibility impairment as well as other PM-related welfare effects, including ecological effects, effects on materials, and climate impacts. Specifically, this section explains the Administrator's decision, consistent with the proposal, to retain the current suite of secondary PM standards generally, while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. It also explains the Administrator's decision, contrary to what was proposed, not to establish a distinct standard to address PM-related visibility impairment.

In reaching conclusions regarding the need to revise the secondary PM standards for both visibility and non-visibility welfare effects, the Administrator has taken into account several key factors, including: (1) The latest scientific information on both visibility and non-visibility welfare effects associated with PM, as previously described; (2) the advice of CASAC; and (3) the comments received during the public comment period, as discussed above. Based on this information, the Administrator has reached final conclusions about the secondary PM standards and made final decisions about those standards, as outlined below. Because the Administrator's final conclusions with regard to the need to establish a distinct secondary standard to protect against visibility impairment reflect, in part, her conclusions on secondary PM standards for non-visibility welfare effects, section VI.D.1 first outlines her conclusions regarding secondary PM standards to address non-visibility welfare effects. This is followed by section VI.D.2 which outlines her conclusions regarding a secondary PM standard to address PM-related visibility impairment. Finally, section VI.D.3 summarizes the Administrator's final decisions with regard to the secondary PM standards for both visibility and non-visibility welfare effects.

1. Conclusions Regarding Secondary PM Standards To Address Non-Visibility Welfare Effects

With regard to the secondary PM standards to address non-visibility welfare effects, the Administrator concludes that it is generally appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address non-visibility PM-related welfare effects. This conclusion is based on the considerations discussed above in section VI.B.2, including the latest scientific information and the advice of CASAC, and the public comments received on the proposal, as discussed above in section VI.C.2. The Administrator concurs with the advice of CASAC and the conclusions expressed at the time of proposal that it is important to maintain an appropriate

[203] This conclusion applies for both the secondary (welfare-based) and the primary (health-based) standards.

degree of control of both fine and coarse particles to address non-visibility welfare effects, including ecological effects, effects on materials, and climate impacts. In the absence of information that would support any different standards the Administrator concludes that it is appropriate to retain the existing suite of secondary standards to address non-visibility welfare effects, as proposed. More specifically, the Administrator concludes it is appropriate to retain all aspects of the current 24-hour $PM_{2.5}$ and PM_{10} standards. With regard to the secondary annual $PM_{2.5}$ standard, the Administrator concludes that it is appropriate to retain a level of 15.0 μg/m³ for this standard while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. In reaching this conclusion, the Administrator notes that no areas in the country are currently using the option for spatial averaging to demonstrate attainment with the secondary annual $PM_{2.5}$ standard.

2. Conclusions Regarding Secondary PM Standards for Visibility Protection

Having reached the conclusion that it is generally appropriate to retain the existing secondary standards to protect against non-visibility welfare effects, the Administrator next considered the target level of protection that would be requisite to protect public welfare with regard to visual air quality. The Administrator then determined whether to adopt a distinct secondary standard to achieve this target level of protection. In making this decision, the Administrator compared the degree of protection for visibility that would be provided by such a distinct secondary standard to the degree of protection provided by the existing secondary standards, focusing specifically on the secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³.[204]

Based on the considerations discussed above in section VI.B and VI.C, the Administrator first concludes that a target level of protection for a secondary standard is most appropriately defined in terms of a $PM_{2.5}$ visibility index as proposed, since it would provide a measure of PM-related light extinction that directly takes into account the factors (i.e., species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in the ambient air and PM-related visibility impairment. Such a $PM_{2.5}$ visibility index standard would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by virtue of directly incorporating the effects of differences in $PM_{2.5}$ composition and relative humidity across the country.

In defining a target level of protection based on a $PM_{2.5}$ visibility index, the Administrator has considered specific aspects of such an index, including the appropriate indicator, averaging time, level, and form. First, with regard to indicator, the Administrator notes the conclusion of CASAC that relying on a calculated $PM_{2.5}$ light extinction indicator based on $PM_{2.5}$ chemical speciation and relative humidity data represented a reasonable approach. Based on the analyses conducted in support of this rulemaking, as described above, as well as the advice of CASAC, the Administrator concludes that a calculated $PM_{2.5}$ light extinction indicator that utilizes the original IMPROVE algorithm, adjusted to use a 1.6 OC multiplier and exclude the term for coarse particles, in conjunction with monthly average relative humidity data (i.e., f(RH) values) based on long-term climatological means would be the most appropriate indicator for a $PM_{2.5}$ visibility index standard.

With regard to averaging time, the Administrator notes that both CASAC and EPA staff have concluded that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. However, in light of the important data quality uncertainties that have recently been identified in association with currently available instruments that would be used to provide the hourly $PM_{2.5}$ mass measurements that would be needed in conjunction with an averaging time shorter than 24 hours, the Administrator concludes it would not be appropriate at this time to set a standard based on a sub-daily averaging time. Moreover, the Administrator notes that analyses conducted by the EPA during this review clearly indicate that $PM_{2.5}$ light extinction calculated on a 24-hour average basis would be a reasonable and appropriate surrogate for $PM_{2.5}$ light extinction calculated on a 4-hour basis. Thus, the Administrator concludes that a 24-hour averaging time would be appropriate for a $PM_{2.5}$ visibility index. The Administrator recognizes that a 24-hour averaging time would effectively reduce the influence of peak hours of visibility impairment on visibility index values, but concludes that in light of the concern that peak hourly measurements may be significantly influenced by atypical conditions and/or atypical instrument performance, it is appropriate to adopt a longer averaging time to ensure that hour-specific influences and uncertainties are balanced against more robust measurements.

With regard to form, the Administrator notes that consistent with the approach taken in other NAAQS, including the current 24-hour $PM_{2.5}$ NAAQS, a multi-year percentile form offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. Utilizing a three-year average form provides stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year. Moreover, considering the lack of information on and the high degree of uncertainty regarding the impact on public welfare of the number of days with visibility impairment over the course of a year, the Administrator considers it reasonable to focus on the 90th percentile, which represents the median of the distribution of the 20 percent worst visibility days, a key focus of the Regional Haze program. The Administrator concludes that ensuring that 90 percent of days have visual air quality that is at or below the target level of protection could be reasonably expected to lead to improvements in visual air quality on the 20 percent most impaired days, and that the limited information available in this review provides no basis for adopting a different form which would limit the occurrence of days with peak PM-related light extinction in urban areas to a greater degree. Therefore, the Administrator concludes that a 90th percentile form, averaged over 3 years, is appropriate, for purposes of establishing a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index.

With regard to level, the Administrator concludes that in light of the uncertainty associated with the high degree of variability in visibility conditions and the potential variability in visibility preferences across different parts of the country, it is appropriate to establish a target level of protection based on the upper end of the range of Candidate Protection Levels (CPLs)

[204] This focus on the 24-hour $PM_{2.5}$ standard reflects the Administrator's judgments that PM-related visibility impairment is principally related to fine particle concentrations and that perception of visibility impairment is most directly related to short-term levels of visual air quality.

identified in the Policy Assessment (i.e., 20–30 dv) and generally supported by CASAC. Thus, the Administrator concludes that it would be appropriate to set a target level of protection in terms of a $PM_{2.5}$ visibility index with a 24-hour averaging time that would provide protection equivalent to the protection afforded by a 4-hour $PM_{2.5}$ visibility index with a level of 30 dv. Furthermore, the Administrator notes that the approaches used to estimate generally equivalent levels for a 24-hour $PM_{2.5}$ visibility index generated 90th percentile 24-hour values similar to the 4-hour values and a range of city-specific estimates of generally equivalent 24-hour levels that encompassed the range of levels considered appropriate for 4-hour CPLs, including the CPL of 30 dv at the upper end of that range. The Administrator thus concludes that it would be appropriate to use an unadjusted 4-hour CPL for purposes of establishing a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index.

In considering the alternative levels proposed for a 24-hour standard, either 28 dv or 30 dv, the Administrator concludes that the current substantial degrees of variability and uncertainty inherent in the public preference studies should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain. In addition, she concludes that, in light of the significant uncertainties, it is appropriate to place less weight on the results of western visibility preference studies and that the CPL value (30 dv) that is based on the eastern preference study results is likely to be more representative of urban areas that do not have associated mountains or other valued objects visible in the distant background For all of these reasons, the Administrator concludes that it is appropriate to set a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index at 30 dv.

In summary, in light of all the information available in this review, the Administrator concludes that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction), a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv, would be requisite to protect public welfare with regard to visual air quality.

In reaching this conclusion, the Administrator notes that any national ambient air quality standard to address PM-related visibility impairment would be designed to work in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in all areas of the country, including urban, non-urban, and Federal Class I areas. While the Regional Haze Program is focused on improving visibility in Federal Class I areas and a secondary NAAQS to address PM-related visibility impairment would focus on protecting visual air quality principally in urban areas, both programs could be expected to provide benefits in surrounding areas. In addition, the development of local programs, such as those in Denver and Phoenix, could continue to be an effective and appropriate approach to provide additional protection, beyond that afforded by a national standard, for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas.

Having concluded that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index, with a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv, would be requisite to protect public welfare with regard to visual air quality, the Administrator next has to determine whether to adopt such a visibility index as a distinct secondary standard. This determination requires considering such a secondary standard not in isolation but in the context of the full suite of secondary standards. As discussed above, the Administrator has determined to retain the current suite of secondary PM standards to address non-visibility welfare effects (except for the form of the annual standard). A distinct secondary standard to address visibility impairment is properly considered in a context where there is also a 24-hour $PM_{2.5}$ standard of 35 μg/m³.

In this context, the Administrator has considered the degree of protection from visibility impairment afforded by the existing secondary $PM_{2.5}$ standards. The Administrator has considered both whether the existing 24-hour $PM_{2.5}$ standard of 35 μg/m³ is sufficient (i.e. not under-protective) and whether it is not more stringent than necessary (i.e. not over-protective).

As discussed above in section VI.C.1.f, the results of the Kelly *et al.* (2012a; 2012b) analyses indicate that based on 2008–2010 and 2009–2011 data, all areas meeting the 24-hour $PM_{2.5}$ standard of 35 μg/m³ had visual air quality at least as good as 30 dv (24-hour average, based on 90th percentile form averaged over 3 years). This means that it is highly likely that the secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³ would be controlling relative to a 24-hour standard based on a $PM_{2.5}$ visibility index set at a level of 30 dv, and highly unlikely that areas would exceed the target level of protection for visibility of 30 dv without also exceeding the existing secondary 24-hour standard. On the basis of this evidence, and the supporting public comments, the Administrator judges that the 24-hour $PM_{2.5}$ standard of 35 μg/m³ provides sufficient protection in all areas against the effects of visibility impairment—i.e., that the existing 24-hour $PM_{2.5}$ standard would provide *at least* the target level of protection for visual air quality of 30 dv which the Administrator judges appropriate.

The Administrator also recognizes that the analyses presented in Kelly *et al.* (2012a; 2012b) indicate that the 24-hour $PM_{2.5}$ standard of 35 μg/m³ also would likely achieve *more than* the target level of protection of visual air quality (30 dv) in some areas. That is, when meeting a mass-based standard of 35 μg/m³, some areas would have levels of PM-related visibility impairment below 30 dv. Thus, the 24-hour $PM_{2.5}$ standard of 35 μg/m³ would be over-protective in some areas (i.e. more stringent than necessary) relative to the target level of protection for visibility. This is not surprising, as the current mass-based standard does not account for variation in particle species and relative humidity. The 24-hour $PM_{2.5}$ standard of 35 μg/m³ would provide more than the necessary protection in the areas where this would be expected, for example western areas with lower relative humidity.

In light of the Administrator's conclusion that it is appropriate to retain the current secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³ for non-visibility welfare effects, the Administrator notes that this standard will remain in place regardless of whether she elects to set a distinct secondary standard in terms of a $PM_{2.5}$ visibility index. The issue is not whether to adopt a $PM_{2.5}$ visibility index standard when viewed in isolation, but whether such a distinct secondary standard should be adopted in addition to the current secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³. The EPA notes that adoption of such a distinct secondary standard is not needed to provide sufficient protection from visibility impairment with respect to the target level of protection determined above. In addition, adoption of such a distinct secondary standard would not change the fact that the current secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³ would result in over-protection

from visibility impairment in certain areas of the country. Such over-protection will occur whether or not such a distinct secondary standard is adopted. In effect, adopting such a distinct secondary standard would have no impact on the degree of protection provided from visibility impairment. Since sufficient protection from visibility impairment would be provided for all areas of the country without adoption of a distinct secondary standard, and adoption of a distinct secondary standard will not change the degree of over-protection provided for some areas of the country, the Administrator judges that adoption of such a distinct secondary standard is not needed to provide requisite protection for both visibility and non-visibility related welfare effects.

It is important to note that this conclusion is based on the specific target level of protection determined above, and the specific set of current secondary standards. The Administrator's conclusion with regard to the sufficiency of the protection provided by the current suite of secondary standards is based on comparing the a 30 dv target level of protection for a $PM_{2.5}$ visibility index standard against the degree of protection provided by the current secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³. It is the combination of the specific target level of protection and the current suite of secondary standards that is the basis for the decision not to adopt a distinct secondary standard in terms of a $PM_{2.5}$ visibility index at this time.

The EPA recognizes that, as in the last review, the final decision is to not adopt a distinct secondary standard to address visibility impairment. While the DC Circuit remanded the decision on a secondary standard in the last review, the EPA's decision in this review has addressed the issues raised in the court's remand. Here the EPA has clearly identified the target degree of protection (defined in terms of a $PM_{2.5}$ visibility index at a level of 30 dv based on a 24-hour averaging time, and a 90th percentile form, averaged over 3 years) that would be requisite to protect public welfare with regard to visual air quality. The EPA has carefully compared this degree of protection with that provided by the current secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³, based on an area-specific analysis of recent air quality data and concluded that the degree of protection from visibility impairment provided by the current secondary standard is sufficient to protect public welfare consistent with section 109(b)(2). This provides a clear basis for judging that the current secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³ would provide sufficient protection. The analysis also shows that the current secondary 24-hour $PM_{2.5}$ standard would provide more protection than is needed in some areas, largely because it does not take into account variable factors such as relative humidity. However, the EPA has recognized that adoption of a distinct secondary standard to address visibility, in addition to retaining the current secondary standard, would not change this result. The EPA has therefore concluded that adoption of such a distinct secondary standard, in addition to the current suite of secondary PM standards, is not needed to provide requisite protection for both visibility and non-visibility related welfare effects. Thus the EPA's decision has carefully considered and accounted for the views of the court in the remand of the 2006 NAAQS.

E. Administrator's Final Decisions on Secondary PM Standards

To address PM-related welfare effects, including ecological effects, effects on materials, climate impacts, and visibility impairment, the Administrator is retaining the current suite of secondary PM standards, except for a change to the form of the annual standard. Specifically, to address PM-related non-visibility welfare effects including ecological effects, effects on materials, and climate impacts, the EPA is retaining the current secondary 24-hour $PM_{2.5}$ and PM_{10} standard and is revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. With respect to PM-related visibility impairment, the Administrator has identified a target degree of protection, defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction), a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, and a level of 30 deciviews (dv), which she judges to be requisite to protect public welfare with regard to visual air quality. The EPA's analysis of monitoring data provides the basis for concluding that the current secondary 24-hour $PM_{2.5}$ standard would provide sufficient protection, and in some areas greater protection, relative to this target protection level. Adding a distinct secondary standard to address PM-related visibility impairment would not affect this protection. Since sufficient protection from visibility impairment will be provided for all areas of the country without adoption of a distinct secondary standard, and adoption of a distinct secondary standard will not change the degree of over-protection of visual air quality provided for some areas of the country by the secondary 24-hour $PM_{2.5}$ standard, the Administrator judges that adoption of a distinct secondary standard, in addition to the current suite of secondary standards, is not needed to provide requisite protection for both visibility and non-visibility related welfare effects.

VII. Interpretation of the NAAQS for PM

This section discusses the EPA Administrator's final decisions on the revisions proposed to the data handling procedures for the primary and secondary $PM_{2.5}$ standards. Appendix N to 40 CFR part 50 describes the computations necessary for determining when the $PM_{2.5}$ standards are met and also addresses which measurement data are appropriate for comparison to the standards; as well, it specifies associated data reporting protocols, data completeness criteria, and rounding conventions. The EPA is modifying appendix N to conform to the revised $PM_{2.5}$ standards; most notably, the EPA is amending the appendix N procedures by removing the option for spatial averaging. In addition to making changes to appendix N that correspond to the changes in the annual standard form and the revised primary annual standard level, the EPA is also finalizing additional proposed revisions to the appendix in order to codify existing practices currently included in guidance documents or implemented as EPA standard operating procedures; better align appendix N language and requirements with changes in $PM_{2.5}$ ambient monitoring and reporting requirements; provide greater clarity and transparency in the provisions; and enhance consistency with data handling protocols utilized for other pollutants.

A. Revised Amendments to Appendix N: Interpretation of the NAAQS for $PM_{2.5}$

As discussed in sections III and VI above, the EPA Administrator has decided to: (1) Revise the form and level of the primary annual $PM_{2.5}$ standard, and retain the current primary 24-hour $PM_{2.5}$ standard (section III.F) and (2) retain the current secondary 24-hour $PM_{2.5}$ standard, and revise the form and retain the level of the secondary annual $PM_{2.5}$ standard (for visibility and non-visibility-related welfare protection) (section VI.E). Appendix N is being revised to conform to those changes to the standards. In the proposal, the EPA

recommended additional data handling procedures to appendix N for the proposed distinct secondary standard to address $PM_{2.5}$-related visibility impairment. However, as discussed in section VI.E, the Administrator has decided not to establish the proposed distinct secondary standard to address visibility impairment, and therefore, the associated proposed data handling procedures related to that proposed standard are not included in the final revised appendix N.

In addition to the changes to appendix N necessitated by the annual NAAQS form and level revisions (discussed in depth in sections III and VI above), the EPA is also finalizing additional revisions to appendix N in order to: (1) Better align appendix N language and requirements with changes in the $PM_{2.5}$ ambient monitoring and reporting requirements as discussed in section VIII below; (2) enhance consistency with recently codified changes in data handling procedures for other criteria pollutants; (3) codify existing practices currently included in guidance documents or implemented as the EPA standard operating procedures; and (4) provide enhanced clarity and consistency in the articulation and application of appendix N provisions. Key elements of the finalized revisions to appendix N are summarized in sections VII.A.1 through VII.A.4 below which correspond to the similarly numbered sections in appendix N. The proposed potential new fifth section of appendix N dealt with the proposed distinct $PM_{2.5}$-related visibility secondary standard that was not finalized by the Administrator and thus the proposed appendix N section 5 is not included in the final appendix N. Furthermore, proposed changes to sections 1 through 4 of appendix N that also dealt with the proposed secondary visibility index standard (e.g., term definitions, rounding conventions, etc.) are also omitted from the final revised appendix.

1. General

As proposed, the EPA is finalizing modifications to section 1.0 of appendix N to provide additional clarity regarding the scope and interpretation of the $PM_{2.5}$ NAAQS. This appendix section now references the finalized revisions of the primary annual $PM_{2.5}$ standard (40 CFR 50.18) and the retained secondary $PM_{2.5}$ NAAQS. With regard to the appendix N term definitions which are delineated in this initial section, the EPA has added, modified, and eliminated term definitions, as appropriate, in accordance with the final data handling rule revisions such as the modification of terms that referenced spatial averaging. Additional term definitions were also added to reference otherwise unchanged appendix N content in an effort to streamline the appendix text, enhance clarity and thus improve readability and understanding. In particular, the definition of data substitution tests was shortened, and a definition for ''test design value'' (TDV) was added for completeness and for further clarity. This term was previously part of the data substitution definition and now it is more explicitly defined. The EPA notes that there were no substantive public comments received with regard to this section.

2. Monitoring Considerations; Spatial Averaging

As proposed, the EPA has finalized revisions to section 2.0 of appendix N consistent with the concurrent modification of the form of the primary annual $PM_{2.5}$ standard that removes the option for spatial averaging. As described in more detail in section III.E.3.a above, the EPA decided to remove this option as part of the form of the primary annual $PM_{2.5}$ standard in light of analysis that indicates that the existing constraints on spatial averaging, as modified in 2006, may be inadequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on susceptible populations (Schmidt 2011a, Analysis A).

With respect to the form of the secondary annual $PM_{2.5}$ standard, as discussed in section VI.E above, the EPA has decided to retain the current secondary annual $PM_{2.5}$ standard to provide protection for welfare effects. In the proposal, the EPA believed it would be reasonable and appropriate to align the data handling procedures for the primary and secondary annual $PM_{2.5}$ standards and remove the option for spatial averaging for the secondary annual $PM_{2.5}$ standard to be consistent with the revised form of the primary annual $PM_{2.5}$ standard (FR 77 39000, June 29, 2012). The EPA noted that no areas in the country are currently using the option for spatial averaging to demonstrate attainment with the secondary annual $PM_{2.5}$ standard. There were no comments on the proposed change and the EPA has therefore concluded it appropriate to remove the option for spatial averaging for the secondary annual $PM_{2.5}$ standard from Appendix N.

Consistent with the revised form of the primary and secondary annual $PM_{2.5}$ standards, the levels of both standards will be compared to measurements from each appropriate (i.e., ''eligible'') monitoring site in an area, as specified in 40 CFR 58.30, with no allowance for spatial averaging. Thus, for an area with multiple eligible monitoring sites, the site with the highest design value would determine the attainment status for that area. As a result of the decision to eliminate the spatial averaging option for both the primary and secondary annual standards, the EPA omitted all references to the spatial averaging option in the finalized version of appendix N. See section III.E.3.a above for a discussion of EPA's response to received public comment on the issue of removal of the spatial averaging option.

3. Requirements for Data Use and Reporting for Comparisons With the NAAQS for $PM_{2.5}$

In the proposal, the EPA suggested changes to section 3.0 of appendix N to correspond to the proposed new secondary standard to address PM-related visibility impairment. Since the EPA is not finalizing the proposed distinct secondary standard to address visibility impairment, none of these proposed changes are necessary and are not being made. The EPA is, however, finalizing proposed changes to improve consistency with procedures used for other NAAQS as well as to improve consistency with current standard operating procedures. Specifically, the EPA proposed revisions to this section regarding: (1) Clarification of monitoring data appropriate to compare to the $PM_{2.5}$ NAAQS; (2) clarification of procedures for combining monitoring data from collocated instruments into a single ''combined site'' record; and (3) codification of the current standard operating procedure whereby the EPA uses data for which the certification deadline has passed but the monitoring agency has not requested certification of the data to determine compliance with the $PM_{2.5}$ NAAQS provided the data are complete and accurate (thus making appendix N consistent with data handling appendices for other criteria pollutants). In the final revision to appendix N, the EPA is incorporating all the above noted modifications to section 3 of appendix N. Additional details describing the incorporated modifications are provided below.

With regard to clarification of which monitoring data are appropriate for comparison to the $PM_{2.5}$ NAAQS, the proposal acknowledged important data quality concerns associated with the $PM_{2.5}$ measurements collected by continuous $PM_{2.5}$ FEMs and referenced a subsequent preamble proposal section that discussed the issue in more depth and put forward a solution to mitigate the data quality concerns. The revised

monitoring rule, promulgated today in conjunction with the PM NAAQS revision, includes, as proposed, language allowing monitoring agencies to identify $PM_{2.5}$ FEMs that are not providing data of sufficient comparability to the FRM and, with EPA approval, to allow such data to be deemed ineligible for comparisons with the $PM_{2.5}$ NAAQS [205]; see detailed discussion of this decision in section VIII.A.1 below. Rule language for the definition of ''suitable monitors'' in section 1.0 of the finalized revised appendix N accommodates and references this monitoring rule revision codified in 40 CFR 58.11.

With respect to the procedures for combining monitored data from collocated instruments into a single ''combined site'' data record, the EPA proposed to revise the current methodology in situations where an FRM monitor operating on a non-daily schedule is collocated with a continuous FEM monitor (that has acceptable comparability with an FRM). As noted in the proposal, the EPA was not advocating a change to the actual procedures for constructing a combined site record but rather a modification to the subsequent evaluation of whether the specific measurements were considered ''creditable'' or ''extra'' samples.[206] The language clarification proposed is currently standard operating procedure in Agency design value computations so the language modification in appendix N merely proposed to modify actual practices.[207] The revised appendix N finalized in today's action incorporates the modification as proposed. The EPA notes that there were no substantive public comments received regarding this change.

4. Comparisons with the $PM_{2.5}$ NAAQS

Section 4.0 of appendix N specifies the procedures for comparing monitored data to the $PM_{2.5}$ standards. The EPA proposed revisions to section 4.0 of appendix N to: (1) Provide consistency with the proposed primary and secondary annual $PM_{2.5}$ standards; (2) expand the data completeness assessments to be consistent with current guidance and standard operating procedures; and (3) simplify the procedure for calculating annual 98th percentile concentrations when using an approved seasonal sampling schedule.

Consistent with the proposed decisions to revise the level of the primary annual $PM_{2.5}$ standard (section III.E.4.b.iii) and to retain the current level of the secondary annual $PM_{2.5}$ standard (section VI.B.1.c.vi), the EPA proposed to modify section 4.1(a) of appendix N to separately list the levels of the primary and secondary annual $PM_{2.5}$ standards. The final revised appendix N incorporates this proposed change; this appendix N section now references the revised primary annual standard level of 12.0 μg/m³ and the retained secondary annual standard level of 15.0 μg/m³. However, as discussed above with respect to the final decision to not establish a distinct secondary standard to provide protection for visibility impairment, the final appendix N now explicitly references all $PM_{2.5}$ secondary standard protection (that is, protection from visibility impairment and non-visibility-related welfare effects) to be provided by the revised annual standard with retained level of 15.0 μg/m³ and the retained 24-hour standard with retained level of 35 μg/m³. Consistent with the final decisions to remove the option for spatial averaging for the primary annual $PM_{2.5}$ standard (section III.F), as well as for the secondary annual $PM_{2.5}$ standard (section VII.A.2), the EPA amended section 4.4 of appendix N to remove equations and associated instructions relating to spatial averaging.

With regard to assessments of data completeness, the EPA proposal included two additional data substitution tests [208] (making a total of three data substitution tests) into appendix N for validating annual and 24-hour $PM_{2.5}$ design values otherwise deemed incomplete (via the 75 percent and 11 creditable sample minimum quarterly data completeness requirements). The EPA proposed to add these tests in order to codify existing practices currently included in guidance documents (U.S. EPA, 1999) and implemented as EPA standard operating procedures, and further, to make the data handling procedures for $PM_{2.5}$ more consistent with the procedures used for other NAAQS. While the need for data substitution will lessen as more continuous $PM_{2.5}$ monitors continue to be deployed in $PM_{2.5}$ networks, the EPA believes that these substitution procedures are important to ensure that available data, if incomplete, can be confidently used to make comparisons to the NAAQS. As noted in the EPA proposal, data substitution tests are diagnostic in nature; that is; they are only used in an illustrative manner to show that the NAAQS status based on incomplete data is reasonable. As codified in section 4 of Appendix N, data are substituted for missing data to produce a ''test design value'' which is compared to the level of the NAAQS. If the test design value passes the diagnostic test, the ''incomplete'' design value (without the data substitutions) is then considered a valid design value. If an ''incomplete'' design value does not pass any data substitution test, then the original

[205] The EPA also allows use of alternative methods where explicitly stated in the monitoring methodology requirements (appendix C of 40 CFR part 58), such as $PM_{2.5}$ Approved Regional Methods (ARMs) which can be used to determine compliance with the NAAQS. Monitoring agencies identifying ARMs that are not providing data of sufficient quality will also be allowed to exclude these data in making comparisons to the $PM_{2.5}$ NAAQS. Currently, there are no designated ARMs for $PM_{2.5}$.

[206] Data for a combined site record originates by default from the designated ''primary'' monitor at the site location and is then augmented with data from collocated FRM or FEM monitors whenever valid data are not generated by the primary monitor. Samples in the combined site record are deemed ''creditable'' or ''extra'' according to the required sampling frequency for a specific monitoring site (i.e., ''site-level sampling frequency'') which, by default, is defined to be the same as the sampling frequency required of the primary monitor. Samples in the combined site data record that correspond to scheduled days according to the site-level sampling frequency are deemed ''creditable'' and, thus, are considered for determining whether or not a specific monitoring site meets data completeness requirements. These samples also determine which daily value in the ranked list of daily values for a year represents the annual 98th percentile concentration. Samples that are not deemed ''creditable'' are classified as ''extra'' samples. These samples do not count towards data completeness requirements and do not affect which daily values represent the annual 98th percentile concentration; ''extra'' samples, however, are candidates for selection as the 98th percentile.

[207] Before the introduction of continuous FEMs, when two or more samplers were collocated at the same site, monitoring agencies typically identified the sampler that operated on the more frequent sampling schedule as the ''primary'' monitor for developing a single site record. However, due to concerns regarding the comparability of FEMs to FRMs operated in some monitoring agency networks, and as briefly discussed above and in more detail in section VIII.B.3.b.iii below, many monitoring agencies have kept the FRM as the ''primary'' monitor and delegated the continuous FEM (which samples more frequently, except in cases where the FRM operates on an ''every day'' schedule) to be the ''supplemental'' (non-primary) collocated monitor. In such cases, FEM measurements reported on the FRM ''off'' days were technically considered ''extra.'' In light of this practice, EPA modified standing operating procedures whereby supplemental collocated FEM samples reported on the FRM ''off'' days would be considered ''scheduled'' and ''creditable.'' Thus, collocated FEM samples would count towards data capture rates (actually, increasing both the numerator and the denominator in the capture rate equation), and also would count towards identifying annual 98th percentile concentrations. Further, if data from a supplemental collocated FEM are missing on an FRM ''off'' day (and no unscheduled FRM data are reported that day), the EPA proposed not to identify these as ''scheduled'' days consistent with current practice, and thus, reported data generated from the supplemental collocated continuous FEMs can only help increase data capture rates (77 FR 39001, June 29, 2012)).

[208] Data substitution tests are supplemental data completeness assessments that use estimates of 24-hour average concentrations to fill in for missing data (i.e., ''data substitution'').

design value is still considered incomplete (and not valid for NAAQS comparisons). Previously, section 4.1(c) of appendix N specified only one data substitution test for validating an otherwise incomplete design value. That diagnostic test only applied to the primary and secondary annual $PM_{2.5}$ standard and only applies in instances of a violation; this test is referred to as the ''minimum quarterly value'' test and is used to determine if the NAAQS has not been met. The two proposed additional data substitution tests were to be applicable for making comparisons to the primary and secondary annual and 24-hour $PM_{2.5}$ standards, specifically to show that the NAAQS had been met. One of these proposed tests uses collocated PM_{10} data to fill in ''slightly incomplete'' [209] data records, and the other uses quarter-specific maximum values to fill in slightly incomplete data records; these two test are referred to as the ''collocated PM_{10} test'' and the ''maximum quarterly value test'', respectively. Both tests are designed to confirm that the $PM_{2.5}$ design value is valid and is less than the level of the NAAQS.

The EPA received several comments on the proposed addition of the two data substitution tests to determine that the NAAQS was met. The majority of comments generally supported the proposed addition of data substitution tests. However, one commenter questioned the general philosophy of all appendix N data substitution tests (i.e., the existing ''over NAAQS'' test and the two proposed ''under NAAQS'' tests) by suggesting that there were more appropriate techniques for filling in for missing data that would result in better estimates of true design value level. The EPA believes that the data substitution tests provided in the finalized appendix N are all very conservative approaches to verify that the NAAQS standards are either met or not met, and that the test design values are not to be used as the best estimators of the design value concentration.[210]

Another commenter questioned, and argued against, the use of collocated PM_{10} data in $PM_{2.5}$ data substitution tests. The commenter stressed that this type of test is not consistent with those established for other pollutants. The commenter further argued that while PM_{10} and $PM_{2.5}$ are both measurements of particulate matter, they are essentially different pollutants with different sources and different dispersion characteristics, and further, that the ratio of $PM_{2.5}$ to PM_{10} varies spatially and temporally. In general, the commenter claimed that the EPA had offered no explanation of why PM_{10} data were valid for a $PM_{2.5}$ data substitution test. At the time of proposal, the EPA believed that PM_{10} data would be appropriate for a $PM_{2.5}$ data substitution test. After consideration of public comments and additional air quality analyses, the EPA has decided that a collocated PM_{10} test is largely redundant with the maximum quarterly value test and thus not necessary to include it in Appendix N. The EPA has analyzed the most recent three years of $PM_{2.5}$ and PM_{10} data (2009–2011) and assessed the separate benefit of the PM_{10} substitution routine compared to the maximum quarterly value test (Schmidt, 2012b). In this assessment of 2009–2011 $PM_{2.5}$ design values which did not meet the nominal data completeness requirements, the EPA found that the collocated PM_{10} test was almost entirely redundant with the maximum quarterly value test. It was also very infrequently needed as a separate test. For the annual NAAQS, the maximum quarter value test in 100 cases resulted in a test design value (TDV_{max}) less than or equal to 12.0 $\mu g/m^3$. There were only two additional cases (i.e. 2 percent) when TDV_{max} was greater than 12.0 $\mu g/m^3$ but the TDV associated with the collocated PM_{10} test was less than 12.0 $\mu g/m^3$. Similarly for the 24-hour NAAQS, the maximum quarter value test in 116 cases resulted in a test design value (TDV_{max}) less than or equal to 35 $\mu g/m^3$ and again only 2 additional sites (less than 2 percent) passed the collocated PM_{10} test but not the maximum quarterly value test. Furthermore, the maximum quarterly value tests allowed the annual and 24-hour design value to be validated approximately 5 times more often than through the use of the collocated PM_{10} test. Accordingly, the EPA has decided to not include the collocated PM_{10} data substitution tests in Appendix N, and thereby further simplify the data handling procedures for making comparisons to the annual and daily NAAQS.

With regard to identifying annual 98th percentile concentrations for comparison to the primary and secondary 24-hour $PM_{2.5}$ standards, the EPA suggested in the proposal to simplify the procedures used with an approved seasonal sampling schedule. Specifically, the EPA proposed to eliminate the use of a special formula for calculating annual 98th percentile concentrations with a seasonal sampling schedule and thereby proposed to use only one method for calculating annual 98th percentile concentrations for all sites (77 FR 39002, June 29, 2012).

The proposal explained that with an approved seasonal sampling schedule, a site is typically required to sample during periods of the year when the highest concentrations are expected to occur, but less frequently during periods of the year when lower concentrations are expected to occur (77 FR 39002, June 29, 2012). This type of sampling schedule generally leads to an unbalanced data record; that is, a data record with proportionally more ambient measurements (with respect to the total number of days in the sampling period) in the ''high'' season and proportionally fewer ambient measurements in the ''low'' season. In the last review, the EPA revised section 4.5 of appendix N to include a special formula for computing annual 98th percentile values when a site operates on an approved seasonal sampling schedule. This special formula accounted for an unbalanced data record and was consistent with guidance documentation (US EPA, 1999), and, where appropriate, with official OAQPS design value calculations (71 FR 61211, October 17, 2006). In cases where there is a balanced [211] (or near-balanced) data record, the special formula yields the same result as the regular procedure for calculating annual 98th percentile concentrations.

To qualify for a seasonal sampling schedule, monitoring agencies are required to co-locate a continuous $PM_{2.5}$ instrument with the seasonal sampling FRM. Since the last review, there has been considerable deployment of continuous $PM_{2.5}$ FEM monitors. In situations where a $PM_{2.5}$ FRM monitor operating on a non-daily periodic schedule (such as a 1-day-in-3 or a 1-day-in-6 schedule) is collocated with a continuous $PM_{2.5}$ FEM monitor, data are combined based on procedures stated in section 3.0 of appendix N as modified, as discussed in section VII.A.3 above. Combining collocated FRM and FEM data effectively results in a site which samples everyday and results in a balanced data record. In such a case, if a site used a seasonal sampling schedule regime for the FRM monitor, these data would be balanced by the every-day

[209] Slightly incomplete is defined as less than 75 percent but at least 50 percent quarterly data capture.

[210] Appendix N states that when the data substitution tests are satisfied, then the NAAQS design values derived from reported $PM_{2.5}$ data which otherwise would be considered to be incomplete shall be considered valid for comparisons to the $PM_{2.5}$ NAAQS.

[211] A balanced data record has the same proportion of ambient measurements (with respect to the total number of days in the sampling period) in the ''high'' season as in the ''low'' season.

FEM data and there would be no need for the special formula for calculating annual 98th percentile concentrations on the combined site data.

As EPA noted in the proposal, there are very few $PM_{2.5}$ FRM monitors that operated on an approved seasonal sampling schedule (only 15 sites out of approximately 1,000 total sites in 2010) and that for almost half of those sites, the collocated continuous instrument was a $PM_{2.5}$ FEM (77 FR 39002, June 29, 2012). The proposal stated that for the 3-year period 2008 to 2010, the annual 98th percentile concentrations calculated with the special formula at those 15 sites were approximately five percent lower than if the regular procedure was used. The EPA also noted in the proposal that, in the last review, the Agency modified the monitoring requirements for areas with an FRM operating on a non-daily schedule such that, when the design values were within five percent of the 24-hour $PM_{2.5}$ NAAQS, those areas would be required to increase the frequency of sampling to every day (40 CFR 58.12(d)(1); 71 FR 61165, October 17, 2006; 71 FR 61249, October 17, 2006). In consideration of these facts, the EPA proposed to simplify the data handling procedures for sites operating on a seasonal sampling schedule by eliminating the special formula and all references to it for the following reasons: (1) The small difference between 98th percentile concentrations calculated using the special formula versus the regular procedure and the small number of sites currently using the special formula; (2) the EPA requires every day sampling in areas with design values that are within five percent of the 24-hour $PM_{2.5}$ NAAQS; and (3) FRMs operating on an approved seasonal sampling schedule are required to be collocated with a continuous $PM_{2.5}$ instrument (and if that instrument were an FEM, the resulting combined site record would tend to be balanced over the year and thus the special formula would be superfluous) (77 FR 39002, June 29, 2012). Thus, the EPA proposal included only one method for calculating annual 98th percentile concentrations, the ''regular'' table look-up method specified in section 4.5(a)(1) of appendix N.

In light of the rationale provided above and because EPA received no significant negative comments regarding the proposal, the EPA concludes it is appropriate to eliminate the special seasonal sampling 98th percentile identification procedure from appendix N. The final revised appendix N specifies only one method for identifying annual 98th percentile concentrations; the table look-up method is now the only permitted technique for identifying annual 98th percentile concentrations.

B. Exceptional Events

The EPA is finalizing primary annual $PM_{2.5}$-specific deadlines in 40 CFR 50.14 by which air agencies [212] must flag ambient air quality data that they believe have been affected by exceptional events and submit initial descriptions of those events. The EPA is also finalizing the deadlines by which air agencies must submit detailed exceptional events documentation to support the exclusion of those data from the EPA's monitoring-based determinations of attainment or nonattainment with the revised primary annual $PM_{2.5}$ NAAQS. The final exceptional events-related schedule is aligned with the designations schedule, discussed in greater detail in section IX, and is promulgated as proposed and as supported by multiple commenters. 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 the new or revised NAAQS is promulgated or because the generic deadlines require documentation submission at least 12 months prior to the date that the EPA must make a regulatory decision.

The EPA acknowledges the concern raised by a few commenters that numerous wildfires occurred between 2010 and 2012 that air agencies may determine influenced ambient air quality concentrations potentially affecting compliance with the revised primary annual $PM_{2.5}$ NAAQS, and that air agencies may want to submit detailed exceptional events documentation associated with multiple wildfires. Commenters further noted that 1 year to provide documentation of these potential exceptional events may not be sufficient. The EPA believes that the promulgated schedules provide sufficient time for air agencies to submit information related to the annual standard and for the EPA to fully consider and act on the submitted information during the initial area designation process. The EPA recently released draft exceptional events guidance that clarifies key provisions of the 2007 Exceptional Events Rule, provides examples of best practices, and streamlines the documentation development process. The guidance provides approaches that are broadly applicable to all event/pollutant combinations and would apply to many PM events, including wildfire/PM combinations. Additionally, the EPA has posted several concurred upon wildfire/PM exceptional event demonstration packages on its Web site at: *http://www.epa.gov/ttn/analysis/exevents.htm*. Considered together, the EPA believes this guidance will help air agencies submit information in a timely manner.[213] The EPA notes that under the promulgated schedule, except for events that occur in December 2012, air agencies will have more than 1 year to provide documentation for these potential events. The EPA intends to work with potentially affected areas to identify, screen, and prioritize events potentially influencing compliance with the primary annual $PM_{2.5}$ NAAQS and associated area designations.

Also in response to comments, the EPA is clarifying that this preamble language and the associated promulgated exceptional events schedules apply only to the NAAQS that the EPA is newly promulgating or revising in this action, that is, the revised primary annual $PM_{2.5}$ NAAQS. The promulgated exceptional event schedule revisions do not apply to the retained PM standards (i.e., secondary PM standards, primary 24-hour PM_{10}, primary 24-hour $PM_{2.5}$). Further, the revised/extended exceptional event schedules apply only to those data the EPA will use to establish initial area designations for the revised primary annual $PM_{2.5}$ NAAQS.

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 the proposal, without revisions to 40 CFR 50.14, an air agency may not be able to flag and submit documentation for some relevant data because the generic deadlines may have already passed by the time the new or revised NAAQS is promulgated. Similarly, revisions to 40 CFR 50.14 are needed because air agencies may not be able to flag and submit documentation for events that occurred in December of 2013 by 1 year before the designations

[212] References to ''air agencies'' are meant to include state, local, and tribal air agencies responsible for implementing the Exceptional Events Rule.

[213] The EPA released draft exceptional events guidance documents (U.S. EPA, 2012e) for public comment via a Notice of Availability in the **Federal Register** on July 6, 2012 (77 FR 39959).

are made in 2014 as is required by the existing generic schedule requires.

To support appropriate consideration of exceptional event data influencing ambient air quality concentrations potentially affecting compliance with the revised primary annual $PM_{2.5}$ NAAQS, the EPA is adopting revisions to 40 CFR 50.14 to change the submission dates for claimed exceptional events information affecting $PM_{2.5}$ data considered during the initial area designations process under the promulgated revised primary annual $PM_{2.5}$ NAAQS. As proposed, for air quality data collected in 2010 or 2011, the EPA is extending to July 1, 2013 the otherwise applicable generic deadlines of July 1, 2011 and July 1, 2012, respectively, for flagging data and providing an initial description of an event (40 CFR 50.14(c)(2)(iii)). The EPA is retaining the existing generic deadline in the Exceptional Events Rule of July 1, 2013 for flagging data and providing an initial description of events occurring in 2012. Similarly, the EPA is revising to December 12, 2013, the deadline for submitting documentation to justify exceptional events occurring in 2010 through 2012 and potentially influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS. The EPA believes these revisions/extensions will provide adequate time for air agencies to review potential $PM_{2.5}$ exceptional events influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS from 2010 to 2012, to notify the EPA by flagging the relevant data and providing an initial description in AQS, and to submit documentation to support claims for exceptional events. These schedule revisions will also allow the EPA to fully consider and act on the submitted information during the initial area designation process.

If an air agency intends the EPA to consider in the revised primary annual $PM_{2.5}$ designations decisions whether $PM_{2.5}$ data collected during 2013 influence compliance with the primary annual $PM_{2.5}$ NAAQS, then the air agency must flag these data by the generic Exceptional Event Rule deadline of July 1, 2014. The EPA is finalizing August 1, 2014, as the deadline for submitting documentation to justify $PM_{2.5}$-related exceptional events occurring in 2013 and potentially influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS. The EPA believes that these deadlines provide air agencies with adequate time to review and identify potential exceptional events that occur in calendar year 2013 and for the EPA to fully consider and act on the submitted information during the initial area designation process.

While the EPA will make every effort to designate areas for the primary annual $PM_{2.5}$ NAAQS on a 2 year schedule, the EPA recognizes that it may need up to an additional year for the designations process to ensure that states/tribes and the EPA base designations decisions on complete and sufficient information. If the EPA announces at a later date that it is extending the designations schedule beyond 2 years based on unavailability of data, the EPA will consider extending the 2013 exceptional event documentation submission schedule by promulgating additional revisions to 40 CFR 50.14.

Therefore, using the authority provided in CAA section 319(b)(2) and in the Exceptional Events Rule at 40 CFR 50.14 (c)(2)(vi), the EPA is finalizing the schedule for data flagging and submission of demonstrations for $PM_{2.5}$ exceptional events data potentially influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS considered for initial area designations under the promulgated primary annual $PM_{2.5}$ NAAQS as presented in Table 3.

TABLE 3—REVISED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN INITIAL AREA DESIGNATIONS FOR THE 2012 $PM_{2.5}$ NAAQS

NAAQS Pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
$PM_{2.5}$/Primary Annual Standard (12.0 μg/m³) Promulgated December 14, 2012	2010 and 2011	July 1, 2013	December 12, 2013.
	2012	July 1, 2013[a]	December 12, 2013.
	2013	July 1, 2014[a]	August 1, 2014.

[a] This date is the same as the general schedule in 40 CFR 50.14.

Note: The table of revised deadlines *only* applies to data the EPA will use to establish the initial area designations for the revised primary annual $PM_{2.5}$ NAAQS. The general schedule applies for all other purposes, most notably, for data used by the EPA for redesignations to attainment.

C. Updates for Data Handling Procedures for Reporting the Air Quality Index

There were no comments regarding the proposed updates for data handling procedures for reporting the AQI. However, two table footnotes that were part of the existing rule were inadvertently omitted from the proposal. The inadvertently dropped footnotes were footnotes 3 and 4 of Table 2 (''Breakpoints for the AQI'') of appendix G (''Uniform Air Quality Index (AQI) and Daily Reporting'') to Part 58. Since the footnotes are still applicable, the EPA has included them in the final rule. The final rule also codifies all changes identified in the EPA proposal regarding data handling procedures for the AQI.

VIII. Amendments to Ambient Monitoring and Reporting Requirements

The EPA is finalizing a number of changes to the ambient air monitoring, reporting, and network design requirements associated with the PM NAAQS. Ambient PM monitoring data are used to meet a variety of monitoring objectives including determining whether an area is in violation of the PM NAAQS. Ambient PM monitoring data are collected by state, local, and tribal monitoring agencies (''monitoring agencies'') in accordance with the monitoring requirements contained in 40 CFR parts 50, 53, and 58. This section discusses the monitoring changes that the EPA is finalizing to support the revised PM NAAQS summarized in sections III.F, IV.F, and VI.F above.

The monitoring changes being finalized primarily relate to the revised primary $PM_{2.5}$ NAAQS. Several monitoring changes were proposed specifically in support of a potential distinct secondary $PM_{2.5}$ visibility index standard; however, as explained in Section VI, EPA is not finalizing a distinct secondary standard using a visibility index and therefore is not finalizing the monitoring changes that would have been necessary to support it. The EPA did not propose any monitoring changes associated with the

PM_{10} NAAQS and is not adopting any in this final rule.

A. Issues Related to 40 CFR Part 53 (Reference and Equivalent Methods)

To be used in a determination of compliance with the PM NAAQS, PM data are typically collected using samplers or monitors employing an FRM or FEM. The EPA also allows use of alternative methods where explicitly stated in the monitoring methodology requirements (appendix C of 40 CFR part 58), such as $PM_{2.5}$ ARMs which can be used to determine compliance with the NAAQS. The EPA prescribes testing and approval criteria for FRM and FEM methods in 40 CFR part 53.

1. $PM_{2.5}$ and $PM_{10\text{-}2.5}$ Federal Equivalent Methods

As described in the proposal, the EPA continues to believe that an effective $PM_{2.5}$ monitoring strategy includes the use of both filter-based FRM samplers and well-performing continuous $PM_{2.5}$ monitors. Well-performing continuous $PM_{2.5}$ monitors would include both non-designated continuous $PM_{2.5}$ monitors and designated Class III [214] continuous FEMs that meet the performance criteria described in table C–4 of 40 CFR part 53 when comparing to a collocated FRM operated by the monitoring agency. Only designated methods (i.e., FRMs, FEMs, and ARMs) are approved to be used in comparison to the NAAQS; however, non-designated methods may be useful to meet other monitoring objectives (e.g., reporting the AQI). The use of Class III continuous FEMs at SLAMS is described in more detail in section VIII.B.3.b.ii below. Monitoring agencies are encouraged to evaluate the quality of data being generated by FEMs and, where appropriate, to reduce the use of manual, filter-based samplers to improve operational efficiency and to lower overall operating costs. To encourage such a strategy, the EPA is working with numerous stakeholders including the monitoring committee of NACAA, instrument manufacturers, and monitoring agencies to support national data analyses of continuous $PM_{2.5}$ FEM performance, and where such performance does not meet data quality objectives, to develop and institute a program of best practices to improve the quality and consistency of resulting data.

The EPA believes that progress is being made to implement well performing $PM_{2.5}$ continuous FEMs across the nation. As noted in the proposal, the first few steps involved the EPA developing and approving the testing and performance criteria which were finalized in 2006, followed by instrument companies performing field testing and submitting applications to the EPA, and the EPA review and approval, as appropriate, of Class III FEMs. In the current step, monitoring agencies are testing and assessing the data comparability from continuous $PM_{2.5}$ FEMs.

While EPA did not propose any changes to the performance or testing criteria in 40 CFR part 53 used to approve $PM_{2.5}$ continuous FEMs, the EPA did propose an administrative change to part 53.9—''Conditions of designations.'' See 77 FR 39006. This section describes a number of conditions that must be met by a manufacturer as a condition of maintaining designation of an FRM or FEM. Subsection (c) of this section reads, ''Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10\text{-}2.5}$ sampler offered for sale as part of a FRM or FEM shall function within the limits of the performance specifications referred to in 40 CFR 53.20(a), 53.30(a), 53.50, or 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in 40 CFR 53.4(b)(3).'' The EPA's intent in this requirement is to ensure that monitoring methods work within performance criteria, which includes methods for $PM_{2.5}$ and $PM_{10\text{-}2.5}$; however, there was no specific reference to performance criteria for Class II [215] and III $PM_{2.5}$ and $PM_{10\text{-}2.5}$ methods. The EPA proposed to link the performance criteria referred to in 40 CFR part 53.35 associated with Class II and III $PM_{2.5}$ and $PM_{10\text{-}2.5}$ methods with this requirement for maintaining designation of approved FEMs. The specific performance criteria identified in 40 CFR 53.35 for $PM_{2.5}$ and $PM_{10\text{-}2.5}$ methods are available in table C–4 to subpart C of 40 CFR part 53.

All comments received on this proposed change were supportive and EPA is finalizing this change. The implication of this change is that instrument manufacturers and air agencies operating the equipment will have a shared responsibility for approved FEMs to meet required performance criteria for at least the first 12 months of operation, which is the typical warranty period for an instrument. By having a shared responsibility for an FEM to meet the performance criteria, instrument companies and air agencies will both be motivated to ensure the best practices for installing, operating, and servicing an instrument are carried out according to the instrument company's operating manual and other readily available materials [216] in support of each method.

2. Use of Chemical Speciation Network (CSN) Methods To Support the Proposed New Secondary $PM_{2.5}$ Visibility Index NAAQS

The EPA had proposed to use CSN methods to support the proposed new secondary $PM_{2.5}$ visibility index NAAQS; however, as explained in Section VI of this final rule, EPA is not finalizing the new secondary $PM_{2.5}$ visibility index NAAQS and therefore has no need to finalize the CSN methods to support such a standard.

Despite our decision not to finalize formal requirements for CSN methods, this network remains a critical component in our PM monitoring program. The EPA, monitoring agencies, and external scientists and policy makers use $PM_{2.5}$ data from the CSN to support several important monitoring objectives such as: Development of modeling tools and the application of source apportionment modeling for control strategy development to implement the NAAQS; health effects and exposure research studies; assessment of the effectiveness of emission reductions strategies through the characterization of air quality; and development of SIPs. The use of the CSN to support all of these objectives will continue.

B. Changes to 40 CFR Part 58 (Ambient Air Quality Surveillance)

1. Terminology Changes

The EPA proposed to revise several terms associated with $PM_{2.5}$ monitor placement to ensure consistency with other NAAQS and to conform with long-standing practices in siting of equipment by monitoring agencies (77 FR 39007).

The EPA proposed to revoke the term ''community-oriented'' and replace it

[214] Class III refers to those methods for $PM_{2.5}$ or $PM_{10\text{-}2.5}$ that are employed to provide $PM_{2.5}$ or $PM_{10\text{-}2.5}$ ambient air measurements representative of one-hour or less integrated $PM_{2.5}$ or $PM_{10\text{-}2.5}$ concentrations, as well as 24-hour measurements determined as, or equivalent to, the mean of 24 one-hour consecutive measurements.

[215] Class II refers to those methods for $PM_{2.5}$ or $PM_{10\text{-}2.5}$ in which integrated samples are taken by filtration and subjected to a subsequent filter conditioning process followed by a gravimetric mass determination, but which is not a Class I equivalent methods because of substantial deviations from the design specification of the sampler specified for reference methods in appendix L or O (as applicable) of part 50 of the CFR.

[216] At the recent National Air Quality Conference in May of 2012, a training session on ''Best Practices for Operating $PM_{2.5}$ Continuous FEMs'' was conducted. Presentations from this session are publically available on EPA's web site at: *http://www.epa.gov/ttn/amtic/2012present.html.*

with the term ''area-wide.'' The term ''community-oriented,'' while used within the description of the design criteria for $PM_{2.5}$, is not defined and has not been used in the design criteria for other NAAQS pollutants. Appendix D to 40 CFR part 58 presents a functional usage of the term where sites at the neighborhood and urban scale area are considered to be ''community-oriented.'' In addition, population-oriented, micro- or middle-scale $PM_{2.5}$ monitoring may also be considered ''community-oriented'' when determined by the Regional Administrator to represent many such locations throughout a metropolitan area. The EPA proposed to replace this usage of ''community-oriented'' with the term ''area-wide'' in the text of the $PM_{2.5}$ network design criteria and to define it in 40 CFR 58.1 to provide a more consistent usage of this concept throughout appendix D of 40 CFR part 58. Specifically, the EPA proposed that the terminology would read—''Area-wide means all monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro-or middle-scale that are representative of many such locations in the same CBSA.''

The EPA proposed to revoke the term ''Community Monitoring Zone'' (CMZ) and to remove references to it in 40 CFR part 58. Community monitoring zone is currently defined as ''an optional averaging area with established, well defined boundaries, such as county or census block, within an MPA [217] that has relatively uniform concentrations of annual $PM_{2.5}$ as defined by appendix N of 40 CFR part 50 of this chapter. Two or more community oriented state and local air monitoring stations (SLAMS) monitors within a CMZ that meet certain requirements as set forth in appendix N of 40 CFR part 50 may be averaged for making comparisons to the annual $PM_{2.5}$ NAAQS.'' The EPA proposed to revoke this term and references to it since, as discussed in section VII.A.2 above, the EPA proposed to eliminate all references to the now-revoked spatial averaging option throughout appendix N.

The one comment directly addressing the proposed rule changes (from a state air agency) supported the proposal. A few industry commenters noted the change in the context of how monitoring data are used to compare to the NAAQS, but did not address the proposed specific terminology changes. However, as explained in section III.E.3.a, several industry commenters did provide comments critical of EPA's proposal to revoke spatial averaging which is related to revoking the term ''Community Monitoring Zone''.

For the reasons explained above, the EPA is finalizing its proposed change to revoke the term ''community-oriented'' and to replace it with the term ''area-wide.'' The EPA is also finalizing its proposal to revoke the term ''Community Monitoring Zone'' (CMZ) and references to it in 40 CFR part 58.

2. Special Considerations for Comparability of $PM_{2.5}$ Ambient Air Monitoring Data to the NAAQS

In general, ambient monitors must meet a basic set of requirements before the resulting data can be used for comparison to the NAAQS. These requirements include the presence and implementation of an approved quality assurance project plan; the use of methods that are reference, equivalent, or other approved method as described in appendix C to 40 CFR part 58; and compliance with the probe and siting path criteria as described in appendix E to 40 CFR part 58. While these 40 CFR part 58 requirements apply to any monitor that provides data for comparison to the NAAQS, there are certain additional restrictions that apply only to $PM_{2.5}$ monitoring.[218] These additional restrictions provide that sites must be ''population-oriented'' for comparison to either the 24-hour or annual NAAQS, and specifically for comparison to the annual NAAQS, sites must be sited to represent area-wide locations. There is a related provision that provides for comparing sites at micro- or middle-scales to the annual $PM_{2.5}$ NAAQS when the site is determined by the Regional Administrator to represent a larger region of localized high ambient $PM_{2.5}$ concentration.

These provisions have been in the monitoring regulations since the inception of the $PM_{2.5}$ NAAQS. Nonetheless, these provisions and the fact that such monitoring requirements are not found in the requirements for all other criteria pollutants have created areas of uncertainty for the EPA and state, local, and tribal agencies that base implementation decisions on monitoring requirements through programs such as dispersion modeling, SIP planning, and the calculation of transportation conformity budgets. For example, in developing modeling guidance to support near-road transportation conformity modeling, the EPA struggled to determine how the identification of acceptable $PM_{2.5}$ receptor locations can be reconciled with the $PM_{2.5}$ monitoring regulations that reference potentially acceptable (or unacceptable) monitoring locations that may, or may not, be considered unique for purposes of comparing to the annual $PM_{2.5}$ NAAQS. Accordingly, the EPA proposed to revise these particular $PM_{2.5}$ requirements for consistency with long-standing practices in all other NAAQS pollutant monitoring networks, and to ensure that interpretation of the monitoring rules does not cause ambiguity in implementation examples that also include the treatment of unmonitored areas (see 77 FR 39007–009). Each of these topics is described below.

a. Eliminating the Term ''Population Oriented'' From Section 58.30

The EPA proposed to remove the term ''population oriented'' from section 58.30 so that there would no longer be an explicit requirement that $PM_{2.5}$ monitoring sites be ''population-oriented'' for comparison to the $PM_{2.5}$ NAAQS. The EPA noted that this requirement is not entirely consistent with the definition of ''ambient'' used in the NAAQS. The EPA's definition of ambient air is specified in 40 CFR 50.1—''*Ambient air* means that portion of the atmosphere, external to buildings, to which the general public has access.'' The EPA's definition of ''population-oriented'' is provided in 40 CFR 58.1—''*Population-oriented monitoring (or sites)* means residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day.'' The NAAQS are standards for concentrations ''in the ambient air'' [219]—i.e., air to which members of the public could be exposed— and all monitors used for NAAQS regulatory purposes must be representative of ambient air concentrations.[220] Consistent with this requirement and the long-standing practice of monitoring agencies locating ambient monitors, the EPA's experience is that $PM_{2.5}$ monitors are placed in areas that are representative of population exposures. There are no $PM_{2.5}$ monitors currently operating as

[217] Monitoring Planning Area (MPA) means a contiguous geographic area with well established, well defined boundaries, such as a CBSA, county or State, having a common areas that is used for planning monitoring locations for $PM_{2.5}$.

[218] These are found in 40 CFR 58.30 (Special considerations for data comparisons to the NAAQS).

[219] See 40 CFR part 50.

[220] See, e.g., 40 CFR 58.1 (defining ''federal reference method'' as ''a method for sampling and analyzing the ambient air for an air pollutant * * *'')

''non-population oriented'' and the EPA does not believe that the requirement for near-road monitoring (discussed in detail further below) will result in monitors that are not representative of population exposures. At the same time, the specification that certain $PM_{2.5}$ monitors must be ''population-oriented'' in the rules has created substantial confusion in how to treat potential locations of exposure for NAAQS-related regulatory requirements other than monitoring network design, such as in applying modeling as part of a PSD or SIP exercise.[221]

The EPA's intention in proposing to remove the term ''population oriented'' from section 58.30 was to remove a potential source of inconsistency in the monitoring rules as they apply for all the NAAQS. As noted earlier, the NAAQS provide protection for the public health and welfare in areas where the public can be exposed. For all other criteria pollutants, the monitoring requirements have no such restriction on the comparability of a monitor. In the case of $PM_{2.5}$ however, the additional restriction of monitors being required to be ''population-oriented'' for comparability to the NAAQS has existed. The term ''population oriented'' has lacked a quantitative definition (e.g., the interpretation of ''substantial number'' in the definition of ''population-oriented''), therefore monitoring agencies and those stakeholders who based implementation strategies and decisions on monitoring regulations have been uncertain about which locations would meet requirements described in § 58.30, which do not exist for any other NAAQS. Monitoring agencies are also not in a position to precisely forecast where future residential, commercial, or recreational development may occur, therefore requiring that $PM_{2.5}$ monitors that are to be compared to the NAAQS can only be located where ''substantial numbers of people'' live, work, or play (i.e., in the present tense) represents an unwise limitation on the flexibility of monitoring agencies to revise their $PM_{2.5}$ networks to account for anticipated changes in demographics or development as well as a contradiction with the inherent applicability of the NAAQS in ambient air locations where the public has access (e.g., in any location outside the perimeter of a industrial facility). From an operational standpoint, we note that revoking this term would not change the requirements in the $PM_{2.5}$ network design criteria. To the extent that the phrase ''population-oriented'' served to emphasize the need for micro- or middle-scale monitors to be representative of locations with population exposure to be comparable to the annual NAAQS, the definition of ambient air, together with the requirement in revised section 58.30 that such sites must be ''area-wide'' to be comparable to the annual NAAQS, adequately serves the same purpose. By revising the $PM_{2.5}$ monitoring rules to ensure consistency with the long-standing definition of ambient air applied to the other NAAQS pollutants, the EPA will be able to more clearly define how to treat potential exposure receptors for other NAAQS regulatory requirements, regardless of whether monitoring exists or not.

Public comments on this issue were supported by air agencies and public health and environmental groups. Two commenters from state agencies supported the proposed change, with one noting further that regardless of a change it is still the air agency's responsibility to plan a network with sites that are appropriate for comparison to the NAAQS. Several public health and environmental groups supported revoking ''population oriented'' as a condition for comparability of $PM_{2.5}$ monitoring sites to the NAAQS stating that retaining such a policy is inconsistent with the text, purpose and intent of the Clean Air Act. Most industry commenters did not support revoking ''population-oriented'' as a condition for comparison to the NAAQS. Most of these comments raised concerns with using data from an area where potentially no one is exposed.

In considering these comments, the EPA agrees that it is appropriate for individual air agencies to provide a recommendation in the annual monitoring network plan regarding whether any site may or may not be appropriate for comparison to the $PM_{2.5}$ (or any) NAAQS. The roles of the air agency and the EPA in this process of identifying whether a site is, or is not, consistent with the network plan requirements for a NAAQS are specified in the already-established monitoring requirements of § 58.10. In this approval process, the air agency initiates the recommendations and the EPA has the responsibility to approve, as appropriate, any plans that provide for changes to the network.

EPA disagrees with the industry comments. As noted above, monitors (including those for $PM_{2.5}$) must already meet the test of being representative of ambient air to be compared to the NAAQS, and thus such monitors meeting this test will be sited in locations where people are already located, or where they could be exposed, whether or not the term ''population oriented'' appears in section 58.30. Moreover, as discussed below, comparisons to the annual $PM_{2.5}$ NAAQS can be only be from monitors ''that are representative of area-wide air quality.'' ''Area-wide'' monitors are those at the neighborhood scale or larger, or at smaller scales if they are representative of many such locations in the same CBSA. The EPA anticipates that a monitor that is sited as representative of ambient air at the neighborhood scale or larger (or of ambient air at many smaller areas) will be representative of population exposure. This conclusion is further supported by the fact that all current monitors used for comparison with the $PM_{2.5}$ NAAQS are designated as ''population-oriented.''[222]

After consideration of the public comments, the EPA is finalizing its decision to revoke use of ''population-oriented'' as a condition for comparability of $PM_{2.5}$ monitoring sites to the NAAQS. The EPA concludes that the ''population-oriented'' language is unnecessary and inconsistent with other monitoring rules, and should therefore be removed.

b. Applicability of Micro- and Middle-Scale Monitoring Sites to the Annual $PM_{2.5}$ NAAQS

The EPA proposed language in 40 CFR section 58.30 to clarify when data from $PM_{2.5}$ monitoring sites at micro- and middle-scale locations can be compared to the annual $PM_{2.5}$ NAAQS. The EPA's intent was to provide consistency and predictability in the interpretation of the monitoring regulations. The EPA's current rules state that ''$PM_{2.5}$ data that are representative, not of area-wide but rather, of relatively unique population-oriented micro-scale, or localized hot spot, or unique population-oriented middle-scale impact sites are only eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. For example, if the $PM_{2.5}$ monitoring site is adjacent to a unique dominating local $PM_{2.5}$ source or can be shown to have average 24-hour concentrations representative of a smaller than neighborhood spatial scale, then data from a monitor at the site would only be eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS.'' We proposed clarifying language to

[221] Examples include dispersion modeling to support NAAQS attainment planning, associated SIP development, and the calculation of transportation conformity budgets.

[222] The last known non population-oriented site at Sun Metro in El Paso Texas (AQS ID: 48–141–0053), was shut down in October 2010 and is in the process of being moved to a nearby neighborhood.

explicitly state that measuring $PM_{2.5}$ in micro- and middle-scale environments near emissions of mobile sources, such as a highway, does not constitute being impacted by a ''unique'' source and so could be compared to the annual $PM_{2.5}$ NAAQS. We explained that mobile sources are rather ubiquitous and there are many locations throughout an urban area where elevated exposures attributable to such sources could occur. Therefore, we proposed that in most cases the potential location for a $PM_{2.5}$ monitoring site, including micro- and middle-scale sites near roadways, would be eligible for comparison to the annual NAAQS. We further noted that the existing definition of ''middle scale'' in appendix D to part 58 already indicates that traffic corridors can be middle scale, and hence not unique, and therefore comparable to the annual $PM_{2.5}$ NAAQS (as well as to the 24-hour $PM_{2.5}$ NAAQS) (77 FR 39008).

Air agencies that commented on this part of the proposed rule offered a variety of positions. One air agency stated that sites at these smaller scales should not be compared to the annual NAAQS. Another air agency stated that these sites should be considered for comparison with the annual $PM_{2.5}$ NAAQS only when the air agency initiates a decision that such sites at these smaller scales are area-wide. A different air agency offered that all micro- and middle-scale sites should be compared to the annual NAAQS since the wording of the provision is problematic and will be difficult for agencies to implement.

Industry commenters were largely against finalizing such a provision. The major concern raised was that such a provision combined with other related provisions represented an unwarranted tightening of the NAAQS. Some industry commenters pointed out that there are examples of unique locations in near road environments and as such EPA should not presume that $PM_{2.5}$ monitors in these locations should be applicable to the annual $PM_{2.5}$ NAAQS.

In considering comments on this part of the rule, the EPA notes that there are already examples of where the States and EPA have determined certain micro- and middle-scale locations as applicable to the annual NAAQS and others where they were determined as not applicable to the annual $PM_{2.5}$ NAAQS. These cases exist where a State proposed and the Regional Administrator determined that either the micro-scale or middle-scale site did or did not represent many similar areas in a CBSA (40 CFR 58.30 and section 4.7 to Appendix D, part 58). The EPA also notes that the existing descriptions of the types of micro- and middle-scale sites which are unique and cited in § 58.30 are not being amended and that data from these types of sites would remain as not comparable to the annual $PM_{2.5}$ NAAQS. Accordingly, $PM_{2.5}$ data that are representative, not of area-wide but rather, of relatively unique population-oriented microscale, or localized hot spots, or unique middle scale impact sites will only be eligible for comparison to the 24-hour NAAQS. Our proposal was to clarify language to explicitly state that measuring $PM_{2.5}$ in micro- and middle-scale environments near emissions of mobile sources, such as a highway, does not constitute being impacted by a ''unique'' source and so the site could be compared to the annual $PM_{2.5}$ NAAQS. However, in light of public comments pointing out that there are cases where near-road environments can be considered a unique location; EPA is not finalizing this part of the rule language. Examples of such locations that are considered unique and should therefore not be considered applicable to the annual $PM_{2.5}$ NAAQS are explained later in section VIII.B.3.b.i. As noted in the preamble to the proposed rule (77 FR 39008–09), air agencies and the EPA will use the annual monitoring network plan described in 40 CFR 58.10 for identification and approval of sites that are suitable and sites that are not suitable for comparison with the annual $PM_{2.5}$ NAAQS.

The EPA disagrees with those comments that asserted that the proposed change would have represented a tightening of the NAAQS. As explained in section III.E.3.a on the form of the annual NAAQS, the EPA carefully considered that areas such as traffic corridors were potential high exposure areas, since a significant fraction of the population, including at-risk populations, live in proximity to major roads and should be afforded the degree of protection intended by the revisions to the form and level of the annual $PM_{2.5}$ standard being adopted. Monitoring in such areas as traffic corridors does not make the annual standard more stringent than intended, but rather affords the populations of such middle- and micro-scale areas (where determined to represent area-wide air quality) the requisite level of protection from long-term exposure to $PM_{2.5}$.

3. Changes to Monitoring for the National Ambient Air Monitoring System

a. Background

As described in appendix D to 40 CFR part 58, the ambient air monitoring networks must be designed to meet three basic monitoring objectives:

(a) Provide air pollution data to the general public in a timely manner. Data can be presented to the public in a number of attractive ways including through air quality maps, newspapers, Internet sites, and as part of weather forecasts and public advisories.

(b) Support compliance with ambient air quality standards and emissions strategy development. Data from FRM, FEM, and ARM monitors for NAAQS pollutants will be used for comparing an area's air pollution levels against the NAAQS. Data from monitors of various types can be used in the development of attainment and maintenance plans. SLAMS, and especially National Core Monitoring Network (NCore) [223] station data, will be used to evaluate the regional air quality models used in developing emission strategies and to track trends in air pollution abatement control measures' impact on improving air quality. In monitoring locations near major air pollution sources, source-oriented monitoring data can provide insight into how well industrial sources are controlling their pollutant emissions.

(c) Support for air pollution research studies. Air pollution data from the NCore network can be used to supplement data collected by researchers working on health effects assessments and atmospheric processes or for monitoring methods development work.

To support the air quality management work indicated in the three basic air monitoring objectives, a network must be designed with a variety of types of monitoring sites. Monitoring sites must be capable of informing managers about many things including the peak air pollution levels, typical levels in populated areas, air pollution transported into and outside of a city or region, and air pollution levels near specific sources. Following is a listing of six general site types: (a) Sites located to determine the highest concentrations expected to occur in the area covered by the network (highest concentration); (b)

[223] NCore is a multi-pollutant network that integrates several advanced measurements for particles, gases and meteorology (U.S. EPA, 2011a, Appendix B, section B.4). Measurements required at NCore include $PM_{2.5}$ mass and speciation, $PM_{10-2.5}$ mass, ozone, CO, SO_2, NO, NO_y, and basic meteorology.

sites located to measure typical concentrations in areas of high population density (population oriented); (c) sites located to determine the impact of significant sources or source categories on air quality (source impact or source oriented); (d) sites located to determine general background concentration levels (general background); and (e) sites located to determine the extent of regional pollutant transport among populated areas (regional transport); and in support of secondary standards (welfare related impacts).

b. Primary $PM_{2.5}$ NAAQS

The EPA proposed to add a near-road component to the $PM_{2.5}$ network design criteria and to clarify the use of approved $PM_{2.5}$ continuous FEMs at SLAMS.

ii. Addition of a Near-Road Component to the $PM_{2.5}$ Monitoring Network

The EPA proposed to add a near-road component to the $PM_{2.5}$ monitoring network (77 FR 39009). The EPA explained that there are gradients in near-roadway $PM_{2.5}$ that are most likely to be associated with heavily travelled roads (particularly those with significant heavy-duty diesel activity), and that the largest numbers of impacted populations are located in the largest CBSAs in the country (Ntziachristos *et al.,* 2007; Ross *et al.,* 2007; Yanosky *et al.,* 2009; Zwack *et al.,* 2011). The EPA further noted that by adding a modest number of $PM_{2.5}$ monitoring sites that are leveraged with measurements of other pollutants in the near-road environment, a number of key monitoring objectives will be supported, including collection of NAAQS comparable data in the near-road environment, support for long-term health studies investigating adverse effects on people, providing a better understanding of pollutant gradients impacting neighborhoods that parallel major roads, availability of data to validate performance of models simulating near-road dispersion, characterization of areas with potentially elevated concentrations and/or poor air quality, implementation of a multi-pollutant paradigm as stated in the NO_2 NAAQS proposed rule (74 FR 34442, July 15, 2009), and monitoring goals consistent with existing objectives noted in the specific design criteria for $PM_{2.5}$ described in appendix D, 4.7.1(b) to 40 CFR part 58.

The monitoring methods that are appropriate for this purpose are an FRM, FEM, or ARM. The EPA recognized that there are limitations in the ability of some of these methods to accurately measure $PM_{2.5}$ mass due to the incomplete retention of semi-volatile material on the sampling medium (U.S. EPA, 2009a, section 3.4.1.1). This limitation is relevant to the near-road environment as well as to other environments where PM is expected to have semi-volatile components. The EPA also recognized that continuous $PM_{2.5}$ FEMs, which provide mass concentration data on an hourly basis, are better suited to accomplish the goals of near-road monitoring as they will complement the time resolution of the other air quality measurements and traffic data collected at the same sites. In this regard, particular $PM_{2.5}$ FEMs are generally better suited for near-road monitoring than FRMs. However, filter-based FRMs do offer some advantages which may be highly desirable for near-road monitoring, such as readily available filters for later chemical analysis such as for elemental composition by x-ray fluorescence and black carbon (BC) by transmissometry. As a result of these tradeoffs, monitoring agencies are encouraged to select one or more $PM_{2.5}$ methods for deployment at near-road monitoring stations that best meet their agencies monitoring objectives while ensuring that at least one of those methods is appropriate for comparison to the NAAQS (i.e., a FRM, FEM, or ARM). The EPA believes that by allowing monitoring agencies to choose the FRM, FEM, or ARM method(s) that best fits their needs, whether filter-based or continuous, the data will still be able to meet the objectives cited above while ensuring maximum flexibility for the monitoring agencies in the operation of their network.

The EPA believes that requiring a modest network of near-road compliance $PM_{2.5}$ monitors is necessary to provide characterization of concentrations in near-road environments including for comparison to the NAAQS. These long-term monitors will supplement shorter-term networks to support the tracking of long-term trends [224] of near-road $PM_{2.5}$ mass concentrations and other pollutants in near-road environments where people are exposed. Therefore, the EPA proposed to require near-roadway monitoring of $PM_{2.5}$ at one location within each CBSA with a population of one million persons or greater. The EPA believes that this network will be adequate to support the NAAQS since the largest CBSAs are likely to have greater numbers of exposed populations, a higher likelihood of elevated near-road $PM_{2.5}$ concentrations, and a wide range of diverse situations with regard to traffic volumes, traffic patterns, roadway designs, terrain/topography, meteorology, climate, surrounding land use and population characteristics. Given the latest population data available, the proposed requirement would result in approximately 52 required near-road $PM_{2.5}$ monitors across the country. An indirect benefit of this network design is that monitoring agencies in these largest CBSAs are more likely to already have redundant monitors that could be relocated to the near-road environment, reducing costs for equipment and ongoing operation.[225] While only a single near-road $PM_{2.5}$ monitor is required within each of the CBSAs, agencies may elect to add additional $PM_{2.5}$ monitoring sites in near-road environments.

While the EPA recognized that the location of maximum concentration of $PM_{2.5}$ exposure from roadway sources might differ from the maximum location of NO_2 or other pollutants, the EPA proposed to require that near-road $PM_{2.5}$ monitors be collocated with the planned NO_2 monitors. The NO_2 network design considers multiple factors that are also relevant for $PM_{2.5}$ concentrations (i.e., average annual daily traffic, fleet mix, roadway design, congestion patterns, terrain, and meteorology) and significant thought and review has already gone into its design, including pilot studies at five locations, and the development of a technical assistance document in conjunction with the affected monitoring agencies and the CASAC AAMMS (Russell and Samet, 2010b) to support deployment. Further, this collocation will allow multiple pollutants to be tracked in the near-road environment. To the extent that air agencies are still determining the optimum location for their multi-pollutant [226] near-road monitoring stations, EPA encourages consideration of sites that best reflect measurement of maximum concentrations associated with exposure of people living in areas

[224] For example, the emissions used for the PM NAAQS RIA modeling show that nationwide on-road primary $PM_{2.5}$ emissions are expected to be reduced by 63% between 2007 and 2020. Additionally, the elemental carbon portion of the on-road emissions is expected to drop by 81 percent between 2007 and 2020. Therefore, we expect that measured near-road $PM_{2.5}$ gradients will be much lower in the future as elemental carbon is a large fraction of the gradient, due to future impacts of existing mobile source controls.

[225] EPA Regional Administrator approval would be required prior to the discontinuation of SLAMS monitors, based on the criteria described in 40 CFR 58.14(c).

[226] NO_2, CO, and now $PM_{2.5}$ measurements are all expected to be collocated at near-road monitoring stations.

that parallel major roads, to maximize the value of the data for use later in health studies. Therefore, while compromises may be necessary when siting a multi-pollutant near road monitoring station, on balance, the EPA believes this is the most efficient and beneficial approach for deployment of this component of the network.

The EPA notes that the planned 52 near-road monitors represent a small number of the total approximate 900 operating $PM_{2.5}$ monitoring stations across the country. The EPA could have proposed more near-road sites, however, the addition of sites in lower population CBSAs is not expected to lead to much if any difference in characterization of air quality since the bump in $PM_{2.5}$ concentration associated with near-road environments in lower population CBSAs, which typically have correspondingly less travelled roads, is expected to be very small. The EPA could also have proposed multiple sites in larger CBSAs; however, State monitoring programs are already working towards representative near-road monitoring stations and there is a synergistic value in ensuring these measurements are collocated with multiple other measurements to serve the monitoring objectives noted above. Since EPA has already finalized requirement of CO monitoring at near-road stations in CBSA's with a population of 1 million or more at sites that are collocated with NO_2, there would be less value in requiring any more than 52 $PM_{2.5}$ monitors as any more stations will not have CO for use in multi-pollutant monitoring objectives (e.g., health studies and model evaluation).

Ideally, near-road sites would be located at the elevation and distance from the road where maximum $PM_{2.5}$ levels occur in this environment, representing locations where populations are exposed; for example, in apartments and other housing; schools located along major roadways; industrial parks where workers exposed; and in recreational areas such as greenways, bikeways, and other park facilities that are often developed along roads. Specific to probe and siting criteria for near-road $PM_{2.5}$ monitors, which is explained later in this section, EPA did not set additional criteria on what the elevation and distance requirements should be, beyond what is already defined for $PM_{2.5}$ or near-road NO_2 monitors for reasons explained above. Also, the EPA did not propose that the near-road $PM_{2.5}$ monitors be located within a specific distance of other area-wide sites; however, monitoring agencies are encouraged to consider that a near-road site selected in accordance with monitoring requirements and also located in proximity to a robust area-wide site, such as an NCore station, would provide useful information in characterizing the near-road contribution to multiple pollutants, including $PM_{2.5}$ and tracking the decreasing trend that is expected in the $PM_{2.5}$ near-road gradient over time, due to future impacts of existing mobile source controls.

The timeline to implement the near-road $PM_{2.5}$ monitors should be as minimally disruptive to on-going operations of monitoring agency programs as possible recognizing monitoring agency resource constraints, while still meeting the need to collect for near-road $PM_{2.5}$ data in a timely fashion. Since the near-road $PM_{2.5}$ monitors were proposed to be collocated with the emerging near-road NO_2 network that was scheduled to be operational by January 1, 2013,[227] the EPA believes it is appropriate to wait until after the near-road NO_2 network is established before implementing the near-road $PM_{2.5}$ monitors. Therefore, the EPA proposed that each $PM_{2.5}$ monitor planned for collocation with a near-road NO_2 monitoring site be implemented no later than January 1, 2015.

The EPA received comments from a number of air agencies, industrial groups, and environmental and public health organizations on its proposal to require $PM_{2.5}$ monitoring in near-road environments.

Among comments from air agencies, several commenters did not support the addition of near road monitoring citing the challenges of siting these stations and the additional cost it would require to operate the monitors. Several air agencies recognized the value of adding monitors to provide better characterization of exposures in near-road environments, but recommended a slower deployment of the $PM_{2.5}$ monitors so that it can be phased in over a multi-year period. Several air agencies recommended that the $PM_{2.5}$ monitoring in the near-road environment be deployed on a phased-in schedule with the first such monitors being required no sooner than one year after deployment of the NO_2 sites. These air agencies stated that phasing in of the $PM_{2.5}$ monitors in the near road environment would allow more time to learn and share information on what worked best in deploying the NO_2 monitors at near-road monitoring stations, since NO_2 is the first pollutant required to be monitored at near-road stations. A few air agencies identified a need to more clearly support or require the maintenance of as much of the existing network of neighborhood scale $PM_{2.5}$ monitoring sites as possible in regulatory text. These neighborhood scale $PM_{2.5}$ sites were identified by commenters as the most broadly representative sites for characterizing CBSA wide exposures that are supportive of a number of monitoring objectives. A few air agencies also identified a need for flexibility in the proposed network design requirement that $PM_{2.5}$ near-road monitors must be collocated with the NO_2 monitors in the near-road environment. The commenters suggested allowing flexibility for air agencies to meet the requirement for $PM_{2.5}$ in a near-road environment by siting at a different near-road location where $PM_{2.5}$ concentrations are expected to be high.

Most industry commenters did not support the addition of near-road monitoring for $PM_{2.5}$, again arguing that using data from such monitors, for comparison to the NAAQS, combined with other changes (i.e., elimination of ''population-oriented'' as a criteria for comparison to the NAAQS and the elimination of spatial averaging) would represent, in their judgement, a tightening of the $PM_{2.5}$ NAAQS. A few of these commenters asserted that monitoring in the near-road environment is not representative of ambient air exposures. A few industry comments noted that if the EPA required $PM_{2.5}$ monitoring in the near-road environment, any data collected should not be used for comparison to the NAAQS. One commenter stated it had no problem with monitoring in the near-road environment, so long as any such monitoring used to compare to the $PM_{2.5}$ annual NAAQS is population–oriented. One commenter stated that the decision to co-locate with NO_2 monitors was based on convenience and the intent of the NO_2 near-road monitoring is to find the highest micro-scale concentrations within a few meters of the most heavily travelled expressways, representing a unique situation.

Environmental and public health groups strongly support the addition of $PM_{2.5}$ monitoring to the near-road environment. Commenters cited the large number of people that live in proximity to major roadways[228] in their

[227] The EPA has proposed a revised timeline for deployment of the near-road NO_2 monitors, where all CBSAs with one million or more people are to have their first near-road NO_2 station operational by January 1, 2014 (77 FR 64244, October 19, 2012).

[228] One study identified that 45 million Americans live within 300 feet of a major roadway or other source of mobile emissions. The commenters' information is based on the American Housing Survey, which is available on the Web at:

Continued

support for adding these monitors, that such protection of people in these environments is long overdue, and that such data therefore be used for comparison to the NAAQS.

Regarding comments from air agencies that the near-road monitors are challenging to site and that there is additional cost in operating these monitors, the EPA maintains that the major challenges in siting would already be accomplished by implementing the required NO_2 monitoring stations in near-road environments since the EPA fully expects that the $PM_{2.5}$ monitors will be placed at the NO_2 near roadway stations and has revised the $PM_{2.5}$ monitoring requirements consistent with that expectation. The EPA also points out that the requirements for the minimum number of $PM_{2.5}$ monitors is unchanged and that in most cases the addition of near-road $PM_{2.5}$ monitors can be accomplished by relocating an existing monitor, with no net increase in monitors. Thus, while we are requiring a new component of the $PM_{2.5}$ monitoring network, the overall size of the network is expected to remain about the same, and we expect that air agencies can meet this requirement by relocating existing lower-priority monitors. In considering comments from air agencies on a schedule for implementing $PM_{2.5}$ monitors at near road monitoring stations, the EPA is persuaded by commenters from air agencies who stated that a phased deployment of the $PM_{2.5}$ monitors would be a better approach as it would allow agencies to learn from the deployment of the NO_2 monitors and a first phase of $PM_{2.5}$ monitors. Phasing in the deployment of monitors is also consistent with previous CASAC advice (Russell and Samet, 2010b) on a schedule for deployment of near-road NO_2 monitors.

Regarding comments from air agencies on maintaining the neighborhood scale monitoring stations as the largest part of the network as these sites are the most broadly representative of exposures across CBSAs, the EPA supports such a goal. Neighborhood scale monitoring sites remain the backbone of the $PM_{2.5}$ monitoring network and they will continue to represent over two thirds of the operating network following the deployment of the near-road monitors. The EPA expects that each CBSA required to monitor for $PM_{2.5}$ will maintain its existing highest concentration area-wide monitoring site (referred to as the design value site) and not attempt to move such sites to near-road environments. Maintaining the area-wide and largely neighborhood scale design value sites is critical to the long-standing goal of using data to support a variety of monitoring objectives. The EPA also recognizes that while every $PM_{2.5}$ monitor has value in some capacity at its current location, air agencies are expected to recommend relocation of monitors that are relatively low in priority to meet the near-road requirement.

Regarding comments from air agencies on the need for flexibility in the network design requirement that $PM_{2.5}$ near-road monitors must be collocated with the NO_2 monitors in the near-road environment, the EPA points out that it prefers to maintain this requirement so that the multi-pollutant data are available to support the monitoring objectives cited above. However, the EPA also recognizes there may be cases where an air agency recommends siting their near-road $PM_{2.5}$ monitor in another high concentration near-road environment. The EPA believes such cases will be very limited, but that these situations can be supported in one of two ways. First, EPA and the air agency can use their discretion to site two near-road $PM_{2.5}$ monitors in the area. Second, the EPA can use its discretion in approving a deviation from the $PM_{2.5}$ monitoring requirements as already exists in the network design criteria. Such deviations are to be approved by the Regional Administrator as described in section 4.7.1 of Appendix D to part 58.

Regarding the comment that $PM_{2.5}$ monitors in near-road environments were sited for convenience, which due to siting with NO_2 monitors a few meters from the road presents a unique situation, the EPA disagrees that these monitors were sited solely for convenience or that they would represent a unique situation within an urban area. On the initial point, the EPA believes that the characterization of representative maximum $PM_{2.5}$ concentrations due to on-road mobile sources and the appropriate location of such $PM_{2.5}$ monitors will be the same approximate locations that are the focus of the near-road NO_2 network. This is due to the fact that $PM_{2.5}$, like NO_X, is disproportionately influenced by heavy duty (HD) vehicles which are predominantly diesel fueled, when compared to light duty (LD) vehicles which are primarily gasoline fueled. Specifically, for both $PM_{2.5}$ and NO_X, HD vehicles emit more of these two pollutants and their precursors on a per vehicle basis than LD vehicles. The EPA recognized this fact in the near-road NO_2 network by requiring states to consider the fleet mix of candidate road segments where near-road monitoring might occur. In the design of the NO_2 near-road network where the $PM_{2.5}$ monitors will be installed, states were instructed to place a higher priority on those highly trafficked roads which have more diesel fueled vehicles using a metric called the fleet equivalent average annual daily traffic.[229] As such, the Agency believes it is appropriate that required near-road $PM_{2.5}$ monitors would be located with near-road NO_2 monitors as they are similarly influenced not only by fleet mix but also by total traffic count, congestion patterns, roadway design, terrain, and meteorology. On the second point with regard to such sites representing a unique situation within an urban area, EPA points out that the determination of a near-road micro- or middle-scale site being considered to represent ''area-wide'' air quality or ''unique'' will be made on a case by case basis with the monitoring agency providing such recommendations in their annual monitoring network plans described in § 58.10. Examples of such ''unique'' micro- and middle-scale locations are provided later in this section.

We do not accept the comment that siting some monitors in near roadway environments makes the standard impermissibly more stringent. A significant fraction of the population lives in proximity to major roads. These exposures occur in locations that represent ambient air for which the agency has a responsibility to ensure the public is protected with an adequate margin of safety. Ignoring monitoring results from such areas (or not monitoring at all) would abdicate this responsibility. Put another way, monitoring in such areas does not make the standard more stringent, but rather affords requisite protection to the populations, among them at-risk populations, exposed to fine particulate in these areas. Thus, the EPA has made a determination to protect all area-wide locations, including those locations with populations living near major roads that are representative of many such locations throughout an area. As discussed above, EPA concludes that the requirement to locate monitors to represent ambient air, along with other siting requirements, will ensure that monitors represent $PM_{2.5}$ concentrations in areas of potential public exposure.

http://www.census.gov/housing/ahs/data/ahs2009.html. The survey provides an estimate of the county's housing units in the U.S. that are located with 300 feet of a highway with four or more lanes, or a railroad, or an airport.

[229] See the Near-road NO_2 Monitoring Technical Assistance Document at: *http://www.epa.gov/ttn/amtic/files/nearroad/NearRoadTAD.pdf.*

We do recognize, however, the possibility that some near-road monitoring stations may be representative of relatively unique locations versus the more representative area-wide situation mentioned above. This could occur because an air agency made a siting decision based on NO_2 criteria that resulted in the characterization of a microscale environment that is not considered area-wide for $PM_{2.5}$; for example, due to proximity to a unique source like a tunnel entrance, nearby major point source, or other relatively unique microscale hot spot. In these types of scenarios, air agencies would identify the site as a unique monitor comparable only to the 24-hour $PM_{2.5}$ NAAQS per the language in section 58.30, and not comparable to the annual NAAQS, through the Annual Monitoring Network Plan process described earlier. Although EPA expects most near-road $PM_{2.5}$ monitors to be sited to represent area-wide conditions, since a vast majority of the near-road stations have yet to be installed, we believe that providing such clarity and flexibility in siting and NAAQS comparability is warranted.

After careful consideration of the public comments, the EPA is finalizing its decision to add $PM_{2.5}$ monitors to the near-road monitoring stations. The EPA is finalizing this decision as the near-road environment is an area where significant public exposure can occur, recognizing that this is a gap in the current $PM_{2.5}$ monitoring networks, and because these $PM_{2.5}$ monitors will be collocated with NO_2 monitors in the near-road environment, there will not be a significant additional burden on the air agencies.[230] However, in recognition of the comments from air agencies above, EPA is finalizing a revised and phased schedule for deployment of the $PM_{2.5}$ monitors at near-road stations. A minimum of one $PM_{2.5}$ monitor in each CBSA with a population greater than or equal to 2.5 million is to be collocated at a near-road NO_2 monitoring station and must to be operational by January 1, 2015. The remaining CBSAs (i.e., those CBSAs with populations greater than or equal to 1M, but less than 2.5M) must be operational by January 1, 2017. This schedule will ensure that air agencies have sufficient time to learn from deployment of the NO_2 monitors in near-road environments, that the highest population CBSAs begin operating their $PM_{2.5}$ monitors in near-road environments first, and that the remaining $PM_{2.5}$ monitors are deployed on the same schedule as the CO monitors (also, required by January 1, 2017).[231] In consideration of the comments regarding maintaining neighborhood scale monitoring sites as the largest portion of the network, the EPA is revising the wording of a requirement that requires at least one site to be in an area-wide location of expected maximum concentration, to wording that states that such sites must be in an area-wide location of expected maximum concentration while also being at the neighborhood or larger scale of representation.

iii. Use of $PM_{2.5}$ Continuous FEMs at SLAMS

The EPA proposed that each agency specify its intention and rationale to use or not use data from continuous $PM_{2.5}$ FEMs that are eligible for comparison to the NAAQS as part of its annual monitoring network plan due to the applicable EPA Region Office by July 1 each year. The proposal also provided that the EPA Regional Administrator would be responsible for approving annual monitoring network plans where agencies have provided a recommendation that certain $PM_{2.5}$ FEMs be considered ineligible for comparison to the NAAQS.

In 2006, the EPA finalized new performance criteria for approval of continuous $PM_{2.5}$ monitors as either Class III FEMs or ARMs. At the time of proposal, the EPA had already approved six $PM_{2.5}$ continuous FEMs[232] and there are nearly 200 of these monitors already operating in State, local, and Tribal networks. Monitoring agencies have been deploying and field-testing these units over the last couple of years and the EPA recently compiled an assessment of the FEM data in relationship to collocated FRMs (Hanley and Reff, 2011; U.S. EPA, 2011a, pp. 4–50 to 4–51). As described in the proposal (FR 38983), the EPA found that some sites with continuous $PM_{2.5}$ FEMs have an acceptable degree of comparability with collocated FRMs, while others had poor data comparability that would not meet the performance criteria used to approve the FEMs (71 FR 61285–61286, Table C–4, October 17, 2006). The EPA is encouraging use of the FEM data from those sites with acceptable data comparability including for purposes of comparison to the NAAQS. For sites with unacceptable data comparability, the EPA is working closely with the monitoring committee of the NACAA, instrument manufacturers, and monitoring agencies to document best practices on these methods to improve the comparability and consistency of resulting data wherever possible. The EPA believes that the performance of many of these continuous $PM_{2.5}$ FEMs at locations with poor data comparability can be improved to a point where the acceptance criteria noted above can be met.

Given the varying data comparability of continuous $PM_{2.5}$ FEMs noted above, we believe that a need exists for flexibility in the approaches for how such data are used, particularly for the objective of determining NAAQS compliance. Accordingly, we proposed that monitoring agencies address the use of data from $PM_{2.5}$ continuous FEMs in their annual monitoring network plans due to the applicable EPA Regional Office by July 1 of each year for any cases where the agency believes that the data generated by $PM_{2.5}$ continuous FEMs in their network should not to be compared to the NAAQS. The annual network plans would include assessments such as comparisons of continuous FEMs to collocated FRMs, and analyses of whether the resulting statistical performance would meet the established approval criteria. Based on these quantitative analyses, monitoring agencies would have the option of requesting that data from continuous FEMs be excluded from NAAQS comparison subject to EPA approval; however, these data could still be utilized for other objectives such as AQI reporting.

The issue exists of whether such data use provisions should be prospective only (i.e., future NAAQS comparability excluded based on an analysis of recent past performance) or a combination of retrospective and prospective (i.e., the implications of unacceptable FEM performance impacting usage of previously collected data as well as future data). In the proposal, the EPA stated that in most cases, monitoring agencies should be restricted to addressing prospective data issues to provide stability and predictability in the long-term $PM_{2.5}$ data sets used for supporting attainment decisions. However, in the first year after this proposed option would become effective, we indicated it would be appropriate to provide monitoring agencies with a one-time opportunity to review already reported continuous $PM_{2.5}$ FEM data and request that data with unacceptable performance be restricted (retrospectively) from NAAQS

[230] The incremental one-time cost of moving the 52 monitors required to be located in the near-road environment is described in section X.B—Paperwork Reduction Act.

[231] 76 FR 54294, August 31, 2011.

[232] The EPA maintains a list of approved Reference and Equivalent Methods on its Web site at: *http://www.epa.gov/ttn/amtic/criteria.html*.

comparability. Accordingly, in the first year after this rule becomes effective, we proposed that monitoring agencies have the option of requesting in their annual monitoring network plans that a portion or all of the existing continuous $PM_{2.5}$ FEM data, as applicable, as well as future data, be restricted from NAAQS comparability for the period of time that the plan covers.[233] In the proposal we stated that annual monitoring network plans in subsequent years would only need to cover new data for the period of time that the plan covers.

As noted above, in cases where an agency is operating a $PM_{2.5}$ continuous FEM that is not meeting the expected performance criteria used to approve the FEMs (71 FR 61285 to 61286, Table C–4, October 17, 2006) when compared to their collocated FRMs, an agency can recommend that the data not be used for comparison to the NAAQS. However, all required SLAMS would still be required to have an operating FRM (or other well performing FEM) to ensure a data record is available for comparison to the NAAQS. In cases where a $PM_{2.5}$ continuous FEM was not meeting the expected performance criteria, and the Regional Administrator has approved a recommendation that the FEM data not be considered eligible for comparison to the NAAQS, the data would still be required to be loaded to AQS; however, these data would be identified distinctly from data used for comparison to the NAAQS.

The goal of proposing to allow monitoring agencies the opportunity to recommend not having data from $PM_{2.5}$ continuous FEMs as comparable to the NAAQS is to ensure that only high quality data (i.e., data from FRMs which are already well established and new continuous FEMs that meet the performance criteria used to approve FEMs when compared to collocated FRMs operated in each agencies network) are used when comparing data to the $PM_{2.5}$ NAAQS. Under the current monitoring regulations, a monitoring agency can identify a $PM_{2.5}$ continuous FEM as an SPM, which allows the monitor to be operated for up to 24 months without its data being used in comparison to the NAAQS. While 24 months should be sufficient time to operate the monitor across all seasons, assess the data quality, and in some cases resolve operational issues with the instrument, it may still leave some agencies with monitors whose data are not sufficiently comparable to data from their FRMs. In these cases there may be a disincentive to continue operating the $PM_{2.5}$ continuous FEM, especially in networks where the monitoring data are near the level of the NAAQS. With the proposed provision, where a monitoring agency can recommend not having data from $PM_{2.5}$ continuous FEMs be comparable to the NAAQS, a monitoring agency can continue to operate their $PM_{2.5}$ continuous FEM to support other monitoring objectives (e.g., diurnal characterization of $PM_{2.5}$, AQI forecasting and reporting), while working through options for improved data comparability while still providing data for comparison to the NAAQS from an FRM.

The EPA believes that an assessment of FEM performance should include several elements based on the original performance criteria. The Agency also believes that certain modifications to the performance criteria are appropriate in recognition of the differences between how monitoring agencies operate routine monitors and how instrument manufacturers conduct required FRM and FEM testing protocols. The details below summarize these issues.

The EPA proposed to use the performance criteria used to approve the FEMs (71 FR 61285 to 61286, Table C–4, October 17, 2006) for those agencies that recommend not having data from $PM_{2.5}$ continuous FEMs be comparable to the NAAQS. To accommodate how routine monitoring networks operate, the EPA proposed that agencies seeking to demonstrate insufficient data comparability base their assessment mainly on collocated data from FRMs and continuous FEMs at monitoring stations in their network. The EPA does not believe it is practical to utilize the requirement in table C–4 of 40 CFR part 53 for having multiple FRMs and FEMs at each site since such arrangements are not typically found in monitoring agency networks. Accordingly, the requirement for assessing intra-method replicate precision would be inapplicable. Another consideration is the range of 24-hour data concentrations, for instance, the performance criteria in table C–4 of 40 CFR part 53, provides for an acceptable concentration range of 3 to 200 $\mu g/m^3$. However, the EPA notes that during an evaluation of data quality from two FEMs (U.S. EPA, 2011a, p. 4–50), the Agency found that including low concentration data was helpful for understanding whether an intercept or slope was driving a potential bias in an instrument. Therefore, the EPA proposed that agencies may include low concentration data (i.e., below 3 $\mu g/m^3$) for purposes of evaluating the data comparability of continuous FEMs. With regard to the minimum number of samples needed for the assessment, the EPA notes that a minimum of 23 sample pairs are specified for each season in table C–4 of 40 CFR part 53. Having 23 sample pairs per season should be easily obtainable within one year for sites with a FRM operating on at least a 1 in 3 day sample frequency and we proposed that this requirement be applicable to the assessments being discussed here. For sites on a one in 6 day sampling frequency, two years of data may be necessary to meet this requirement. The EPA recognizes that it would be best to assess the data based on the most recently available information; however, having data across all seasons in multiple years will provide a more robust data set for use in the data comparability assessment; therefore, the EPA proposed that data quality assessments be permitted to utilize up to the last three years of data for purposes of recommending not having data from $PM_{2.5}$ continuous FEMs be comparable to the NAAQS.

The EPA recognizes that only a portion of continuous $PM_{2.5}$ FEMs will be collocated with FRMs, and it would be impractical to restrict the applicability of data comparability assessments to only those sites that had collocated FRM and FEM monitors. In these cases, the monitoring agency will be permitted to group the sites that are not collocated with an FRM with another similar site that is collocated with an FRM for purposes of recommending that the data are not eligible for use in comparison to the NAAQS. Monitoring agencies may recommend having $PM_{2.5}$ continuous FEM data eligible for comparison to the NAAQS from locations where the method has been demonstrated to provide acceptable data comparability, while also recommending not having it eligible in other types of areas where the method has not been demonstrated to meet data comparability criteria. For example, a rural site may be more closely associated with aged particles where volatilization issues are minimized resulting in acceptable data comparability between filter-based and continuous methods, while a highly populated urban site with fresh emissions with higher volatility may result in higher readings on the $PM_{2.5}$ continuous FEM that would not meet the expected performance criteria as compared to a collocated FRM. In all cases where a monitoring agency chose to group sites for purposes of identifying a subset of $PM_{2.5}$ continuous FEMs that would not be comparable to the

[233] Data from any $PM_{2.5}$ monitor being used to meet minimum monitoring requirements could not be restricted from NAAQS comparability.

NAAQS, the assessment submitted with the annual monitoring network plan would have to provide sufficient detail to support the identification of which combinations of method and sites would, and would not, be comparable to the NAAQS, as well as the rationale and quantitative basis for the grouping and recommendation.

Most comments received on this issue were from air agencies. All air agencies either supported the proposal or supported it with a recommendation to continue to allow for retrospective assessments to be used such that data would not be compared to the NAAQS, if such an assessment showed that the data were not of sufficient comparability to a collocated FRM such that the continuous FEM should not be compared to the NAAQS. One air agency supported the proposal, except though it had reservations about how to best group sites together when a particular $PM_{2.5}$ continuous FEM is not collocated with a FRM.

The EPA notes the support by air agencies to finalize this provision. EPA also notes that all commenters who offered input on the retrospective use of assessments were supportive of allowing continued retrospective assessments in annual monitoring networks plans so that data may be recommended as excluded from comparison to the NAAQS under certain provisions. However, the EPA has some reservations about how and under what circumstances such an allowance should be made. The EPA notes the concern expressed from one agency about how to best group sites together when considering an assessment.

On the issue of whether to allow data collected to be retrospectively excluded from comparison to the NAAQS, the EPA notes there are a number of considerations, including that several air agencies support such a policy. The EPA has evaluated how this issue can be achieved and believes that some consideration should be allowed, but also wants to ensure there is a consistent and easily recognizable interpretation of such cases where air agencies recommend excluding already collected and reported data. To help illustrate the possible outcomes of how this could work consider the following examples. Example 1: An agency finds that the bias between a collocated $PM_{2.5}$ continuous FEM and FRM are acceptable, but near the limit of that acceptability and then finds a year later that the assessment indicates that the bias is just outside the limit of that acceptability. Such relatively small changes where an assessment indicates flipping in or out of the acceptable bias are in themselves acceptable since the overall Data Quality Objectives (DQOs) can still be met. The overall DQOs can still be met since there are a number of other factors that feed into the DQOs such as precision, data completeness, and especially sample frequency, which when operating a continuous FEM is a daily sample. Daily sampling provides less uncertainty than sampling at the one-in-three day or one-in-six day sampling frequencies, which are routinely employed by filter-based FRM samplers. Therefore, in this example the existing data should still be compared to the NAAQS, but the air agency should thoughtfully consider whether to recommend [234] and the EPA will consider whether to approve that any new data from $PM_{2.5}$ continuous FEMs are used in comparison to the NAAQS. If an air agency recommends to not use a $PM_{2.5}$ continuous FEM for comparison to the NAAQS, it would need to ensure another approved method (i.e., a filter-based FRM/FEM or other continuous FEM which is performing within acceptable performance criteria) is operating at the site or sites of interest. This would be expected for all SLAMS, but at a minimum the design value monitoring station for the area of interest would be required to have another approved $PM_{2.5}$ method (i.e., an FRM, other filter-based FEM, or other continuous FEM or ARM with acceptable data comparability) operating on the required sample frequency or more often for that location. Example 2: A $PM_{2.5}$ continuous FEM operated by an air agency is found to have a significant bias compared to a collocated FRM. If the air agency finds cause to invalidate the data (e.g., a flow sensor is found to be outside of acceptable limits), then it should invalidate the relevant data (i.e., data from the period going back to the last successful flow check or audit or other information that points to a cause that the flow sensor is not meeting its performance criteria) for all data uses and there is no follow-up issue of retrospective analysis. A case of finding cause to invalidate data would be based on validation criteria found in an air agencies approved quality assurance project plan (QAPP). Example 3: A $PM_{2.5}$ continuous FEM operated by an air agency and previously identified as appropriate to compare to the NAAQS, is found to have a significant and unacceptable bias compared to a collocated FRM and there is no other reason to invalidate the data. That is, all other information points to the data being valid; however, there has been a significant shift in the comparability of the $PM_{2.5}$ continuous FEM compared to a collocated FRM (which itself is found to be operating correctly and data are valid). A significant shift in the comparability would be noticeable by comparing assessments for a site from one year to the next and seeing a significant and unacceptable change in one of the key statistical metrics used in the evaluation (i.e., additive or multiplicative bias). Such a case of retrospectively recommending not using $PM_{2.5}$ continuous FEM data should also take into account all other available information that can help inform approving such a recommendation as part of an annual monitoring network plan. For example, do data from the $PM_{2.5}$ performance evaluation program data also suggest an unacceptable bias for a specific period of interest with this method as used in the air agencies network? Note: This type of assessment is often limited by the small number of samples taken in the PEP program relative to the large number of collocated samples expected when an FRM and $PM_{2.5}$ continuous FEM are collocated. In this type of example, the air agency might want to recommend not using the continuous FEM data for comparison to the NAAQS; however, the continuous FEM data could be appropriate for use in reporting the Air Quality Index (AQI) or other data uses either as is or if statistically correlated [235] and corrected back to the collocated FRM. So in this last example, the $PM_{2.5}$ continuous FEM data would be stored separately in the EPA's data system so that they are eligible for use in AQI calculations, but not used in comparison to the NAAQS, if approved by the EPA. Again, the air agency should thoughtfully consider and state its position and rationale in the annual monitoring network plan on whether any future data should be compared to the NAAQS.

Another issue to consider is the transparent and consistent use of $PM_{2.5}$ continuous FEM data from a method where one air agency recommends using the data for comparison to the NAAQS and another specifically recommends to not use it for comparison to the NAAQS. The use of the annual monitoring plans ensures that the process is transparent; however, it may not ensure a consistent

[234] Through the annual monitoring network plan explained in § 58.10.

[235] The EPA has had a long-standing policy of allowing $PM_{2.5}$ continuous data to be statistically correlated and corrected to use in AQI reporting. A report is available on this: See "Data Quality Objectives (DQOs) for Relating Federal Reference Method (FRM) and Continuous $PM_{2.5}$ Measurements to Report an Air Quality Index (AQI), EPA–454/B–02–002, November 2002".

approach if one agency recommends exclusion of data and another agency does not. For example, consider two adjacent air agencies operating the same make and model of a $PM_{2.5}$ continuous FEM, where one air agency recommends using data and the other air agency recommends not using it for comparison to the NAAQS. While on its face it may seem straightforward that a method with acceptable comparability to a collocated FRM should perform similarly in other air agency networks where they have similar aerosol composition and climate, in practice there are a number of other variables that affect data comparability. Such factors that lead to differences in comparability might include differences in installation, training, development of SOPs, control of shelter conditions, maintenance of the continuous FEM, and performance of the FRMs which are being used as the basis of comparison to the continuous FEM. Also, there may be cases where the concentration levels are so far away from the level of the NAAQS (either substantially higher or lower) that it would not matter if the data are excluded or not, the same NAAQS determination would result. The EPA has considered these issues and in general believes that it would still be acceptable for one agency to use data for comparison to the NAAQS, while another agency does not, even if it's the same method used in adjacent air agency networks.

On the issue of grouping sites for purposes of allowing monitors that are not collocated to be included when recommending a method should not be compared to the NAAQS, the EPA believes that it is not necessary to provide specific details on what criteria are necessary to group sites as air agencies are in the best position to determine a recommendation of when such sites should or should not be grouped. However, to illustrate examples of possible ways to group sites, the air agency could take into account factors such as whether the sites are all in either a rural or urban location, since urban locations tend to be impacted more directly by fresh emissions which are known to be more volatile, or whether there is consistency in the climate for the sites of interest as might be the case for sites near a large water body or at a high altitude. The EPA will consider these issues when evaluating air agency requests for approval.

The EPA is finalizing its proposal to allow each air agency to specify its intention to use or not use data from continuous $PM_{2.5}$ FEMs that are eligible for comparison to the NAAQS as part of their annual monitoring network plan due to the applicable EPA Region Office by July 1 each year where adequate FRM data are available. The EPA's approval of an annual monitoring network plan [236] as a whole, or in part, will constitute concurrence with an air agency's recommendation to use or not use data from continuous $PM_{2.5}$ FEMs as eligible for comparison to the NAAQS, unless otherwise noted in the approval of the plan. The absence of an air agency statement specifying a position on use of data from a continuous $PM_{2.5}$ FEM for comparison to the NAAQS will be interpreted as meaning that all such data are applicable for comparison to the NAAQS following the provisions in Part 50, Appendix N on data handling and Part 58 on the monitoring requirements. In finalizing this decision the EPA will ensure, as proposed, that air agencies can identify already collected data from $PM_{2.5}$ continuous FEMs that should not be used for comparison to the NAAQS. After considering comments in support of allowing additional retrospective assessments, the EPA is also finalizing an approach of allowing for the continued use of retrospective assessments to inform when already collected data should not be compared to the NAAQS, if there has been a significant change in the assessment of that data from previous years.

c. Revoking $PM_{10\text{-}2.5}$ Speciation Requirements at NCore Sites

The EPA proposed to revoke the requirement for $PM_{10\text{-}2.5}$ speciation monitoring as part of the current suite of NCore monitoring requirements. The requirement to monitor for $PM_{10\text{-}2.5}$ mass (total) at all NCore multi-pollutant sites remains. $PM_{10\text{-}2.5}$ mass monitoring commenced on January 1, 2011 as part of the nationwide startup of the NCore network (U.S. EPA, 2011a, p. 1–15).

As part of the process to further define appropriate techniques for $PM_{10\text{-}2.5}$ speciation monitoring, a public consultation with the CASAC AAMMS on monitoring issues related to $PM_{10\text{-}2.5}$ speciation was held in February 2009 (74 FR 4196, January 23, 2009). The subcommittee noted the lack of consensus on appropriate sampling and analytical methods for $PM_{10\text{-}2.5}$ speciation and expressed concern that the Agency's commitment to launch the $PM_{10\text{-}2.5}$ monitoring network without sufficient time to analyze the data from a planned pilot project was premature (Russell, 2009). Based on the noted lack of consensus on $PM_{10\text{-}2.5}$ speciation monitoring techniques, the Agency did implement a small pilot monitoring project to evaluate the available monitoring and analytical technologies.

The EPA pilot monitoring project was completed in 2011, with plans to analyze the data and prepare a final report on findings and recommendations in 2013. At that time, the EPA will consider what $PM_{10\text{-}2.5}$ speciation sampling techniques, analytical methodologies, and monitoring design strategies would be most appropriate as part of a potential nation-wide monitoring deployment. Such a deployment could be based on the NCore multi-pollutant framework or some other strategy that allows flexibility and targets measurements in areas with higher levels of coarse particles.

All comments received from air agencies and multi-state organizations were supportive of the removal of the $PM_{10\text{-}2.5}$ speciation requirement.

A few industry commenters raised concerns about the availability of $PM_{10\text{-}2.5}$ speciation data for research purposes. One environmental group opposed revoking the $PM_{10\text{-}2.5}$ speciation requirement and expressed the need for $PM_{10\text{-}2.5}$ data to support health effects research and future regulatory efforts.

The EPA has considered the comments from air agencies that were all supportive of revoking the requirement, as well as the industry and environmental groups concerns that $PM_{10\text{-}2.5}$ speciation data will not be available for research. In considering these comments, the EPA recognizes the importance of efforts to develop and evaluate speciation monitoring approaches for $PM_{10\text{-}2.5}$ given that there is relatively little information available on the chemical and biological composition of $PM_{10\text{-}2.5}$ and on the health effects associated with the various components (U.S. EPA, 2009a, section 2.3.4). Without more information on the chemical speciation of $PM_{10\text{-}2.5}$, the apparent variability in associations with health effects across locations is difficult to characterize (U.S. EPA, 2009a, section 6.5.2.3). However, the EPA believes that until a final report on the findings from the pilot study is completed in 2013 and the results of the study can be considered, $PM_{10\text{-}2.5}$ speciation is not ready for nationwide deployment. Therefore, the EPA is finalizing its decision to revoke the $PM_{10\text{-}2.5}$ speciation requirement at NCore stations. Given the continued importance of characterizing $PM_{10\text{-}2.5}$ species, and given that ongoing and future research will likely further

[236] Approval of an annual monitoring network plan is subject to approval of the EPA Regional Administrator as provided for in § 58.10(a)(2).

inform the development of speciation methods, the appropriateness of requiring speciation monitoring for $PM_{10-2.5}$ will be revisited in future reviews.

d. Measurements for the Proposed New $PM_{2.5}$ Visibility Index NAAQS

The EPA proposed requirements for sampling of $PM_{2.5}$ chemical speciation in states with large CBSAs. However, as explained in section VI, the EPA is not finalizing the proposed secondary $PM_{2.5}$ visibility index NAAQS and therefore is not finalizing the proposed monitoring changes associated with that standard.

4. Revisions to the Quality Assurance Requirements for SLAMS, SPMs, and PSD

a. Quality Assurance Weight of Evidence

The EPA proposed to use a weight-of-evidence approach for determining whether the quality of data is appropriate for regulatory decision-making purposes. While the EPA believes that it is essential to require a minimum set of checks and procedures in appendix A to support the successful implementation of a quality system, the success or failure of any one check or series of checks should not preclude the EPA from determining that data are of acceptable quality to be used for regulatory decision-making purposes. Accordingly, the EPA proposed to include additional wording in appendix A to clarify the role that appendix A generated data quality indicators have in the overall quality system that supports ambient air monitoring activities.

The EPA received eight comments on the weight of evidence approach with the majority of commenters endorsing the approach. One commenter felt that the ''paragraph, as written, undermines the importance of the quality control/quality assurance system dictated in Part 58.'' Some that supported the approach also provided a word of caution that ''while a common sense approach to the assessment of quality data is important, minimum requirements are necessary to ensure scientifically-defensible data is being used in decision making''. The EPA agrees with the commenter's points that data should be subject to a minimum set of requirements for data collection, reporting and quality. In developing the weight of evidence approach, the EPA is not attempting to diminish the requirements of appendix A but rather ensure that other elements of a quality system that air agencies implement and are documented in their QAPP can also be used when judging whether data are valid for a particular monitoring objective. While the EPA considers the appendix A requirements the minimum for reporting, it is not the only data that the EPA and the air agencies use to judge quality. Therefore, if an appendix A requirement for some reason is not complete, the EPA concludes that it should not necessarily be the sole reason to declare the data invalid or unusable. One commenter who felt that the approach may be appropriate also suggested that the language of the proposal was vague and may weaken the ability of air monitoring agencies to validate their own data and instead allows the EPA to make decisions regarding data validity. In the majority of cases when the quality of ambient air data is called into question, the EPA Regions and air agencies work together and reach consensus on data usability. The EPA agrees that the air agencies know more about their data and it is the air agencies responsibility to certify the data as valid. In most cases, the EPA and the air agencies will be in agreement on the validity and usability of this data. However, since the EPA is responsible for making final regulatory decisions concerning the NAAQS, in rare cases it may ultimately have to make a validity decision that the air agencies may not agree with. After consideration of the general support received, the EPA will finalize the language as proposed. For the reasons explained above, the EPA concludes that this will not undermine the quality assurance system, but rather strengthen it.

A few commenters, although supporting the weight of evidence approach, also commented that appendix A minimum requirements should not only apply to all air quality data collected by state, local, and tribal agencies, but also to ''secondary'' data collected by other monitoring efforts. The EPA understands that this term is used by these commenters to either represent the Chemical Speciation and IMPROVE Network data being used to calculate light extinction for the secondary $PM_{2.5}$ visibility index NAAQS, or for criteria pollutant data collected by entities other than the state, local or tribal monitoring organizations. The EPA agrees with the comments that the appendix A requirements must apply to the CSN and IMPROVE data, if the data were being used for comparison to the secondary NAAQS, and included the term ''$PM_{2.5}$ CSN'' to refer to both networks. However, since as explained in Section VI, the secondary $PM_{2.5}$ visibility index NAAQS is not being finalized, the EPA will be removing any text related to the CSN and IMPROVE requirements from appendix A. If the term is being used by commenters to refer to criteria pollutant data collected by entities other than the state, local or tribal monitoring organizations then the appendix A requirements, as has always been the case, apply to those monitors.

b. Quality Assurance Requirements for the Chemical Speciation Network

The EPA proposed to include requirements for flow rate verifications and flow rate audits for the $PM_{2.5}$ CSN. Air agencies currently perform these audits even though they are not currently required. Thus, although they would be considered a new requirement, they are not new implementation activities. In addition, the CSN already includes six collocated sites which the EPA proposes to include in the 40 CFR part 58 appendix A requirements. The EPA proposed that PSD sites would not be required to collocate a second set of instruments for speciated $PM_{2.5}$ mass monitoring.

There were no comments that specifically addressed the addition of collocation and flow rate requirements in appendix A for the chemical speciation network (CSN). Since these flow rates have historically been included in the Agencies' CSN Network Quality Assurance Project Plan and implemented for many years, air agencies may not have considered them any additional burden on the program. However, as explained in Section VI, the secondary $PM_{2.5}$ visibility index NAAQS is not being finalized; therefore, the EPA will not include these QA requirements into appendix A since the networks will not produce data to be used for NAAQS decisions.

c. Waivers for Maximum Allowable Separation of Collocated $PM_{2.5}$ Samplers and Monitors

The EPA proposed to allow waivers, when approved by the EPA Regional Administrator, for collocation of $PM_{2.5}$ samplers and monitors of up to 10 meters so long as the site is at a neighborhood scale or larger. The EPA proposed to allow waivers for the maximum allowable distance associated with collocated $PM_{2.5}$ samplers and monitors. Ensuring $PM_{2.5}$ continuous FEMs and $PM_{2.5}$ FRMs meet collocation requirements (i.e., 1 to 4 meters for $PM_{2.5}$ samplers with flow rates of less than 200 liters/minute) can be challenging, since in some cases multiple instruments, FEMs installed in the shelter and FRMs installed on a platform, are being sited at the same station. The EPA believes that

instruments spaced farther apart could be maintained within the operational precision of the instruments, especially at sites located at larger scales of representation (e.g., neighborhood scale and larger).

All comments received responded in support of the requirement allowing up to 10 meter horizontal spacing for sites at a neighborhood or larger scale of representation. The EPA received no negative comments on this part of the proposal. During stakeholder presentations of the proposal, the EPA received a verbal comment that air agencies were also having difficulty meeting the one meter vertical criteria since $PM_{2.5}$ FEMs are typically housed in shelters with inlets extending through shelter roofs while the collocated FRM monitors are placed outside, usually on platforms somewhat lower to the ground. After considering this comment, and further discussion with EPA Office of Research and Development on spacing requirements, the agency will amend the appendix A requirements to allow for a 1–3 meter vertical spacing which may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation. In addition, the language will be amended to allow for waiver approvals during annual network plan approval processes. Alternatively, the existing waiver provision outlined in paragraph 10 of Appendix E may be used.

5. Revisions to Probe and Monitoring Path Siting Criteria

a. Near-Road Component to the $PM_{2.5}$ Monitoring Network

The EPA proposed that the probe and siting criteria for the near-road component of the $PM_{2.5}$ monitoring network design follow the same probe and siting criteria as the NO_2 near-road monitoring sites. These requirements would provide that the monitoring probe be sited ''* * * as near as practicable to the outside nearest edge of the traffic lanes of the target road segments; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment'' (section 6.4 of appendix E to 40 CFR part 58).

The EPA received comments from several stakeholders on the probe and siting criteria for $PM_{2.5}$ monitors in the near-road environment. One public health group offered detailed comments on the probe and siting criteria for $PM_{2.5}$ monitors in near-road environments. While the commenter offered support for collocating the $PM_{2.5}$ monitors with NO_2 monitors in the near-road environment, there was concern expressed regarding allowing monitors at sites of more than 15 meters from the traffic corridor which is the source of the air quality concern. The commenter points out that the EPA's existing rules for siting localized hot spot sites in areas of highest concentration require sites at microscale locations which provide for a distance of no more than 15 meters from a major roadway. Several air agencies offered consistent comments that the inlet of the $PM_{2.5}$ monitors should be the same as that of the near-roadway NO_2 monitors; however, one of the commenters suggested that the requirements for distance to the nearest vertical wall or obstruction should match the requirements for current micro and middle scale installations of $PM_{2.5}$ monitors. The concern expressed is that a wall or obstruction may disrupt the normal downwind flow across a roadway.

In reviewing comments on probe and monitoring path criteria for $PM_{2.5}$ monitors in near road environments, and whether to make any changes, the EPA has several issues to consider. One of the most important things to consider is what the intended network design of these monitors should be. As stated in the proposal our goal is to ''better understand the health impacts of these (near-road $PM_{2.5}$) exposures,'' that a number of monitoring objectives can be supported by having near-road $PM_{2.5}$ monitors, and that while it might be that the location of maximum concentration of $PM_{2.5}$ exposure from near-roadway sources might differ from the maximum location of NO_2 or other pollutants, we proposed to require that the near-road $PM_{2.5}$ monitors be collocated with the planned NO_2 monitors. The EPA did not propose to change the distance from obstructions for $PM_{2.5}$ monitors in its proposal.

As we stated in the proposal, the planned NO_2 monitors are using several relevant factors that are also relevant for siting of $PM_{2.5}$ (e.g., average annual daily traffic and fleet mix [accounting for heavy duty vehicles] by road segment) and that significant thought and review are going into the design of the near-road stations. Therefore, the EPA is not persuaded that we should provide any additional constraints to the siting of the station (i.e., the distance from the roadway) than is already provided for in the NO_2 near-road monitor probe and monitoring path siting criteria. The EPA is concerned that additional constraints (i.e., to require sites within 15 meters of the road), might have some advantages, but also might unnecessarily eliminate otherwise useful near-road locations that on balance might be a better candidate location.

The EPA recognizes that there may be cases where the physical location of a near-road monitoring station is farther than 15 meters, but no greater than 50 meters from the roadway, but such cases are presumed to still be the most useful location for the siting of the NO_2 monitors, which we then proposed to collocate with $PM_{2.5}$. Regardless of the actual distance of the inlet for the $PM_{2.5}$ monitor at the near-road monitoring station, so long as it is collocated with the approved near-road station for NO_2 and meets existing criteria, the EPA will consider this site to be appropriate as a near-road $PM_{2.5}$ monitoring station. As explained in the proposal, there are a number of reasons to collect multi-pollutant data in the near-road environment. The EPA believes that these sites will be sufficient as representative maximum concentration sites for NO_2 and $PM_{2.5}$ in the near-road environment. As noted above, where an air agency believes a different location is a more appropriate site for a near-road $PM_{2.5}$ monitor, the EPA can use its discretion in approving a deviation from the $PM_{2.5}$ monitoring requirements as already exists in the network design criteria. A deviation would be appropriate for consideration where, for example, a state provides quantitative evidence demonstrating that peak ambient $PM_{2.5}$ concentrations would occur in a near-road location which meets siting criteria but is not a near-road NO_2 monitoring site. Such deviations are to be approved by the Regional Administrator as described in section 4.7.1 of Appendix D to part 58.

While it is still desirable for the near-road stations to be as close to the road as practical, there may be differences in the scale of representation of the near-road $PM_{2.5}$ monitor from one location to another, while the NO_2 near-road monitors are at the same scale of representation (i.e., micro-scale) in different locations. This is a result of the scale of representation being based on the pollutant at a location and not the location alone. Therefore, in cases where the station is 20 meters from a major road, the NO_2 measurement may still be micro-scale, while the $PM_{2.5}$ measurement would be middle-scale if the average daily traffic count were sufficiently large enough.[237] If a site with both measurements were 10 meters

[237] See Table E–1 in Appendix E to Part 58 for defining the scale of representation of a PM sampler based on its distance to the nearest traffic lane and average daily traffic count.

from a major road they would both be expected to be micro-scale sites.

In considering the comment on distance from obstructions, the EPA notes that a monitoring station with multiple measurements is effectively considered collocated for those measurements, even though the actual location of the inlets is slightly different from each other within the station. For example, a gas monitor (e.g., for carbon monoxide) may be pulling ambient air from a manifold with an inlet located on one part of a station roof, while a PM monitor is pulling air directly from its inlet located a few meters away on the same roof. The EPA believes it is appropriate and consistent with the public comment above on distance from obstructions to maintain the existing requirements for distance from obstructions on a pollutant by pollutant basis, even if they are different for $PM_{2.5}$ and NO_2 monitors that will be at the same station. Air agencies will need to consider these distances from obstructions for each pollutant inlet probe (i.e., >1 meter for NO_2 monitors and >2 meters for $PM_{2.5}$ monitors) in locating monitors at the station.

The EPA is maintaining the existing probe and siting criteria for $PM_{2.5}$ monitors; however, we are finalizing the provision that the required near-road component of the $PM_{2.5}$ monitoring network design shall be collocated with a required NO_2 monitor at near-road monitoring station. These near-road NO_2 monitoring stations are to be sited ''* * * as near as practicable to the outside nearest edge of the traffic lanes of the target road segments; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment'' (section 6.4 of appendix E to 40 CFR part 58). The EPA is retaining the existing requirement that $PM_{2.5}$ inlets, including those at near road stations, must be >2 meters from obstructions.

b. CSN Network

As explained in Section VI, the EPA is not finalizing the proposed secondary standard based on a $PM_{2.5}$ visibility index and therefore will not be finalizing probe and siting criteria associated with the use of CSN measurements.

c. Reinsertion of Table E–1 to Appendix E

The EPA proposed to reinsert table E–1 to appendix E of 40 CFR part 58. This table presents the minimum separation distance between roadways and probes or monitoring paths for monitoring neighborhood and urban scale ozone (O_3) and oxides of nitrogen (NO, NO_2, NO_X, NO_y). This table was inadvertently removed during a previous CFR revision process.

The only comments received on this topic were supportive of the reinsertion of table E–1; therefore, the EPA is finalizing the reinsertion of this table, unchanged from its prior iteration, back into the CFR.

6. Additional Ambient Air Monitoring Topics

a. Annual Monitoring Network Plan and Periodic Assessment

In October of 2006, the EPA finalized new requirements for each state, or where applicable, local agency to perform and submit to their EPA Regional Offices an Assessment of the Air Quality Surveillance System (40 CFR 58.10). This assessment is required every five years. The first required five year assessments were due to EPA Regional Offices by July 1, 2010. The assessments are intended to provide a comprehensive look at each monitoring agency's ambient air monitoring network to ensure that the network is meeting the minimum monitoring objectives defined in appendix D to 40 CFR part 58, whether new sites are needed, whether existing sites are no longer needed and can be terminated, and whether new technologies are appropriate for incorporation into the ambient air monitoring network.[238]

Since each agency has completed its first required five-year assessment, and several monitoring rule requirements have either been added or changed since this requirement was added in 2006, the EPA thought it was appropriate to review this requirement and solicit comment on any possible changes the EPA should consider that may improve the usefulness of the assessments. Specifically, the EPA solicited comment on ways to either streamline or add additional criteria for future assessments.

The EPA also proposed to remove references to ''community monitoring zones'' and ''spatial averaging'' in the annual monitoring network plans due to EPA Regional Offices by July 1 of each year. The Agency proposed to remove these references since, as discussed in section VII.A.2 above, the EPA proposed to remove all references to the spatial averaging option throughout 40 CFR part 50 appendix N. Consistent with these changes, the EPA also proposed to remove references to community monitoring zones under the annual monitoring network plans described in 40 CFR 58.10.

The EPA received comments from several air agencies on the five year assessments. Most comments on the five year assessments focused on the type and usefulness of assessment tools made available to air agencies during the last review. Of specific note were concerns that assessment tools used to evaluate networks on a regional or national basis do not provide the spatial resolution necessary to adequately assess state networks on a scale most useful to air agencies. This is especially true when attempting to evaluate smaller scale monitoring or pollutant gradients associated with near-road and source oriented monitoring. Suggestions for improvement identified the need for the EPA to work closely with air agencies early in the next cycle of assessments (due in 2015) so that any tools developed can be of benefit to the questions air agencies need to address for their programs. The EPA did not receive any comments on removing references to community monitoring zones specifically as it pertains to their listing in the annual monitoring network plans described in 40 CFR 58.10.[239]

The EPA took comment on potential improvements to the five year assessments. All the recommendations received focused on the types of assessments to perform and ensuring that the EPA works closely with air agencies so that assessments will be of benefit to the air agencies. No specific recommendations were made to add or remove any of the requirements of the five year assessments and consequently the EPA is not making any changes. The EPA intends to work with air agencies to ensure future tools are as helpful as practicable.

Consistent with the decision to end the practice of spatial averaging, the EPA is finalizing the removal of language that references ''community monitoring zones'' and ''spatial averaging'' in the annual monitoring network plans due to EPA Regional Offices by July 1 of each year.

b. Operating Schedules

The EPA generally requires $PM_{2.5}$ SLAMS to operate on at least a 1-day-in-3 sampling schedule, unless a reduced sampling frequency is approved such as might be the case with

[238] The EPA provides a link to these assessments on EPA's Web site at: *http://www.epa.gov/ttn/amtic/plans.html.* A detailed description of the requirements for the assessments is described in 40 CFR 58.10.

[239] Comments on the substantive question of whether to revoke references to community monitoring zones were addressed in section VIII.B.1.

a site that has a collocated continuous operating $PM_{2.5}$ monitor.[240] However, in the 2006 monitoring rule amendments, the EPA finalized a new requirement for the operating schedule of $PM_{2.5}$ SLAMS sites (40 CFR 58.12). The new requirement stated that sites with a design value within plus or minus five percent of the 24-hour $PM_{2.5}$ NAAQS must have an FRM or FEM operating on a daily sampling schedule. This requirement was included to minimize any statistical error associated with the form of the 24-hour $PM_{2.5}$ NAAQS (i.e., the 98th percentile). In section III.F, the Administrator is finalizing revisions to the level of the primary annual $PM_{2.5}$ NAAQS. Accordingly, possible changes to sampling frequency requirements were also considered.

The EPA had previously considered how sample frequency affects the Data Quality Objectives in a consultation with the CASAC AAMMS in September of 2005 (70 FR 51353 to 51354, August 30, 2005). As a result of that consultation, the EPA proposed (71 FR 2710 to 2808, January 17, 2006) and finalized (71 FR 61236 to 61328, October 17, 2006) changes to the sample frequency requirements as part of the monitoring rule changes in 2006. In that work, the EPA demonstrated that having a higher sample count is generally more useful to minimize uncertainty for a percentile standard than an annual average. Given the decision to strengthen the primary annual $PM_{2.5}$ NAAQS and the known burden of performing daily sampling using the filter-based samplers that are still a mainstay in monitoring agency networks, the issue of needing daily sampling for sites that have design values close to the level of the 24-hour $PM_{2.5}$ standard was reconsidered if the site already has a design value above the level of the primary annual $PM_{2.5}$ NAAQS.

In a related issue, since the EPA finalized the requirement for daily sampling at sites within 5 percent of the 24-hour $PM_{2.5}$ NAAQS in 2006, there has been confusion over the procedures for adjusting sample frequencies, where necessary, to account for variations in year-to-year design values. Therefore, the EPA proposed to revise this requirement in the following ways: (1) The EPA proposed that monitors would only be required to operate on a daily schedule if their 24-hour design values were within five percent of the 24-hour $PM_{2.5}$ NAAQS and the site had a design value that was not above the level of the annual $PM_{2.5}$ NAAQS. (2) The EPA proposed that review of data for purposes of determining applicability of this requirement at a minimum be included in each agency's annual monitoring network plan described in 40 CFR 58.10 based on the three most recent years of ambient data that were certified as of the May 1 annual deadline. However, monitoring agencies may request changes to sample frequency at any time of the year by submitting such a request to their applicable EPA Regional Office. Changes in sampling frequency are expected to take place by January 1 of the following year. Increased sampling is expected to be conducted for at least three years, unless a reduction in sampling frequency has been approved in a subsequent annual monitoring network plan or otherwise approved by the Regional Administrator.

Comments received on the sample frequency requirements for $PM_{2.5}$ were from air agencies, who were generally supportive of the EPA's proposed approach.

The EPA is finalizing its proposal to modify the sample frequency requirements for triggering daily sampling so that only those areas with 24-hour design values within five percent of the 24-hour $PM_{2.5}$ NAAQS and where the design value site is not above the level of the annual $PM_{2.5}$ NAAQS would be required to operate on a daily sample frequency. The EPA is also finalizing all other aspects of this part of the proposal.

c. Data Reporting and Certification for CSN and IMPROVE Data

The EPA is not finalizing its proposal on minor changes to reporting and certification of data associated with CSN and IMPROVE networks since as explained in Section VI, EPA is not finalizing a secondary standard to support visibility impairment that would have used CSN and IMPROVE data.

d. Requirements for Archiving Filters

The EPA proposed to extend the requirement for archival of $PM_{2.5}$, PM_{10}, and $PM_{10\text{-}2.5}$ filters from manual low-volume samplers (samplers with a flow rate of less than 200 liters/minute) at SLAMS from one year after data collection to five years after data collection. The archive of low-volume PM filters is an important resource for on-going research and development of emission control strategies and for use in health and epidemiology research. During a workshop on Ambient Air Quality Monitoring and Health Research in 2008, retaining filters for laboratory analysis was identified as a key recommendation to provide daily measurements of metals and elements (U.S. EPA, 2008d, pp. 17 to 21). The EPA's previous requirement of one-year is not sufficiently long for retrospective analysis of important episodes and for use in long-term epidemiology research. Since initially requiring filter archival of low-volume PM filters in 1997, the EPA has always recommended longer archiving of filters and most agencies are already doing so. However, a small number of agencies have reported discarding older filters, despite the minimal cost of storing these filters. Since cold storage of a large number of filters may be cost prohibitive and of little benefit in retaining key aerosol species in the x-ray fluorescence (XRF) analyses, the EPA proposed to minimize the costs of retaining filters by only requiring cold storage during the first year after sample collection.

All comments received on this issue were from air agencies, which were largely supportive of such a change to this requirement. One air agency did report that it would present a hardship to store filters for such a long period of time as they did not have the room to support such a requirement.

The EPA is finalizing the requirement for archival of $PM_{2.5}$, PM_{10}, and $PM_{10\text{-}2.5}$ filters from manual low-volume samplers (samplers with a flow rate of less than 200 liters/minute) at SLAMS for a minimum of five years after data collection, with cold storage only required for the first 12 months of archiving. The EPA will work closely with air agencies through its EPA Regional Offices and laboratories to support any air agency unable to store filters for the new five year requirement.

IX. Clean Air Act Implementation Requirements for the PM NAAQS

This section of the preamble discusses the general approach for air agencies[241] to meet certain CAA requirements for implementing the revised primary annual $PM_{2.5}$ NAAQS as part of the revised suite of NAAQS for PM. In accordance with CAA section 107(d), the PM NAAQS revisions trigger a process under which states must and tribes may make recommendations to the Administrator regarding area designations, and the EPA will take final action on those designations. Under section 110 of the CAA and related provisions, states are also required to submit, for the EPA's

[240] All NCore stations must operate on at least a one-in-three day sample frequency for filter-based PM sampling.

[241] This and all subsequent references to ''air agency'' are meant to include state, local and tribal agencies responsible for the implementation of a $PM_{2.5}$ control program.

approval, SIPs that provide for the attainment and maintenance of the revised NAAQS through control programs directed at sources of direct $PM_{2.5}$ and precursor emissions. If a state fails to adopt and implement the required SIPs by the time periods provided in the CAA, the EPA has responsibility under the CAA to adopt a Federal Implementation Plan (FIP) to assure that areas attain the NAAQS in an expeditious manner. Additionally, emissions sources and air agencies must address the revised PM NAAQS in the context of preconstruction air permitting requirements and the transportation conformity and general conformity processes.

In addition to today's revisions to the primary annual $PM_{2.5}$ NAAQS, the EPA is taking final action on a PSD implementation provision. To facilitate timely implementation of the PSD requirements resulting from the revised NAAQS, which would otherwise become applicable to all PSD permit applications upon the effective date of this final PM NAAQS rule, the EPA is finalizing a grandfathering provision for pending permit applications. This final rule incorporates revisions to the PSD regulations that provide for grandfathering of PSD permit applications that have been determined to be complete on or before December 14, 2012 or for which public notice of a draft permit or preliminary determination has been published as of the effective date of today's revised $PM_{2.5}$ NAAQS. Accordingly, for projects eligible under the grandfathering provision, sources must meet the requirements associated with the prior primary annual $PM_{2.5}$ NAAQS rather than the revised primary annual $PM_{2.5}$ NAAQS.

The EPA also proposed to implement a surrogacy approach for addressing PSD requirements associated with the proposed distinct secondary visibility index NAAQS. As described in section VI, the EPA is not finalizing a distinct secondary visibility index standard at this time and therefore the proposed surrogacy approach for implementing such a standard under the PSD program is unnecessary. Additionally, as discussed in section IV, today's final rule does not include any changes to the existing PM_{10} NAAQS. Accordingly, this section of the preamble does not include any discussion of implementation specifically related to the PM_{10} NAAQS.

Under the schedule in section 107(d)(1) of the CAA, as confirmed in this action, state Governors and tribes, if they choose, are required to submit their initial designation recommendations for the revised primary annual $PM_{2.5}$ NAAQS to the EPA no later than 1 year following promulgation of the revised NAAQS (i.e., by December 13, 2013). The EPA will provide designation guidance to air agencies shortly after today's final NAAQS rule to assist them in formulating their designation recommendations. The EPA intends to complete initial designations for the revised primary annual $PM_{2.5}$ NAAQS by December 12, 2014 using available air quality data from the current $PM_{2.5}$ monitoring networks.

In addition to describing the PSD grandfathering provision being finalized in today's rule and responding to associated public comments, this section of the preamble describes the EPA's future plans for addressing the remaining aspects of implementation, such as infrastructure SIP submittals and nonattainment area planning. In the proposed rule, the EPA solicited preliminary comment on some of the issues that the Agency anticipates will need to be addressed in future guidance or regulatory actions related to implementation of the revised $PM_{2.5}$ NAAQS. The EPA received comments on a few of these issues and, as explained in greater detail later in this section, the EPA either has considered or will consider, as appropriate, all substantive comments received as future guidance and proposed rules are developed.

A. Designation of Areas

1. Overview of Clean Air Act Designations Requirements

After the EPA establishes or revises a NAAQS, the CAA requires the EPA and states to take steps to ensure that the new or revised NAAQS is met. The first step, 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 the nearby areas contributing to violations. Section 107(d)(1) of the CAA states that, ''By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109, the Governor of each state shall * * * submit to the Administrator a list of all areas (or portions thereof) in the State'' that designates those areas as nonattainment, attainment, or unclassifiable.[242] Section 107(d)(1)(B)(i) further provides, ''Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) * * * as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations.'' The term ''promulgation'' has been interpreted by the courts with respect to the NAAQS to be signature and widespread dissemination of a rule. By no later than 120 days prior to promulgating designations, the EPA is required to notify states of any intended modifications to their recommendations, including area boundaries, that the EPA may deem necessary. States then have an opportunity to demonstrate why the EPA's intended modification is inappropriate. Whether or not a state provides a recommendation, the EPA must timely promulgate the designation that it deems appropriate. While section 107 of the CAA specifically addresses states, the EPA intends to follow the same process for tribes that choose to make a recommendation to the extent practicable, pursuant to section 301(d) of the CAA 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 designations process (Page, 2011).

2. Proposed Designations Schedules

When the EPA proposed the new and revised PM NAAQS on June 29, 2012, the EPA indicated an intention to follow the standard 2-year schedule for initial area designations for both the revised primary annual $PM_{2.5}$ standard and the proposed secondary PM visibility index standard, noting that promulgating initial area designations for these standards on the same schedule would provide early regulatory certainty for states. Under this approach, the EPA intended to complete initial designations for both the revised primary annual $PM_{2.5}$ NAAQS and the secondary PM visibility index NAAQS by December 2014 using available air quality data from the current $PM_{2.5}$ and speciation monitoring networks using the most recent 3 consecutive years of certified air quality monitoring data (i.e., most likely data from 2011–2013).

[242] While the CAA says ''designating'' with respect to the Governor's list, in the full context of the CAA section it is clear that the Governor actually makes a recommendation to which the EPA must respond via a specified process if the EPA does not accept it.

The EPA's June 29, 2012 notice proposed new requirements for establishing near-road $PM_{2.5}$ monitors in certain cities (section VIII.B.3.b.i of the proposal) and new requirements for each state with a CBSA over 1 million in population to add or relocate an existing CSN (or IMPROVE) monitoring site in at least one of its CBSAs to collect speciated $PM_{2.5}$ data to support implementation of the proposed secondary standard to address visibility impairment (section VIII.A.2 of the proposal). The EPA anticipated that 3 consecutive years of air quality data from any near-road monitoring sites or newly placed CSN (or IMPROVE) $PM_{2.5}$ speciated monitoring site would not be available until 2018. The timing for both of these proposed monitoring changes would preclude the use of the collected data in initial area designations, and therefore, the EPA stated in the proposal that initial area designations would not take into account monitoring data from any newly established near-road monitoring sites, nor from newly established speciation monitoring sites.

3. Comments and Responses

The EPA received numerous comments on the proposed designations schedules from states, state organizations, local air pollution control agencies, regional organizations, industry, environmental organizations, and health-related organizations. Most commenters expressed support for a standard 2-year schedule for initial area designations for the primary annual standard. Several commenters also encouraged the EPA to consider an additional year for initial area designations associated with the proposed secondary PM visibility index standard due to the lag in obtaining data from speciation monitoring networks, the variability in monitored relative humidity data, and the ''unique'' nature of the proposed secondary standard. For the reasons stated in section VI.D.2, the Administrator has decided not to establish the proposed distinct secondary standard to address visibility impairment, and therefore, the EPA will not promulgate initial area designations for a secondary PM visibility index standard. Because data are currently available from numerous existing $PM_{2.5}$ mass monitoring sites to determine compliance with the revised primary annual $PM_{2.5}$ NAAQS, the EPA believes it is appropriate to pursue a standard 2-year schedule for initial area designations for the primary annual $PM_{2.5}$ NAAQS.

The EPA also received numerous comments related to the use of data from the proposed new near-road monitors in the designations process. Several commenters asked the EPA to clarify whether these data will be used if available for initial area designations. Others asked the EPA to provide guidance related to establishing boundaries for areas containing violating near-road monitors. One commenter suggested that the EPA conduct dispersion modeling around transportation facilities in accordance with the EPA's transportation conformity hotspot modeling guidance and use concentrations to determine attainment status for designations process. This same commenter also supported using modeling for unmonitored areas, e.g., communities near roadways.

As previously stated, the EPA does not believe that data from the new near-road monitors will be available for the EPA to consider within the timeframe for initial area designation provided by the CAA. Section 107(d)(1)(B) of the CAA requires the EPA to designate areas no later than 2 years following promulgation of a new or revised NAAQS, or by December 2014. (The CAA provides the Agency an additional third year from promulgation should there be insufficient information on which to make compliance determinations). For initial area designations for the primary annual $PM_{2.5}$ NAAQS, the EPA relies exclusively on monitoring data to identify areas to be designated nonattainment due to violations of the standards and then uses other information to identify areas contributing to violations in those areas. *See Catawba County* v. *EPA,* 571 F.3d 12–13 (D.C. Cir. 2009). As indicated in the proposal, the initial set of near-roadway $PM_{2.5}$ monitors will be fully deployed by January 2015, with the requisite 3 years of air quality data available in 2018.[243] The EPA intends to proceed with initial area designations using 3 years of consecutive air quality data from the existing, area-wide FRM/FEM/ARM $PM_{2.5}$ monitoring sites to complete designations by December 2014. Consistent with previous area designations processes used in informing boundary decisions, the EPA would then analyze a variety of area-specific information[244] in determining which nearby areas contribute to a violation. As previously indicated, the EPA relies on monitoring data to identify areas to be designated nonattainment due to violations of the standards and does not intend to conduct or use dispersion modeling around transportation facilities or in unmonitored areas to determine whether an area is violating the primary annual $PM_{2.5}$ NAAQS for purposes of establishing nonattainment areas as this is not required by the statute. *See Catawba County* v. *EPA,* 571 F.3d 12–13 (D.C. Cir. 2009). The EPA intends to address the use of area-specific information and the boundary setting process, including the presumptive starting area boundary, in the designation guidance to the states, expected to be available shortly after promulgation of the PM NAAQS.

4. Intended Designations Schedules

In this final rule, the EPA is setting a revised, more protective primary annual $PM_{2.5}$ NAAQS. After considering the public comments and for the reasons discussed above, the EPA intends to designate areas for the primary annual $PM_{2.5}$ NAAQS on a 2-year schedule from signature of this final PM NAAQS rule, as prescribed in CAA section 107.[245] Under the schedule in section 107(d)(1) of the CAA, as confirmed in this action, state Governors and tribes, if they choose, are required to submit their initial designation recommendations for the revised primary annual $PM_{2.5}$ NAAQS to the EPA no later than 1 year following promulgation of the revised NAAQS (i.e., by December 13, 2013). These recommendations should be based on air quality data from the years 2010 to 2012. If the EPA intends to make any modifications to a state's or tribe's recommendations, the EPA is required to notify the state or tribe no later than 120 days prior to finalizing the designation; this would be no later than August 14, 2014. States and tribes will then have an opportunity to demonstrate why the EPA's intended modification is inappropriate before the EPA makes the final designation decisions. Prior to the EPA's signing a final rule by December 12, 2014, promulgating the initial area

[243] The remainder of the near-road monitors in CBSAs with populations between 1 million but less than 2.5 million will be deployed by January 1, 2017.

[244] The EPA has used area-specific information to support boundary determinations by evaluating factors such as air quality data, emissions and emissions-related data, meteorology, geography/topography, and existing jurisdictional boundaries. This may include, as appropriate, information from non-FRM/FEM/ARM monitors and air quality modeling, where available, to help define an appropriate boundary for areas contributing to FRM/FEM/ARM-based monitored violations.

[245] While the EPA intends to make every effort to designate areas for the primary annual $PM_{2.5}$ NAAQS on a 2-year schedule, the EPA recognizes that new information may later arise that justifies the need for additional time, up to 1 additional year available based on insufficiency of data, to complete the process. Any subsequent change to the designations schedule would be announced.

designations for the 2012 primary annual $PM_{2.5}$ NAAQS, data from 2013 may be available. If so, the EPA's designations decisions will be based on air quality data from the years 2011 to 2013. States and tribes may update their recommendations when these new data become available.

In the proposal, the EPA stated its intention to provide technical information and guidance to states shortly after promulgation of the NAAQS to assist states and tribes in the development of their designation recommendations. The EPA understands that developing recommendations on appropriate nonattainment area boundaries is a significant effort for states, especially for states with little or no experience in $PM_{2.5}$ air quality planning. Therefore, the EPA plans to assist states throughout the designations process on technical and policy-related issues through outreach efforts that will provide information and data sources relevant to making designations decisions. The EPA will include such information for the revised primary annual $PM_{2.5}$ NAAQS on the general $PM_{2.5}$ designations Web site at *http://www.epa.gov/pmdesignations.* The EPA also encourages states and tribes to consult with their EPA regional office as they develop their area recommendations.

B. Section 110(a)(2) Infrastructure SIP Requirements

The proposal described the CAA requirements for air quality management infrastructure SIPs that states must submit to the EPA within 3 years after promulgation of a new or revised primary standard. As discussed in the proposal, 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. In the proposal, the EPA solicited comment on infrastructure SIP submittal timing, in addition to ''all aspects'' of infrastructure SIPs, for the Agency to consider in developing future guidance. The EPA received comments recommending that the EPA provide states an additional 18 months to submit SIPs for any revised secondary standard, but because the Agency is not revising the secondary NAAQS in this rule, the issue of whether or not to allow states extra time to submit infrastructure SIPs for the secondary NAAQS is now moot. The EPA received several comments on other aspects of infrastructure SIPs, which are being considered in the development of a forthcoming guidance document on section 110 infrastructure SIP requirements that will apply to all NAAQS, including the revised $PM_{2.5}$ NAAQS. In addition, the EPA may issue supplemental infrastructure SIP guidance specific to the revised $PM_{2.5}$ NAAQS if needed.

C. Implementing the Revised Primary Annual $PM_{2.5}$ NAAQS in Nonattainment Areas

In the proposal, the EPA described the basic CAA requirements that govern SIP submittals for nonattainment areas (77 FR 38890, June 29, 2012 at 39019–21). The Agency did not propose any particular approach for implementing any revised $PM_{2.5}$ standards, but rather indicated its intent to carry out a notice-and-comment rulemaking to propose and issue a final implementation rule that would spell out the implementation requirements for the revised primary annual $PM_{2.5}$ NAAQS and the revised monitoring regulations. The EPA acknowledges that several states and industry groups commented on the need for the EPA to issue an implementation rule, either in proposed or final form, simultaneous with this final PM NAAQS rule. Other commenters commented that the EPA should consult with states and local air agencies to develop the future implementation rule and to do so expeditiously, while another state commenter requested that the EPA commit to firm deadlines for issuing the future implementation rule and guidance related to infrastructure SIPs, among other things.

The EPA acknowledges states' need for timely guidance on how to implement the revised NAAQS. However, due to the number of unique and complex issues associated with the PM NAAQS proposal and uncertainty about the outcome of the final NAAQS, the EPA is not able to propose an implementation rule or finalize any aspect of the implementation program beyond the PSD grandfathering provision discussed later in this section at this time. Because we agree that it is beneficial to engage with air agencies early in the rule development process, however, we have initiated such discussions to inform the upcoming proposed rule. The EPA intends to finalize the implementation rule around the time the initial area designations process is finalized.

One particular implementation-related issue that the EPA sought preliminary comment on in the proposal was the concept of a transition period during which any changes in monitoring requirements would not affect attainment plans and maintenance plans for the 1997 and 2006 $PM_{2.5}$ NAAQS. The EPA received a range of comments both in support of and in opposition to such a concept. Upon further analysis of the potential effect of monitoring requirement changes, and in consideration of comments received, we believe that it will not be necessary to provide for such a transition period in the future implementation rule because the changes in monitoring requirements included in this final rule would not automatically affect attainment plans and maintenance plans for the 1997 or 2006 $PM_{2.5}$ NAAQS. Specifically, there are currently approximately ten $PM_{2.5}$ air quality monitors that have been identified as not comparable to the annual standards as part of the annual state monitoring plan revision process. If a state chooses to revise the status of one of these monitors in order to make it comparable to the annual standards because it is determined to be representative of many other similar locations, it would propose a change in status for that monitor in the next revision of the state $PM_{2.5}$ monitoring plan (state revisions are due in June of each year). The EPA would then review and take action on the state's proposed change. The EPA believes that the monitoring plan revision process provides adequate procedural steps for identifying which monitors are to be comparable to the annual $PM_{2.5}$ standards. Thus for this reason, there is no need to include any ''transition period'' in a future rule.

The EPA appreciates the input received from commenters on implementation issues and will take it into consideration as we continue to work with air agencies to develop our proposed implementation rule. In developing the future implementation rule proposal, the EPA also plans to address any potential impact of the monitoring requirement changes being finalized in this rule, particularly on attainment planning and development of attainment demonstrations by states, and in doing so, we will consider the preliminary comments received on this topic.

D. Prevention of Significant Deterioration and Nonattainment New Source Review Programs for the Revised Primary Annual $PM_{2.5}$ NAAQS

The CAA requires states to include SIP provisions that address the preconstruction review of new stationary sources and the modification of existing sources. The preconstruction review of each new and modified source generally applies on a pollutant-specific basis and the requirements for each pollutant vary depending on whether the area is designated attainment (or unclassifiable) or nonattainment for that pollutant. Parts C and D of title I of the CAA contain specific requirements for

the preconstruction review and permitting of new major stationary sources and major modifications, referred to as the PSD program and the nonattainment new source review (NNSR) program, respectively. Collectively, those permit requirements are commonly referred to as the ''major NSR program'' because of their applicability to new major stationary sources and major modifications.

Today's final rule revising the primary annual $PM_{2.5}$ NAAQS will affect PSD permitting requirements as of the effective date of today's final rule, March 18, 2013, which is also the effective date of the revised $PM_{2.5}$ NAAQS. In addition, certain NNSR permitting requirements related to the revised $PM_{2.5}$ NAAQS will take effect on and after the effective date of any nonattainment area designation for $PM_{2.5}$. In order to minimize potential delays for pending PSD permit applications and to provide a reasonable transition, the EPA is finalizing a grandfathering provision for PSD permit applications that have reached a specified milestone in the permitting process. This final rule incorporates revisions to the PSD regulations that provide for grandfathering of PSD permit applications for which the reviewing authority has determined the application to be complete on or before December 14, 2012 or for which the reviewing authority has first published public notice that a draft permit or preliminary determination for the permit has been issued prior to the effective date of today's revised PM NAAQS. Accordingly, projects eligible under the grandfathering provision must meet the requirements associated with the prior primary annual $PM_{2.5}$ NAAQS rather than the revised primary annual $PM_{2.5}$ NAAQS. As discussed in more detail in the following sections, the EPA is not now making any changes to the $PM_{2.5}$ increments, nor are we revising any of the screening tools that are now used to implement the major NSR program for $PM_{2.5}$. These screening tools include the significant emission rate (''SER''), used as a threshold for determining whether a given project is subject to major NSR permitting requirements under both PSD and NNSR; the significant impact levels (''SILs''), used to determine the scope of the required air quality analysis that must be carried out in order to demonstrate that the source's emissions will not cause or contribute to a violation of any NAAQS or increment under the PSD program; and the significant monitoring concentration (''SMC''), a screening tool used to determine whether it may be appropriate to exempt a proposed source from the requirement to collect preconstruction ambient monitoring data as part of the required air quality analysis.

1. Prevention of Significant Deterioration

The PSD requirements set forth under part C (sections 160 through 169) of the CAA apply to new major stationary sources and major modifications locating in areas designated as ''attainment'' or ''unclassifiable'' with respect to the NAAQS for a particular pollutant. The EPA regulations addressing the statutory requirements under part C for a PSD permit program can be found at 40 CFR 51.166 (containing the PSD requirements for an approved SIP) and 40 CFR 52.21 (the federal PSD permit program). For PSD, a ''major stationary source'' is one with the potential to emit 250 tons per year (tpy) or more of any air pollutant, unless the source or modification 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 listed source categories, a ''major stationary source'' is one with the potential to emit 100 tpy or more of any air pollutant. A ''major modification'' is a physical change or a change in the method of operation of an existing major stationary source that results in a significant emissions increase and a significant net emissions increase of a regulated NSR pollutant. Under PSD, new major sources and major modifications must apply best available control technology (BACT) for each applicable pollutant and conduct an air quality analysis to demonstrate that the proposed source or project will not cause or contribute to a violation of any NAAQS or PSD increments (*see* CAA section 165(a)(3); 40 CFR 51.166(k); 40 CFR 52.21(k)). PSD requirements also include in appropriate cases an analysis of potential adverse impacts on Class I areas (*see* sections 162 and 165 of the CAA).

PSD permitting requirements generally first became applicable to $PM_{2.5}$ in 1997, on the effective date of the NAAQS for $PM_{2.5}$ (Seitz, 1997). The EPA's regulations define the term ''regulated NSR pollutant'' to include any pollutant for which a NAAQS has been promulgated or that is otherwise identified as a constituent or precursor to a NAAQS pollutant (40 CFR 51.166(b)(49); 40 CFR 52.21(b)(50)).[246] In addition, on May 16, 2008, the EPA amended its regulations to identify certain $PM_{2.5}$ precursors (SO_2 and NO_X) as regulated NSR pollutants and adopt other provisions, such as a significant emissions rate for $PM_{2.5}$, to facilitate implementation of PSD and NNSR program requirements for $PM_{2.5}$ (73 FR 28321).[247] Air agencies were required to revise their SIPs by May 16, 2011, to incorporate the required elements of the 2008 final rule.

On October 20, 2010, the EPA again amended the PSD regulations at 40 CFR 51.166 and 52.21 to add PSD increments as well as two screening tools for $PM_{2.5}$—SILs and SMC (75 FR 64864). The October 2010 final rule became effective on December 20, 2010. The EPA indicated that the SILs and SMC for $PM_{2.5}$, while useful tools for program implementation, are not considered mandatory elements of an approvable SIP; thus, no schedule was imposed on states for addressing those screening tools in their PSD rules. For the portions of the rule that addressed the PSD increments for $PM_{2.5}$, states were required to submit the necessary SIP revisions (at least as stringent as the PSD requirements at 40 CFR 51.166) to the EPA for approval within 21 months from the date on which the EPA promulgated the new $PM_{2.5}$ increments—by July 20, 2012. The schedule for developing and submitting the revisions specifically for the adoption of new PSD increments in state PSD programs is prescribed by the CAA section 166(b). As of October 20, 2011, sources for which PSD permits have been issued pursuant to the federal PSD program at 40 CFR 52.21 have been required, where applicable, to determine their impact on the $PM_{2.5}$ increments.

The PSD program currently regulates emissions of PM using several indicators of particles, including ''particulate matter emissions'' (as regulated under various new source performance standards under 40 CFR part 60), ''PM_{10} emissions,'' and ''$PM_{2.5}$ emissions.'' The latter two emission indicators are designed to be consistent

[246] Under various provisions of the CAA, PSD requirements are applicable to each pollutant subject to regulation under the CAA, excluding hazardous air pollutants. The definition of ''regulated NSR pollutant'' also includes pollutants subject to any standard under section 111 of the CAA or any Class I or II substance subject to title VI of the CAA.

[247] It should be noted that on October 25, 2012, the definition of ''regulated NSR pollutant'' was revised to remove the requirement that condensable PM be included when considering ''particulate matter emissions.'' Accordingly, the definition now requires condensable PM to be counted for PM_{10} emissions and $PM_{2.5}$ emissions, and for ''particulate matter emissions'' only when required by the applicable New Source Performance Standard or SIP. (*See* 77 FR 65107.)

with the ambient air indicators for PM that the EPA currently uses to define the PM NAAQS. As already noted, the PSD program also limits $PM_{2.5}$ concentrations by regulating emissions of gaseous pollutants that result in the secondary formation of particulate matter. Those pollutants, known as $PM_{2.5}$ precursors, generally include SO_2 and NO_X.

In addition to the NAAQS revisions contained in today's final rule, the EPA is finalizing certain clarifications to the existing monitoring regulations codified at 40 CFR 58.30 (Special considerations for data comparisons to the NAAQS). These clarifications are presented in detail in section VIII.B.2 of this preamble. The monitoring regulations provide a basis for determining whether specific monitoring sites are comparable to specific NAAQS. By extension, the EPA has also used the principles for making these determinations for monitoring sites to guide permitting authorities in assessing the comparability of specific receptor locations involved in PSD air quality analyses. Receptors are used in PSD modeling analyses to predict potential air quality impacts in the vicinity of the proposed new or modified facility and in some cases also at more distant Class I areas. Since the EPA interprets the regulation at 40 CFR 58.30 to apply in this context, the EPA will continue to use the principles in the revised regulations in guiding PSD modeling analysis design. Accordingly, the EPA recommends that specific receptor locations used in PSD air quality analyses are evaluated consistent with the final monitoring regulations, as amended by today's rule.

a. Transition Provision (Grandfathering)

i. Proposal

As discussed previously in this preamble, today's final rule establishes a revised level of the primary annual $PM_{2.5}$ NAAQS.[248] Longstanding EPA policy interprets the CAA and 40 CFR 52.21(k)(1) and 51.166(k)(1) to generally require that PSD permit applications include a demonstration that new major stationary sources and major modifications will not cause or contribute to a violation of any NAAQS that is in effect as of the date the PSD permit is issued (Page, 2010a; Seitz, 1997). Thus, as a result of today's final rule, any proposed major new and modified sources with permits pending at the time the $PM_{2.5}$ NAAQS changes take effect would be expected to demonstrate compliance with the revised standard, absent some type of transition provision exempting such applications from the new requirements.

In order to provide for a reasonable transition into the new PSD permitting requirements that will result from the revision of the primary annual $PM_{2.5}$ NAAQS (primarily the requirement to demonstrate that emissions will not cause or contribute to a violation of the revised NAAQS) and the changes to the monitoring requirements discussed earlier, the EPA proposed to add a grandfathering provision to the federal PSD program codified at 40 CFR 52.21 that would apply to certain PSD permit applications that are pending on the effective date of the revised $PM_{2.5}$ NAAQS. Specifically, the EPA proposed to amend the federal PSD regulations at 40 CFR 52.21 to grandfather pending permit applications for which the Administrator or delegated air agency has published a public notice on the draft permit prior to the effective date of the revised $PM_{2.5}$ NAAQS. Qualifying applications could continue being processed in accordance with the PSD requirements applicable to the pre-existing suite of PM NAAQS at the time the public notice on the draft permit was first published. The EPA also proposed that air agencies that issue PSD permits under their own SIP-approved PSD permit program should have the discretion to ''grandfather'' proposed PSD permits in the same manner under these same circumstances. Thus, the EPA also proposed to revise section 40 CFR 51.166 to provide a comparable exemption applicable to SIP-approved PSD programs.

In the preamble to the proposal, the EPA provided a detailed rationale and legal basis for the proposed grandfathering provision, also citing examples in which the EPA previously recognized that the CAA provides discretion for the EPA to grandfather PSD permit applications from requirements that become applicable while the application is pending (45 FR 52683, Aug. 7, 1980; 52 FR 24672, July 1, 1987; U.S. EPA, 2011c, pp. 54 to 61). In summary, when read in combination, sections 165(a)(3), 165(c) and 301[249] of the CAA provide the EPA with the discretion to promulgate regulations to grandfather pending permit applications from having to address a revised NAAQS where necessary to achieve a balance between the CAA objectives in order to protect the NAAQS on the one hand, and to avoid delays in processing PSD permit applications on the other. The EPA has also construed section 160(3) of the CAA, which states that a purpose of the PSD program is to ''insure that economic growth will occur in a manner consistent with the preservation of existing clean air resources,'' to call for a balancing of economic growth and protection of air quality (70 FR 59582, Oct. 12, 2005 at 59587 to 59588). The reasoning of those prior EPA actions is also applicable to the promulgation of revised PM NAAQS.

In developing the proposed grandfathering provision, the EPA considered whether such a provision should include a sunset clause. A sunset clause would add a time limit beyond which an otherwise eligible permit application would no longer be grandfathered from specified new PSD permitting requirements. Consistent with past grandfathering actions described above, the EPA did not propose to include a sunset clause for the proposed grandfathering provision.

ii. Comments and Responses

The majority of commenters, including all industry and state agency representatives, supported the EPA's proposal to adopt a grandfathering provision based on the purpose and rationale described in the preamble to the proposal. These commenters agreed that grandfathering certain pending PSD permit applications was reasonable to balance the CAA objectives to protect the NAAQS on one hand, and to avoid delays in processing PSD permit applications on the other. They also agreed grandfathering provides a reasonable transition into the PSD requirements associated with the revised NAAQS. Industry commenters also indicated that such a provision was important to economic growth and recovery, and was consistent with the purposes of the PSD program, i.e., to ensure that economic growth will occur in a manner consistent with preservation of air quality. Several state commenters pointed out that finalizing the revised $PM_{2.5}$ NAAQS without a grandfathering provision would result

[248] The EPA is also revising the form of the annual primary standard by removing the option for spatial averaging. However, this provision has played no role in PSD so its removal has no implications for PSD.

[249] Section 165(a)(3) of the CAA generally requires that no major emitting facility may be constructed unless the owner or operator demonstrates that emissions from construction or operation of such facility will not cause or contribute to a violation of any NAAQS or PSD increment. Section 165(c) of the CAA requires that the EPA grant or deny any completed permit application not later than one year after the date of filing of such complete application. Section 301 of the CAA authorizes the EPA to prescribe such regulations as are necessary to carry out the functions under the CAA.

in a significant additional resource burden on both permit applicants and air agencies, which would have to reopen pending permit applications that have reached advanced stages in processing to address the revised standard. The commenters further noted that there would likely be little if any environmental benefit afforded by such a process. One state agency commenter performed a preliminary review of recent PSD permitting actions and determined that in all cases, the proposed primary annual $PM_{2.5}$ standard would not have led to tighter permit restrictions or reduced emissions, and that a re-noticing of the preliminary permit decisions would accomplish nothing more than to change the margins of compliance. In other words, re-noticing would have led to project delays with no reduction in $PM_{2.5}$ impacts.

Four environmental group commenters (one representing a coalition of a health advocacy group and several environmental groups) opposed the proposed grandfathering provision based either on concerns about further delay in implementation of the revised PM NAAQS or on a position that the proposed grandfathering provision exceeds the EPA's statutory authority and is unlawful. Commenters challenging the EPA's legal authority to implement the proposed grandfathering provision contended that CAA sections 165 and 301 do not confer any authority on the EPA to grandfather PSD permit applications. The commenters asserted that CAA section 165(a) forecloses the EPA's proposed approach, specifically citing CAA section 165(a)(3)(B) which provides that no major emitting facility ''may be constructed'' unless the facility's owner or operator demonstrates emissions from the facility will not cause or contribute to the violation of ''any * * * national ambient air quality standard in any air quality control region.'' These commenters further claimed that because Congress limited the applicability of the new PSD requirements in several ways, including specific grandfathering relief for sources constructed before the enactment of the 1977 Amendments to the CAA, the EPA is not authorized to waive otherwise applicable statutory requirements (citing *Andrus* v. *Glover Constr. Co.,* 446 U.S 608, 616–17 (1980)).

A subset of commenters also stated that the EPA's proposed grandfathering approach undermines the policy choices made by Congress in adopting the PSD program that (1) it is preferable to prevent air pollution from becoming a problem in the first place, and (2) controls should be installed when new sources are being constructed rather than as retrofits on existing sources.

One commenter asserted that there is no conflict between CAA sections 165(a) and 165(c) as the EPA had implied; therefore, there is no need for the EPA to invoke the regulatory authority of CAA section 301. This commenter also concluded that the EPA's rationale of balancing of economic growth and the protection of air quality pursuant to CAA section 160(3) was unlawful, and that the EPA had not adequately explained the considerations it sought to balance and how the proposal would achieve its goals. The same commenter questioned the EPA's authority to leverage principles of equity and fairness in proposing the grandfathering provision. The commenter also objected to the EPA's rationale for choosing the public notice date of a draft permit as the milestone triggering the grandfathering provision, stating that the approach was contrary to statute because it would deprive interested persons of their statutory right to comment on elements of the application related to the current NAAQS.

The EPA does not agree with the interpretations of the CAA offered by the commenters opposing the proposed grandfathering provision. The EPA has previously exercised this discretion to establish grandfathering provisions in regulations. Indeed, the EPA has done so where provisions of the CAA contradict each other, citing the authority under section 301(a)(1) ''to set transitional rules which accommodate reasonably the purpose and concerns behind the two contradictory provisions'' (45 FR 52676, August 7, 1980 at 52683). Furthermore, the EPA has noted and continues to recognize that even in the absence of a conflict between sections of the Act, ''EPA would have the authority under section 301(a)(1) to exempt those projects in order to phase-in new requirements on a reasonable schedule.'' *Id.* at 52683 n. 5.

There is a conflict or tension between certain provisions of the CAA that the EPA must reconcile in situations where the ability of air agencies to complete action on a permit application within the statutory one-year deadline is likely to be impeded if a new or revised NAAQS becomes applicable during the permit application review process. We do not agree with the commenters' arguments to the contrary. The CAA does not provide clear direction concerning how the EPA should apply section 165(a)(3) of the Act to NAAQS that become effective in circumstances where efforts to update a permit application to address the new or revised NAAQS would be time consuming and impede compliance with the CAA obligation to take action on the application within one year after the completeness determination. Since Congress has not precisely spoken to this issue, the EPA has the discretion to apply a permissible interpretation of the Act that balances the requirements in the Act 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. *Chevron, U.S.A., Inc.* v. *Natural Res. Def. Council, Inc.,* 467 U.S. 837, 843–44 (1984).

Targeted grandfathering applicable to a specific NAAQS does not waive the statutory requirements in section 165(a)(3), as some commenters assert. Rather, the grandfathering provision makes clear which NAAQS are covered by this provision of the Act when it is applied to a permit application that has reached a specific stage in the review process (i.e., the date the application is determined to be complete or the first date of publication of a public notice on the draft permit or preliminary determination) before a specified date. Grandfathering resolves the question of how the EPA and other permitting authorities should interpret and apply section 165(a)(3) of the Act in the case of today's PM NAAQS revisions considering the requirement of section 165(c) of the Act that reviewing authorities make a decision on a permit application within one year of the date the application was determined complete. This is not a question of whether section 165(a)(3) applies; it is a question of which NAAQS this requirement should cover in the case of a pending PSD permit.

The EPA agrees that as a general rule, section 165(a)(3) applies to ''any NAAQS'' that is effective as of the date a final PSD permit is initially issued (before any administrative appeal proceeding commences). However, these provisions cannot be read in isolation and should be construed in the context of other provisions in section 165 of the Act, such as section 165(c). Since the EPA is required to give effect to all provisions of the Act, in those circumstances where a strict reading of sections 165(a)(3) would frustrate congressional intent that the EPA and other implementing air agencies act in a timely manner, the Agency has the discretion to interpret the reach of section 165(a)(3) to be limited to particular NAAQS that were proposed or effective prior to significant milestones in the permitting process.

Thus, the EPA does not agree with the view expressed by some commenters that section 165(a)(3) must be read strictly in all circumstances to apply to all NAAQS in effect on the date the EPA issues a final permit decision, regardless of other circumstances or other requirements of the CAA. Such a reading fails to acknowledge or give meaning to section 165(c) of the Act. 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'').

The EPA is also not persuaded that the presence of a grandfathering provision in section 168(b) precludes the EPA from establishing grandfathering exemptions in other circumstances. The commenter's reference to the Supreme Court's observation that when ''Congress expressly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied in the absence of evidence of a contrary legislative intent,'' *Andrus,* 446 U.S. at 616–17, is not persuasive here. The Court applied this principle in a circumstance where there was a provision of law ''expressly relating to contracts of the sort at issue here.'' *Id.* These are not the circumstances here. Section 168(b) of the Act does not expressly relate to the application of PSD permitting requirements to an application pending at the time of the promulgation of a new or revised NAAQS. Section 168(b) exempted facilities that were subject to permitting requirements under an earlier version of the PSD program created solely by the EPA regulation prior to the enactment of section 165 of the CAA and other provisions that expressly authorized and established the requirements of the PSD permitting program applicable today. This exemption operated to continue existing requirements for certain sources after a fundamental change in the statutory and regulatory regime under which such sources were required to obtain authorization to construct or modify major stationary sources of air pollutants. Such an exemption does not expressly relate to the incorporation of a new requirement into the PSD program, under existing statutory authority, when the EPA promulgates a regulation that creates such a requirement. In this case, the EPA is not grandfathering permit applications from the general prohibition in section 165(a) against commencing construction in the absence of a permit issued ''in accordance with the requirements of this part.'' The CAA does not contain any express exemptions to the phrase ''the requirements of this part'' or from section 165(a)(3) of the Act that apply when the EPA promulgates a new or revised NAAQS. Furthermore, section 168(b) applied to sources that had commenced construction before new provisions of the CAA were enacted, whereas the grandfathering that the EPA proposed for purposes of the revised PM NAAQS is applicable to changes in regulatory requirements prior to the issuance of a permit. Thus, the adoption of a one-time grandfather provision upon enactment of the statutory PSD program is clearly different from grandfathering when the EPA promulgates a new or revised NAAQS, which the Act does not address. The fact that Congress expressly enumerated an exemption in section 168 intended to ease transition upon enactment of the PSD provisions in the Act does not constrain the Agency with respect to offering reasonable transitional exemption provisions when EPA regulations create new PSD program requirements under those statutory provisions.

The EPA agrees that the PSD program is based on the goals of preventing air pollution and installing controls when new sources are being constructed, but section 160(3) of the Act also states that a purpose of the PSD program is to ''insure that economic growth will occur in a manner consistent with the preservation of existing clean air resources.'' The EPA continues to construe this provision to call for a balancing of economic growth and protection of air quality. *See* 70 FR 59582, October 12, 2005 at 59587–88. Legislative history illustrates Congressional intent to avoid a moratorium on construction and delays in permit processing. The House Committee report describes how ''the committee went to extraordinary lengths to assure that this legislation and the time needed to develop and implement regulations would not cause current construction to be halted or clamp even a temporary moratorium on planned industrial and economic development.'' H.R. Rep. No. 95–294, 95th Cong., 1st Sess., at 171 (1977). As an illustration of the lengths to which the committee went, the report lists five elements of the legislation, including the following statement: ''To prevent disruption of present or planned sources, the committee has authorized extensive 'grandfathering' of both existing and planned sources.'' *Id.* Furthermore, the Senate Committee report specifically discusses concerns about delays in program implementation. 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'').

In the 1980 PSD regulation, the EPA sought to strike a balance between competing goals of the CAA (45 FR 52683). The EPA explained that delaying certain construction ''by imposing new PSD requirements could frustrate economic development'' and noted that the grandfathered projects ''have a relatively minor effect on air quality.'' *Id.* As a result, the EPA adopted a grandfathering provision that ''would strike a rough balance between the benefits and costs of applying PSD to those projects.'' *Id.* Although the EPA used issuance of permits previously required under the SIP in that case to determine eligibility for grandfathering, this precedent does not preclude the EPA from using another milestone in the permit process to determine eligibility in order to strike the appropriate balance in a different situation. The interests behind section 165 include both protection of air quality and timely decision-making on pending permit applications. The EPA is seeking here to balance the requirements in the Act 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.

Moreover, this action is not based on an assertion of equitable power to disregard or override law, but rather on an interpretation of our statutory authority. In so doing, the EPA has in this case determined which regulatory requirements are covered by the statutory requirements that apply to an application that has reached a specified milestone when the regulatory requirement was established. The EPA does not dispute that administrative agencies only have the powers conferred by statute. However, the EPA may interpret the statutory requirements consistent with Congressional intent and exercise its discretion in a thoughtful way in doing so. Thus, while an administrative agency in the executive branch does not have the equitable powers of a court, this does not necessarily mean an administrative agency cannot interpret its statutory authority to achieve equitable outcomes consistent with Congressional intent.

Based on the foregoing, the EPA believes it has adequately explained its consideration of the CAA requirements related to both NAAQS protection and timely decision-making on permit applications in designing the proposed grandfathering provision. As described below, the EPA is finalizing a grandfathering provision that applies to two categories of PSD permit applications: (1) Those that the reviewing authority has determined to be complete on or before December 14, 2012, or (2) those for which the reviewing authority has first published a public notice that a draft permit or preliminary determination had been prepared prior to the effective date of the revised PM NAAQS. In the proposal, the EPA proposed to grandfather only the latter category, based on publication of a public notice on a draft permit or preliminary determination by the effective date of the final PM NAAQS. However, as described later in this section, based on consideration of public comments received on the proposal, the EPA decided to augment the grandfathering provision to include applications that had been determined to be complete on or before December 14, 2012, the date of signature of the final rule. Permit applications qualifying under the final grandfathering provision must demonstrate that a qualifying new or modified source will not cause or contribute to a violation of the $PM_{2.5}$ NAAQS and increments in effect as of the date the permit application is determined to be complete by the reviewing authority or as of the date the reviewing authority first publishes public notice of the draft permit or preliminary determination, depending on which prong of the grandfathering provision is applicable.

The grandfathering provision does not apply to any other applicable PSD requirements related to $PM_{2.5}$. Sources with projects qualifying under the grandfathering provision will be required to install BACT for $PM_{2.5}$ emissions, demonstrate that project emissions will not cause or contribute to a violation of the PSD increments for $PM_{2.5}$ or the $PM_{2.5}$ NAAQS in effect at the time the permit application is determined to be complete or the public notice is first published on the draft permit or preliminary determination, and address Class I and additional impacts in accordance with the PSD regulatory requirements. Accordingly, the EPA does not expect that the grandfathering provision being finalized in today's rule will result in significantly different air quality impacts than would occur absent any type of grandfathering or transition provision. One commenter has submitted an analysis to support this conclusion.

As described in the proposal and some of the comments received from state agencies, if the EPA and other reviewing authorities were to require permit applicants to demonstrate that they will not cause or contribute to a violation of the revised PM NAAQS after the public comment period has begun, this would unduly delay the processing of the permit application by potentially requiring an additional public comment period and increased demand on the limited resources of the reviewing authority. The EPA disagrees with commenters who contend that grandfathering is contrary to statute because it would preclude public comment on elements of the application related to the current NAAQS. With respect to an application grandfathered under the new provisions provided by today's rule, interested persons will have the opportunity to comment on all aspects of PSD review for $PM_{2.5}$, including the air quality impacts associated with the revised NAAQS that became effective after the application was determined to be complete or after a public notice was published on the draft permit or preliminary determination, depending on which prong of the grandfathering provision applies. Section 165(a)(2) of the CAA and section 51.166(q)(2)(v) require an opportunity for the public to comment on ''the air quality impact of the source'' and ''other appropriate considerations.'' The grandfathering provision does not necessarily take away the ability of the public to comment on the impact the source may have on the revised NAAQS (including the standard proposed several months earlier) or the discretion of the permitting authority to consider these comments. However, as provided by the grandfathering provision established today in the EPA's PSD regulations, a permit applicant is not required to complete an analysis after the date of the applicable grandfathering milestone to demonstrate that it will not cause or contribute to a violation of the NAAQS that became effective after that date to obtain a permit. Thus, consistent with CAA section 165(a)(2), ''the required analysis'' will have ''been conducted in accordance with regulation promulgated by the Administrator'' and made available for public comment.

Several of the commenters supporting the proposed grandfathering provision in general recommended that the EPA establish the grandfathering milestone as the date that a complete permit application is submitted (or that a submitted permit application is deemed complete by the reviewing agency) rather than the publication date of public notice for a draft permit or preliminary determination as proposed. These commenters pointed out the significant level of effort, resources and time involved in preparing all of the information necessary for a complete permit application, including a BACT analysis, air quality analysis, additional impacts analyses, and a Class I area impact analysis. They claimed that it would be unfair to establish a grandfathering milestone past the complete application date because the processes and timeframes involved in generating the draft permit or preliminary determination materials and publishing the public notice are largely out of the control of the permit applicant and vary from agency to agency. They further stated that requiring reevaluation of a proposed project to assess impacts with respect to the revised NAAQS after a permit application has been deemed complete would result in significant additional cost and delay. One industry commenter pointed out that the EPA's proposed grandfathering approach could place considerable pressure on permit authorities to expedite review of publication of draft permits or decisions before adequate internal review was completed, which could result in subsequent withdrawal of the permit. Several commenters cited prior EPA grandfathering provisions that relied upon that milestone, including the 1987 PM_{10} NAAQS (52 FR 24672, July 1, 1987) and the 1988 NO_2 increments (53 FR 40656, October 17, 1998), and contended that the EPA had not justified the use of an alternative date for purposes of the proposed revisions to the $PM_{2.5}$ NAAQS.

Some state commenters also indicated that the proposed draft permit public notice date milestone could result in additional resource burden on the agency to expedite completion of draft permit packages and process public notices. Other state commenters supported the EPA's proposed draft permit or preliminary determination public notice date as the appropriate grandfathering eligibility milestone, indicating that this approach would provide states and industry certainty on the NAAQS demonstration required during the $PM_{2.5}$ NAAQS transition period.

The EPA acknowledges the comments raising concerns about an approach based solely on the public notice milestone date, and agrees that they

warrant consideration of a different milestone date. Further, we agree that an alternate milestone for grandfathering based on the date a permit application is determined complete would address many of these concerns. Therefore, the EPA has modified its proposed approach to address these concerns. In particular, the EPA agrees with commenters that a substantial portion of the level of effort, resource investment, and time involved in the PSD permit process occurs during the process of preparing a PSD permit application and obtaining a completeness determination from the reviewing authority. Of particular importance is the issue of the time delay and the effect on permitting authorities to meet permit issuance deadlines, as previously noted. Commenters have persuaded the EPA that reevaluation of a proposed project to assess impacts with respect to the revised NAAQS after a permit application has been deemed complete would result in significant additional delay, thus frustrating the statutory requirement to complete action on a permit application within one year of the completeness date.

We also agree with commenters that after the permit application completeness determination stage in the permitting process, the applicant must have completed all of the required technical demonstrations (including a BACT analysis, air quality analysis, additional impacts analyses, and Class I area impact analyses), and that the final stages of the permitting process prior to public notice (i.e., developing the draft permit or preliminary determination, developing supporting materials and publishing the public notice) are under the control of the permitting authority. Given the variable practices and timelines of permitting authorities in processing these final steps between permit application completeness and publication of a public notice on the draft permit or preliminary determination pointed out by commenters, we agree that the proposed grandfathering approach could result in inequitable and burdensome outcomes in some circumstances.

The EPA has therefore concluded based on public comments that it should add an additional grandfathering milestone to avoid substantial additional burden and delay for permit applications that have reached a stage in the review process by which significant resources have been expended to complete fundamental PSD analyses and demonstrations that would have to be redone. After a PSD permit application has been determined complete, it may be time consuming for the applicant to amend its permit application to address new or revised NAAQS promulgated after that date. The time required to both amend the application and review the amended application would impose unreasonable additional burden and delay upon the applicant and the reviewing authority. As a result, if the EPA and other reviewing authorities were to require permit applicants to demonstrate that they will not cause or contribute to a violation of the revised PM NAAQS after the permit application is determined to be complete, or any later stage in the permitting process, this would unduly delay the processing of the permit application and place increased demand on the limited resources of the reviewing authority at a time when it should be focused on preparing the draft permit and supporting materials, preparing a public notice, considering public comments and preparing a final permit decision in order to conclude its review of a permit application in a timely manner.

The EPA also agrees with commenters' concerns that the proposed grandfathering approach, based solely on the date of publication of a public notice on a draft permit or preliminary determination, could in some cases result in pressure on permitting authorities to expedite review of publication of draft permits, resulting in additional burden on such permitting authorities and other potential adverse consequences. We note that expediting review is consistent with the requirement of section 165(c) of the CAA to process permit applications in a timely manner. We also observe that using the milestone of a completeness determination to determine eligibility for grandfathering could simply shift this pressure back to the stage in which a permitting authority is reviewing an application to determine if it is complete. A significant distinction, however, is that the one-year deadline for completing action on a permit does not begin to run until the date that a permit application is determined complete.

Based on the comments received and the EPA's consideration of those comments described above, the EPA has decided to modify the proposed grandfathering approach by adding a second category of applications to the proposed qualifying criteria. Specifically, the EPA is finalizing a grandfathering provision that extends grandfathering to permit applications that the reviewing authority has determined, on or before December 14, 2012 (the signature date of the final rule), to be complete. We are adding this category to our originally proposed category: Permit applications for which the permitting authority has first published a public notice that the draft permit or preliminary determination has been prepared prior to the effective date of the revised PM NAAQS.

We are adding eligibility criteria rather than wholly replacing what we proposed for two reasons. First, the EPA understands that there may be some permitting authorities that do not issue formal determinations that an application is complete. Applications in these jurisdictions that may in fact have been complete and far enough along in the review process that a public notice could be issued before the effective date of the revised NAAQS could be significantly delayed if the EPA removed the eligibility criteria based on the publication of the public notice. Second, given that the EPA proposed to establish eligibility for grandfathering based on the timing of the public notice, some permitting authorities and applicants may have anticipated that they had more time to take action to qualify for grandfathering and may have not acted as promptly as they could have to submit additional information or make a completeness determination. Retaining the proposed eligibility criteria avoids prejudice to parties that may have relied on the proposed rule in such a manner.

For the second eligibility criterion added in this final rule, the EPA chose to use the date an application is determined complete, as requested by several commenters. In several existing provisions in sections 51.166(i) and 52.21(i) of the EPA's regulations, a pending application was able to quality for grandfathering if it was submitted before the applicable date but subsequently determined complete after that date. However, this historic approach can be cumbersome to implement and can lead to inconsistent implementation and potential abuse. These concerns stem from the fact that there is a time lag between submittal and the completeness determination during which there are typically additional data requests by the permitting authority and supplemental application material submittals by the applicant. Therefore, it can be difficult to determine the specific date that the submitted application actually became complete; since this date could range from the initial submittal date, through a number of supplemental submittal dates, to the date the permitting authority formally determines the application to be complete. The EPA has chosen to use the date an application is determined complete because this date

is easier to identify and apply. For PSD permits issued under 40 CFR 52.21, the EPA's regulations in 40 CFR part 124 define the effective date of an application as the date the permitting authority notifies the applicant that the application is complete. 40 CFR 124.3(f).

The EPA chose to base the second eligibility criterion on the date this rule has been signed by the Administrator to avoid creating pressure on permitting authorities to determine applications complete. Such pressure could lead to premature findings of completeness and grandfathering of a larger number of applications than is warranted to avoid undue delays, thus increasing the air quality impact of the grandfathering provision. Notably, the one-year deadline for completing action on a permit does not begin to run until the date that a permit application is determined complete. While Congress desired timely action on a permit application, the statute gives permitting authorities leeway to ensure they have all the necessary information to proceed expeditiously on a permit application before the clock starts running. The goal of protecting air quality can thus be fulfilled without compromising Congressional intent for timely action by conducting a careful review of an application to determine that it is complete. Applications that have not yet been determined complete may be supplemented to ensure the proposed source does not cause or contribute to a violation of the revised NAAQS without compromising compliance with the one-year deadline in section 165(c). The EPA thus selected the signature date of the final rule to ensure the integrity of completeness determinations issued after the rule is signed and to limit the number of additional sources eligible for grandfathering.

The final grandfathering provision appropriately balances the objectives of CAA section 165 to protect air quality and ensure timely decision-making on permit applications, while also addressing concerns about resource burdens raised by commenters. In addition, as pointed out by commenters, the final grandfathering provision also provides an approach that is more consistent with prior EPA grandfathering actions, e.g., in the 1987 PM_{10} NAAQS, wherein the EPA selected the date of application completeness for grandfathering projects from requirements associated with the new NAAQS.

Regarding the need for a sunset clause for the grandfathering provision, the majority of commenters supported, as proposed, not including such a clause, and no commenters specifically recommended that a sunset clause be established. Commenters pointed out that permit applicants and reviewing authorities already have strong incentives to issue final permits in a timely manner following the public notice stage, and that a sunset clause would not add any meaningful incentive to expedite the permitting process, rather potentially causing additional delays. One commenter stated that permitting authorities have ample discretion, which they routinely use, to refuse to issue a draft permit if additional information is requested during a comment period or the agency itself wants additional information following publication of a draft permit or preliminary determination. The same commenter indicated that permitting authorities also have sufficient discretion to reopen permit proceedings if they consider information in an application to be stale.

The EPA agrees with commenters that the addition of a sunset clause to the proposed grandfathering provision would not add meaningful additional incentive for sources or permitting authorities to expedite permitting processes. The EPA also agrees that a sunset clause could in fact result in further delays for permit actions that qualify for the proposed grandfathering provision in circumstances where unrelated and not reasonably avoidable factors cause final permit issuance to lapse beyond the sunset date. In such cases, the already delayed permit action would necessarily be further delayed to address PSD permitting requirements associated with the revised $PM_{2.5}$ NAAQS, potentially triggering a domino effect of newly applicable requirements. As such, the EPA believes a sunset clause would diminish the value of the grandfathering provision and likely introduce additional complexities in relation to specific permit actions.

A few industry commenters suggested, as an alternative to our proposed approach, that the EPA should effectively grandfather PSD permit actions from meeting requirements associated with the revised PM NAAQS by extending the effective date of the NAAQS by one year. These commenters argued that such an approach is preferable because it would address potential concerns about the inability of state agencies to implement the proposed grandfathering provision prior to rule adoption and SIP approval. Several industry groups and representatives also commented that the EPA should not eliminate state discretion to grandfather individual permits even without an express exemption.

The EPA disagrees with extending the effective date of the revised PM NAAQS by one year because this approach would entirely defer the important health benefits associated with the revised PM NAAQS. Further, as discussed in the proposal, the EPA does not anticipate any issues related to implementation of the grandfathering provision in SIP approved state/local jurisdictions. The EPA proposed and is finalizing a revision to 40 CFR 51.166 to provide a comparable exemption applicable to SIP-approved PSD programs, and air agencies that issue PSD permits under an EPA-approved PSD permit program should have the discretion to ''grandfather'' proposed PSD permits consistent with these final rule provisions. Even absent an express grandfathering provision in state rules, states have the discretion to permit grandfathering consistent with the federal regulations if the particular state's laws and regulations may be interpreted to provide such discretion.[250] However, state SIPs may not be less stringent than federal requirements. Accordingly, the EPA believes that such discretion must be limited to applying grandfathering consistent with the federal rule provisions.

iii. Final Action

For the reasons articulated above, the EPA is finalizing a grandfathering provision under the PSD regulations that provides that qualifying sources and modifications shall not be required to demonstrate that their proposed emissions will not cause or contribute to a violation of the revised primary annual $PM_{2.5}$ NAAQS but instead shall demonstrate that such emissions will not cause or contribute to the $PM_{2.5}$ NAAQS in effect on the date the reviewing authority determines the permit application to be complete or the date the public notice on the draft permit or preliminary determination is first published, depending on which prong of the grandfathering provision is applicable. Under the final

[250] In one extraordinary case where the EPA had not previously adopted a grandfathering provision in regulations and had significantly exceeded the deadline in section 165(c) of the CAA, the EPA has taken the position that it may grandfather a specific source through adjudication, thus interpreting its regulations, as well as other authorities, to allow grandfathering in that extraordinary circumstance (U.S. EPA, 2011c, pp. 67 to 71). Although grandfathering without a specific exemption in regulations was justified based on the particular facts in that specific instance, the preferred approach is to enable grandfathering through express regulatory exemptions of the type being finalized in this action (U.S. EPA, 2011c, p. 68).

grandfathering provision, qualifying sources and modifications are those for which the reviewing authority has determined that the permit application is complete on or before December 14, 2012 or the permitting authority has first published a public notice that a draft permit or preliminary determination has been prepared prior to the effective date of today's final revisions to the PM NAAQS.[251] The relevant public notice requirements for EPA and delegated agency issued permits are those in 40 CFR 124.10(c)(2), and the corresponding provisions for implementation-plan approved agency permits are those in 40 CFR 51.166(q)(2)(iii). The grandfathering provision is being incorporated into the regulations at 40 CFR 52.21 and 51.166 to provide the same transition for the EPA, delegated jurisdictions, and implementation plan-approved jurisdictions. The EPA is not establishing a sunset date for this grandfathering provision.

b. Modeling Tools and Guidance Applicable to the Revised Primary Annual $PM_{2.5}$ NAAQS

Today's final rule revising the level of the primary annual $PM_{2.5}$ NAAQS from 15.0 μg/m^3 to 12.0 μg/m^3 generally will require proposed new major stationary sources and modifications to take these changes into account as part of the required air quality analysis to demonstrate that the proposed emissions increase will not cause or contribute to a violation of the PM NAAQS. Upon the effective date of today's final revisions to the PM NAAQS, proposed new major stationary sources and major modifications that are not grandfathered from the new requirements (as described in section IX.D.1.a) will be required to demonstrate compliance with the suite of PM NAAQS, including the revised primary annual $PM_{2.5}$ NAAQS.

PSD applicants are currently required to demonstrate compliance with the existing primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS and will need to consider the impact of their proposed emissions increases on the revised primary annual $PM_{2.5}$ NAAQS. To assist sources and permitting authorities in carrying out the required air quality analysis for $PM_{2.5}$ under the existing standards, the EPA issued, on March 23, 2010, a guidance memorandum that recommends certain interim procedures to address the fact that compliance with the 24-hour $PM_{2.5}$ NAAQS is based on a particular statistical form, and that there are technical complications associated with the ability of existing models to estimate the impacts of secondarily formed $PM_{2.5}$ resulting from emissions of $PM_{2.5}$ precursors (Page, 2010b). For the latter issue, the EPA recommended that special attention be given to the evaluation of monitored background air quality data, since such data readily account for the contribution of both primary and secondarily formed $PM_{2.5}$ from existing sources affecting the area.

To provide more detail and to address potential issues associated with the modeling of direct and precursor emissions of $PM_{2.5}$, the EPA is now developing additional permit modeling guidance that will recommend appropriate technical approaches for conducting a $PM_{2.5}$ NAAQS compliance demonstration, which includes more adequate accounting for contributions from secondary formation of ambient $PM_{2.5}$ resulting from a proposed new or modified source's precursor emissions. To this end, the EPA discussed this draft guidance in March 2012 at the EPA's 10th Modeling Conference.[252] Based on its review of comments received through the conference and further technical analyses, the EPA intends to issue final guidance by the end of calendar year 2012, prior to the effective date of today's final PM NAAQS revisions.

The EPA also received a number of industry and state comments on the $PM_{2.5}$ NAAQS proposal related to $PM_{2.5}$ air quality impact analyses and associated existing modeling tools and procedures. In general, commenters identified the lack of approved air quality modeling tools and procedures to predict the impacts of single source emissions on $PM_{2.5}$ concentration in ambient air as well as limitations associated with existing $PM_{2.5}$ modeling tools and guidance. Commenters recommended the EPA address these existing issues and provide updated guidance through an open stakeholder process and preferably through notice-and-comment rulemaking. As described above, the EPA intends to issue revised $PM_{2.5}$ modeling guidance prior to the effective date of today's revised PM NAAQS to assist permit applicants and reviewing authorities in performing required air quality impact analyses. The EPA expects that this revised guidance will address all or most of the remaining issues related to $PM_{2.5}$ air quality impact demonstrations under the PSD program, at least on an interim basis, until the EPA takes additional steps to improve existing regulatory models and procedures. To that end, the EPA is also pursuing regulatory updates to the Guideline on Air Quality Models (40 CFR part 51 Appendix W) to formalize new models and techniques as appropriate. The EPA recently granted a petition for rulemaking to specifically evaluate whether to incorporate into the Guideline new analytical techniques or models for secondary $PM_{2.5}$ (McCarthy, 2012). The EPA anticipates that this rulemaking will be proposed by the end of calendar year 2014 or early in calendar year 2015.

c. PSD Screening Tools: Significant Emissions Rates, Significant Impact Levels, and Significant Monitoring Concentration

The EPA has historically allowed the use of screening tools to help facilitate the implementation of the NSR program by reducing the permit applicant's burden and streamlining the permitting process for circumstances where emissions or concentrations could be considered *de minimis.* These screening tools, which all provide *de minimis* thresholds of some kind, include SERs, SILs, and a SMC. The EPA promulgated a SER for $PM_{2.5}$ in the 2008 final rule on NSR implementation as part of the first phase of NSR amendments to address $PM_{2.5}$ (74 FR 28333, May 16, 2008). The $PM_{2.5}$ SER is used to determine whether any proposed major stationary source or major modification will emit sufficient amounts of $PM_{2.5}$ to require review under the PSD program.[253] Under the terms of the existing EPA regulations, the applicable SER for $PM_{2.5}$ is 10 tpy of direct $PM_{2.5}$ emissions (including condensable PM) and, for precursors, 40 tpy of SO_2 and 40 tpy of NO_X emissions. 40 CFR 51.166(b)(23); 40 CFR 52.21(b)(23). This SER applies to permitting requirements based on both the annual and 24-hour $PM_{2.5}$ NAAQS. The SERs are pollutant-specific but not specific to the averaging

[251] There may be application completeness determinations or draft permits/preliminary determinations for which a public notice was issued prior to October 20, 2011, which is the date that $PM_{2.5}$ increments became applicable requirements for any newly issued federal PSD permits under 40 CFR 52.21. It is not the EPA's intention that the final grandfathering provision should relieve such a permit from the requirement to demonstrate compliance with those new $PM_{2.5}$ increments, for which the EPA did not adopt any grandfathering provisions but deferred implementation in accordance with the requirements of the CAA.

[252] The presentation on this draft guidance was posted on the EPA Web site at: *http://www.epa.gov/ttn/scram/10thmodconf.htm.*

[253] The PSD rules provide that a source that would emit major amounts of any regulated NSR pollutant must undergo review for that pollutant as well as any other regulated NSR pollutant that the source would emit in significant amounts.

time of any NAAQS for a particular pollutant.

Once it is determined that emissions resulting from the proposed new source or modification are significant for $PM_{2.5}$, the permit applicant must complete an air quality analysis. 40 CFR 51.166(m)(1)(i); 40 CFR 52.21(m)(1)(i). The SIL helps to determine the scope of the required air quality analysis that must be carried out in order to demonstrate that the source's emissions will not cause or contribute to a violation of any NAAQS or increment. The EPA promulgated SILs for $PM_{2.5}$ in 2010 under a final rule that established increments, SILs, and a SMC for $PM_{2.5}$ (75 FR 64864, October 20, 2010 at 64890 to 64894).

Historically, the EPA and other permitting authorities have allowed permit applicants to determine the scope of analysis required to satisfy section 165(a)(3) of the CAA by modeling their proposed emissions increase to predict ambient air quality impacts associated with that emissions increase, and by comparing this predicted increase in ambient concentration of $PM_{2.5}$ to the applicable SIL, which is also expressed as an ambient $PM_{2.5}$ concentration over a prescribed averaging time consistent with the NAAQS and increments. The EPA notes that the current $PM_{2.5}$ SILs are the subject of a petition that challenges the EPA's legal authority under the CAA to develop and implement those SILs, and also alleges that the $PM_{2.5}$ SILs established by the EPA have not been adequately demonstrated to represent *de minimis* values. *Sierra Club* v. *EPA, No. 10–1413* (D.C. Cir. filed Dec. 17, 2010). In the course of this litigation, the EPA has recognized the need to correct the text addressing the use of the $PM_{2.5}$ SILs in the PSD regulations (40 CFR 51.166(k)(2); 40 CFR 52.21(k)(2)), and the EPA has asked the court to vacate and remand those provisions so that the EPA may correct them. However, the EPA does not believe this corrective action would preclude appropriate use of the $PM_{2.5}$ SILs in the interim. The EPA has not asked the court to vacate the SILs in section 51.165(b) of its regulations. Furthermore, SILs that are not reflected in rules may be used if the permitting record provides adequate support that the values reflect a *de minimis* impact on air quality, consistent with the principles described in EPA memoranda establishing interim SILs for the one-hour SO_2 and NO_2 NAAQS.[254] The revisions to the primary annual $PM_{2.5}$ NAAQS do not affect the continued used of the $PM_{2.5}$ SILs.

Finally, the SMC, also measured as an ambient pollutant concentration ($\mu g/m^3$), is a screening tool used to determine whether it may be appropriate to exempt a proposed source from the requirement to collect pre-construction ambient monitoring data as part of the required air quality analysis for a particular pollutant. The EPA promulgated the existing SMC for $PM_{2.5}$ in 2010 on the basis of the defined minimum detection limit for $PM_{2.5}$ and the current information at that time concerning the physical capabilities of the $PM_{2.5}$ FRM samplers. In that rulemaking, the EPA addressed uncertainties introduced into the measurement of $PM_{2.5}$ due to variability in the mechanical performance of the $PM_{2.5}$ samplers and micro-gravimetric analytical balances that weigh filter samples. Like the $PM_{2.5}$ SILs, the SMC was challenged by the Sierra Club in the same petition, and is currently under review by the Court.

In the proposal, the EPA did not propose any changes to the existing $PM_{2.5}$ SERs, SILs and SMC, but solicited preliminary comment on whether any such changes would be appropriate. The EPA also indicated that any changes to the $PM_{2.5}$ screening values would be addressed in a subsequent rulemaking that would specifically address various PSD implementation issues.

The EPA received several comments from industry and state agencies regarding the existing PSD screening tools and the potential need to adjust associated values based on the revised primary annual $PM_{2.5}$ NAAQS. The majority of these commenters supported retaining the existing SERs, SILs and SMC for $PM_{2.5}$ (and $PM_{2.5}$ precursors in the case of the SERs), indicating that there was no compelling technical reason for revision based on the proposed revision to the primary $PM_{2.5}$ NAAQS. One industry commenter indicated that there might be a need to revise the annual $PM_{2.5}$ SILs based on the approach used in establishing the current value. However, this commenter and others recommended that any revisions to the PSD screening levels for $PM_{2.5}$ be accomplished through a separate notice-and-comment rulemaking. Several state commenters that supported retention of the current $PM_{2.5}$ SILs also urged the EPA to provide guidance on the use of those existing SILs.

One set of collaborative comments from health and environmental advocacy groups stated that the EPA's proposal to leave in place the PSD screening tools adopted with the previous PM NAAQS had no rational basis and was contrary to statutory requirements. These commenters claimed that the EPA has no statutory authority to establish SILs and SMC for $PM_{2.5}$, which is the subject of current litigation in *Sierra Club* v. *EPA,* No. 10–1413 (D.C. Cir. filed Dec. 17, 2010). The EPA's argument in support of the existing PSD screening tools is contained in a brief filed in that case, which is included in the docket for the final rule. *Id.,* Brief of Respondent at 26–56 (June 26, 2012). These same commenters and one additional collaborative comment letter from academic researchers also stated that the EPA should revise the current $PM_{2.5}$ SERs, SILs and SMC to reflect the revised NAAQS and true *de minimis* levels.

The EPA did not propose to make and is not finalizing any changes to the existing $PM_{2.5}$ SERs, SILs and SMC as part of this final rule. The EPA intends to consider the need for any future changes to these values in light of today's revision of the primary annual $PM_{2.5}$ NAAQS and considering public comments received. The EPA will address any changes to the $PM_{2.5}$ SERs, SILs and SMC in a subsequent PSD implementation rulemaking if deemed necessary or appropriate. The EPA will determine the need for, and develop such rulemaking expeditiously, and any such forthcoming rulemaking will provide an additional opportunity for public comment on specific proposed revisions to the PSD screening tool values for $PM_{2.5}$. Until any rulemaking to amend existing regulations is completed, permitting decisions should continue to be based on the SERs for $PM_{2.5}$ (and its precursors) and the SILs and SMC for $PM_{2.5}$ in existing regulations.

d. PSD Increments

Section 166(a) of the CAA requires the EPA to promulgate ''regulations to prevent the significant deterioration of air quality'' for pollutants covered by the NAAQS. Among other things, the EPA has implemented this requirement through promulgation of PSD increments. The EPA promulgated $PM_{2.5}$ increments in 2010 to prevent significant air quality deterioration with regard to the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS (75 FR 64864, October 20, 2010). The revision to the primary annual $PM_{2.5}$ NAAQS raises the question of whether

[254] Page, 2010c; Page, 2010d. The EPA provided similar advice before it finalized the proposed $PM_{2.5}$ SILs (Page, 2010b). *See* also, *In re Mississippi Lime Co.,* PSD Permit Appeal 11–01, Slip. Op. at 34–41 (EAB August 9, 2011) and U.S. EPA, 2012d.

the EPA should consider revising the annual $PM_{2.5}$ increments. The EPA does not interpret section 166(a) of the Act to require that the EPA revise existing increments whenever the EPA revises a NAAQS for the same pollutant and averaging time,[255] but the Agency interprets the Act to afford the EPA the discretion to do so. In the proposal, the EPA did not propose to revise the $PM_{2.5}$ increments. In the meantime, the current $PM_{2.5}$ increments remain in effect, and PSD permitting should continue pursuant to the current increments, with a minimum of disruption to the permitting process when the revised NAAQS take effect.

The EPA received few comments on whether there was any need or justification to revise the existing PSD increments for $PM_{2.5}$. Industry and state agency commenters generally supported retaining the existing increments. Commenters again recommended that any revisions to the PSD increments for $PM_{2.5}$ be accomplished through a separate notice-and-comment rulemaking.

The EPA did not propose to make and is not finalizing any changes to the existing PSD increments for $PM_{2.5}$ as part of this final rule. The EPA will consider whether it is appropriate to propose any revised PSD increments for $PM_{2.5}$ in the future. Any such forthcoming rulemaking will provide an additional opportunity for public comment on specific proposed revisions to the PSD increments for $PM_{2.5}$. Until any rulemaking to amend existing regulations is completed, permitting decisions should continue to be based on the PSD increments for $PM_{2.5}$ in existing regulations.

e. Other PSD Transition Issues

Several industry commenters expressed concern that a permitting problem would result from the fact that, upon promulgation of the revised $PM_{2.5}$ NAAQS, ambient air quality monitoring data would show that for some areas, $PM_{2.5}$ concentrations exceed the revised NAAQS, although those areas would not be formally designated as ''nonattainment'' until a later date pursuant to the designation process provided by the CAA. The commenters noted that sources locating in such areas would be required to obtain a PSD permit in order to construct or modify, but could not do so because the requirement that the new or modified source must demonstrate that it will not cause or contribute to a NAAQS violation, even though the area would technically already be in nonattainment. The commenters further noted that once the nonattainment designation is made, section 173 of the Act provides a nonattainment area permit program that specifies conditions under which a permit will be issued, including obtaining offsetting reductions in emissions rather than demonstrating through modeling or other analysis that the source will not cause or contribute to a violation of the NAAQS as required in PSD. Thus, the commenters urged the EPA to offer an interim approach that would avoid the imposition of an effective construction ban on such areas until such time as the nonattainment area designations and the nonattainment NSR offset requirements are in place instead of the PSD requirements. Some of the commenters specifically requested that the EPA provide either a surrogacy approach based on showing compliance with the pre-existing annual $PM_{2.5}$ NAAQS or a PSD offset approach to avoid a construction moratorium in such areas.

The commenters are correct in that areas already in violation of the revised annual $PM_{2.5}$ NAAQS upon the effective date of such NAAQS may not be formally designated nonattainment for two years or potentially longer in accordance with the statutory procedures for promulgating such area designations. In addition, it is the EPA's longstanding policy that new and revised NAAQS must be implemented through the permitting process as of the NAAQS effective date (except for earlier projects that would qualify for any EPA-authorized grandfathering). Accordingly, new major stationary sources and major modifications for which permits will be issued on or after the effective date of the revised annual $PM_{2.5}$ NAAQS must comply with the PSD requirement to demonstrate compliance with that and any other applicable NAAQS.

We disagree, however, with the commenters' conclusion that such circumstances will result in ''the imposition of an effective construction ban on such areas.'' First, as already described, the EPA is promulgating a grandfathering provision that allows certain proposed new and modified sources to proceed with the permit process based on the requirements that were in effect previously, provided the permitting authority either has determined on or before December 14, 2012 that the permit application is complete or has proposed the permit (i.e., the draft permit or preliminary determination has been noticed for public comment) prior to the date the revised PM standards become effective, which is 60 days after publication in the **Federal Register**. The grandfathering provision thus will enable some sources to avoid issues associated with potential violations of the revised annual $PM_{2.5}$ NAAQS.

Second, for those sources that are not eligible to be grandfathered under the new provision, permitting authorities have the discretion to consider offsetting emissions reductions at other sources as part of a demonstration that an individual source seeking a permit will not cause or contribute to violation of the NAAQS. See, Page (2010c). The EPA has historically recognized in regulations and through other actions that sources applying for PSD permits may utilize offsets as part of the required PSD demonstration, even though the PSD provisions of the Clean Air Act do not expressly reference offsets in the same manner as the nonattainment NSR provisions of the Act. See, 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).

Existing EPA regulations provide a procedure by which major stationary sources and major modifications locating in an area designated as attainment or unclassifiable for any NAAQS, and found to cause or contribute to a NAAQS violation in any area, may utilize offsets to address such adverse impacts and ultimately be issued a permit. *See* 40 CFR 51.165(b). Specifically, paragraph (b)(3) of those regulations provides that the required permit program may include a provision allowing a proposed major source or major modification to reduce the impact of its emissions on air quality by obtaining sufficient emissions reductions to, at a minimum, compensate for its adverse ambient impact where the source or modification would otherwise cause or contribute to a violation of any NAAQS. On October 20, 2010, the EPA amended the requirements at 40 CFR 51.165(b) to define a significant impact with regard to the $PM_{2.5}$ NAAQS. *See* 75 FR 64864 at 64902.

As noted by some of the commenters, the EPA addressed this same issue in 1987 when it promulgated a new set of NAAQS for PM_{10} and revised 40 CFR 51.165(b) of the regulations. *See* 52 FR 24672 (July 1, 1987) at 24684, 24686–87,

[255] A United States District Court has upheld the EPA's interpretation. *See* Order Granting Defendant's Motion to Dismiss Mandatory Duty Claim, *Wildearth Guardians* v. *Jackson,* Case No. 11–cv–5651–YGR (N.D. Cal. May 7, 2012). An appeal of this decision is now pending with the United States Court of Appeals for the Ninth Circuit.

24698. For PM_{10}, the EPA made it clear that when a proposed PSD source was found to cause or contribute to violation of the PM_{10} NAAQS, the source would be required satisfy the requirements of 40 CFR 51.165(b) ''to obtain, at a minimum, sufficient PM_{10} emission offsets to compensate for the source's ambient impact in the area of the violation.'' Such offsets were considered to satisfy the ''cause or contribute to'' language under section 165(a)(3)(B) of the CAA. *Id.* at 24698.[256] In response to comments concerning the appropriate criteria for applying this offset requirement for PSD purposes, the EPA also stated that any emissions offsets used for PSD purposes must meet applicability criteria that are at least as stringent as the offset criteria set forth in the nonattainment NSR requirements for offsets under 40 CFR 51.165(a)(3). *Id.* at 24684.

We continue to believe that the 40 CFR 51.165(a)(3) criteria provide the most appropriate guide for determining the creditability of PSD offsets, including any offsets obtained to satisfy the PSD requirements for the revised $PM_{2.5}$ NAAQS prior to any anticipated designation of any area as nonattainment with that NAAQS. Since the purpose for using offsets in PSD is to show that additional emissions from the proposed construction will not cause or contribute to a violation, the EPA has not codified a requirement that such offsets necessarily must meet the same criteria that apply to offsets under the nonattainment NSR program. In fact, the EPA has previously observed that, in the context of PSD, it may not be necessary for a permit applicant to fully offset the proposed emissions increase if an emissions reduction of lesser quantity will be sufficient to mitigate the proposed source's adverse air quality impact on a modeled violation. Page (2010c); 44 FR 3274, January 16, 1979, at 3278 (''Although full emission offsets are not required, such a source must obtain emission offsets sufficient to compensate for its air quality impact where the violation occurs.''). This may be particularly true where anticipated reductions from existing air quality regulations may mitigate the impacts of a proposed source's emissions by the time the source begins operating in an area that is expected to be designated nonattainment. This would need to be evaluated on a case-by-case basis. To the extent that any permit applicants may experience difficulties making the NAAQS compliance showing required to obtain a PSD permit in areas and as set forth in the Memorandum noted above, the EPA is committed to working with permitting authorities and applicants to identify ways to apply offsets under the PSD program as necessary to meet PSD requirements.

2. Nonattainment New Source Review

Part D of Title I of the CAA pertains to the preconstruction review and permitting requirements for new major stationary sources and major modifications locating in areas designated ''nonattainment'' for a particular pollutant. Those requirements are commonly referred to as the NNSR program. The EPA regulations for the NNSR program are contained at 40 CFR 51.165, 52.24 and part 51, appendix S.

For NNSR, ''major stationary source'' is generally defined as a source with the potential to emit at least 100 tpy or more of a pollutant for which an area has been designated ''nonattainment.'' The NNSR program applies only to pollutants for which the EPA has promulgated NAAQS. Because the EPA has defined the PM NAAQS, and has established area designations for PM, in terms of two separate indicators—PM_{10} and $PM_{2.5}$—each indicator is regulated separately for purposes of NNSR applicability. That is, for PM_{10}, a ''major stationary source'' for NNSR applicability generally is a source that is located in a PM_{10} nonattainment area and has the potential to emit at least 100 tpy of PM_{10} emissions.[257] For $PM_{2.5}$, a ''major stationary source'' for NNSR applicability is a source that is located in a $PM_{2.5}$ nonattainment area and has the potential to emit at least 100 tpy of direct $PM_{2.5}$ (''$PM_{2.5}$ emissions'') or any individual precursor of $PM_{2.5}$.

For a major modification, the NNSR regulations rely upon SERs described previously in the PSD discussion in section IX.D.1. For NNSR, a major modification is a physical change or a change in the method of operation of an existing stationary source that is major for the nonattainment pollutant and results in a significant emissions increase and a significant net emissions increase of that nonattainment pollutant or any individual precursor of that pollutant. As described earlier, the EPA will be evaluating the existing SERs for $PM_{2.5}$ and $PM_{2.5}$ precursors, and will determine whether there is any basis for proposing changes to any of the existing values. Any decision to propose changing the existing SERs in a future rulemaking would also apply to their use in the NNSR program requirements.

The EPA has designated nonattainment areas for the existing primary annual and 24-hour $PM_{2.5}$ NAAQS independently, and the EPA also approves redesignations to attainment separately for the two averaging periods. Thus, an area may be nonattainment for the annual standard and unclassifiable/attainment or attainment for the 24-hour standard. In the proposal, the EPA indicated that no formal policy has yet been developed to address this situation, but that the EPA presently believes that it is reasonable to require that only NNSR (and not PSD) applies for $PM_{2.5}$ in any area that is nonattainment for either averaging period.[258] The same situation would have existed with respect to the proposed secondary visibility index standard, had the EPA elected to finalize such a standard. Accordingly, the EPA indicated in the proposal that it intends to address this issue in a future NSR rulemaking, but invited preliminary comment on whether it is appropriate to apply the NNSR program requirements for any pollutant that is designated nonattainment for at least one averaging period or at least one primary or secondary NAAQS for a particular pollutant.

New major stationary sources or major modifications that trigger NNSR based on $PM_{2.5}$ emissions (or emissions of a $PM_{2.5}$ precursor) in a $PM_{2.5}$ nonattainment area must install technology that meets the lowest achievable emission rate (LAER); secure appropriate emissions reductions to offset the proposed emissions increases;

[256] In 1980, the EPA had determined that the statutory requirement under CAA section 165(a)(3)(B), providing that a proposed new or modified PSD source must demonstrate that it will not cause or contribute to a violation of any NAAQS, taken together with the requirements of section 110(a)(2)(D) of the CAA required all major stationary sources locating outside a nonattainment area but causing or contributing to a NAAQS violation to reduce the impact on air quality so as to assure attainment and maintenance of the NAAQS. In a footnote, the EPA further indicated that this offset requirement must apply to sources causing or contributing to a newly discovered NAAQS violation until the area is designated nonattainment. *See* 45 FR 31307 (May 13, 1980) at 31310. In this 1980 rule, EPA adopted section 51.18(k), which was later renumbered section 51.165(b). EPA revised 51.165(b) in 1987 to expressly authorize an offset program to meet the requirements of section 110(a)(2)(D)(i), but this provision may also be interpreted to apply to section 165(a)(3)(B) of the CAA, consistent with EPA's reading of section 51.18(k) in 1980.

[257] In some cases, however, the CAA and the EPA's regulations define ''major stationary source'' for nonattainment area NSR in terms of a lower emissions rate dependent on the pollutant. For PM_{10}, for example, a source having the potential to emit at least 70 tpy of PM_{10} is considered ''major'' if the source is located in a nonattainment area classified as a ''Serious Area.''

[258] However, transportation conformity requirements discussed in section IX.E below are dependent upon the averaging period(s) for which an area is designated nonattainment.

and perform other analyses as required under section 173 of the CAA. Following the promulgation of any revised NAAQS for $PM_{2.5}$, some new nonattainment areas for $PM_{2.5}$ may result. Where a state does not have any NNSR program or the current NNSR program does not apply to $PM_{2.5}$, that state will be required to submit the necessary SIP revisions to ensure that new major stationary sources and major modifications for $PM_{2.5}$ undergo preconstruction review pursuant to the NNSR program. Under section 172(b) of the CAA, the Administrator may provide states up to 3 years from the effective date of nonattainment area designations to submit the necessary SIP revisions meeting the applicable NNSR requirements. Nevertheless, permits issued to sources in nonattainment areas must satisfy the applicable requirements for nonattainment areas as of the effective date of the specific nonattainment designation; therefore, states whose existing NNSR program requirements, if any, cannot be interpreted to apply to the revised primary annual $PM_{2.5}$ NAAQS at that time will be allowed to issue the necessary permits in accordance with the applicable nonattainment permitting requirements contained in the Emissions Offset Interpretative Ruling at 40 CFR part 51, appendix S, which would apply to the revised $PM_{2.5}$ NAAQS upon its effective date (*see* 73 FR 38321, May 16, 2008 at 28340). The EPA did not propose any type of $PM_{2.5}$ grandfathering provision at this time for purposes of NNSR.

Several industry commenters recommended that the EPA establish a grandfathering provision for NNSR as was proposed under the PSD program. A subset of these commenters recommended that grandfathering be accomplished by establishing an effective date for designations one year after initial publication in the **Federal Register**. However, no commenters provided any rationale or supporting basis for such a grandfathering provision or the underlying need for a transition into NNSR permitting for the revised $PM_{2.5}$ NAAQS.

The EPA disagrees with commenters that recommended a grandfathering provision for NNSR requirements associated with the revised $PM_{2.5}$ NAAQS. As described in the proposal, the timetable for adopting new provisions under a state's NNSR program will not apply with regard to the revised NAAQS for $PM_{2.5}$ until such time that an area is designated nonattainment for a particular standard. Major NSR permits for $PM_{2.5}$ issued in areas newly designated as nonattainment for the revised primary annual $PM_{2.5}$ NAAQS must, as of the effective date of such designation, meet the applicable NNSR requirements for $PM_{2.5}$ (Seitz, 1991). As such, there may be cases where applicants with PSD permit applications for $PM_{2.5}$ in progress will be required to revise their applications to address NNSR requirements for a newly designated $PM_{2.5}$ nonattainment area, and such revisions could result in additional resource burden and permit delays. However, the EPA believes at this time that such cases will be very limited, and in addition there is a substantial lead time between the effective date of the revised $PM_{2.5}$ NAAQS and the effective date of any associated new nonattainment designations for permit applicants and air agencies to anticipate when the NNSR requirements will apply. Therefore, the EPA is not inclined at this time to pursue a rulemaking to establish a grandfathering provision for the revised $PM_{2.5}$ NAAQS under the NNSR program. The EPA will independently, and in consultation with other reviewing authorities, work with permit applicants on specific projects requiring additional measures to achieve a workable transition into NNSR permitting requirements. The EPA will also continue to consider whether regulatory grandfathering may become necessary for NNSR, and if determined to be, will undertake any such action as part of a subsequent NSR implementation rulemaking with additional opportunity for public comment.

A few industry and state commenters addressed the issue of potential dual review (applying NNSR and PSD simultaneously) based on distinct designations for separate averaging times of the $PM_{2.5}$ NAAQS. These commenters generally agreed with the EPA's conclusion that it was reasonable to apply only the NNSR permitting requirements to such situations and not PSD. Regarding the issue of potential dual review for multiple averaging times of the $PM_{2.5}$ NAAQS, since the proposal, the EPA has determined that existing regulations resolve this issue in favor of the conclusion suggested in the proposed rule. Based on the express terms of existing regulations, only the NNSR permit requirements, and not PSD, apply for the pollutant $PM_{2.5}$ in cases where the area is designated nonattainment for at least one averaging time of the $PM_{2.5}$ NAAQS. The federal PSD regulations provide that the PSD requirements (the requirements of paragraphs (j) through (r) of each section) ''do not apply to a major stationary source or major modification *with respect to a particular pollutant* if the owner or operator demonstrates that, as to that pollutant, the source or modification is located in an area designated as nonattainment under section 107 of the Act.'' 40 CFR 52.21(i)(2) and 40 CFR 51.166(i)(2) (emphasis added). Thus, this provision expressly excludes from PSD any pollutant for which an area is designated nonattainment, without reference to a particular averaging period. For a number of years, it was the EPA's practice to establish a single designation in an area for a particular pollutant. Accordingly, if the area was not meeting the NAAQS for a particular averaging period, the area was designated nonattainment—even though the area was likely meeting the NAAQS for one or more averaging periods for the same pollutant. The EPA's statement in the proposal that we had not yet established a policy on the dual review question for $PM_{2.5}$ was based on the fact that we had only recently begun establishing designations for each averaging time in the case of the $PM_{2.5}$ NAAQS. However, at the time of the proposal, the EPA had not closely examined the applicability of the language in sections 51.166(i)(2) and 52.21(i)(2) in this context. After closer inspection prompted by the comments on this issue, we do not read these provisions to authorize application of PSD to a pollutant when an area may be designated nonattainment for a particular averaging time, while also designated attainment or unclassifiable for a different averaging time for the same pollutant.

As proposed, the EPA is not finalizing any changes under the NNSR program regulations as part of this final NAAQS rule. The EPA will consider the need for any changes to the NNSR program provisions and will implement any such changes as part of a future NSR implementation rule and/or guidance.

E. Transportation Conformity Program

Transportation conformity is required under CAA section 176(c) to ensure that transportation plans, transportation improvement programs (TIPs) and federally supported highway and transit projects will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. Transportation conformity applies to areas that are designated nonattainment and maintenance for transportation-related criteria pollutants: Carbon monoxide, ozone, NO_2, and $PM_{2.5}$, and PM_{10}. Transportation conformity for any

revised NAAQS for $PM_{2.5}$ does not apply until 1 year after the effective date of the nonattainment designation for that revised NAAQS (*see* CAA section 176(c)(6) and 40 CFR 93.102(d)). The EPA's Transportation Conformity Rule (40 CFR part 51, subpart T, and 40 CFR part 93, subpart A) establishes the criteria and procedures for determining whether transportation activities conform to the SIP. The EPA is not making any changes to the transportation conformity rule in this rulemaking. The EPA notes that the transportation conformity rule already addresses the $PM_{2.5}$ and PM_{10} NAAQS. The EPA will review whether there is a need to issue new or revised transportation conformity guidance in light of this final rule. In developing new or revised guidance the EPA will consider the comments related to implementation of the transportation conformity rule that were received in response to the proposal.

As discussed in section VIII above, the EPA finalized certain clarifying changes to $PM_{2.5}$ air quality monitoring regulations. These changes are designed to align different elements of the monitoring regulations for consistency.

Due to these changes to the monitoring regulations, the EPA will update its guidance on conformity quantitative $PM_{2.5}$ hot-spot analyses as appropriate to make it consistent with the revised monitoring requirements (U.S. EPA, 2010j). The EPA intends that the current quantitative $PM_{2.5}$ hot-spot guidance continues to apply to any quantitative $PM_{2.5}$ hot-spot analysis that was begun before the effective date of these revisions to the monitoring regulations. Revised guidance for quantitative $PM_{2.5}$ hot-spot analyses would apply to any quantitative $PM_{2.5}$ hot-spot analysis begun after the effective date of the revised monitoring regulations. Nonattainment and maintenance areas are encouraged to use their interagency consultation processes to determine whether an analysis for a given project was started before the effective date of changes to the monitoring requirements. Applying the current guidance to $PM_{2.5}$ analyses that had begun before the effective date of changes to the monitoring regulations is consistent with how the conformity rule and guidance address the transitional period for new emissions factor models or local planning assumptions (40 CFR 93.110(a) and 93.111(b) and (c)). In both of those cases, analyses begun before the new model or data became available can be completed using the data and/or model that were available when the analyses began. The EPA rules allow this in order to conserve state resources by not making transportation planning agencies redo analyses simply because a model has been revised, new data have become available, or in this case, the EPA has revised its regulations for $PM_{2.5}$ monitoring.

F. General Conformity Program

General conformity is required by CAA section 176(c). This section requires that actions by federal agencies do not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. General conformity applies to any federal action (e.g., funding, licensing, permitting, or approving), other than projects that are Federal Highway Administration (FHWA)/ Federal Transit Administration (FTA) projects as defined in 40 CFR 93.101 (which are covered under transportation conformity described above), if the action takes place in a nonattainment or maintenance area for ozone, PM, NO_2, carbon monoxide, lead, or SO_2. General conformity also applies to a federal highway and transit project if it does not involve either Title 23 or 49 funding, but does involve FHWA or FTA approval such as is required for a connection to an Interstate highway or for a deviation from applicable design standards per 40 CFR 93.101. (The FHWA and FTA actions described here as not subject to general conformity are subject to transportation conformity.) General conformity for the revised PM NAAQS will not apply until 1 year after the effective date of a nonattainment designation for that NAAQS. The EPA's General Conformity Rule (40 CFR 93.150 to 93.165) establishes the criteria and procedures for determining if a federal action conforms to the SIP. With respect to the revised PM NAAQS, federal agencies are expected to continue to estimate emissions for conformity analyses in the same manner as they are estimated for conformity analyses for the 1997 and 2006 p.m. NAAQS. The EPA's existing general conformity regulations include the basic requirement that a federal agency's general conformity analysis be based on the latest and most accurate emissions estimation techniques available (40 CFR 93.159(b)), and the EPA expects that this same principle will be followed for analyses needed for these revised PM NAAQS. When updated and improved emissions estimation techniques become available, the EPA expects the federal agency to use those techniques. With this final rule, the EPA is making no changes to the general conformity rule as it already addresses the $PM_{2.5}$ and PM_{10} NAAQS. As noted in the proposal, the EPA will review the need to issue guidance describing how the current conformity rule applies in nonattainment and maintenance areas for the final revised primary annual $PM_{2.5}$ NAAQS.

X. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), this action is an ''economically significant regulatory action'' because it is likely to have an annual effect on the economy of $100 million or more. The $100 million threshold can be triggered by either costs or benefits, or a combination of them. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations have been documented in the docket 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 for the Final Revisions to the National Ambient Air Quality Standards for Particulate Matter,* EPA 452/R–12–003. A copy of the analysis is available in Docket No. EPA–HQ–OAR–2010–0955.

The estimates in the RIA are associated with the revised standard and alternative standard levels (in $\mu g/m^3$) of the primary annual $PM_{2.5}$ standards including: 13, 12, and 11. Table 4 provides a summary of the estimated costs, monetized benefits, and net benefits associated with full attainment of these alternative standards.

TABLE 4—TOTAL COSTS, MONETIZED BENEFITS AND NET BENEFITS IN 2020 (MILLIONS OF 2010$) FULL ATTAINMENT [a]

Alternative $PM_{2.5}$ annual standards (μg/m³)	Total costs [b]		Monetized benefits [d]		Net benefits	
	3% Discount rate [c]	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate [d]	7% Discount rate
13	$11 to $100	$11 to $100	$1,300 to $2,900	$1,200 to $2,600	$1,200 to $2,900	$1,100 to $2,600
12	$53 to $350	$53 to $350	$4,000 to $9,100	$3,600 to $8,200	$3,700 to $9,000	$3,300 to $8,100
11	$320 to $1,700	$320 to $1,700	$13,000 to $29,000	$12,000 to $26,000	$11,000 to $29,000	$10,000 to $26,000

[a] These estimates reflect incremental emissions reductions from an analytical baseline that gives an "adjustment " to the San Joaquin and South Coast areas in California for NO_X emissions reductions expected to occur between 2020 and 2025, when those areas are expected to demonstrate attainment with the revised standards. Full benefits of the revised standards in those two areas will not be realized until 2025.

[b] The two cost estimates do not represent lower and upper bound estimates, but represent estimates generated by two different methodologies. The lower estimate is generated using the fixed-cost methodology, which assumes that technological change and innovation will result in the availability of additional controls by 2020 that are similar in cost to the higher end of the cost range for current, known controls. The higher estimate is generated using the hybrid methodology, which assumes that while additional controls may become available by 2020, they become available at an increasing cost and the increasing cost varies by geographic area and by degree of difficulty associated with obtaining the needed emissions reductions.

[c] Due to data limitations, we were unable to discount compliance costs for all sectors at 3%. See section 7.2.2 of the RIA for additional details on the data limitations. As a result, the net benefit calculations at 3% were computed by subtracting the costs at 7% from the monetized benefits at 3%.

[d] The reduction in premature deaths each year accounts for over 90% of total monetized benefits. Mortality risk valuation assumes discounting over the SAB-recommended 20-year segmented lag structure. Not all possible benefits or disbenefits are quantified and monetized in this analysis. B is the sum of all unquantified benefits. Data limitations prevented us from quantifying these endpoints, and as such, these benefits are inherently more uncertain than those benefits that we were able to quantify. The range of benefits reflects the range of the central estimates from two mortality cohort studies (i.e., Krewski *et al.* (2009) to Lepeule *et al.* (2012)).

B. Paperwork Reduction Act

The information collection requirements in this final rule have been submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The information collection requirements are not enforceable until OMB approves them. The Information Collection Request (ICR) document prepared by the EPA for these revisions to part 58 has been assigned EPA ICR number 0940.26. The information collected under 40 CFR part 53 (e.g., test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the NAAQS in 40 CFR part 50 will meet the design, performance, and/or comparability requirements for designation as an FRM or FEM. The EPA does not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with PM_{10}, $PM_{2.5}$, or $PM_{10\text{-}2.5}$ FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 0940.24). As such, no change in the burden estimate for 40 CFR part 53 has been made as part of this rulemaking.

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 impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The amendments finalized in this rule will revise the network design requirements for $PM_{2.5}$ monitoring sites, resulting in the movement of 21 monitors to established near-road monitoring stations by January 1, 2015. The incremental burden associated with moving these 21 monitors that are required in 40 CFR part 58 (this is a one-time cost of relocating the monitors) is $28,570. 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 monitors and 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 the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, the EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA–HQ–OAR–2007–0492. Submit any comments related to the ICR to the EPA and OMB. Send comments to the EPA at the Air and Radiation Docket and Information Center Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket and Information Center Docket is (202) 566–1742. An electronic version of the public docket is available at *www.regulations.gov.* Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after January 15, 2013, a comment to OMB is best assured of having its full effect if OMB receives it by February 14, 2013.

C. Regulatory Flexibility Act

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

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental

jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of particulate matter 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). We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for state, local, or tribal governments or the private sector. The action imposes no enforceable duty on any state, local or tribal governments or the private sector beyond those duties already established in the CAA. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA.

This action is also not subject to the requirements section 205 of the UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This action imposes no new expenditure or enforceable duty on any state, local, or tribal governments or the private sector, and the EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

Furthermore, in setting a NAAQS, the EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards although such factors may be considered to a degree in the development of state plans to implement the standards. *See also American Trucking Associations* v. *EPA,* 175 F. 3d at 1043 (noting that because the EPA is precluded from considering costs of implementation in establishing NAAQS, preparation of a Regulatory Impact Analysis pursuant to the Unfunded Mandates Reform Act would not furnish any information which the court could consider in reviewing the NAAQS). The EPA acknowledges, however, that any corresponding revisions to associated SIP requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively, might result in such effects. Accordingly, the EPA will address, as appropriate, unfunded mandates if and when it proposes any revisions to 40 CFR parts 51 or 58.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the states regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, the EPA is mandated to establish and review NAAQS; however, CAA section 116 preserves the rights of states to establish more stringent requirements if deemed necessary by a state. Furthermore, this final rule does not impact CAA section 107 which establishes that the states have primary responsibility for implementation of the NAAQS. Finally, as noted in section D (above) on UMRA, this rule does not impose significant costs on state, local, or Tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this action.

However, as also noted in section D (above) on UMRA, the EPA recognizes that states will have a substantial interest in this rule and any corresponding revisions to associated air quality surveillance requirements, 40 CFR part 58.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires the EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This rule concerns the establishment of national standards to address the health and welfare effects of particulate matter. Historically, the EPA's definition of ''tribal implications'' has been limited to situations in which it can be shown that a rule has impacts on the tribes' ability to govern or implications for tribal sovereignty. Based on this historic definition, this action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), i.e. because it does not have a substantial direct effect on one or more Indian tribes, since tribes are not obligated to adopt or implement any NAAQS. Nevertheless, we were aware that many tribes would be interested in this rule and we undertook a number of outreach activities to inform tribes about the PM NAAQS review and offered to two consultations with tribes.

Although Executive Order 13175 does not apply to this rule, the EPA undertook a consultation process including: Prior to proposal on March 29, 2012 we sent letters to tribal leadership inviting consultation on the rule and then sent a second round of letters offering consultation after the proposal was issued on June 29, 2012. No tribe requested a formal consultation with the EPA. We conducted outreach and information calls to tribal environmental staff on May 9, 2012; June 15, 2012; and August 1, 2012. We also participated on the National Tribal Air Association call on June 28, 2012.

As a result we received comments from the National Tribal Air Association, the Southern Ute Mountain Ute Tribe, and the Navajo Nation EPA. In general, these tribal organizations were supportive of the EPA's proposal.

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

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of PM exposures on children. The protection offered by these standards is especially important for children because childhood represents a lifestage associated with increased susceptibility to PM-related health effects. Because children have been identified as an at-risk population, we have carefully evaluated the environmental health effects of exposure to PM pollution among children. Discussions of the results of the evaluation of the scientific evidence and policy considerations pertaining to

children are contained in sections III.B, III.D, III.E, IV.B, and IV.C of this preamble. The revised primary $PM_{2.5}$ NAAQS discussed above will provide greater public health protection, including increased protection for at-risk populations such as children.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this action concerns the review of the NAAQS for PM. The action does not prescribe specific pollution control strategies by which these ambient standards will be met. Such strategies are 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.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs the EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rulemaking involves technical standards for environmental monitoring and measurement. Specifically, the EPA proposes to retain the indicators for fine ($PM_{2.5}$) and coarse (PM_{10}) particles. The indicator for fine particles is measured using the Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere (appendix L to 40 CFR part 50), which is known as the $PM_{2.5}$ FRM, and the indicator for coarse particles is measured using the Reference Method for the Determination of Particulate Matter as PM_{10} in the Atmosphere (appendix J to 40 CFR part 50), which is known as the PM_{10} FRM.

To the extent feasible, the EPA employs a Performance-Based Measurement System (PBMS), which does not require the use of specific, prescribed analytic methods. The PBMS is defined as a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner. It 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. Though the FRM defines the particular specifications for ambient monitors, there is some variability with regard to how monitors measure PM, depending on the type and size of PM and environmental conditions. Therefore, it is not practically possible to fully define the FRM in performance terms to account for this variability. Nevertheless, our approach in the past has resulted in multiple brands of monitors being approved as FRM for PM, and we expect this to continue. Also, the FRMs described in 40 CFR part 50 and the equivalency criteria described in 40 CFR part 53, constitute a performance-based measurement system for PM, since methods that meet the field testing and performance criteria can be approved as FEMs. Since finalized in 2006 (71 FR, 61236, October 17, 2006) the new field and performance criteria for approval of $PM_{2.5}$ continuous FEMs has resulted in the approval of six approved FEMs.[259] In summary, for measurement of $PM_{2.5}$ and PM_{10}, the EPA relies on both FRMs and FEMs, with FEMs relying on a PBMS approach for their approval. The EPA is not precluding the use of any other 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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

The EPA maintains an ongoing commitment to ensure environmental justice for all people, regardless of race, color, national origin, or income. Ensuring environmental justice means not only protecting human health and the environment for everyone, but also ensuring that all people are treated fairly and are given the opportunity to participate meaningfully in the development, implementation, and enforcement of environmental laws, regulations, and policies. We conducted an outreach and information call with environmental justice organizations on August 9, 2012.

The EPA has identified potential disproportionately high and adverse effects on minority and/or low-income populations related to $PM_{2.5}$ exposures. In addition, the EPA has identified persons from lower socioeconomic strata as an at-risk population for PM-related health effects. As a result, the EPA has carefully evaluated the potential impacts on low-income and minority populations as discussed in section III.E.3.a of this preamble. Based on this evaluation and consideration of public comments on the proposal, the EPA is eliminating the spatial averaging provisions as part of the form of the primary annual $PM_{2.5}$ standard to avoid potential disproportionate impacts on at-risk populations. The Agency expects this final rule will lead to the establishment of uniform NAAQS for PM. The Integrated Science Assessment and Policy Assessment contain the evaluation of the scientific evidence and policy considerations that pertain to these populations. These documents are available as described in the Supplementary Information section of this preamble and copies of all documents have been placed in the public docket for this action.

K. Congressional Review Act

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. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal**

[259] A list of designated reference and equivalent methods is available on EPA's Web site at: *http://www.epa.gov/ttn/amtic/criteria.html.*

Register. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective March 18, 2013.

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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, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 58

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

Dated: December 14, 2012.

Lisa P. Jackson,

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. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (e.g., micrograms per cubic meter) other than for particulate matter ($PM_{2.5}$) standards contained in §§ 50.7, 50.13, and 50.18, and lead standards contained in § 50.16 shall be corrected to a reference temperature of 25 (deg) C and a reference pressure of 760 millimeters of mercury (1,013.2 millibars). Measurements of $PM_{2.5}$ for purposes of comparison to the standards contained in §§ 50.7, 50.13, and 50.18, and of lead for purposes of comparison to the standards contained in § 50.16 shall be reported based on actual ambient air volume measured at the actual ambient temperature and pressure at the monitoring site during the measurement period.

■ 3. Table 1 in § 50.14(c)(2)(vi) is revised to read as follows:

§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.

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(c) * * *

(2) * * *

(vi) * * *

TABLE 1—SPECIAL SCHEDULES FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN INITIAL DESIGNATIONS FOR NEW OR REVISED NAAQS

NAAQS pollutant/ standard/(level)/ promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
$PM_{2.5}$/24-Hr Standard (35 μg/m³) Promulgated October 17, 2006.	2004–2006	October 1, 2007	April 15, 2008.
Ozone/8-Hr Standard (0.075 ppm) Promulgated March 12, 2008.	2005–2007	June 18, 2009	June 18, 2009.
	2008	June 18, 2009	June 18, 2009.
	2009	60 days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first.	60 days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first.
NO_2/1-Hr Standard (100 ppb) Promulgated February 9, 2010.	2008	July 1, 2010	January 22, 2011.
	2009	July 1, 2010 [a]	January 22, 2011.
	2010	April 1, 2011	July 1, 2011.
SO_2/1-Hr Standard (75 ppb) Promulgated June 22, 2010.	2008	October 1, 2010	June 1, 2011.
	2009	October 1, 2010	June 1, 2011.
	2010	June 1, 2011	June 1, 2011.
	2011	60 days after the end of the calendar quarter in which the event occurred or March 31, 2012, whichever date occurs first.	60 days after the end of the calendar quarter in which the event occurred or March 31, 2012, whichever date occurs first.
$PM_{2.5}$/Primary Annual Standard (12 μg/m³) Promulgated December 14, 2012.	2010 and 2011	July 1, 2013	December 12, 2013.
	2012	July 1, 2013 [a]	December 12, 2013.
	2013	July 1, 2014 [a]	August 1, 2014.

[a] This date is the same as the general schedule in 40 CFR 50.14.

Note: The table of revised deadlines *only* applies to data EPA will use to establish the initial area designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by the EPA for redesignations to attainment.

* * * * *

■ 4. Add § 50.18 to read as follows:

§ 50.18 National primary ambient air quality standards for $PM_{2.5}$.

(a) The national primary ambient air quality standards for $PM_{2.5}$ are 12.0 micrograms per cubic meter (μg/m³) annual arithmetic mean concentration and 35 μg/m³ 24-hour average concentration measured in the ambient air as $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) by either:

(1) A reference method based on appendix L to this part and designated in accordance with part 53 of this chapter; or

(2) An equivalent method designated in accordance with part 53 of this chapter.

(b) The primary annual $PM_{2.5}$ standard is met when the annual arithmetic mean concentration, as determined in accordance with appendix N of this part, is less than or equal to 12.0 μg/m³.

(c) The primary 24-hour $PM_{2.5}$ standard is met when the 98th percentile 24-hour concentration, as determined in accordance with appendix N of this part, is less than or equal to 35 μg/m³.

■ 5. Appendix N to part 50 is revised to read as follows:

Appendix N to Part 50—Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$

1.0 General

(a) This appendix explains the data handling conventions and computations necessary for determining when the national ambient air quality standards (NAAQS) for $PM_{2.5}$ are met, specifically the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS specified in § 50.7, 50.13, and 50.18. $PM_{2.5}$ is defined, in general terms, as particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers. $PM_{2.5}$ mass concentrations are measured in the ambient air by a Federal Reference Method (FRM) based on appendix L of this part, as applicable, and designated in accordance with part 53 of this chapter; or by a Federal Equivalent Method (FEM) designated in accordance with part 53 of this chapter; or by an Approved Regional Method (ARM) designated in accordance with part 58 of this chapter. Only those FRM, FEM, and ARM measurements that are derived in accordance with part 58 of this chapter (i.e., that are deemed ''suitable'') shall be used in comparisons with the $PM_{2.5}$ NAAQS. The data handling and computation procedures to be used to construct annual and 24-hour

NAAQS metrics from reported $PM_{2.5}$ mass concentrations, and the associated instructions for comparing these calculated metrics to the levels of the $PM_{2.5}$ NAAQS, are specified in sections 2.0, 3.0, and 4.0 of this appendix.

(b) Decisions to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, are made according to the requirements and process deadlines specified in §§ 50.1, 50.14 and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

Annual mean refers to a weighted arithmetic mean, based on quarterly means, as defined in section 4.4 of this appendix.

The *Air Quality System (AQS)* is EPA's official repository of ambient air data.

Collocated monitors refers to two or more air measurement instruments for the same parameter (e.g., $PM_{2.5}$ mass) operated at the same site location, and whose placement is consistent with § 53.1 of this chapter. For purposes of considering a combined site record in this appendix, when two or more monitors are operated at the same site, one monitor is designated as the ''primary'' monitor with any additional monitors designated as ''collocated.'' It is implicit in these appendix procedures that the primary monitor and collocated monitor(s) are all deemed suitable for the applicable NAAQS comparison; however, it is not a requirement that the primary and monitors utilize the same specific sampling and analysis method.

Combined site data record is the data set used for performing calculations in appendix N. It represents data for the primary monitors augmented with data from collocated monitors according to the procedure specified in section 3.0(d) of this appendix.

Creditable samples are daily values in the combined site record that are given credit for data completeness. The number of creditable samples (cn) for a given year also governs which value in the sorted series of daily values represents the 98th percentile for that year. Creditable samples include daily values collected on scheduled sampling days and valid make-up samples taken for missed or invalidated samples on scheduled sampling days.

Daily values refer to the 24-hour average concentrations of $PM_{2.5}$ mass measured (or averaged from hourly measurements in AQS) from midnight to midnight (local standard time) from suitable monitors.

Data substitution tests are diagnostic evaluations performed on an annual $PM_{2.5}$ NAAQS design value (DV) or a 24-hour $PM_{2.5}$ NAAQS DV to determine if those metrics, which are judged to be based on incomplete data in accordance with 4.1(b) or 4.2(b) of this appendix shall nevertheless be deemed valid for NAAQS comparisons, or alternatively, shall still be considered incomplete and not valid for NAAQS comparisons. There are two data substitution tests, the ''minimum quarterly value'' test and the ''maximum quarterly value'' test.

Design values (DVs) are the 3-year average NAAQS metrics that are compared to the NAAQS levels to determine when a monitoring site meets or does not meet the NAAQS, calculated as shown in section 4. There are two separate DVs specified in this appendix:

(1) The 3-year average of $PM_{2.5}$ annual mean mass concentrations for each eligible monitoring site is referred to as the ''*annual $PM_{2.5}$ NAAQS DV*''.

(2) The 3-year average of annual 98th percentile 24-hour average $PM_{2.5}$ mass concentration values recorded at each eligible monitoring site is referred to as the ''*24-hour (or daily) $PM_{2.5}$ NAAQS DV*''.

Eligible sites are monitoring stations that meet the criteria specified in § 58.11 and § 58.30 of this chapter, and thus are approved for comparison to the annual $PM_{2.5}$ NAAQS. For the 24-hour $PM_{2.5}$ NAAQS, all site locations that meet the criteria specified in § 58.11 are approved (i.e., eligible) for NAAQS comparisons.

Extra samples are non-creditable samples. They are daily values that do not occur on scheduled sampling days and that cannot be used as make-up samples for missed or invalidated scheduled samples. Extra samples are used in mean calculations and are included in the series of all daily values subject to selection as a 98th percentile value, but are not used to determine which value in the sorted list represents the 98th percentile.

Make-up samples are samples collected to take the place of missed or invalidated required scheduled samples. Make-up samples can be made by either the primary or the collocated monitor. Make-up samples are either taken before the next required sampling day or exactly one week after the missed (or voided) sampling day.

The *maximum quarterly value data substitution test* substitutes actual ''high'' reported daily $PM_{2.5}$ values from the same site (specifically, the highest reported non-excluded quarterly value(s) (year non-specific) contained in the combined site record for the evaluated 3-year period) for missing daily values.

The *minimum quarterly value data substitution test* substitutes actual ''low'' reported daily $PM_{2.5}$ values from the same site (specifically, the lowest reported quarterly value(s) (year non-specific) contained in the combined site record for the evaluated 3-year period) for missing daily values.

98th percentile is the smallest daily value out of a year of $PM_{2.5}$ mass monitoring data below which no more than 98 percent of all daily values fall using the ranking and selection method specified in section 4.5(a) of this appendix.

Primary monitors are suitable monitors designated by a state or local agency in their annual network plan (and in AQS) as the default data source for creating a combined site record for purposes of NAAQS comparisons. If there is only one suitable monitor at a particular site location, then it is presumed to be a primary monitor.

Quarter refers to a calendar quarter (e.g., January through March).

Quarterly data capture rate is the percentage of scheduled samples in a calendar quarter that have corresponding valid reported sample values. Quarterly data capture rates are specifically calculated as the number of creditable samples for the quarter divided by the number of scheduled samples for the quarter, the result then multiplied by 100 and rounded to the nearest integer.

Scheduled $PM_{2.5}$ samples refers to those reported daily values which are consistent with the required sampling frequency (per § 58.12 of this chapter) for the primary monitor, or those that meet the special exception noted in section 3.0(e) of this appendix.

Seasonal sampling is the practice of collecting data at a reduced frequency during a season of expected low concentrations.

Suitable monitors are instruments that use sampling and analysis methods approved for NAAQS comparisons. For the annual and 24-hour $PM_{2.5}$ NAAQS, suitable monitors include all FRMs, and all FEMs/ARMs except those specific continuous FEMs/ARMs disqualified by a particular monitoring agency network in accordance with § 58.10(b)(13) and approved by the EPA Regional Administrator per § 58.11(e) of this chapter.

Test design values (TDV) are numerical values that used in the data substitution tests described in sections 4.1(c)(i), 4.1(c)(ii) and 4.2(c)(i) of this appendix to determine if the $PM_{2.5}$ NAAQS DV with incomplete data are judged to be valid for NAAQS comparisons. There are two TDVs: TDV_{min} to determine if the NAAQS is not met and is used in the ''minimum quarterly value'' data substitution test and TDV_{max} to determine if the NAAQS is met and is used in the ''maximum quarterly value'' data substitution test. These TDV's are derived by substituting historically low or historically high daily concentration values for missing data in an incomplete year(s).

Year refers to a calendar year.

2.0 Monitoring Considerations

(a) Section 58.30 of this chapter provides special considerations for data comparisons to the annual $PM_{2.5}$ NAAQS.

(b) Monitors meeting the network technical requirements detailed in § 58.11 of this chapter are suitable for comparison with the NAAQS for $PM_{2.5}$.

(c) Section 58.12 of this chapter specifies the required minimum frequency of sampling for $PM_{2.5}$. Exceptions to the specified sampling frequencies, such as seasonal sampling, are subject to the approval of the EPA Regional Administrator and must be documented in the state or local agency Annual Monitoring Network Plan as required in § 58.10 of this chapter and also in AQS.

3.0 Requirements for Data Use and Data Reporting for Comparisons With the NAAQS for $PM_{2.5}$

(a) Except as otherwise provided in this appendix, all valid FRM/FEM/ARM $PM_{2.5}$ mass concentration data produced by suitable monitors that are required to be submitted to AQS, or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in the DV calculations. Generally, EPA will only use such data if they have been certified by the reporting organization (as prescribed by § 58.15 of this chapter); however, data not certified by the

reporting organization can nevertheless be used, if the deadline for certification has passed and EPA judges the data to be complete and accurate.

(b) $PM_{2.5}$ mass concentration data (typically collected hourly for continuous instruments and daily for filter-based instruments) shall be reported to AQS in micrograms per cubic meter (μg/m³) to at least one decimal place. If concentrations are reported to one decimal place, additional digits to the right of the tenths decimal place shall be truncated. If concentrations are reported to AQS with more than one decimal place, AQS will truncate the value to one decimal place for NAAQS usage (i.e., for implementing the procedures in this appendix). In situations where suitable $PM_{2.5}$ data are available to EPA but not reported to AQS, the same truncation protocol shall be applied to that data. In situations where $PM_{2.5}$ mass data are submitted to AQS, or are otherwise available, with less precision than specified above, these data shall nevertheless still be deemed appropriate for NAAQS usage.

(c) Twenty-four-hour average concentrations will be computed in AQS from submitted hourly $PM_{2.5}$ concentration data for each corresponding day of the year and the result will be stored in the first, or start, hour (i.e., midnight, hour '0') of the 24-hour period. A 24-hour average concentration shall be considered valid if at least 75 percent of the hourly averages (i.e., 18 hourly values) for the 24-hour period are available. In the event that less than all 24 hourly average concentrations are available (i.e., less than 24, but at least 18), the 24-hour average concentration shall be computed on the basis of the hours available using the number of available hours within the 24-hour period as the divisor (e.g., 19, if 19 hourly values are available). Twenty-four-hour periods with seven or more missing hours shall also be considered valid if, after substituting zero for all missing hourly concentrations, the resulting 24-hour average daily value is greater than the level of the 24-hour $PM_{2.5}$ NAAQS (i.e., greater than or equal to 35.5 μg/m³). Twenty-four hour average $PM_{2.5}$ mass concentrations that are averaged in AQS from hourly values will be truncated to one decimal place, consistent with the data handling procedure for the reported hourly (and also 24-hour filter-based) data.

(d) All calculations shown in this appendix shall be implemented on a site-level basis. Site level concentration data shall be processed as follows:

(1) The default dataset for $PM_{2.5}$ mass concentrations for a site shall consist of the measured concentrations recorded from the designated primary monitor(s). All daily values produced by the primary monitor are considered part of the site record; this includes all creditable samples and all extra samples.

(2) Data for the primary monitors shall be augmented as much as possible with data from collocated monitors. If a valid daily value is not produced by the primary monitor for a particular day (scheduled or otherwise), but a value is available from a collocated monitor, then that collocated value shall be considered part of the combined site data record. If more than one collocated daily value is available, the average of those valid collocated values shall be used as the daily value. The data record resulting from this procedure is referred to as the ''combined site data record.''

(e) All daily values in a combined site data record are used in the calculations specified in this appendix; however, not all daily values are given credit towards data completeness requirements. Only creditable samples are given credit for data completeness. Creditable samples include daily values in the combined site record that are collected on scheduled sampling days and valid make-up samples taken for missed or invalidated samples on scheduled sampling days. Days are considered scheduled according to the required sampling frequency of the designated primary monitor with one exception. The exception is, if a collocated continuous FEM/ARM monitor has a more intensive sampling frequency than the primary FRM monitor, then samples contributed to the combined site record from that continuous FEM/ARM monitor are always considered scheduled and, hence, also creditable. Daily values in the combined site data record that are reported for nonscheduled days, but that are not valid make-up samples are referred to as extra samples.

4.0 Comparisons With the Annual and 24-Hour $PM_{2.5}$ NAAQS

4.1 Annual $PM_{2.5}$ NAAQS

(a) The primary annual $PM_{2.5}$ NAAQS is met when the annual $PM_{2.5}$ NAAQS DV is less than or equal to 12.0 μg/m³ at each eligible monitoring site. The secondary annual $PM_{2.5}$ NAAQS is met when the annual $PM_{2.5}$ NAAQS DV is less than or equal to 15.0 μg/m³ at each eligible monitoring site.

(b) Three years of valid annual means are required to produce a valid annual $PM_{2.5}$ NAAQS DV. A year meets data completeness requirements when quarterly data capture rates for all four quarters are at least 75 percent. However, years with at least 11 creditable samples in each quarter shall also be considered valid if the resulting annual mean or resulting annual $PM_{2.5}$ NAAQS DV (rounded according to the conventions of section 4.3 of this appendix) is greater than the level of the applicable primary or secondary annual $PM_{2.5}$ NAAQS. Furthermore, where the explicit 75 percent data capture and/or 11 sample minimum requirements are not met, the 3-year annual $PM_{2.5}$ NAAQS DV shall still be considered valid if it passes at least one of the two data substitution tests stipulated below.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 4.1(b) of this appendix and thus would normally not be useable for the calculation of a valid annual $PM_{2.5}$ NAAQS DV, the annual $PM_{2.5}$ NAAQS DV shall nevertheless be considered valid if one of the test conditions specified in sections 4.1(c)(i) and 4.1(c)(ii) of this appendix is met.

(i) An annual $PM_{2.5}$ NAAQS DV that is above the level of the NAAQS can be validated if it passes the minimum quarterly value data substitution test. This type of data substitution is permitted only if there are at least 30 days across the three quarters of the three years under consideration (e.g., collectively, quarter 1 of year 1, quarter 1 of year 2 and quarter 1 of year 3) from which to select the quarter-specific low value. Data substitution will be performed in all quarter periods that have less than 11 creditable samples.

Procedure: Identify for each deficient quarter (i.e., those with less than 11 creditable samples) the lowest reported daily value for that quarter, looking across those three months of all three years under consideration. If after substituting the lowest reported daily value for a quarter for (11 − cn) daily values in the matching deficient quarter(s) (i.e., to bring the creditable number for those quarters up to 11), the procedure yields a recalculated annual $PM_{2.5}$ NAAQS test DV (TDV_{min}) that is greater than the level of the standard, then the annual $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the annual $PM_{2.5}$ NAAQS is deemed to have been violated in that 3-year period.

(ii) An annual $PM_{2.5}$ NAAQS DV that is equal to or below the level of the NAAQS can be validated if it passes the maximum quarterly value data substitution test. This type of data substitution is permitted only if there is at least 50 percent data capture in each quarter that is deficient of 75 percent data capture in each of the three years under consideration. Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture. If any quarter has less than 50 percent data capture then this substitution test cannot be used.

Procedure: Identify for each deficient quarter (i.e., those with less than 75 percent but at least 50 percent data capture) the highest reported daily value for that quarter, excluding state-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, looking across those three quarters of all three years under consideration. If after substituting the highest reported daily $PM_{2.5}$ value for a quarter for all missing daily data in the matching deficient quarter(s) (i.e., to make those quarters 100 percent complete), the procedure yields a recalculated annual $PM_{2.5}$ NAAQS test DV (TDV_{max}) that is less than or equal to the level of the standard, then the annual $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the annual $PM_{2.5}$ NAAQS is deemed to have been met in that 3-year period.

(d) An annual $PM_{2.5}$ NAAQS DV based on data that do not meet the completeness criteria stated in 4(b) and also do not satisfy the test conditions specified in section 4(c), may also be considered valid with the approval of, or at the initiative of, the EPA Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the daily values that are available, and nearby concentrations in determining whether to use such data.

(e) The equations for calculating the annual $PM_{2.5}$ NAAQS DVs are given in section 4.4 of this appendix.

4.2 Twenty-four-hour $PM_{2.5}$ NAAQS

(a) The primary and secondary 24-hour $PM_{2.5}$ NAAQS are met when the 24-hour $PM_{2.5}$ NAAQS DV at each eligible monitoring site is less than or equal to 35 μg/m³.

(b) Three years of valid annual $PM_{2.5}$ 98th percentile mass concentrations are required to produce a valid 24-hour $PM_{2.5}$ NAAQS DV. A year meets data completeness requirements when quarterly data capture rates for all four quarters are at least 75 percent. However, years shall be considered valid, notwithstanding quarters with less than complete data (even quarters with less than 11 creditable samples, but at least one creditable sample must be present for the year), if the resulting annual 98th percentile value or resulting 24-hour NAAQS DV (rounded according to the conventions of section 4.3 of this appendix) is greater than the level of the standard. Furthermore, where the explicit 75 percent quarterly data capture requirement is not met, the 24-hour $PM_{2.5}$ NAAQS DV shall still be considered valid if it passes the maximum quarterly value data substitution test.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 4.2(b) of this appendix and thus would normally not be useable for the calculation of a valid 24-hour $PM_{2.5}$ NAAQS DV, the 24-hour $PM_{2.5}$ NAAQS DV shall nevertheless be considered valid if the test conditions specified in section 4.2(c)(i) of this appendix are met.

(i) A $PM_{2.5}$ 24-hour mass NAAQS DV that is equal to or below the level of the NAAQS can be validated if it passes the maximum quarterly value data substitution test. This type of data substitution is permitted only if there is at least 50 percent data capture in each quarter that is deficient of 75 percent data capture in each of the three years under consideration. Data substitution will be performed in all quarters that have less than 75 percent data capture but at least 50 percent data capture. If any quarter has less than 50 percent data capture then this substitution test cannot be used.

Procedure: Identify for each deficient quarter (i.e., those with less than 75 percent but at least 50 percent data capture) the highest reported daily $PM_{2.5}$ value for that quarter, excluding state-flagged data affected by exceptional events which have been approved for exclusion by the Regional Administrator, looking across those three quarters of all three years under consideration. If, after substituting the highest reported daily maximum $PM_{2.5}$ value for a quarter for all missing daily data in the matching deficient quarter(s) (i.e., to make those quarters 100 percent complete), the procedure yields a recalculated 3-year 24-hour NAAQS test DV (TDV_{max}) less than or equal to the level of the standard, then the 24-hour $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the 24-hour $PM_{2.5}$ NAAQS is deemed to have been met in that 3-year period.

(d) A 24-hour $PM_{2.5}$ NAAQS DV based on data that do not meet the completeness criteria stated in section 4(b) of this appendix and also do not satisfy the test conditions specified in section 4(c) of this appendix, may also be considered valid with the approval of, or at the initiative of, the EPA Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the daily values that are available, and nearby concentrations in determining whether to use such data.

(e) The procedures and equations for calculating the 24-hour $PM_{2.5}$ NAAQS DVs are given in section 4.5 of this appendix.

4.3 Rounding Conventions. For the purposes of comparing calculated $PM_{2.5}$ NAAQS DVs to the applicable level of the standard, it is necessary to round the final results of the calculations described in sections 4.4 and 4.5 of this appendix. Results for all intermediate calculations shall not be rounded.

(a) Annual $PM_{2.5}$ NAAQS DVs shall be rounded to the nearest tenth of a μg/m³ (decimals x.x5 and greater are rounded up to the next tenth, and any decimal lower than x.x5 is rounded down to the nearest tenth).

(b) Twenty-four-hour $PM_{2.5}$ NAAQS DVs shall be rounded to the nearest 1 μg/m³ (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

4.4 Equations for the Annual $PM_{2.5}$ NAAQS.

(a) An annual mean value for $PM_{2.5}$ is determined by first averaging the daily values of a calendar quarter using equation 1 of this appendix:

Equation 1

$$\overline{X}_{q,y} = \frac{1}{n_q} \sum_{i=1}^{n_q} X_{i,q,y}$$

Where:

$\bar{X}_{q,y}$ = the mean for quarter q of the year y;

n_q = the number of daily values in the quarter; and

$x_{i\ q,y}$ = the ith value in quarter q for year y.

(b) Equation 2 of this appendix is then used to calculate the site annual mean:

Equation 2

$$\overline{X}_y = \frac{1}{4} \sum_{q=1}^{4} \overline{X}_{q,y}$$

Where:

$\bar{X}_y$ = the annual mean concentration for year y (y = 1, 2, or 3); and

$\bar{X}_{q,y}$ = the mean for quarter q of year y (result of equation 1).

(c) The annual $PM_{2.5}$ NAAQS DV is calculated using equation 3 of this appendix:

Equation 3

$$\overline{X} = \frac{1}{3} \sum_{y=1}^{3} \overline{X}_y$$

Where:

$\bar{X}$ = the annual $PM_{2.5}$ NAAQS DV; and

$\bar{X}_y$ = the annual mean for year y (result of equation 2)

(d) The annual $PM_{2.5}$ NAAQS DV is rounded according to the conventions in section 4.3 of this appendix before comparisons with the levels of the primary and secondary annual $PM_{2.5}$ NAAQS are made.

4.5 Procedures and Equations for the 24-Hour $PM_{2.5}$ NAAQS

(a) When the data for a particular site and year meet the data completeness requirements in section 4.2 of this appendix, calculation of the 98th percentile is accomplished by the steps provided in this subsection. Table 1 of this appendix shall be used to identify annual 98th percentile values.

Identification of annual 98th percentile values using the Table 1 procedure will be based on the creditable number of samples (as described below), rather than on the actual number of samples. Credit will not be granted for extra (non-creditable) samples. Extra samples, however, are candidates for selection as the annual 98th percentile. [The creditable number of samples will determine how deep to go into the data distribution, but all samples (creditable and extra) will be considered when making the percentile assignment.] The annual creditable number of samples is the sum of the four quarterly creditable number of samples.

Procedure: Sort all the daily values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 98th percentile value is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range for the annual creditable number of samples for year y (cn_y) (e.g., for 120 creditable samples per year, the appropriate range would be 101 to 150). The corresponding ''n'' value in the right column identifies the rank of the annual 98th percentile value in the descending sorted list of site specific daily values for year y (e.g., for the range of 101 to 150, n would be 3). Thus, $P_{0.98,\ y}$ = the nth largest value (e.g., for the range of 101 to 150, the 98th percentile value would be the third highest value in the sorted series of daily values.

TABLE 1

Annual number of creditable samples for year *y* (cn_y)	The 98th percentile for year y ($P_{0.98,y}$), is the nth maximum 24-hour average value for the year where *n* is the listed number
1 to 50	1
51 to 100	2
101 to 150	3
151 to 200	4
201 to 250	5
251 to 300	6
301 to 350	7
351 to 366	8

(b) The 24-hour $PM_{2.5}$ NAAQS DV is then calculated by averaging the annual 98th percentiles using equation 4 of this appendix: $P_{0.98,y}$

Equation 4

$$\overline{P}_{0.98} = \frac{1}{3}\sum_{y=1}^{3} P_{0.98,y}$$

Where:

$\bar{P}_{0.98}$ = the 24-hour $PM_{2.5}$ NAAQS DV; and

$P_{0.98,\ y}$ = the annual 98th percentile for year *y*

(c) The 24-hour $PM_{2.5}$ NAAQS DV is rounded according to the conventions in section 4.3 of this appendix before a comparison with the level of the primary and secondary 24-hour NAAQS are made.

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. 7401–7671*q*.

Subpart I—[Amended]

■ 7. In § 51.166, add paragraph (i)(10) to read as follows:

§ 51.166 Prevention of significant deterioration of air quality.

* * * * *

(i) * * *

(10) The plan may provide that the requirements of paragraph (k)(1) of this section shall not apply to a stationary source or modification with respect to the national ambient air quality standards for $PM_{2.5}$ in effect on March 18, 2013 if:

(i) The reviewing authority has determined a permit application subject to this section to be complete on or before December 14, 2012. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ in effect at the time the reviewing authority determined the permit application to be complete; or

(ii) The reviewing authority has first published before March 18, 2013 a public notice of a preliminary determination 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 $PM_{2.5}$ in effect at the time of first publication of a public notice on the preliminary determination.

* * * * *

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. In § 52.21, add paragraph (i)(11) to read as follows:

§ 52.21 Prevention of significant deterioration of air quality.

* * * * *

(i) * * *

(11) The requirements of paragraph (k)(1) of this section shall not apply to a stationary source or modification with respect to the national ambient air quality standards for $PM_{2.5}$ in effect on March 18, 2013 if:

(i) The Administrator has determined a permit application subject to this section to be complete on or before December 14, 2012. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ in effect at the time the Administrator determined the permit application to be complete; or

(ii) The Administrator has first published before March 18, 2013 a public notice that a draft permit subject to this section has been prepared. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ in effect on the date the Administrator first published a public notice that a draft permit has been prepared.

* * * * *

PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

■ 10. The authority citation for part 53 continues to read as follows:

Authority: Section 301(a) of the CAA (42 U.S.C. sec. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

■ 11. In § 53.9, revise paragraph (c) to read as follows:

§ 53.9 Conditions of designation.

* * * * *

(c) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10\text{-}2.5}$ sampler offered for sale as part of an FRM or FEM shall function within the limits of the performance specifications referred to in § 53.20(a), § 53.30(a), § 53.35, § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).

* * * * *

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

■ 12. The authority citation of part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7405, 7410, 7414, 7601, 7611, 7614, and 7619.

■ 13. Section 58.1 is amended by adding in alphabetical order a definition for ''Area-wide'' and by removing the definition for ''Community monitoring zone (CMZ)'' to read as follows:

§ 58.1 Definitions.

* * * * *

Area-wide means all monitors sited at neighborhood, urban, and regional

scales, as well as those monitors sited at either micro- or middle-scale that are representative of many such locations in the same CBSA.

* * * * *

■ 14. Section 58.10 is amended as follows:

■ a. By revising paragraph (a)(2).

■ b. By adding paragraph (a)(8).

■ c. By adding paragraph (b)(13).

■ d. By revising paragraph (c).

■ e. By revising paragraph (d).

§ 58.10 Annual monitoring network plan and periodic network assessment.

(a) * * *

(2) Any annual monitoring network plan that proposes SLAMS network modifications (including new monitoring sites, new determinations that data are not of sufficient quality to be compared to the NAAQS, and changes in identification of monitors as suitable or not suitable for comparison against the annual $PM_{2.5}$ NAAQS) is subject to the approval of the EPA Regional Administrator, who shall provide opportunity for public comment and shall approve or disapprove the plan and schedule within 120 days. If the State or local agency has already provided a public comment opportunity on its plan and has made no changes subsequent to that comment opportunity, and has submitted the received comments together with the plan, the Regional Administrator is not required to provide a separate opportunity for comment.

* * *

(8)(i) A plan for establishing near-road $PM_{2.5}$ monitoring sites in CBSAs having 2.5 million or more persons, in accordance with the requirements of appendix D to this part, shall be submitted as part of the annual monitoring network plan to the EPA Regional Administrator by July 1, 2014. The plan shall provide for these required monitoring stations to be operational by January 1, 2015.

(ii) A plan for establishing near-road $PM_{2.5}$ monitoring sites in CBSAs having 1 million or more persons, but less than 2.5 million persons, in accordance with the requirements of appendix D to this part, shall be submitted as part of the annual monitoring network plan to the EPA Regional Administrator by July 1, 2016. The plan shall provide for these required monitoring stations to be operational by January 1, 2017.

(b) * * *

(13) The identification of any $PM_{2.5}$ FEMs and/or ARMs used in the monitoring agency's network where the data are not of sufficient quality such that data are not to be compared to the NAAQS. For required SLAMS where the agency identifies that the $PM_{2.5}$ Class III FEM or ARM does not produce data of sufficient quality for comparison to the NAAQS, the monitoring agency must ensure that an operating FRM or filter-based FEM meeting the sample frequency requirements described in § 58.12 or other Class III $PM_{2.5}$ FEM or ARM with data of sufficient quality is operating and reporting data to meet the network design criteria described in appendix D to this part.

(c) The annual monitoring network plan must document how state and local agencies provide for the review of changes to a $PM_{2.5}$ monitoring network that impact the location of a violating $PM_{2.5}$ monitor. The affected state or local agency must document the process for obtaining public comment and include any comments received through the public notification process within their submitted plan.

(d) The state, or where applicable local, agency shall perform and submit to the EPA Regional Administrator an assessment of the air quality surveillance system every 5 years to determine, at a minimum, if the network meets the monitoring objectives defined in appendix D to this part, whether new sites are needed, whether existing sites are no longer needed and can be terminated, and whether new technologies are appropriate for incorporation into the ambient air monitoring network. The network assessment must consider the ability of existing and proposed sites to support air quality characterization for areas with relatively high populations of susceptible individuals (e.g., children with asthma), and, for any sites that are being proposed for discontinuance, the effect on data users other than the agency itself, such as nearby states and tribes or health effects studies. The state, or where applicable local, agency must submit a copy of this 5-year assessment, along with a revised annual network plan, to the Regional Administrator. The assessments are due every five years beginning July 1, 2010.

* * * * *

■ 15. Section 58.11 is amended by adding paragraph (e) to read as follows:

§ 58.11 Network technical requirements.

* * * * *

(e) State and local governments must assess data from Class III $PM_{2.5}$ FEM and ARM monitors operated within their network using the performance criteria described in table C–4 to subpart C of part 53 of this chapter, for cases where the data are identified as not of sufficient comparability to a collocated FRM, and the monitoring agency requests that the FEM or ARM data should not be used in comparison to the NAAQS. These assessments are required in the monitoring agency's annual monitoring network plan described in § 58.10(b) for cases where the FEM or ARM is identified as not of sufficient comparability to a collocated FRM. For these collocated $PM_{2.5}$ monitors the performance criteria apply with the following additional provisions:

(1) The acceptable concentration range (Rj), $\mu g/m^3$ may include values down to 0 $\mu g/m^3$.

(2) The minimum number of test sites shall be at least one; however, the number of test sites will generally include all locations within an agency's network with collocated FRMs and FEMs or ARMs.

(3) The minimum number of methods shall include at least one FRM and at least one FEM or ARM.

(4) Since multiple FRMs and FEMs may not be present at each site; the precision statistic requirement does not apply, even if precision data are available.

(5) All seasons must be covered with no more than thirty-six consecutive months of data in total aggregated together.

(6) The key statistical metric to include in an assessment is the bias (both additive and multiplicative) of the $PM_{2.5}$ continuous FEM(s) compared to a collocated FRM(s). Correlation is required to be reported in the assessment, but failure to meet the correlation criteria, by itself, is not cause to exclude data from a continuous FEM monitor.

■ 16. Section 58.12 is amended by revising paragraph (d)(1)(iii) and by removing and reserving paragraph (f)(2) to read as follows:

§ 58.12 Operating schedules.

* * * * *

(d) * * *

(1) * * *

(iii) Required SLAMS stations whose measurements determine the 24-hour design value for their area and whose data are within plus or minus 5 percent of the level of the 24-hour $PM_{2.5}$ NAAQS must have an FRM or FEM operate on a daily schedule if that area's design value for the annual NAAQS is less than the level of the annual $PM_{2.5}$ standard. A continuously operating FEM or ARM $PM_{2.5}$ monitor satisfies this requirement unless it is identified in the monitoring agency's annual monitoring network plan as not appropriate for comparison to the NAAQS.

* * * * *

(f) * * *

(2) [Reserved]

* * * * *

■ 17. Section 58.13 is amended by adding paragraph (f) to read as follows:

§ 58.13 Monitoring network completion.

* * * * *

(f) $PM_{2.5}$ monitors required in near-road environments as described in appendix D to this part, must be physically established and operating under all of the requirements of this part, including the requirements of appendices A, C, D, and E to this part, no later than:

(1) January 1, 2015 for $PM_{2.5}$ monitors in CBSAs having 2.5 million persons or more; or

(2) January 1, 2017 for $PM_{2.5}$ monitors in CBSAs having 1 million or more, but less than 2.5 million persons.

■ 18. Section 58.16 is amended by revising paragraphs (a) and (f) to read as follows:

§ 58.16 Data submittal and archiving requirements.

(a) The state, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO_2; CO; O_3; NO_2; NO; NOy; NO_X; Pb-TSP mass concentration; Pb-PM_{10} mass concentration; PM_{10} mass concentration; $PM_{2.5}$ mass concentration; for filter-based $PM_{2.5}$ FRM/FEM the field blank mass, sampler-generated average daily temperature, and sampler-generated average daily pressure; chemically speciated $PM_{2.5}$ mass concentration data; $PM_{10\text{-}2.5}$ mass concentration; meteorological data from NCore and PAMS sites; average daily temperature and average daily pressure for Pb sites if not already reported from sampler generated records; and metadata records and information specified by the AQS Data Coding Manual (*http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm*). The state, or where appropriate, local agency, may report site specific meteorological measurements generated by onsite equipment (meteorological instruments, or sampler generated) or measurements from the nearest airport reporting ambient pressure and temperature. Such air quality data and information must be submitted directly to the AQS via electronic transmission on the specified quarterly schedule described in paragraph (b) of this section.

* * * * *

(f) The state, or where applicable, local agency shall archive all $PM_{2.5}$, PM_{10}, and $PM_{10\text{-}2.5}$ filters from manual low-volume samplers (samplers having flow rates less than 200 liters/minute) from all SLAMS sites for a minimum period of 5 years after collection. These filters shall be made available for supplemental analyses, including destructive analyses if necessary, at the request of EPA or to provide information to state and local agencies on particulate matter composition. Other Federal agencies may request access to filters for purposes of supporting air quality management or community health—such as biological assay—through the applicable EPA Regional Administrator. The filters shall be archived according to procedures approved by the Administrator, which shall include cold storage of filters after post-sampling laboratory analyses for at least 12 months following field sampling. The EPA recommends that particulate matter filters be archived for longer periods, especially for key sites in making NAAQS-related decisions or for supporting health-related air pollution studies.

* * * * *

■ 19. Section 58.20 is amended by revising paragraph (c) to read as follows:

§ 58.20 Special purpose monitors (SPM).

* * * * *

(c) All data from an SPM using an FRM, FEM, or ARM which has operated for more than 24 months are eligible for comparison to the relevant NAAQS, subject to the conditions of §§ 58.11(e) and 58.30, unless the air monitoring agency demonstrates that the data came from a particular period during which the requirements of appendix A, appendix C, or appendix E to this part were not met, subject to review and EPA Regional Office approval as part of the annual monitoring network plan described in § 58.10.

* * * * *

■ 20. The heading for Subpart D is revised to read as follows:

Subpart D—Comparability of Ambient Data to the NAAQS

■ 21. Section 58.30 is amended by revising paragraph (a) to read as follows:

§ 58.30 Special considerations for data comparisons to the NAAQS.

(a) *Comparability of* $PM_{2.5}$ *data.* The primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS are described in part 50 of this chapter. Monitors that follow the network technical requirements specified in § 58.11 are eligible for comparison to the NAAQS subject to the additional requirements of this section. $PM_{2.5}$ measurement data from all eligible monitors are comparable to the 24-hour $PM_{2.5}$ NAAQS. $PM_{2.5}$ measurement data from all eligible monitors that are representative of area-wide air quality are comparable to the annual $PM_{2.5}$ NAAQS. Consistent with appendix D to this part, section 4.7.1, when micro- or middle-scale $PM_{2.5}$ monitoring sites collectively identify a larger region of localized high ambient $PM_{2.5}$ concentrations, such sites would be considered representative of an area-wide location and, therefore, eligible for comparison to the annual $PM_{2.5}$ NAAQS. $PM_{2.5}$ measurement data from monitors that are not representative of area-wide air quality but rather of relatively unique micro-scale, or localized hot spot, or unique middle-scale impact sites are not eligible for comparison to the annual $PM_{2.5}$ NAAQS. $PM_{2.5}$ measurement data from these monitors are eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. For example, if a micro- or middle-scale $PM_{2.5}$ monitoring site is adjacent to a unique dominating local $PM_{2.5}$ source, then the $PM_{2.5}$ measurement data from such a site would only be eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. Approval of sites that are suitable and sites that are not suitable for comparison with the annual $PM_{2.5}$ NAAQS is provided for as part of the annual monitoring network plan described in § 58.10.

* * * * *

■ 22. Appendix A to part 58 is amended as follows:

■ a. By redesignating the existing introductory paragraph in section 1 as paragraph (b) in section 1, and revising newly redesignated paragraph (b).

■ b. By adding paragraph (a) to section 1.

■ c. By revising paragraphs 3.2.5.6, and 3.2.6.3.

■ d. By revising Table A–1.

The revisions and additions read as follows:

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *

1. * * *

(a) Each monitoring organization is required to implement a quality system that provides sufficient information to assess the quality of the monitoring data. The quality system must, at a minimum, include the specific requirements described in this appendix of this subpart. Failure to conduct or pass a required check or procedure, or a series of required checks or procedures, does not by itself invalidate data for regulatory decision making. Rather, monitoring agencies and EPA shall use the checks and procedures required in this appendix in combination with other data quality information, reports, and similar documents showing overall compliance with part 58. Accordingly, EPA

and monitoring agencies shall use a ''weight of evidence'' approach when determining the suitability of data for regulatory decisions. The EPA reserves the authority to use or not use monitoring data submitted by a monitoring organization when making regulatory decisions based on the EPA's assessment of the quality of the data. Generally, consensus built validation templates or validation criteria already approved in Quality Assurance Project Plans (QAPPs) should be used as the basis for the weight of evidence approach.

(b) This appendix specifies the minimum quality system requirements applicable to SLAMS air monitoring data and PSD data for the pollutants SO_2, NO_2, O_3, CO, Pb, $PM_{2.5}$, PM_{10} and $PM_{10\text{-}2.5}$ submitted to EPA. This appendix also applies to all SPM stations using FRM, FEM, or ARM methods which also meet the requirements of appendix E of this part, unless alternatives to this appendix for SPMs have been approved in accordance with § 58.11(a)(2). Monitoring organizations are encouraged to develop and maintain quality systems more extensive than the required minimums. The permit-granting authority for PSD may require more frequent or more stringent requirements. Monitoring organizations may, based on their quality objectives, develop and maintain quality systems beyond the required minimum. Additional guidance for the requirements reflected in this appendix can be found in the ''Quality Assurance Handbook for Air Pollution Measurement Systems'', Volume II (see reference 10 of this appendix) and at a national level in references 1, 2, and 3 of this appendix.

* * * * *

3.2.5* * *

3.2.5.6 The two collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference. A waiver allowing up to 10 meters horizontal distance and up to 3 meters vertical distance (inlet to inlet) between a primary and collocated sampler may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation. This waiver may be approved during the annual network plan approval process. Calibration, sampling, and analysis must be the same for all the collocated samplers in each agency's network.

* * * * *

3.2.6 * * *

3.2.6.3 The two collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference. A waiver allowing up to 10 meters horizontal distance and up to 3 meters vertical distance (inlet to inlet) between a primary and a collocated sampler may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation taking into consideration safety, logistics, and space availability. This waiver may be approved during the annual network plan approval process. Calibration, sampling, and analysis must be the same for all the collocated samplers in each agency's network.

* * * * *

TABLE A–1 OF APPENDIX A TO PART 58—DIFFERENCE AND SIMILARITIES BETWEEN SLAMS AND PSD REQUIREMENTS

Topic	SLAMS	PSD
Requirements	1. The development, documentation, and implementation of an approved quality system. 2. The assessment of data quality. 3. The use of reference, equivalent, or approved methods. 4. The use of calibration standards traceable to NIST or other primary standard. 5. The participation in EPA performance evaluations and the permission for EPA to conduct system audits.	Same as SLAMS. Same as SLAMS
Monitoring and QA Responsibility	State/local agency via the ''primary quality assurance organization''.	Source owner/operator.
Monitoring Duration	Indefinitely	Usually up to 12 months.
Annual Performance Evaluation (PE)	Standards and equipment different from those used for spanning, calibration, and verifications. Prefer different personnel.	Personnel, standards and equipment different from those used for spanning, calibration, and verifications.
PE audit rate:		
—Automated	100% per year	100% per quarter.
—Manual	Varies depending on pollutant. See Table A–2 of this appendix.	100% per quarter.
Precision Assessment:		
—Automated	One-point QC check biweekly but data quality dependent.	One point QC check biweekly.
—Manual	Varies depending on pollutant. See Table A–2 of this appendix.	One site: 1 every 6 days or every third day for daily monitoring (TSP and Pb).
Reporting		
—Automated	By site—EPA performs calculations annually	By site—source owner/operator performs calculations each sampling quarter.
—Manual	By reporting organization—EPA performs calculations annually.	By site—source owner/operator performs calculations each sampling quarter.

* * * * *

■ 23. Appendix D to part 58 is amended as follows:

■ a. By revising paragraphs 4.7.1(b) and 4.7.1(c)(1).

■ b. By removing paragraph 4.7.5.

■ c. By removing and reserving paragraph 4.8.2.

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

4.7.1 * * *

(b) Specific Design Criteria for $PM_{2.5}$. The required monitoring stations or sites must be sited to represent area-wide air quality. These sites can include sites collocated at PAMS. These monitoring stations will typically be at neighborhood or urban-scale; however, micro-or middle-scale $PM_{2.5}$ monitoring sites that represent many such locations throughout a metropolitan area are considered to represent area-wide air quality.

(1) At least one monitoring station is to be sited at neighborhood or larger scale in an area of expected maximum concentration.

(2) For CBSAs with a population of 1,000,000 or more persons, at least one $PM_{2.5}$ monitor is to be collocated at a near-road NO_2

station required in section 4.3.2(a) of this appendix.

(3) For areas with additional required SLAMS, a monitoring station is to be sited in an area of poor air quality.

(4) Additional technical guidance for siting $PM_{2.5}$ monitors is provided in references 6 and 7 of this appendix.

(c) * * *

(1) *Micro-scale.* This scale would typify areas such as downtown street canyons and traffic corridors where the general public would be exposed to maximum concentrations from mobile sources. In some circumstances, the micro-scale is appropriate for particulate sites. SLAMS sites measured at the micro-scale level should, however, be limited to urban sites that are representative of long-term human exposure and of many such microenvironments in the area. In general, micro-scale particulate matter sites should be located near inhabited buildings or locations where the general public can be expected to be exposed to the concentration measured. Emissions from stationary sources such as primary and secondary smelters, power plants, and other large industrial processes may, under certain plume conditions, likewise result in high ground level concentrations at the micro-scale. In the latter case, the micro-scale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Data collected at micro-scale sites provide information for evaluating and developing hot spot control measures.

* * * * *

4.8 * * *

4.8.2 [Reserved]

* * * * *

■ 24. Appendix E to part 58 is amended as follows:

■ a. By adding table E–1 to paragraph 6 above paragraph 6.1.

■ b. By revising table E–4.

Appendix E to Part 58—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

* * * * *

6. * * *

TABLE E–1 TO APPENDIX E OF PART 58—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES OR MONITORING PATHS FOR MONITORING NEIGHBORHOOD AND URBAN SCALE OZONE (O_3) AND OXIDES OF NITROGEN (NO, NO_2, NO_X, NO_y)

Roadway average daily traffic, vehicles per day	Minimum distance [1] (meters)	Minimum distance [1 2] meters)
≤ 1,000	10	10
10,000	10	20
15,000	20	30
20,000	30	40
40,000	50	60
70,000	100	100
≥ 110,000	250	250

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2] Applicable for ozone monitors whose placement has not already been approved as of December 18, 2006.

* * * * *

11. * * *

TABLE E–4 OF APPENDIX E TO PART 58—SUMMARY OF PROBE AND MONITORING PATH SITING CRITERIA

Pollutant	Scale (maximum monitoring path length, meters)	Height from ground to probe, inlet or 80% of monitoring path [1] (meters)	Horizontal and vertical distance from supporting structures [2] to probe, inlet or 90% of monitoring path[1] (meters)	Distance from trees to probe, inlet or 90% of monitoring path [1] (meters)	Distance from roadways to probe, inlet or monitoring path [1] (meters)
SO_2 [3 4 5 6]	Middle (300 m) Neighborhood Urban, and Regional (1 km).	2–15	>1	>10	N/A.
CO [4 5 7]	Micro [downtown or street canyon sites], micro [near-road sites], middle (300 m) and Neighborhood (1 km).	2.5–3.5; 2–7; 2–15	>1	>10	2–10 for downtown areas or street canyon microscale; ≤50 for near-road microscale; see Table E–2 of this appendix for middle and neighborhood scales.
O_3 [3 4 5]	Middle (300 m) Neighborhood, Urban, and Regional (1 km).	2–15	>1	>10	*See* Table E–1 of this appendix for all scales.
NO_2 [3 4 5]	Micro (Near-road [50–300 m]).	2–7 (micro);	>1	>10	≤50 for near-road microscale.
	Middle (300 m)	2–15 (all other scales).			
	Neighborhood, Urban, and Regional (1 km).				*See* Table E–1 of this appendix for all other scales.
Ozone precursors (for PAMS) [3 4 5].	Neighborhood and Urban (1 km).	2–15	>1	>10	*See* Table E–4 of this appendix for all scales.
PM, Pb [3 4 5 6 8]	Micro, Middle, Neighborhood, Urban and Regional.	2–7 (micro); 2–7 (middle $PM_{10-2.5}$); 2–7 for near-road; 2–15 (all other scales).	>2 (all scales, horizontal distance only).	>10 (all scales)	2–10 (micro); *see* Figure E–1 of this appendix for all other scales. ≤50 for near-road.

N/A—Not applicable.

[1] Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring, middle, neighborhood, urban, and regional scale NO_2 monitoring, and all applicable scales for monitoring SO_2, O_3, and O_3 precursors.

[2] When probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.

[3] Should be greater than 20 meters from the dripline of tree(s) and must be 10 meters from the dripline when the tree(s) act as an obstruction.

[4] Distance from sampler, probe, or 90 percent of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the sampler, probe, or monitoring path. Sites not meeting this criterion may be classified as middle scale (*see* text).

[5] Must have unrestricted airflow 270 degrees around the probe or sampler; 180 degrees if the probe is on the side of a building or a wall.

[6] The probe, sampler, or monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.

[7] For micro-scale CO monitoring sites, the probe must be >10 meters from a street intersection and preferably at a midblock location.

[8] Collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference, unless a waiver is in place as approved by the Regional Administrator pursuant to section 3 of Appendix A.

* * * * *

■ 25. Appendix G to part 58 is amended as follows:
■ a. By revising section 9.
■ b. By revising section 10.
■ c. By revising paragraphs 12.1 introductory text and 12.1.a, and table 2.
■ d. By revising section 13.

Appendix G to Part 58—Uniform Air Quality Index (AQI) and Daily Reporting

* * * * *

9. How does the AQI relate to air pollution levels?

For each pollutant, the AQI transforms ambient concentrations to a scale from 0 to 500. The AQI is keyed as appropriate to the national ambient air quality standards (NAAQS) for each pollutant. In most cases, the index value of 100 is associated with the numerical level of the short-term standard (i.e., averaging time of 24-hours or less) for each pollutant. The index value of 50 is associated with the numerical level of the annual standard for a pollutant, if there is one, at one-half the level of the short-term standard for the pollutant, or at the level at which it is appropriate to begin to provide guidance on cautionary language. Higher categories of the index are based on increasingly serious health effects and increasing proportions of the population that are likely to be affected. The index is related to other air pollution concentrations through linear interpolation based on these levels. The AQI is equal to the highest of the numbers corresponding to each pollutant. For the purposes of reporting the AQI, the sub-indexes for PM_{10} and $PM_{2.5}$ are to be considered separately. The pollutant responsible for the highest index value (the reported AQI) is called the ''critical'' pollutant.

10. What monitors should I use to get the pollutant concentrations for calculating the AQI?

You must use concentration data from State/Local Air Monitoring Station (SLAMS) or parts of the SLAMS required by 40 CFR 58.10 for each pollutant except PM. For PM, calculate and report the AQI on days for which you have measured air quality data (e.g., from continuous $PM_{2.5}$ monitors required in Appendix D to this part). You may use PM measurements from monitors that are not reference or equivalent methods (for example, continuous PM_{10} or $PM_{2.5}$ monitors). Detailed guidance for relating non-approved measurements to approved methods by statistical linear regression is referenced in section 13 below.

* * * * *

12. How do I calculate the AQI?

i. The AQI is the highest value calculated for each pollutant as follows:

a. Identify the highest concentration among all of the monitors within each reporting area and truncate as follows:

(1) Ozone—truncate to 3 decimal places
$PM_{2.5}$—truncate to 1 decimal place
PM_{10}—truncate to integer
CO—truncate to 1 decimal place
SO_2—truncate to integer
NO_2—truncate to integer

(2) [Reserved]

* * * * *

TABLE 2—BREAKPOINTS FOR THE AQI

These breakpoints							Equal these AQI's	
O_3 (ppm) 8-hour	O_3 (ppm) 1-hour[1]	$PM_{2.5}$ (µg/m³) 24-hour	PM_{10} (µg/m³) 24-hour	CO (ppm) 8-hour	SO_2 (ppb) 1-hour	NO_2 (ppb) 1-hour	AQI	Category
0.000–0.059	.....	0.0–12.0	0–54	0.0–4.4	0–35	0–53	0–50	Good.
0.060–0.075	.....	12.1–35.4	55–154	4.5–9.4	36–75	54–100	51–100	Moderate.
0.076–0.095	0.125–0.164	35.5–55.4	155–254	9.5–12.4	76–185	101–360	101–150	Unhealthy for Sensitive Groups.
0.096–0.115	0.165–0.204	[3] 55.5–150.4	255–354	12.5–15.4	[4] 186–304	361–649	151–200	Unhealthy.
0.116–0.374	0.205–0.404	[3] 150.5–250.4	355–424	15.5–30.4	[4] 305–604	650–1249	201–300	Very Unhealthy.
([2])	0.405–0.504	[3] 250.5–350.4	425–504	30.5–40.4	[4] 605–804	1250–1649	301–400	Hazardous.
([2])	0.505–0.604	[3] 350.5–500.4	505–604	40.5–50.4	[4] 805–1004	1650–2049	401–500	

[1] 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.
[2] 8-hour O^3 values do not define higher AQI values (≥301). AQI values of 301 or greater are calculated with 1-hour O_3 concentrations.
[3] If a different SHL for $PM_{2.5}$ is promulgated, these numbers will change accordingly.
[4] 1-hr SO_2 values do not define higher AQI values (≥ 200). AQI values of 200 or greater are calculated with 24-hour SO_2 concentrations.

* * * * *

13. What additional information should I know?

The EPA has developed a computer program to calculate the AQI for you. The program prompts for inputs, and it displays all the pertinent information for the AQI (the index value, color, category, sensitive group, health effects, and cautionary language). The EPA has also prepared a brochure on the AQI that explains the index in detail (The Air Quality Index), Reporting Guidance (Technical Assistance Document for the Reporting of Daily Air Quality—the Air Quality Index (AQI)) that provides associated health effects and cautionary statements, and Forecasting Guidance (Guideline for Developing an Ozone Forecasting Program) that explains the steps necessary to start an air pollution forecasting program. You can download the program and the guidance documents at *www.airnow.gov.* Reference for relating non-approved PM measurements to approved methods (Eberly, S., T. Fitz-Simons, T. Hanley, L. Weinstock., T. Tamanini, G. Denniston, B. Lambeth, E. Michel, S. Bortnick. Data Quality Objectives (DQOs) For Relating Federal Reference Method (FRM) and Continuous $PM_{2.5}$ Measurements to Report an Air Quality Index (AQI). U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA–454/B–02–002, November 2002) can be found on the Ambient Monitoring Technology Information Center

(AMTIC) Web site, *http://www.epa.gov/ttnamti1/.*

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Part III

Department of Transportation

Semiannual Regulatory Agenda; Republication

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Chs. I–III

23 CFR Chs. I–III

33 CFR Chs. I and IV

46 CFR Chs. I–III

48 CFR Ch. 12

49 CFR Subtitle A, Chs. I–VI and Chs. X–XII

[OST Docket 99–5129]

Department Regulatory Agenda; Semiannual Summary

AGENCY: Office of the Secretary, DOT.

ACTION: Republication.

SUMMARY: The entire Department of Transportation Fall 2012 Unified Agenda published in the **Federal Register** on January 8, 2013 (78 FR 1604), is being republished to correct missing portions of the fall 2012 preamble. This information was omitted in error, and is therefore being reprinted to publish the data in its entirety.

DATES: This republication is effective January 15, 2013.

FOR FURTHER INFORMATION CONTACT:

General

You should direct all comments and inquiries on the Agenda in general to Neil R. Eisner, Assistant General Counsel for Regulation and Enforcement, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590; (202) 366–4723.

Specific

You should direct all comments and inquiries on particular items in the Agenda to the individual listed for the regulation or the general rulemaking contact person for the operating administration in Appendix B. Individuals who use a telecommunications device for the deaf (TDD) may call (202) 755–7687.

SUPPLEMENTARY INFORMATION SECTION: The entire Department of Transportation Fall 2012 Unified Agenda is being republished to correct missing portions of the fall 2012 preamble.

Brett Jortland,

Deputy Assistant General Counsel, Department of Transportation.

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Chs. I–III

23 CFR Chs. I–III

33 CFR Chs. I and IV

46 CFR Chs. I–III

48 CFR Ch. 12

49 CFR Subtitle A, Chs. I–VI and Chs. X–XII

[OST Docket 99–5129]

Department Regulatory Agenda; Semiannual Summary

AGENCY: Office of the Secretary, DOT.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Agenda is a semiannual summary of all current and projected rulemakings, reviews of existing regulations, and completed actions of the Department. The Agenda provides the public with information about the Department of Transportation's regulatory activity. It is expected that this information will enable the public to be more aware of and allow it to more effectively participate in the Department's regulatory activity. The public is also invited to submit comments on any aspect of this Agenda.

FOR FURTHER INFORMATION CONTACT:

General

You should direct all comments and inquiries on the Agenda in general to Neil R. Eisner, Assistant General Counsel for Regulation and Enforcement, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590; (202) 366–4723.

Specific

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SUPPLEMENTARY INFORMATION:

Background

Improvement of our regulations is a prime goal of the Department of Transportation (Department or DOT). Our regulations should be clear, simple, timely, fair, reasonable, and necessary. They should not be issued without appropriate involvement of the public; once issued, they should be periodically reviewed and revised, as needed, to assure that they continue to meet the needs for which they originally were designed. To view additional information about the Department of Transportation's regulatory activities online, go to *http://www.dot.gov/regulations*. Among other things, this Web site provides a report, updated monthly, on the status of the DOT significant rulemakings listed in the Semiannual Regulatory Agenda.

To help the Department achieve these goals and in accordance with Executive Order (E.O.) 12866, ''Regulatory Planning and Review,'' (58 FR 51735; Oct. 4, 1993) and the Department's Regulatory Policies and Procedures (44 FR 11034; Feb. 26, 1979), the Department prepares a Semiannual Regulatory Agenda. It summarizes all current and projected rulemaking, reviews of existing regulations, and completed actions of the Department. These are matters on which action has begun or is projected during the succeeding 12 months or such longer period as may be anticipated or for which action has been completed since the last Agenda.

The Agendas are based on reports submitted by the offices initiating the rulemaking and are reviewed by the Department Regulations Council.

The Internet is the basic means for disseminating the Unified Agenda. The complete Unified Agenda is available online at *www.reginfo.gov*, in a format that offers users a greatly enhanced ability to obtain information from the Agenda database.

Because publication in the **Federal Register** is mandated for the regulatory flexibility agendas required by the

Regulatory Flexibility Act (5 U.S.C. 602), DOT's printed Agenda entries include only:

1. The agency's Agenda preamble;
2. Rules that are in the agency's regulatory flexibility agenda, in accordance with the Regulatory Flexibility Act, because they are likely to have a significant economic impact on a substantial number of small entities; and
3. Any rules that the agency has identified for periodic review under section 610 of the Regulatory Flexibility Act.

Printing of these entries is limited to fields that contain information required by the Regulatory Flexibility Act's Agenda requirements. These elements are: Sequence Number; Title; Section 610 Review, if applicable; Legal Authority; Abstract; Timetable; Regulatory Flexibility Analysis Required; Agency Contact; and Regulation Identifier Number (RIN). Additional information (for detailed list see section heading ''Explanation of Information on the Agenda'') on these entries is available in the Unified Agenda published on the Internet.

Significant/Priority Rulemakings

The Agenda covers all rules and regulations of the Department. We have classified rules as a DOT agency priority in the Agenda if they are, essentially, very costly, beneficial, controversial, or of substantial public interest under our Regulatory Policies and Procedures. All DOT agency priority rulemaking documents are subject to review by the Secretary of Transportation. If the Office of Management and Budget (OMB) decide a rule is subject to its review under Executive Order 12866, we have classified it as significant in the Agenda.

Explanation of Information on the Agenda

An Office of Management and Budget memorandum, dated June 13, 2012, requires the format for this Agenda.

First, the Agenda is divided by initiating offices. Then, the Agenda is divided into five categories: (1) Prerule stage, (2) proposed rule stage, (3) final rule stage, (4) long-term actions, and (5) completed actions. For each entry, the Agenda provides the following information: (1) Its ''significance''; (2) a short, descriptive title; (3) its legal basis; (4) the related regulatory citation in the Code of Federal Regulations; (5) any legal deadline and, if so, for what action (e.g., NPRM, final rule); (6) an abstract; (7) a timetable, including the earliest expected date for a decision on whether to take the action; (8) whether the rulemaking will affect small entities and/or levels of government and, if so, which categories; (9) whether a Regulatory Flexibility Act (RFA) analysis is required (for rules that would have a significant economic impact on a substantial number of small entities); (10) a listing of any analyses an office will prepare or has prepared for the action (with minor exceptions, DOT requires an economic analysis for all its rulemakings.); (11) an agency contact office or official who can provide further information; (12) a Regulation Identifier Number (RIN) assigned to identify an individual rulemaking in the Agenda and facilitate tracing further action on the issue; (13) whether the action is subject to the Unfunded Mandates Reform Act; (14) whether the action is subject to the Energy Act; and (15) whether the action is major under the congressional review provisions of the Small Business Regulatory Enforcement Fairness Act. If there is information that does not fit in the other categories, it will be included under a separate heading entitled ''Additional Information.'' One such example of this is the letters ''SB,'' ''IC,'' ''SLT.'' These refer to information used as part of our required reports on Retrospective Review of DOT rulemakings. A ''Y'' or an ''N,'' for yes and no, respectively, follow the letters to indicate whether or not a particular rulemaking would have effects on: Small businesses (SB); information collections (IC); or State, local, or tribal (SLT) governments.

For nonsignificant regulations issued routinely and frequently as a part of an established body of technical requirements (such as the Federal Aviation Administration's Airspace Rules), to keep those requirements operationally current, we only include the general category of the regulations, the identity of a contact office or official, and an indication of the expected number of regulations; we do not list individual regulations.

In the ''Timetable'' column, we use abbreviations to indicate the particular documents being considered. ANPRM stands for Advance Notice of Proposed Rulemaking, SNPRM for Supplemental Notice of Proposed Rulemaking, and NPRM for Notice of Proposed Rulemaking. Listing a future date in this column does not mean we have made a decision to issue a document; it is the earliest date on which we expect to make a decision on whether to issue it. In addition, these dates are based on current schedules. Information received subsequent to the issuance of this Agenda could result in a decision not to take regulatory action or in changes to proposed publication dates. For example, the need for further evaluation could result in a later publication date; evidence of a greater need for the regulation could result in an earlier publication date.

Finally, a dot (•) preceding an entry indicates that the entry appears in the Agenda for the first time.

Request for Comments

General

Our agenda is intended primarily for the use of the public. Since its inception, we have made modifications and refinements that we believe provide the public with more helpful information, as well as make the Agenda easier to use. We would like you, the public, to make suggestions or comments on how the Agenda could be further improved.

Reviews

We also seek your suggestions on which of our existing regulations you believe need to be reviewed to determine whether they should be revised or revoked. We particularly draw your attention to the Department's review plan in appendix D. In response to Executive Order 13563 ''Retrospective Review and Analysis of Existing Rules,'' we have prepared a retrospective review plan providing more detail on the process we use to conduct reviews of existing rules, including changes in response to Executive Order 13563. We provided the public opportunities to comment at regulations.gov and IdeaScale on both our process and any existing DOT rules the public thought needed review. The plan and the results of our review can be found at *http://www.dot.gov/regulations*.

Regulatory Flexibility Act

The Department is especially interested in obtaining information on requirements that have a ''significant economic impact on a substantial number of small entities'' and, therefore, must be reviewed under the Regulatory Flexibility Act. If you have any suggested regulations, please submit them to us, along with your explanation of why they should be reviewed.

In accordance with the Regulatory Flexibility Act, comments are specifically invited on regulations that we have targeted for review under section 610 of the Act. The phrase (sec. 610 Review) appears at the end of the title for these reviews. Please see appendix D for the Department's section 610 review plans.

Consultation With State, Local, and Tribal Governments

Executive orders 13132 and 13175 require us to develop an accountable process to ensure ''meaningful and timely input'' by State, local, and tribal officials in the development of regulatory policies that have federalism or tribal implications. These policies are defined in the Executive orders to include regulations that have ''substantial direct effects'' on States or Indian tribes, on the relationship between the Federal Government and them, or on the distribution of power and responsibilities between the Federal Government and various levels of government or Indian tribes. Therefore, we encourage State and local governments or Indian tribes to provide us with information about how the Department's rulemakings impact them.

Purpose

The Department is publishing this regulatory Agenda in the **Federal Register** to share with interested members of the public the Department's preliminary expectations regarding its future regulatory actions. This should enable the public to be more aware of the Department's regulatory activity and should result in more effective public participation. This publication in the **Federal Register** does not impose any binding obligation on the Department or any of the offices within the Department with regard to any specific item on the Agenda. Regulatory action, in addition to the items listed, is not precluded.

Dated: November 2, 2012.

Ray LaHood,

Secretary of Transportation.

Appendix A—Instructions for Obtaining Copies of Regulatory Documents

To obtain a copy of a specific regulatory document in the Agenda, you should communicate directly with the contact person listed with the regulation at the address below. We note that most, if not all, such documents, including the Semiannual Regulatory Agenda, are available through the Internet at *http://www.regulations.gov*. See appendix C for more information.

(Name of contact person), (Name of the DOT agency), 1200 New Jersey Avenue SE., Washington, DC 20590. (For the Federal Aviation Administration, substitute the following address: Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591).

Appendix B—General Rulemaking Contact Persons

The following is a list of persons who can be contacted within the Department for general information concerning the rulemaking process within the various operating administrations.

FAA—Rebecca MacPherson, Office of Chief Counsel, Regulations and Enforcement Division, 800 Independence Avenue SW., Room 915A, Washington, DC 20591; telephone (202) 267–3073.

FHWA—Jennifer Outhouse, Office of Chief Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–0761.

FMCSA—Steven J. LaFreniere, Regulatory Ombudsman, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–0596.

NHTSA—Steve Wood, Office of Chief Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–2992.

FRA—Kathryn Shelton, Office of Chief Counsel, 1200 New Jersey Avenue SE., Room W31–214, Washington, DC 20590; telephone (202) 493–6063.

FTA—Richard Wong, Office of Chief Counsel, 1200 New Jersey Avenue SE., Room E56–308, Washington, DC 20590; telephone (202) 366–0675.

SLSDC—Carrie Mann Lavigne, Chief Counsel, 180 Andrews Street, Massena, NY 13662; telephone (315) 764–3200.

PHMSA—Patricia Burke, Office of Chief Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–4400.

MARAD—Christine Gurland, Office of Chief Counsel, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–5157.

RITA—Robert Monniere, Office of Chief Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–5498.

OST—Neil Eisner, Office of Regulation and Enforcement, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–4723.

Appendix C—Public Rulemaking Dockets

All comments via the Internet are submitted through the Federal Docket Management System (FDMS) at the following address: *http://www.regulations.gov*. The FDMS allows the public to search, view, download, and comment on all Federal agency rulemaking documents in one central online system. The above referenced Internet address also allows the public to sign up to receive notification when certain documents are placed in the dockets.

The public also may review regulatory dockets at, or deliver comments on proposed rulemakings to, the Dockets Office at 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, 1–800–647–5527. Working Hours: 9–5.

Appendix D—Review Plans for Section 610 and Other Requirements

Part I—The Plan

General

The Department of Transportation has long recognized the importance of regularly reviewing its existing regulations to determine whether they need to be revised or revoked. Our 1979 Regulatory Policies and Procedures require such reviews. We also have responsibilities under Executive Order 12866, ''Regulatory Planning and Review,'' and section 610 of the Regulatory Flexibility Act to conduct such reviews. This includes the use of plain language techniques in new rules and considering its use in existing rules when we have the opportunity and resources to permit its use. We are committed to continuing our reviews of existing rules and, if needed, will initiate rulemaking actions based on these reviews.

In accordance with Executive Order 13563, ''Improving Regulation and Regulatory Review,'' issued by the President on January 18, 2011, the Department has added other elements to its review plan. The Department has decided to improve its plan by adding special oversight processes within the Department; encouraging effective and timely reviews, including providing additional guidance on particular problems that warrant review; and expanding opportunities for public participation. These new actions are in addition to the other steps described in this Appendix.

Section 610 Review Plan

Section 610 requires that we conduct reviews of rules that (1): Have been published within the last 10 years, and (2) have a ''significant economic impact on a substantial number of small entities'' (SEIOSNOSE). It also requires that we publish in the **Federal Register** each year a list of any such rules that we will review during the next year. The Office of the Secretary and each of the Department's Operating Administrations have a 10-year review plan. These reviews comply with section 610 of the Regulatory Flexibility Act.

Other Review Plan(s)

All elements of the Department, except for the Federal Aviation Administration (FAA), have also elected to use this 10-year plan process to comply with the review requirements of the Department's Regulatory Policies and Procedures and Executive Order 12866.

Changes to the Review Plan

Some reviews may be conducted earlier than scheduled. For example, to the extent resources permit, the plain language reviews will be conducted more quickly. Other events, such as accidents, may result in the need to conduct earlier reviews of some rules. Other factors may also result in the need to make changes; for example, we may make changes in response to public comment on this plan or in response to a Presidentially-mandated review. If there is any change to the review plan, we will note the change in the following Agenda. For any section 610 review, we will provide the required notice prior to the review.

Part II—The Review Process

The Analysis

Generally, the agencies have divided their rules into 10 different groups and plan to analyze one group each year. For purposes of these reviews, a year will coincide with the fall-to-fall schedule for publication of the Agenda. Thus, Year 1 (2008) begins in the fall of 2008 and ends in the fall of 2009; Year 2 (2009) begins in the fall of 2009 and ends in the fall of 2010, and so on. We request public comment on the timing of the reviews. For example, is there a reason for scheduling an analysis and review for a particular rule earlier than we have? Any comments concerning the plan or particular analyses should be submitted to the regulatory contacts listed in Appendix B, General Rulemaking Contact Persons.

Section 610 Review

The agency will analyze each of the rules in a given year's group to determine whether any rule has a SEIOSNOSE and, thus, requires review in accordance with section 610 of the Regulatory Flexibility Act. The level of analysis will, of course, depend on the nature of the rule and its applicability. Publication of agencies' section 610 analyses listed each fall in this Agenda provides the public with notice and an opportunity to comment consistent with the requirements of the Regulatory Flexibility Act. We request that public comments be submitted to us early in the analysis year concerning the small entity impact of the rules to help us in making our determinations.

In each fall Agenda, the agency will publish the results of the analyses it has completed during the previous year. For rules that had a negative finding on SEIOSNOSE, we will give a short explanation (e.g., ''these rules only establish petition processes that have no cost impact'' or ''these rules do not apply to any small entities''). For parts, subparts, or other discrete sections of rules that do have a SEIOSNOSE, we will announce that we will be conducting a formal section 610 review during the following 12 months. At this stage, we will add an entry to the Agenda in the prerulemaking section describing the review in more detail. We also will seek public comment on how best to lessen the impact of these rules and provide a name or docket to which public comments can be submitted. In some cases, the section 610 review may be part of another unrelated review of the rule. In such a case, we plan to clearly indicate which parts of the review are being conducted under section 610.

Other Reviews

The agency will also examine the specified rules to determine whether any other reasons exist for revising or revoking the rule or for rewriting the rule in plain language. In each fall Agenda, the agency will also publish information on the results of the examinations completed during the previous year.

The FAA, in addition to reviewing its rules in accordance with the section 610 Review Plan, has established a tri-annual process to comply with the review requirements of the Department's Regulatory Policies and Procedures, Executive Order 12866, and Plain Language Review Plan. The FAA's latest review notice was published November 15, 2007 (72 FR 64170). In that notice, the FAA requested comments from the public to identify those regulations currently in effect that it should amend, remove, or simplify. The FAA also requested the public to provide any specific suggestions where rules could be developed as performance-based rather than prescriptive, and any specific plain language that might be used, and provide suggested language on how those rules should be written. The FAA will review the issues addressed by the commenters against its regulatory agenda and rulemaking program efforts and adjust its regulatory priorities consistent with its statutory responsibilities. At the end of this process, the FAA will publish a summary and general disposition of comments and indicate, where appropriate, how it will adjust its regulatory priorities.

Part III—List of Pending Section 610 Reviews

The Agenda identifies the pending DOT section 610 Reviews by inserting ''(Section 610 Review),'' after the title for the specific entry. For further information on the pending reviews, see the Agenda entries at *www.reginfo.gov.* For example, to obtain a list of all entries that is section 610 Reviews under the Regulatory Flexibility Act, a user would select the desired responses on the search screen (by selecting ''advanced search'') and, in effect, generate the desired ''index'' of reviews.

OFFICE OF THE SECRETARY

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	49 CFR parts 91 through 99 and 14 CFR parts 200 through 212	2008	2009
2	48 CFR parts 1201 through 1253 and new parts and subparts	2009	2010
3	14 CFR parts 213 through 232	2010	2011
4	14 CFR parts 234 through 254	2011	2012
5	14 CFR parts 255 through 298 and 49 CFR part 40	2012	2013
6	14 CFR parts 300 through 373	2013	2014
7	14 CFR parts 374 through 398	2014	2015
8	14 CFR part 399 and 49 CFR parts 1 through 11	2015	2016
9	49 CFR parts 17 through 28	2016	2017
10	49 CFR parts 29 through 39 and parts 41 through 89	2017	2018

Year 1 (Fall 2008) List of Rules Analyzed and Summary of Results

49 CFR part 95—Advisory Committees

• Section 610: The agency has determined that the rule does not have a significant economic impact on a substantial number of small entities.

• General: The agency plans to remove part 95 because it has been made obsolete by other laws, regulations, and agency procedures. Removal of these regulations would be cost effective and impose no burdens. Since the regulations will be removed, a review for plain language is not necessary.

Year 1 (Fall 2008) List of Rules With Ongoing Analysis

49 CFR part 91—International Air Transportation Fair Competitive Practices
49 CFR part 92—Recovering Debts to the United States by Salary Offset
49 CFR part 98—Enforcement of Restrictions on Post-Employment Activities
49 CFR part 99—Employee Responsibilities and Conduct
14 CFR part 200—Definitions and Instructions
14 CFR part 201—Air Carrier Authority Under Subtitle VII of Title 49 of the United States Code [Amended]
14 CFR part 203—Waiver of Warsaw Convention Liability Limits and Defenses
14 CFR part 204—Data to Support Fitness Determinations
14 CFR part 205—Aircraft Accident Liability Insurance
14 CFR part 206—Certificates of Public Convenience and Necessity: Special Authorizations and Exemptions
14 CFR part 207—Charter Trips by U.S. Scheduled Air Carriers
14 CFR part 208—Charter Trips by U.S. Charter Air Carriers
14 CFR part 211—Applications for Permits to Foreign Air Carriers
14 CFR part 212—Charter Rules for U.S. and Foreign Direct Air Carriers

Year 3 (Fall 2010) List of Rules With Ongoing Analysis

14 CFR part 213—Terms, Conditions, and Limitations of Foreign Air Carrier Permits
14 CFR part 214—Terms, Conditions, and Limitations of Foreign Air Carrier Permits Authorizing Charter Transportation Only
14 CFR part 215—Use and Change of Names of Air Carriers, Foreign Air Carriers, and Commuter Air Carriers
14 CFR part 216—Comingling of Blind Sector Traffic by Foreign Air Carriers
14 CFR part 217—Reporting Traffic Statistics by Foreign Air Carriers in Civilian Scheduled, Charter, and Nonscheduled Services
14 CFR part 218—Lease by Foreign Air Carrier or Other Foreign Person of Aircraft With Crew
14 CFR part 221—Tariffs
14 CFR part 222—Intermodal Cargo Services by Foreign Air Carriers
14 CFR part 223—Free and Reduced-Rate Transportation
14 CFR part 232—Transportation of Mail, Review of Orders of Postmaster General

Year 4 (Fall 2011) List of Rules Analyzed and Summary of Results

14 CFR part 234—Airline Service Quality Performance Reports

• Section 610: The agency has determined that the existing rule does not have a significant effect on a substantial number of small entities.

• General: The Department is anticipating proposing changes to the existing rule to expand the on-time performance ''reporting carrier'' pool to include smaller carriers to enable the Department to obtain and provide to the flying public a more complete picture of the performance of scheduled passenger service in general. Also, in July 2011, the Department proposed to change the way the Department computes mishandled baggage rates from mishandled baggage reports per domestic enplanement to mishandled bags per checked bags as the Department believes that the current matrix for comparing airline mishandled baggage information is outdated. OST's plain language review indicates no need for substantial revision.

14 CFR part 250—Oversales

• Section 610: Certain elements of this existing rule impose requirements on certain small air carriers but the Department has determined that the economic impact is not significant.

• General: The Department made some changes to this part in April 2008 and April 2011. No additional changes are needed. These regulations are cost effective and impose the least burden as all air carriers have control over the extent to which the rule impacts them because they control their own overbooking rates. OST's plain language review indicates no need for substantial revision.

14 CFR part 252—Smoking Aboard Aircraft

• Section 610: The agency has determined that the existing rule does not have a significant effect on a substantial number of small entities.

• General: In September 2011, the Department proposed to change the existing rule to explicitly ban the smoking of electronic cigarettes on air carriers and foreign air carrier flights in scheduled intrastate, interstate and foreign air transportation. The Department is also considering banning smoking on charter flights with 19 or more passenger seats in part out of concern about the health effects of second hand smoke on flight attendants aboard such flights. Carriers that provide air transportation exclusively with aircraft that seat no more than 60 passenger seats are considered to be small entities. OST's plain language review indicates no need for substantial revision.

14 CFR part 253—Notice of Terms of Contract of Carriage

• Section 610: The agency has determined that the existing rule does not have a significant effect on a substantial number of small entities.

• General: A minor change to a provision in this part regarding retroactive changes to contracts of carriage was finalized in 2009. No additional changes are needed. These regulations are cost effective. OST's plain language review indicates no need for substantial revision.

14 CFR part 254—Domestic Baggage Liability

• Section 610: The agency has determined that the existing rule does not have a significant effect on a substantial number of small entities.

• General: The Department periodically raises the minimum limit on domestic baggage liability applicable to air carriers to reflect inflation. The Department anticipates adjusting the minimum limit of liability from the current amount of $3,300 announced by the Department in November 2008 to $3,400, to take into account the changes in consumer prices since the prior revision. This revision would affect only flight segments operated with large aircraft and other flight segments appearing on the same ticket as a large-aircraft segment. As a result, many operations of small entities, such as air taxis and many commuter air carriers, would not be covered by the rule. OST's plain language review indicates no need for substantial revision.

Year 4 (Fall 2011) List of Rules With Ongoing Analysis

14 CFR part 240—Inspection of Accounts and Property
14 CFR part 241—Uniform System of Accounts and Reports for Large Certificated Air Carriers
14 CFR part 243—Passenger Manifest Information

14 CFR part 247—Direct Airport-to-Airport Mileage Records

14 CFR part 248—Submission of Audit Reports

14 CFR part 249—Preservation of Air Carrier Records

Year 5 (Fall 2012) List of Rules To Be Analyzed During the Next Year

14 CFR part 255—Airline Computer Reservations Systems

14 CFR part 256—[Reserved]

14 CFR part 271—Guidelines for Subsidizing Air Carriers Providing Essential Air Transportation

14 CFR part 272—Essential Air Service to the Freely Associated States

14 CFR part 291—Cargo Operations in Interstate Air Transportation

14 CFR part 292—International Cargo Transportation

14 CFR part 293—International Passenger Transportation

14 CFR part 294—Canadian Charter Air Taxi Operators

14 CFR part 296—Indirect Air Transportation of Property

14 CFR part 297—Foreign Air Freight Forwarders and Foreign Cooperative Shippers Associations

14 CFR part 298—Exemptions for Air Taxi and Commuter Air Carrier Operations

Year 5 (Fall 2012) List of Rules Analyzed and a Summary of Results

14 CFR part 257—Disclosure of Code-Sharing Arrangements and Long-Term Wet Leases

• Section 610: The agency has determined that the existing rule does not have a significant effect on a substantial number of small entities.

• General: The Department is anticipating proposing changes to the existing rule to codify the requirements in a statute (49 U.S.C. 41712(c)) and the Department's enforcement policy with respect to Web site disclosure of code-share and long term wet lease arrangements. OST's plain language review indicates no need for substantial revision.

14 CFR part 258—Disclosure of Change-of-Gauge Services

• Section 610: The agency has determined that the rule does not have a significant effect on a substantial number of small entities.

• General: No changes are needed. These regulations are cost effective and impose the least burden. OST's plain language review indicates no need for substantial revision.

14 CFR part 259—Enhanced Protections for Airline Passengers

• Section 610: This rule imposes requirements on small air carriers but the Department believes that the economic impact will not be significant

• General: The Department is anticipating proposing changes to the existing rule to require comfortable cabin temperatures when there is a lengthy tarmac delay and to require a marketing carrier provide assistance to its code-share partner when a flight operated by the code share partner experiences a lengthy tarmac delay. OST's plain language review indicates no need for substantial revision.

FEDERAL AVIATION ADMINISTRATION

Section 610 Review Plan

The FAA has elected to use the two-step, two-year process used by most DOT modes in past plans. As such, the FAA has divided its rules into 10 groups as displayed in the table below. During the first year (the ''*analysis year*''), all rules published during the previous 10 years within a 10% block of the regulations will be *analyzed* to identify those with a SEIOSNOSE. During the second year (the ''*review year*''), each rule identified in the analysis year as having a SEIONOSE will be *reviewed* in accordance with Section 610(b) to determine if it should be continued without change or changed to minimize impact on small entities. Results of those reviews will be published in the DOT Semiannual Regulatory Agenda.

Year	Regulations to be reviewed	Analysis year	Review year
1	14 CFR parts 119 through 129 and parts 150 through 156	2008	2009
2	14 CFR parts 133 through 139 and parts 157 through 169	2009	2010
3	14 CFR parts 141 through 147 and parts 170 through 187	2010	2011
4	14 CFR parts 189 through 198 and parts 1 through 16	2011	2012
5	14 CFR parts 17 through 33	2012	2013
6	14 CFR parts 34 through 39 and parts 400 through 405	2013	2014
7	14 CFR parts 43 through 49 and parts 406 through 415	2014	2015
8	14 CFR parts 60 through 77	2015	2016
9	14 CFR parts 91 through 105	2016	2017
10	14 CFR parts 417 through 460	2017	2018

Year 5 (2012) List of Rules Analyzed and Summary of Results

14 CFR part 17—Procedures for Protests and Contract Disputes

• Section 610: The agency conducted a Section 610 review of this part and found no SEISNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FAA's plain language review of these rules indicates no need for substantial revision.

14 CFR part 21—Certification Procedures for Products and Parts

• Section 610: The agency conducted a Section 610 review of this part and found no SEISNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FAA's plain language review of these rules indicates no need for substantial revision.

14 CFR part 23—Airworthiness Standards: Normal, Utility, Acrobatic, and Commuter Category Airplanes

• Section 610: The agency conducted a Section 610 review of this part and found no SEISNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FAA's plain language review of these rules indicates no need for substantial revision.

14 CFR part 25—Airworthiness Standards: Transport Category Airplanes

• Section 610: The agency conducted a Section 610 review of this part and found that the SEISNOSE no longer exists.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FAA's plain language review of these rules indicates no need for substantial revision.

14 CFR part 26—Continued Airworthiness and Safety Improvements for Transport Category Airplanes

• Section 610: The agency conducted a Section 610 review of this part and found no SEISNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FAA's plain language review of these rules indicates no need for substantial revision.

14 CFR part 27—Airworthiness Standards: Normal Category Rotorcraft

• Section 610: The agency conducted a Section 610 review of this part and found no SEISNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FAA's plain language review of these rules indicates no need for substantial revision.

14 CFR part 29—Airworthiness Standards: Transport Category Rotorcraft

• Section 610: The agency conducted a Section 610 review of this part and found no SEISNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FAA's plain language review of these rules indicates no need for substantial revision.

14 CFR part 31—Airworthiness Standards: Manned Free Balloons

• Section 610: The agency conducted a Section 610 review of this part and found no SEISNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FAA's plain language review of these rules indicates no need for substantial revision.

14 CFR part 33—Airworthiness Standards: Aircraft Engines

• Section 610: The agency conducted a Section 610 review of this part and found no SEISNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FAA's plain language review of these rules indicates no need for substantial revision.

Year 6 (2013) List of Rules To Be Analyzed During the Next Year

14 CFR part 34—Fuel venting and exhaust emission requirements for turbine engine powered airplanes
14 CFR part 35—Airworthiness standards: Propellers
14 CFR part 36—Noise standards: Aircraft type and airworthiness certification
14 CFR part 39—Airworthiness directives
14 CFR part 400—Basis and scope
14 CFR part 401—Organization and definitions
14 CFR part 404—Regulations and licensing requirements
14 CFR part 405—Investigations and enforcement

FEDERAL HIGHWAY ADMINISTRATION

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	None	2008	2009
2	23 CFR parts 1 to 260	2009	2010
3	23 CFR parts 420 to 470	2010	2011
4	23 CFR part 500	2011	2012
5	23 CFR parts 620 to 637	2012	2013
6	23 CFR parts 645 to 669	2013	2014
7	23 CFR 710 to 924	2014	2015
8	23 CFR 940 to 973	2015	2016
9	23 CFR parts 1200 to 1252	2016	2017
10	New parts and subparts	2017	2018

Federal-Aid Highway Program

The FHWA has adopted regulations in title 23 of the CFR, chapter I, related to the Federal-Aid Highway Program. These regulations implement and carry out the provisions of Federal law relating to the administration of Federal aid for highways. The primary law authorizing Federal aid for highways is chapter I of title 23 of the U.S.C. Section 145 of title 23 expressly provides for a federally assisted State program. For this reason, the regulations adopted by the FHWA in title 23 of the CFR primarily relate to the requirements that States must meet to receive Federal funds for the construction and other work related to highways. Because the regulations in title 23 primarily relate to States, which are not defined as small entities under the Regulatory Flexibility Act, the FHWA believes that its regulations in title 23 do not have a significant economic impact on a substantial number of small entities. The FHWA solicits public comment on this preliminary conclusion.

Year 4 (Fall 2011) List of Rules Analyzed and a Summary of Results

23 CFR part 500—Management and Monitoring Systems

• Section 610: No SEIOSNOSE. No small entities are affected.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FHWA's plain language review of these rules indicates no need for substantial revision.

Year 5 (Fall 2012) List of Rules That Will be Analyzed During the Next Year

23 CFR part 620—Engineering

23 CFR part 625—Design Standards for Highways

23 CFR part 626—Pavement Policy

23 CFR part 627—Value Engineering

23 CFR part 630—Preconstruction Procedures

23 CFR part 633—Required Contract Provisions

23 CFR part 635—Construction and Maintenance

23 CFR part 636—Design-build Contracting

23 CFR part 637—Construction Inspection and Approval

FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	49 CFR part 372, subpart A	2008	2009
2	49 CFR part 386	2009	2010
3	49 CFR parts 325 and 390 (General)	2010	2011
4	49 CFR parts 390 (Small Passenger-Carrying Vehicles), 391 to 393 and 396 to 399.	2011	2012
5	49 CFR parts 387	2012	2013
6	49 CFR parts 356, 367, 369 to 371, 372 (subparts B and C)	2013	2014
7	49 CFR parts 373, 374, 376, and 379	2014	2015
8	49 CFR parts 360, 365, 366, and 368	2015	2016
9	49 CFR parts 377, 378	2016	2017
10	49 CFR part 395	2017	2018

Year 1 (Fall 2008) List of Rules Analyzed and a Summary of Results

49 CFR part 372—Exemptions from the operating authority regulations applicable to for-hire motor carriers

• Section 610: There is no SEIOSNOSE. No small entities are affected.

• General: No changes are needed. These regulations provide exemptions from the requirements for certain for-hire motor carriers to apply for operating authority from FMCSA. The regulations reduce the regulatory burden on small businesses by enabling certain for-hire carriers to conduct business without being required to apply for operating authority. The regulations are cost effective and impose the least burden. FMCSA's plain language review of these rules indicates no need for substantive revision.

Year 2 (Fall 2009) List of Rules Analyzed and a Summary of Results

49 CFR part 386—Rules of Practice for Motor Carrier, Broker, Freight Forwarder, and Hazardous Materials Proceedings

• Section 610: There is a SEIOSNOSE, as a significant number of small entities may be affected by legal fees and safety consultants' fees associated with preparing an adequate response to FMCSA notices of claims and notices of violations and the submission of corrective action plans following an unsuccessful new entrant audit or compliance review. It was found that the cost for legal representation and other costs for a formal hearing to appeal a decision may have a significant impact on small firms. However, these proceedings would only come about if the regulated entity failed to comply with applicable Federal regulations and FMCSA initiated enforcement action as a result of non-compliance.

Subpart D, ''General Rules and Hearings,'' addresses rules and procedures for the conduct of formal hearings. The principal economic impact of part 386 is the cost to a small firm of defending itself under these procedures. However, as noted above, carriers that achieve compliance with FMCSA's commercial and safety regulations would not be subject to enforcement actions and therefore would not undergo such procedures.

• General: The Agency considered whether the rules of practice impose unnecessary burdens on small businesses that undergo enforcement actions as a result of non-compliance with the Agency's commercial and safety regulations. The Agency concluded that the rules of practice do not impose unnecessary burdens on such businesses when they achieve compliance with the applicable safety and hazardous materials regulations.

Year 3 (Fall 2010) List of Rules with Ongoing Analysis

49 CFR part 325—Compliance with Interstate Motor Carrier Noise Emission

49 CFR part 390—Federal Motor Carrier Safety Regulations, General

• *This rule was moved up from Year 4 as a result of the Department's Retrospective Regulatory Review.*

Year 4 (Fall 2011) List of Rules with Ongoing Analysis

49 CFR part 391—Driver Qualifications

49 CFR part 392—Driving of Commercial Motor Vehicles

49 CFR part 393—Parts and Accessories Necessary for Safe Operation

49 CFR part 396—Inspection, Repair and Maintenance of Commercial Motor Vehicles

49 CFR part 397—Transportation of Hazardous Materials; Driving and Parking Rules

49 CFR part 398—Transportation of Migrant Workers

49 CFR part 399—Employee Safety and Health Standards

Year 5 (Fall 2012) List of Rule(s) That Will Be Analyzed This Year

49 CFR part 387—Minimum Levels of Financial Responsibility for Motor Carriers

NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	49 CFR parts 571.223 through 571.500, and parts 575 and 579	2008	2009
2	23 CFR parts 1200 through 1300	2009	2010
3	49 CFR parts 501 through 526 and 571.213	2010	2011
4	49 CFR parts 571.131, 571.217, 571.220, 571.221, and 571.222	2011	2012
5	49 CFR parts 571.101 through 571.110, and 571.135, 571.138 and 571.139.	2012	2013
6	49 CFR parts 529 through 578, except parts 571 and 575	2013	2014
7	49 CFR parts 571.111 through 571.129 and parts 580 through 588	2014	2015
8	49 CFR parts 571.201 through 571.212	2015	2016
9	49 CFR parts 571.214 through 571.219, except 571.217	2016	2017
10	49 CFR parts 591 through 595 and new parts and subparts	2017	2018

Year 4 (Fall 2011) List of Rules Analyzed and a Summary of the Results

49 CFR part 571.131—School Bus Pedestrian Safety Devices

• Section 610: There is no SEIOSNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. NHTSA's plain language review of these rules indicates no need for substantial revision.

49 CFR part 571.217—Bus Emergency Exits and Window Retention and Release

• Section 610: There is no SEIOSNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. NHTSA's plain language review of these rules indicates no need for substantial revision.

49 CFR part 571.220—School Bus Rollover Protection

• Section 610: There is no SEIOSNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. NHTSA's plain language review of these rules indicates no need for substantial revision.

49 CFR part 571.221—School Bus Body Joint Strength

• Section 610: There is no SEIOSNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. NHTSA's plain language review of these rules indicates no need for substantial revision.

49 CFR part 571.222—School Bus Passenger Seating and Crash Protection

• Section 610: There is no SEIOSNOSE.

• General: No changes are needed. These regulations are cost effective and impose the least burden. NHTSA's plain language review of these rules indicates no need for substantial revision.

Year 5 (Fall 2012) List of Rules That Will Be Analyzed During the Next Year

49 CFR part 571.101—Controls and Displays

49 CFR part 571.102—Transmission Shift Position Sequence, Starter Interlock, and Transmission Braking Effect

49 CFR part 571.103—Windshield Defrosting and Defogging Systems

49 CFR part 571.104—Windshield Wiping and Washing Systems

49 CFR part 571.105—Hydraulic and Electric Brake Systems

49 CFR part 571.106—Brake Hoses

49 CFR part 571.107—[Reserved]

49 CFR part 571.108—Lamps, Reflective Devices, and Associated Equipment

49 CFR part 571.109—New Pneumatic and Certain Specialty Tires

49 CFR part 571.110—Tire Selection and Rims and Motor Home/Recreation Vehicle Trailer Load Carrying Capacity Information for Motor Vehicles with a GVWR of 4,536 Kilograms (10,000 Pounds) or Less

49 CFR part 571.135—Light Vehicle Brake Systems

49 CFR part 571.138—Tire Pressure Monitoring Systems

49 CFR part 571.139—New Pneumatic Radial Tires for Light Vehicles

FEDERAL RAILROAD ADMINISTRATION

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	49 CFR parts 200 and 201	2008	2009
2	49 CFR parts 207, 209, 211, 215, 238, and 256	2009	2010
3	49 CFR parts 210, 212, 214, 217, and 268	2010	2011
4	49 CFR part 219	2011	2012
5	49 CFR parts 218, 221, 241, and 244	2012	2013
6	49 CFR parts 216, 228, and 229	2013	2014
7	49 CFR parts 223 and 233	2014	2015
8	49 CFR parts 224, 225, 231, and 234	2015	2016
9	49 CFR parts 222, 227, 235, 236, 250, 260, and 266	2016	2017
10	49 CFR parts 213, 220, 230, 232, 239, 240, and 265	2017	2018

Year 4 (Fall 2011) List of Rules Analyzed and a Summary of Results

49 CFR part 219—Control of Alcohol and Drug Use

• Section 610: There is no SEIOSNOSE.

• General: No changes are needed. This rule is cost effective and imposes the least burden. FRA's plain language review of this rule indicates no need for substantial revision.

Year 5 (Fall 2012) List of Rule(s) That Will Be Analyzed During Next Year

49 CFR part 218—Control of Alcohol and Drug Use

49 CFR part 221—Rear End Marking Device Passenger, Commuter and Freight Trains

49 CFR part 241—United States Locational Requirement for Dispatching of United States Rail Operations.

49 CFR part 244—Regulations on Safety Integration Plans Governing Railroad Consolidations, Mergers, and Acquisitions of Control

FEDERAL TRANSIT ADMINISTRATION

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	49 CFR parts 604, 605, and 633	2008	2009
2	49 CFR parts 661 and 665	2009	2010
3	49 CFR part 633	2010	2011
4	49 CFR parts 609 and 611	2011	2012
5	49 CFR parts 613 and 614	2012	2013
6	49 CFR part 622	2013	2014
7	49 CFR part 630	2014	2015
8	49 CFR part 639	2015	2016
9	49 CFR parts 659 and 663	2016	2017

Year	Regulations to be reviewed	Analysis year	Review year
10	49 CFR part 665	2017	2018

Year 3 (Fall 2010) List of Rules Analyzed and Summary of Results

49 CFR part 605—School Bus Operations

• Section 610: The agency has determined that the rule does not have a significant effect on a substantial number of small entities.

• General: No changes are needed. These regulations are cost effective and impose the least burden. FTA's plain language review indicates no need for substantial revision.

Year 4 (Fall 2011) List of Rules With Ongoing Analysis

49 CFR part 609—Transportation for Elderly and Handicapped Persons

Year 5 (Fall 2012) List of Rule(s) That Will Be Analyzed During the Next Year

49 CFR part 613—Planning Assistance and Standards

49 CFR part 614—Transportation Infrastructure Management

MARITIME ADMINISTRATION

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	46 CFR parts 201 through 205	2008	2009
2	46 CFR parts 221 through 232	2009	2010
3	46 CFR parts 249 through 296	2010	2011
4	46 CFR parts 221, 298, 308, and 309	2011	2012
5	46 CFR parts 307 through 309	2012	2013
6	46 CFR part 310	2013	2014
7	46 CFR parts 315 through 340	2014	2015
8	46 CFR parts 345 through 381	2015	2016
9	46 CFR parts 382 through 389	2016	2017
10	46 CFR parts 390 through 393	2017	2018

Year 4 (Fall 2011) List of Rules With Ongoing Analysis

46 CFR part 381—Cargo Preference—U.S.-Flag Vessels

46 CFR part 383—Cargo Preference—Compromise, Assessment, Mitigation, Settlement & Collection of Civil Penalties

46 CFR part 221—Foreign Transfer Regulations

46 CFR part 249—Approval of Underwriters for Marine Hull Insurance

46 CFR part 272—Requirements and Procedures for Conducting Condition Surveys and Administering Maintenance and Repair Subsidy

46 CFR part 287—Establishment of Construction Reserve Funds

46 CFR part 295—Maritime Security Program (MSP)

46 CFR part 296—Maritime Security Program (MSP)

Year 5 (2012) List of Rules That Will Be Analyzed During the Next Year

46 CFR part 307—Mandatory Position Report System for Vessels

46 CFR part 308—War Risk Insurance

46 CFR part 309—War Risk Ship Valuation

PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION (PHMSA)

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	49 CFR part 178	2008	2009
2	49 CFR parts 178 through 180	2009	2010
3	49 CFR parts 172 and 175	2010	2011
4	49 CFR part 171, sections 171.15 and 171.16	2011	2012
5	49 CFR parts 106, 107, 171, 190, and 195	2012	2013
6	49 CFR parts 174, 177, 191, and 192	2013	2014
7	49 CFR parts 176 and 199	2014	2015
8	49 CFR parts 172 through 178	2015	2016
9	49 CFR parts 172, 173, 174, 176, 177, and 193	2016	2017
10	49 CFR parts 173 and 194	2017	2018

Year 4 (Fall 2011) List of rules analyzed and a summary of results

49 CFR section 171.15—Immediate Notice Of Certain Hazardous Materials Incidents

• Section 610: There is no SEIOSNOSE. Annually fewer than 100 small entities are required to file a report telephonic report. Therefore, though some small entities may be affected the economic impact on small entities will not be significant.

• General: This rule prescribes requirements for the immediate notice of certain hazardous materials incidents by telephone to the National Response

Center (NRC). The primary function of the National Response Center is to serve as the sole national point of contact for reporting all oil, chemical, radiological, biological, and etiological discharges into the environment anywhere in the United States and its territories. In addition to gathering and distributing spill data for Federal On-Scene Coordinators and serving as the communications and operations center for the National Response Team, the NRC maintains agreements with a variety of Federal entities to make additional notifications regarding incidents meeting established trigger criteria. Section 171.15(b) establishes the trigger criteria for a reportable hazardous materials incident. PHMSA's plain language review of this rule indicates no need for substantial revision.

49 CFR section 171.16—Detailed Hazardous Materials Incident Reports

• Section 610: There is no SEIOSNOSE. Based on a review of detailed incident reports PHMSA found that only 3 percent of the nearly 15,000 incidents reports submitted in FY2011 were filed by small entities. Therefore, though some small entities may be affected the economic impact on small entities will not be significant.

• General: This rule prescribes requirements for detailed hazardous materials incident reports. PHMSA relies on this data and information to evaluate the effectiveness of the existing regulations; determine the need for regulatory changes to cover changing transportation safety problems; and identify major problem areas that should receive priority attention. In addition, both government and industry use this information to chart trends, identify problems and training inadequacies, evaluate packaging, and assess ways to reduce hazardous materials releases. In FY2011 PHMSA accepted two petitions for rulemaking (P–1562; PHMSA–2010–0207 and P–1566; PHMSA–2010–0225) that request revisions to the incident reporting requirements. As a result of these petitions, PHMSA is currently conducting research to evaluate the effectiveness of the requirements for detailed hazardous materials incident reporting in section 171.16. PHMSA concluded this study in FY2012. Based on the results of the study PHMSA is considering regulatory action to address its findings, the petitions, and simplify the incident reporting process. PHMSA's plain language review of this rule indicates no need for substantial revision.

Year 5 (Fall 2012) List of rules that will be analyzed during the next year

49 CFR part 106—Rulemaking Procedures

49 CFR part 107—Hazardous Materials Program Procedures

49 CFR part 171—General Information, Regulations, and Definitions

49 CFR part 190—Pipeline Safety Programs and Rulemaking Procedures

49 CFR part 195—Transportation of Hazardous liquids by Pipeline

RESEARCH AND INNOVATIVE TECHNOLOGY ADMINISTRATION (RITA)

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	14 CFR part 241, form 41	2008	2009
2	14 CFR part 241, schedule T–100, and part 217	2009	2010
3	14 CFR part 298	2010	2011
4	14 CFR part 241, section 19–7	2011	2012
5	14 CFR part 291	2012	2013
6	14 CFR part 234	2013	2014
7	14 CFR part 249	2014	2015
8	14 CFR part 248	2015	2016
9	14 CFR part 250	2016	2017
10	14 CFR part 374a, ICAO	2017	2018

Year 1 (Fall 2008) List of Rules With Ongoing Analysis

14 CFR part 241—Uniform System of Accounts and Reports for Large Certificated Air Carriers, Form 41

Year 3 (Fall 2010) List of Rules With Ongoing Analysis

14 CFR part 298 subpart f—Exemptions for Air Taxi and Commuter Air Carrier Operations—Reporting Requirements

Year 4 (Fall 2011) List of Rules With Ongoing Analysis

14 CFR part 241, section 19–7—Passenger Origin-Destination Survey

Year 5 (Fall 2012) List of Rules That Will Be Analyzed During the Next Year

14 CFR part 291—Caro Operations in Interstate Air Transportation

SAINT LAWRENCE SEAWAY DEVELOPMENT CORPORATION

Section 610 and Other Reviews

Year	Regulations to be reviewed	Analysis year	Review year
1	33 CFR parts 401 through 403	2008	2009

Year 1 (Fall 2008) List of Rules With Ongoing Analysis

33 CFR part 401—Seaway Regulations and Rules

33 CFR part 402—Tariff of Tolls

33 CFR part 403—Rules of Procedure of the Joint Tolls Review Board

OFFICE OF THE SECRETARY—PROPOSED RULE STAGE

Sequence No.	Title	Regulation identifier No.
337	+Enhancing Airline Passenger Protections III	2105–AE11

+ DOT-designated significant regulation.

OFFICE OF THE SECRETARY—FINAL RULE STAGE

Sequence No.	Title	Regulation identifier No.
338	+Use of the Seat-Strapping Method for Carrying a Wheelchair on an Aircraft	2105–AD87

+ DOT-designated significant regulation.

FEDERAL AVIATION ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation identifier No.
339	+Operation and Certification of Small Unmanned Aircraft Systems (sUAS)	2120–AJ60
340	+Flight Crewmember Mentoring, Leadership and Professional Development (HR 5900).	2120–AJ87

+ DOT-designated significant regulation.

FEDERAL AVIATION ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation identifier No.
341	+Qualification, Service, and Use of Crewmembers and Aircraft Dispatchers	2120–AJ00
342	+Pilot Certification and Qualification Requirements (Formerly First Officer Qualification Requirements) (HR 5900).	2120–AJ67
343	+Safety Management Systems for Certificate Holders **(Section 610 Review)**	2120–AJ86

+ DOT-designated significant regulation.

FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation identifier No.
344	+Electronic Logging Devices and Hours of Service Supporting Documents	2126–AB20
345	+Inspection, Repair, and Maintenance; Driver-Vehicle Inspection Report (RRR)	2126–AB46

+ DOT-designated significant regulation.

FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation identifier No.
346	+Unified Registration System	2126–AA22
347	Self Reporting of Out-of-State Convictions (RRR) **(Section 610 Review)**	2126–AB43

+ DOT-designated significant regulation.

FEDERAL RAILROAD ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation identifier No.
348	+Critical Incident Stress Plan; "Critical Incident" Definition	2130–AC00
349	Risk Reduction Program (RRR)	2130–AC11
350	+Positive Train Control Systems: De Minimis Exception, Yard Movements, En Route Failures; Miscellaneous Grade Crossing/Signal and Train Control Amendments (RRR).	2130–AC32

+ DOT-designated significant regulation.

FEDERAL RAILROAD ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation identifier No.
351	Roadway Worker Protection; Miscellaneous Revisions	2130–AB89
352	+Training Standards for Railroad Employees (RRR)	2130–AC06
353	+Emergency Escape Breathing Apparatus (RRR)	2130–AC14
354	Passenger Train Emergency Systems; Doors, Emergency Lighting, Emergency Signage and Markings for Egress and Access, and Low-Location Emergency Exit Path Marking; Miscellaneous Amendments.	2130–AC22
355	Amendments Expanding the Drug Panel for FRA Post-Accident Toxicological Testing.	2130–AC24
356	Track Safety Standards: Improving Rail Integrity (RRR)	2130–AC28
357	Railroad System Safety Program	2130–AC31
358	Revisions to Passenger Train Emergency Preparedness Regulations	2130–AC33
359	Roadway Worker Protection; Adjacent-Track On-Track Safety—Response to Petitions for Reconsideration.	2130–AC37
360	Telephonic Notification at Grade Crossings—Response to Petitions for Reconsideration.	2130–AC38
361	Locomotive Safety Standards Amendments—Response to Petitions for Reconsideration.	2130–AC39

+ DOT-designated significant regulation.

PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation identifier No.
362	+Pipeline Safety: Safety of On-Shore Liquid Hazardous Pipelines	2137–AE66
363	Pipeline Safety: Miscellaneous Amendments Related to Reauthorization and Petitions for Rulemaking (RRR).	2137–AE94

+ DOT-designated significant regulation.

PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation identifier No.
364	+Hazardous Materials: Revisions to Requirements for the Transportation of Lithium Batteries.	2137–AE44
365	Hazardous Materials: Miscellaneous Amendments (RRR) **(Section 610 Review)**	2137–AE78

+ DOT-designated significant regulation.

MARITIME ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation identifier No.
366	+Regulations To Be Followed by All Departments, Agencies and Shippers Having Responsibility To Provide a Preference for U.S.-Flag Vessels in the Shipment of Cargoes on Ocean Vessels (RRR).	2133–AB74

+ DOT-designated significant regulation.

DEPARTMENT OF TRANSPORTATION (DOT)

Office of the Secretary (OST)

Proposed Rule Stage

337. +Enhancing Airline Passenger Protections III

Legal Authority: 49 U.S.C. 41712; 49 U.S.C. 40101;49 U.S.C. 41702

Abstract: This rulemaking would address the following issues: (1) Whether the Department should require a marketing carrier to provide assistance to its code-share partner when a flight operated by the code-share partner experiences a lengthy tarmac delay; (2) whether the Department should enhance disclosure requirements on code-share operations, including requiring on-time performance data, reporting of certain data code-share operations, and codifying the statutory amendment of 49 U.S.C. 41712(c) regarding Web site schedule disclosure of code-share operations; (3) whether the Department should expand the on-time performance ''reporting carrier'' pool to include smaller carriers; (4) whether the Department should require travel agents to adopt minimum customer service standards in relation to the sale of air transportation; (5) whether the Department should require ticket agents to disclose the carriers whose tickets they sell or do not sell and information regarding any incentive payments they receive in connection with the sale of air transportation; (6) whether the Department should require ticket agents to disclose any preferential display of individual fares or carriers in the ticket agent's Internet displays; (7) whether the Department should require additional or special disclosures regarding certain substantial fees, e.g.,

oversize or overweight baggage fees; (8) whether the Department should prohibit post-purchase price increase for all services and products not purchased with the ticket or whether it is sufficient to prohibit post-purchase prices increases for baggage charges that traditionally have been included in the ticket price; and (9) whether the Department should require that ancillary fees be displayed through all sale channels.

Timetable:

Action	Date	FR Cite
Supplemental NPRM	05/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Blane A. Workie, Attorney, Department of Transportation, Office of the Secretary, 1200 New Jersey Avenue SE., Washington, DC 20590, *Phone:* 202–366–9342, *TDD Phone:* 202–755–7687, *Fax:* 202–366–7152, *Email: blane.workie@ost.dot.gov.*

RIN: 2105–AE11

DEPARTMENT OF TRANSPORTATION (DOT)

Office of the Secretary (OST)

Final Rule Stage

338. +Use of the Seat-Strapping Method for Carrying a Wheelchair on an Aircraft

Legal Authority: 49 U.S.C. 41705

Abstract: This rulemaking would address whether carriers should be allowed to utilize the seat-strapping method to stow a passenger´s wheelchair in the aircraft cabin.

Timetable:

Action	Date	FR Cite
NPRM	06/03/11	76 FR 32107
NPRM Comment Period End.	08/02/11	
Final Rule	01/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Blane A Workie, Attorney, Department of Transportation, Office of the Secretary, 1200 New Jersey Avenue SE., Washington, DC 20590, *Phone:* 202–366–9342, *TDD Phone:* 202–755–7687, *Fax:* 202–366–7152, *Email: blane.workie@ost.dot.gov.*

RIN: 2105–AD87

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION (DOT)

Federal Aviation Administration (FAA)

Proposed Rule Stage

339. +Operation and Certification of Small Unmanned Aircraft Systems (SUAS)

Legal Authority: 49 U.S.C. 44701; Pub. L. 112–95

Abstract: This rulemaking would enable small unmanned aircraft to safely operate in limited portions of the national airspace system (NAS). This action is necessary because it addresses the novel legal or policy issues about the minimum safety parameters for operating recreational remote control model and toy aircraft in the NAS. The intended effect of this action is to develop requirements and standards to ensure that risks are adequately mitigated, such that safety is maintained for the entire aviation community.

Timetable:

Action	Date	FR Cite
NPRM	06/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Stephen A Glowacki, Department of Transportation, Federal Aviation Administration, 800 Independence Ave. SW., Washington, DC 20591, *Phone:* 202–385–4898, *Email: stephen.a.glowacki@faa.gov.*

RIN: 2120–AJ60

340. +Flight Crewmember Mentoring, Leadership and Professional Development (HR 5900)

Legal Authority: 49 U.S.C. 44701(a)(5); Pub. L. 111–216, sec 206

Abstract: This rulemaking would amend the regulations for air carrier training programs under part 121. The action is necessary to ensure that air carriers establish or modify training programs that address mentoring, leadership, and professional development of flight crewmembers in part 121 operations. The amendments are intended to contribute significantly to airline safety by reducing aviation accidents and respond to the mandate in Public Law 111–216.

Timetable:

Action	Date	FR Cite
NPRM	02/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Deke Abbott, Department of Transportation, Federal Aviation Administration, 800 Independence Ave. SW., Washington, DC 20591, *Phone:* 202–267–8266, *Email: deke.abbott@faa.gov.*

RIN: 2120–AJ87

DEPARTMENT OF TRANSPORTATION (DOT)

Federal Aviation Administration (FAA)

Final Rule Stage

341. +Qualification, Service, and Use of Crewmembers and Aircraft Dispatchers

Legal Authority: 49 U.S.C. 106(g); 49 U.S.C. 40113; 49 U.S.C. 40119; 49 U.S.C. 44101; 49 U.S.C. 44701; 49 U.S.C. 44702; 49 U.S.C. 44705; 49 U.S.C. 44709 to 44711; 49 U.S.C. 44713; 49 U.S.C. 44716; 49 U.S.C. 44717; 49 U.S.C. 44722; 49 U.S.C. 44901; 49 U.S.C. 44903; 49 U.S.C. 44904; 49 U.S.C. 44912; 49 U.S.C. 46105

Abstract: This rulemaking would amend the regulations for crewmember and dispatcher training programs in domestic, flag, and supplemental operations. The rulemaking would enhance traditional training programs by requiring the use of flight simulation training devices for flight crewmembers and including additional training requirements in areas that are critical to safety. The rulemaking would also reorganize and revise the qualification and training requirements. The changes are intended to contribute significantly to reducing aviation accidents.

Timetable:

Action	Date	FR Cite
NPRM	01/12/09	74 FR 1280
Proposed rule; notice of public meeting.	03/12/09	74 FR 10689
NPRM Comment Period Extended.	04/20/09	74 FR 17910
Comment Period End.	05/12/09	
Extended Comment Period End.	08/10/09	
Supplemental NPRM.	05/20/11	76 FR 29336
Comment Period Extended.	06/23/11	76 FR 36888
Comment Period End.	07/19/11	
Comment Period End.	09/19/11	
Final Rule	10/00/13	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Nancy L Claussen, Federal Aviation Administration, Department of Transportation, Federal Aviation Administration, 800 Independence Ave. SW., Washington,

DC 20591, *Phone:* 202–267–8166, *Email: nancy.claussen@faa.gov.*

RIN: 2120–AJ00

342. +Pilot Certification and Qualification Requirements (Formerly First Officer Qualification Requirements) (HR 5900)

Legal Authority: 49 U.S.C. 106(g); 49 U.S.C. 35301 to 45302; 49 U.S.C. 40113; 49 U.S.C. 40119; 49 U.S.C. 41706; 49 U.S.C. 44101; 49 U.S.C. 44701(a)(5); 49 U.S.C. 44701 to 44703; 49 U.S.C. 44705; 49 U.S.C. 44707; 49 U.S.C. 44709 to 44711; 49 U.S.C. 44713; 49 U.S.C. 44716; 49 U.S.C. 44722; 49 U.S.C. 45102 to 45103; 49 U.S.C. 46105; 49 U.S.C. 44717; Pub. L. 111–216

Abstract: This rulemaking would amend the eligibility and qualification requirements for pilots engaged in part 121 air carrier operations. Additionally, it would modify the requirements for an airline transport pilot certificate. These actions are necessary because recent airline accidents and incidents have brought considerable attention to the experience level and training of air carrier flight crews. This rulemaking is a result of requirements in Public Law 111–216.

Timetable:

Action	Date	FR Cite
ANPRM	02/08/10	75 FR 6164
ANPRM Comment Period End.	04/09/10	
NPRM	02/29/12	77 FR 12374
NPRM Comment Period End.	04/30/12	
Final Rule	05/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Barbara Adams, Department of Transportation, Federal Aviation Administration, 800 Independence Ave, SW., Washington, DC 20591, *Phone:* 202–267–8166, *Email: barbara.adams@faa.gov.*

RIN: 2120–AJ67

343. +Safety Management Systems for Certificate Holders (Section 610 Review)

Legal Authority: 49 U.S.C. 106(g); 49 U.S.C. 40113; 49 U.S.C. 40119; 49 U.S.C. 41706; 49 U.S.C. 44101; 49 U.S.C. 44701; 49 U.S.C. 44702; 49 U.S.C. 44705; 49 U.S.C. 44709 to 44711; 49 U.S.C. 44713; 49 U.S.C. 44716; 49 U.S.C. 44717; 49 U.S.C. 44722; 49 U.S.C. 46105; Pub. L. 111–216, sec 215

Abstract: This rulemaking would require each certificate holder operating under 14 CFR part 121 to develop and implement a safety management system (SMS) to improve the safety of its aviation related activities. A safety management system is a comprehensive, process-oriented approach to managing safety throughout an organization. An SMS includes an organization-wide safety policy; formal methods for identifying hazards, controlling, and continually assessing risk and safety performance; and promotion of a safety culture. SMS stresses not only compliance with technical standards but increased emphasis on the overall safety performance of the organization.This rulemaking is required under Public Law 111–216, section 215.

Timetable:

Action	Date	FR Cite
NPRM	11/05/10	75 FR 68224
NPRM Comment Period Extended.	01/31/11	76 FR 5296
NPRM Comment Period End.	02/03/11	
NPRM Comment Period Extended End.	03/07/11	
Final Rule	04/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Scott VanBuren, Department of Transportation, Federal Aviation Administration, 800 Independence Ave. SW., Washington, DC 20591, *Phone:* 202–494–8417, *Email: scott.vanburen@faa.gov.*

RIN: 2120–AJ86

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION (DOT)

Federal Motor Carrier Safety Administration (FMCSA)

Proposed Rule Stage

344. +Electronic Logging Devices and Hours of Service Supporting Documents

Legal Authority: 49 U.S.C. 31502; 31136(a); Pub. L. 103.311; 49 U.S.C. 31137(a)

Abstract: This rulemaking would establish: (1) Minimum performance standards for electronic logging devices (ELDs); (2) requirements for the mandatory use of the devices by drivers required to prepare handwritten records of duty status (RODS); (3) requirements concerning HOS supporting documents; and (4) measures to ensure that the mandatory use of ELDs will not result in harassment of drivers by motor carriers and enforcement officials. This rulemaking would supplement the Agency's February 1, 2011, Notice of Proposed Rulemaking (NPRM) and address issues raised by the U.S. Court of Appeals for the Seventh Circuit Court in its 2011 decision vacating the Agency's April 5, 2010, final rule concerning ELDs. This action would improve compliance with the hours-of-service (HOS) rules and thereby decrease the risk of fatigue-related crashes attributable to non-compliance with the applicable HOS requirements.

Timetable:

Action	Date	FR Cite
NPRM	02/01/11	76 FR 5537
NPRM Comment Period End.	02/28/11	
Comment Period Extended.	03/10/11	76 FR 13121
Extended Comment Period End.	05/23/11	
Supplemental NPRM.	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Deborah M Freund, Senior Transportation Specialist, Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, *Phone:* 202–366–5370, *Email: deborah.freund@dot.gov.*

RIN: 2126–AB20

345. +Inspection, Repair, and Maintenance; Driver-Vehicle Inspection Report (RRR)

Legal Authority: 49 U.S.C. 31136; 49 U.S.C. 31502

Abstract: This rulemaking would rescind the requirement that commercial motor vehicle (CMV) drivers operating in interstate commerce submit, and motor carriers retain, driver-vehicle inspection reports when the driver has neither found nor been made aware of any vehicle defects or deficiencies. Specifically, this rulemaking would remove a significant information collection burden without adversely impacting safety. This rulemaking would remove a significant information collection burden without adversely impacting safety. The value of the time saved by eliminating the paperwork burden associated with the filing of no-defect DVIRs is more than 1 billion dollars per year. This rulemaking responds in part to the President's January 2012 Regulatory Review and Reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	05/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Sean Gallagher, MC–PRR, Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202 366–3740, *Email: sean.gallagher@dot.gov.*
RIN: 2126–AB46

DEPARTMENT OF TRANSPORTATION (DOT)

Federal Motor Carrier Safety Administration (FMCSA)

Final Rule Stage

346. +Unified Registration System

Legal Authority: Pub. L. 104–88; 109 Stat 803, 888 (1995); 49 U.S.C. 13908; Pub. L. 109–159, sec 4304

Abstract: This rule would establish a new Unified Registration System (URS) to replace three legacy systems in support of FMCSA´s safety and commercial oversight responsibilities. It would require all entities subject to FMCSA jurisdiction to comply with a new URS registration and biennial update requirement, disclose the cumulative registration information collected by URS and provides a cross-reference to all regulatory requirements necessary to obtain permanent registration. It implements statutory provisions in the ICC Termination Act and SAFTEA–LU. URS would serve as a clearinghouse and depository of information on, and identification of, brokers, freight forwarders, and others required to register with the Department of Transportation. The agency has determined the total net societal benefits of the rule to be $19.5 million and the total societal costs to be $26.5 million.

Timetable:

Action	Date	FR Cite
ANPRM	08/26/96	61 FR 43816
ANPRM Comment Period End.	10/25/96	
NPRM	05/19/05	70 FR 28990
NPRM Comment Period End.	08/17/05	
Supplemental NPRM.	10/26/11	76 FR 66506
Comment Period End.	12/27/11	
Final Rule	04/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Valerie Height, Management Analyst, Department of Transportation, Federal Motor Carrier Safety Administration, Office of Policy (MC–PRR), 1200 New Jersey Avenue SE., Washington, DC 20590, *Phone:* 202–366–0901, *Email: valerie.height@dot.gov.*
RIN: 2126–AA22

347. Self Reporting of Out-of-State Convictions (RRR) (Section 610 Review)

Legal Authority: Commercial Motor Vehicle Safety Act of 1986

Abstract: This rulemaking would clarify the requirement for holders of commercial drivers licenses (CDL) convicted of violating traffic laws in a State other than the State that issued their CDL, to notify the State of issuance about those violations under part 383.31 of FMCSA's Commercial Drivers License Standards; and clarify the requirement for the licensing agency from the jurisdiction in which the conviction takes place to notify the State licensing Agency that issued the CDL under part 384.209 State Compliance with Commercial Drivers License Program. This rulemaking would also ensure that notifications required in sections 383.31 and 384.209 take place within 30 days of the conviction.

Timetable:

Action	Date	FR Cite
NPRM	08/02/12	77 FR 46010
NPRM Comment Period End.	10/01/12	
Final Rule	06/00/13	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Robert Redmond, Senior Transportation Specialist, Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, *Phone:* 202–366–5014, *Email: robert.redmond@dot.gov.*
RIN: 2126–AB43

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION (DOT)

Federal Railroad Administration (FRA)

Proposed Rule Stage

348. +Critical Incident Stress Plan; ''Critical Incident'' Definition

Legal Authority: Pub. L. 110–432, Div A, 122 Stat 4848 *et seq.;* Rail Safety Improvement Act of 2008 sec 410(c)

Abstract: This rulemaking would seek to define the term ''critical incident.'' This rulemaking would also seek to define program elements appropriate for the rail environment for certain railroad´s critical incident response programs, so that appropriate action is taken when a railroad employee is involved in or directly witnesses a critical incident.

Timetable:

Action	Date	FR Cite
NPRM	05/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email: kathryn.shelton@fra.dot.gov.*
RIN: 2130–AC00

349. Risk Reduction Program (RRR)

Legal Authority: Pub. L. 110–432, Div A, 122 Stat 4848 *et seq.;* Rail Safety Improvement Act of 2008; sec 103, 49 U.S.C. 20156 ''Railroad Safety Risk Reduction Program''

Abstract: This rulemaking would require each Class I railroad and each railroad with inadequate safety performance to develop and implement a Risk Reduction Program (RRP) to improve the safety of their operations. Each RRP would be required to include a risk analysis, a technology implementation plan, and a fatigue management plan. Railroads would be required to conduct annual internal assessments of their RRPs, which could also be externally audited by FRA.

Timetable:

Action	Date	FR Cite
ANPRM	12/08/10	75 FR 76345
ANPRM Comment Period End.	02/07/11	
NPRM	05/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email: kathryn.shelton@fra.dot.gov.*
RIN: 2130–AC11

350. +Positive Train Control Systems: De Minimis Exception, Yard Movements, En Route Failures; Miscellaneous Grade Crossing/Signal and Train Control Amendments (RRR)

Legal Authority: 49 U.S.C. 20102 to 20103; 28 U.S.C. 2461, note; 49 CFR 1.49; 49 U.S.C. 20107; 49 U.S.C. 20133; 49 U.S.C. 20141; 49 U.S.C. 20157; 49 U.S.C. 20301 to 20303; 49 U.S.C. 20306; 49 U.S.C. 21301 to 21302; 49 U.S.C. 21304

Abstract: This rulemaking would revise Positive Train Control regulations by defining the de minimis exception and en route failures, proposing exceptions relating to yard movements that may not be considered on the main line system, and amending regulations governing grade crossing and signal and train control systems. The rulemaking is in response to a petition for rulemaking from the Association of American Railroads.

Timetable:

Action	Date	FR Cite
NPRM	12/11/12	77 FR 73589
NPRM Comment Period End.	02/11/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email:* *kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC32

DEPARTMENT OF TRANSPORTATION (DOT)

Federal Railroad Administration (FRA)

Final Rule Stage

351. Roadway Worker Protection; Miscellaneous Revisions

Legal Authority: 28 U.S.C. 2461; 49 CFR 1.49; 49 U.S.C. 20103; 49 U.S.C. 20107; 49 U.S.C. 21301; 49 U.S.C. 21304

Abstract: This rulemaking would revise FRA's Roadway Worker Protection regulations in 49 CFR, Part 214, to further advance the on-track safety of railroad employees and contractors engaged in maintenance-of-way activities throughout the general railroad system of transportation, including clarification of existing regulations. In doing so, FRA will review existing technical bulletins and a safety advisory dealing with on-track safety to consider implications, and as appropriate, consider enhancements to the existing regulations.

Timetable:

Action	Date	FR Cite
NPRM	08/20/12	77 FR 50324
NPRM Comment Period End.	10/19/12	
Final Rule	10/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email:* *kathryn.shelton@fra.dot.gov.*

RIN: 2130–AB89

352. +Training Standards for Railroad Employees (RRR)

Legal Authority: Pub. L. 110 thru 432, Div A, 122 Stat 4848 *et seq.;* Railroad Safety Improvement Act of 2008; sec 401 (49 U.S.C. 20162)

Abstract: This rulemaking would (1) Establish minimum training standards for each class or craft of safety-related employee and equivalent railroad contractor and subcontractor employee that require railroads, contractors, and subcontractors to qualify or otherwise document the proficiency of such employees in each such class and craft regarding their knowledge and ability to comply with Federal railroad safety laws and regulations and railroad rules and procedures intended to implement those laws and regulations, etc.; (2) require submission of railroads', contractors', and subcontractors' training and qualification programs for FRA approval; and (3) establish a minimum training curriculum and ongoing training criteria, testing, and skills evaluation measures for track and equipment inspectors employed by railroads and railroad contractor and subcontractors. It is anticipated that crane operator provisions contained in this rulemaking will further the objectives of EO 13563.

Timetable:

Action	Date	FR Cite
NPRM	02/07/12	77 FR 6412
NPRM Comment Period End.	04/09/12	
Final Rule	05/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email:* *kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC06

353. +Emergency Escape Breathing Apparatus (RRR)

Legal Authority: Pub. L. 110–432, Div A, 122 Stat 4848 *et seq.;* Rail Safety Improvement Act of 2008; sec 413 49 U.S.C. 20166

Abstract: This rulemaking would prescribe regulations that require railroads to provide specified emergency escape breathing apparatus for all crew members in locomotive cabs on freight trains carrying poison-inhalation-hazard hazardous material and provide training in its use.

Timetable:

Action	Date	FR Cite
NPRM	10/05/10	75 FR 61386
NPRM Comment Period End.	12/06/10	
Final Rule	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email:* *kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC14

354. Passenger Train Emergency Systems; Doors, Emergency Lighting, Emergency Signage and Markings for Egress and Access, and Low-Location Emergency Exit Path Marking; Miscellaneous Amendments

Legal Authority: 28 U.S.C. 241, note; 49 CFR 1.49; 49 U.S.C. 20103, 20107, 20133, 20141, 20302 to 20303, 20306, 20701 to 20702; 49 U.S.C. 21301 to 21302, 21304

Abstract: This rulemaking would amend the passenger equipment safety standards to enhance standards for passenger train emergency systems and would clarify the passenger train emergency preparedness standards. Specifically, FRA would incorporate by reference three APTA emergency system standards: ''Standard for Emergency Lighting System Design for Passenger Cars,'' ''Standard for Emergency Signage for Egress/Access of Passenger Rail Equipment,'' and ''Standard for Low-Location Exit Path Marking.'' Miscellaneous amendments to FRA's existing regulations would include: (1) Clarifying that new passenger cars must have at least two exterior side doors, one on each side; (2) requiring removable panels/windows in vestibule doors for new passenger cars; (3) consolidating various door requirements into one section for easier reference; and (4) revising part 239 to explicitly address train crew participation in debrief and critique sessions.

Timetable:

Action	Date	FR Cite
NPRM	01/03/12	77 FR 154
NPRM Comment Period End.	03/05/12	

Action	Date	FR Cite
Final Rule	02/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email:* *kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC22

355. Amendments Expanding the Drug Panel for FRA Post-Accident Toxicological Testing

Legal Authority: 28 U.S.C. 2461, note; 49 CFR 1.49(m); 49 U.S.C. 20103; 49 U.S.C. 20107; 49 U.S.C. 20140; 49 U.S.C. 21301; 49 U.S.C. 21304

Abstract: This rulemaking would expand the drug testing panel for FRA's post-accident toxicological testing (PATT) program, which investigates the role of alcohol and drug use in serious train accidents. This rulemaking would also amend the requirements regarding the analysis of PATT results in 49 CFR SS 219.211 to reflect that some of the drugs in the expanded panel are prescription and over-the-counter drugs that are not controlled substances. FRA has tested for the same basic panel of drugs since the beginning of PATT in 1985. Currently, FRA tests blood and urine specimens for eight drug classifications: alcohol, marijuana, cocaine, the opiates, the amphetamines, phencyclidine (PCP), the barbiturates, and the benzodiazepines. FRA would expand the PATT panel to include synthetic opiates, sedating antihistamines, MDMA and one of its analogues, and additional benzodiazepines. This rulemaking does not make any substantive changes to the prohibitions on the abuse of controlled substances and prescription drugs found in 49 CFR SS 219.102 and 219.103.

Timetable:

Action	Date	FR Cite
NPRM	05/17/12	77 FR 29307
NPRM Comment Period End.	07/16/12	
Final Rule	01/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email:* *kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC24

356. Track Safety Standards: Improving Rail Integrity (RRR)

Legal Authority: 28 U.S.C. 2461, note; 49 CFR 1.49; 49 U.S.C. 20102 to 20114; 49 U.S.C. 20142; sec 403, Div A; Pub. L. 110–432, 122 Stat 4885

Abstract: This rulemaking would prescribe specific requirements for effective rail inspection frequencies, rail flaw remedial actions, minimum operator qualifications, and requirements for rail inspection records. In addition, it would remove the regulatory requirements concerning joint bar fracture reporting. Section 403(c) of the Rail Safety Improvement Act of 2008 mandates that FRA promulgate regulations addressing rail flaw detection inspections.

Timetable:

Action	Date	FR Cite
NPRM	10/19/12	77 FR 64249
NPRM Comment Period End.	12/18/12	
Final Rule	09/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email:* *kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC28

357. Railroad System Safety Program

Legal Authority: 49 U.S.C. 20103; 49 U.S.C. 20107; 49 U.S.C. 20133; 49 U.S.C. 21301 to 21302; 49 U.S.C. 21304; 49 U.S.C. 21311; 28 U.S.C. 2461, note; 49 CFR 1.49

Abstract: This rulemaking would improve passenger railroad safety through structured, proactive processes and procedures developed by passenger railroad operators. It would require passenger railroads to establish a System Safety Program that would systematically evaluate and manage risks in order to reduce the number and rates of railroad accidents, incidents, injuries and fatalities. This rulemaking was bifurcated from 2130–AC11.

Timetable:

Action	Date	FR Cite
NPRM	09/07/12	77 FR 55372
NPRM Comment Period End.	11/06/12	
Final Rule	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email:* *kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC31

358. Revisions to Passenger Train Emergency Preparedness Regulations

Legal Authority: 49 U.S.C. 20103; 49 U.S.C. 20107; 49 U.S.C. 20133; 49 U.S.C. 20141; 49 U.S.C. 20302 to 20303; 49 U.S.C. 20306; 49 U.S.C. 20701 to 20702; 49 U.S.C. 21301 to 21302; 49 U.S.C. 21304; 28 U.S.C. 2461, note; 49 CFR 1.49

Abstract: The rulemaking would propose a series of unrelated revisions to 49 CFR part 239. These proposed revisions would: (1) Create a definition for emergency response communication centers to ensure that railroad personnel who coordinate first responders receive control center employee training provided by part 239; (2) require railroads develop procedures to promote the safe evacuation of disabled passengers; (3) make the FRA emergency preparedness plan approval process more efficient; and (4) create new testing and inspection requirements for railroads covered by part 239. These revisions are based on a recommendation made to FRA by the Railroad Safety Advisory Committee.

Timetable:

Action	Date	FR Cite
NPRM	06/27/12	77 FR 38248
NPRM Comment Period End.	08/27/12	
Final Rule	05/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email:* *kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC33

359. Roadway Worker Protection; Adjacent-Track On-Track Safety—Response to Petitions for Reconsideration

Legal Authority: 49 U.S.C. 20103

Abstract: This rulemaking would respond to petitions for reconsideration of the final rule published on November 30, 2011. FRA received two petitions for reconsideration of the final rule from railroad industry organizations. The first petition raised concern with the final rule's cost-benefit analysis and requested several amendments to the final rule to lessen the potential costs.

The second petition discussed the final rule's potential impact on passenger train service/resultant costs and requested an amendment to the final rule to allow passenger trains to travel at higher speeds when passing maintenance of way work zones implicated by the rulemaking. This Final Rule will make amendments to the original Adjacent-Track On-Track Safety Final Rule.

Timetable:

Action	Date	FR Cite
Final Rule	01/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email: kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC37

360. • Telephonic Notification at Grade Crossings—Response to Petitions for Reconsideration

Legal Authority: 28 U.S.C. 2461, note; 49 CFR 1.49; 49 U.S.C. 20103; 49 U.S.C. 20107; 49 U.S.C. 20152; 49 U.S.C. 21301; 49 U.S.C. 21304; 49 U.S.C. 21311; 49 U.S.C. 22501, note; Pub. L. 110–432, Div, sec 202, 205

Abstract: The rulemaking would respond to petitions for reconsideration of the final rule published June 12, 2012. This final rule will make amendments to the original Systems for Telephonic Notification of Unsafe Conditions at Highway-Rail and Pathway Grade Crossings Final Rule. Amendments will be made to certain compliance dates, signage, and third-party telephone service requirements.

Timetable:

Action	Date	FR Cite
Final Rule	01/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email: kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC38

361. • Locomotive Safety Standards Amendments—Response to Petitions for Reconsideration

Legal Authority: 49 U.S.C. 20701

Abstract: This rulemaking would amend and clarify certain sections of the Locomotive Safety Standards final rule that was issued on April 9, 2012. In response to eight petitions for reconsideration of the final rule, this rulemaking would amend and clarify the requirements related to remote control locomotives (RCL), locomotive alerters, and locomotive electronics. This rulemaking would also clarify how to properly record the air flow method calibration date and the duration of the audio indication for RCL.

Timetable:

Action	Date	FR Cite
Final Rule	01/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathryn Shelton, Trial Attorney, Department of Transportation, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590, *Phone:* 202–493–6063, *Email: kathryn.shelton@fra.dot.gov.*

RIN: 2130–AC39

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DEPARTMENT OF TRANSPORTATION (DOT)

Pipeline and Hazardous Materials Safety Administration (PHMSA)

Proposed Rule Stage

362. +Pipeline Safety: Safety of On-Shore Liquid Hazardous Pipelines

Legal Authority: 49 U.S.C. 60101 *et seq.*

Abstract: This rulemaking would establish effective procedures that hazardous liquid operators can use to improve the protection of High Consequence Areas (HCA) and other vulnerable areas along their hazardous liquid onshore pipelines. PHMSA is considering whether changes are needed to the existing regulations covering hazardous liquid onshore pipelines, whether other areas should be included as HCAs for integrity management (IM) protections, what the repair timeframes should be for areas outside the HCAs that are assessed as part of the IM program, whether leak detection standards are necessary, valve spacing requirements are needed on new construction or existing pipelines, and PHMSA should extend regulation to certain pipelines currently exempt from regulation. The agency would also address the public safety and environmental aspects any new requirements, as well as the cost implications and regulatory burden.

Timetable:

Action	Date	FR Cite
ANPRM	10/18/10	75 FR 63774
ANPRM Comment Period End.	01/18/11	
ANPRM Comment Period Extended.	01/04/11	76 FR 303
ANPRM Extended Comment Period End.	02/18/11	
NPRM	04/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: John A Gale, Transportation Regulations Specialist, Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, *Phone:* 202–366–0434, *Email: john.gale@dot.gov.*

RIN: 2137–AE66

363. • Pipeline Safety: Miscellaneous Amendments Related to Reauthorization and Petitions for Rulemaking (RRR)

Legal Authority: 49 U.S.C. 60101 *et seq.*

Abstract: This rulemaking will address miscellaneous issues that have been raised because of the reauthorization of the pipeline safety program in 2012 and petitions for rulemaking from many affected stakeholders. Some of the issues that this rulemaking would address include, renewal process for special permits, cost recovery for design reviews and incident reporting.

Timetable:

Action	Date	FR Cite
NPRM	06/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: John A Gale, Transportation Regulations Specialist, Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, *Phone:* 202–366–0434, *Email: john.gale@dot.gov.*

RIN: 2137–AE94

DEPARTMENT OF TRANSPORTATION (DOT)

Pipeline and Hazardous Materials Safety Administration (PHMSA)

Final Rule Stage

364. +Hazardous Materials: Revisions to Requirements for the Transportation of Lithium Batteries

Legal Authority: 49 U.S.C. 5101 *et seq.*

Abstract: This rulemaking would amend the Hazardous Materials Regulations to comprehensively address the safe transportation of lithium cells and batteries. The intent of the rulemaking is to strengthen the current regulatory framework by imposing more effective safeguards, including design testing to address risks related to internal short circuits, and enhanced packaging, hazard communication, and operational measures for various types and sizes of lithium batteries in specific transportation contexts. The rulemaking would respond to several recommendations issued by the National Transportation Safety Board.

Timetable:

Action	Date	FR Cite
NPRM	01/11/10	75 FR 1302
NPRM Comment Period End.	03/12/10	
Final Rule	01/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kevin Leary, Transportation Specialist, Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, *Phone:* 202–366–8553, *Email: kevin.leary@dot.gov.*

RIN: 2137–AE44

365. Hazardous Materials: Miscellaneous Amendments (RRR) (Section 610 Review)

Legal Authority: 49 U.S.C. 5101 *et seq.*

Abstract: This rulemaking would update and clarify existing requirements by incorporating changes into the Hazardous Materials Regulations (HMR) based on PHMSA's own initiatives through an extensive review of the HMR and previously issued letters of interpretation. Specifically, among other provisions, PHMSA would provide for the continued use of approvals until final administrative action is taken, when a correct and completed application for approval renewal was received 60 days prior to expiration date; update various entries in the hazardous materials table and the corresponding special provisions; clarify the lab pack requirements for temperature controlled materials; correct an error in the HMR with regard to the inspection of cargo tank motor vehicles containing corrosive materials; and revise the training requirements to require that hazardous materials employers ensure their hazardous materials employee training records are available upon request to an authorized official of the Department of Transportation or the Department of Homeland Security.

Timetable:

Action	Date	FR Cite
NPRM	04/26/12	77 FR 24885
NPRM Comment Period End.	06/25/12	
Final Rule	01/00/13	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Robert Benedict, Transportation Regulations Specialist, Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, *Phone:* 202–366–8553, *Email: robert.benedict@dot.gov.*

RIN: 2137–AE78

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION (DOT)

Maritime Administration (MARAD)

Long-Term Actions

366. +Regulations To Be Followed by All Departments, Agencies and Shippers Having Responsibility To Provide a Preference for U.S.-Flag Vessels in the Shipment of Cargoes on Ocean Vessels (RRR)

Legal Authority: 49 CFR 1.66; 46 app U.S.C. 1101; 46 app U.S.C. 1241; 46 U.S.C. 2302(e)(1); Pub. L. 91–469

Abstract: This rulemaking would revise and clarify the Cargo Preference rules that have not been revised substantially since 1971. Revisions would include an updated purpose and definitions section along with the removal of obsolete provisions. This rulemaking also would establish a new Part 383 to implement the Cargo Preference regulations. This rulemaking would cover Public Law 110–417, section 3511, National Defense Authorization Act for FY2009 changes to the cargo preference rules. The rulemaking also would include compromise, assessment, mitigation, settlement, and collection of civil penalties. Originally the agency had two separate rulemakings in process under RIN 2133–AB74 and 2133–AB75. RIN 2133–AB74 would have revised existing regulations and RIN 2133–AB75 would have established a new part 383: Guidance and Civil Penalties and implement Public Law 110–417, section 3511, National Defense Authorization Act for FY 2009. MARAD has decided it would be more efficient to merge both efforts under one; RIN 2133–AB75 has been merged with this action.

Timetable: Next Action Undetermined.

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Christine Gurland, Department of Transportation, Maritime Administration, 1200 New Jersey Ave SE., Washington, DC 20590, *Phone:* 202 366–5157, *Email: christine.gurland@dot.gov.*

RIN: 2133–AB74

[FR Doc. 2013–00597 Filed 1–14–13; 8:45 am]

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