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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, July 10, 2012
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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SPECIAL INSPECTOR GENERAL FOR AFGHANISTAN RECONSTRUCTION

5 CFR Part 9303

RIN 3460–AA01

Supplemental Standards of Ethical Conduct for Employees

AGENCY: Special Inspector General for Afghanistan Reconstruction.

ACTION: Final rule.

SUMMARY: The Special Inspector General for Afghanistan Reconstruction (SIGAR), with the concurrence of the Office of Government Ethics (OGE), is adopting as final, without changes, an interim rule for SIGAR employees that will supplement the executive branch-wide Standards of Ethical Conduct (Standards) issued by OGE. The final supplemental regulation includes a requirement that SIGAR employees obtain prior approval for certain types of outside activities. The interim final rule was published in the **Federal Register** on April 6, 2012

DATES: Effective Date: June 29, 2012.

FOR FURTHER INFORMATION CONTACT:
Technical information: Christina Beach, Ethics Compliance Officer, 703–545–5994, email: *christina.k.beach.civ@mail.mil.*
Legal information: Patricia Papas, Associate General Counsel, 703–545–5992, email: *patricia.p.papas.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: On April 6, 2012, SIGAR published, with OGE concurrence, in the **Federal Register** (77 FR 20697) an interim final rule that requires SIGAR employees to obtain prior approval for certain types of outside activities.

SIGAR provided a 60-day comment period that ended on June 5, 2012. SIGAR received no comments and will not be making any changes to the interim final rule. Based on the rationale set forth in the interim final rule, SIGAR has determined, with OGE concurrence, to adopt the interim final rule without change as a final rule.

For a detailed analysis of this final rule, see the preamble of the interim final rule as published in 77 FR 20697.

I. Matters of Regulatory Procedure

Administrative Procedure Act

This document affirms as final, without change, the interim final rule that is already in effect. In accordance with 5 U.S.C. 1103(b)(1) and 1105, these regulations are not subject to the rulemaking requirements of the Administrative Procedure Act, at 5 U.S.C. 553 (b), (c), and (d), because they apply solely to SIGAR or its employees.

Regulatory Flexibility Act

As Acting Inspector General of SIGAR, I have determined under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this rule will not have a significant economic impact on a substantial number of small entities because it will primarily affect SIGAR employees.

Paperwork Reduction Act

As Acting Inspector General of SIGAR, I have determined that the Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply to this rule, because it does not contain any information collection requirements that would require the approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), this rule would not significantly or uniquely affect small governments and would not result in increased expenditures by State, local, and tribal governments, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

Congressional Review Act

I have determined that this rule is not a rule as defined in 5 U.S.C. 804 and, thus, does not require review by Congress.

Executive Order 12866

In promulgating this rule, SIGAR has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. This rule has not been reviewed by the Office of Management and Budget under that Executive Order, since it deals with agency organization, management, and personnel matters and is not in any way event deemed ''significant'' thereunder.

Executive Order 12988

As Acting Inspector General of SIGAR, I have reviewed this rule in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects in 5 CFR Part 9303

Conflict of interests, Government employees.

Authority and Issuance

For the reasons stated above, the Special Inspector General for Afghanistan Reconstruction, with the concurrence of the Office of Government Ethics, is submitting the document to the Office of the Federal Register for publication as an official document of the Special Inspector General for Afghanistan Reconstruction.

Accordingly, the interim final rule amending 5 CFR part 9303, which was published at 77 FR 20697 on April 6, 2012, is adopted as a final rule without change.

Dated: June 19, 2012.

Steven J. Trent,

Acting Inspector General, Special Inspector General for Afghanistan Reconstruction.

Approved: June 25, 2012.

Don W. Fox,

Acting Director, Office of Government Ethics.

[FR Doc. 2012–16023 Filed 6–28–12; 8:45 am]

BILLING CODE 3710–L9–P

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Parts 531 and 553

Updating Regulations Issued Under the Fair Labor Standards Act

CFR Correction

In Title 29 of the Code of Federal Regulations, Parts 500 to 899, revised as of July 1, 2011, the following corrections are made:

§ 531.56 [CORRECTED]

■ On page 192, in § 531.56, in the second sentence of paragraph (c), ''$20'' is corrected to read ''$30''.

§ 531.57 [CORRECTED]

■ On page 193, in § 531.57, in the last sentence, ''$20'' is corrected to read ''$30''.

§ 553.223 [CORRECTED]

■ On page 268, in § 553.223, in the first sentence of paragraph (c), ''firefighters'' is corrected to read ''employees in fire protection activities''.

[FR Doc. 2012–16051 Filed 6–28–12; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket No. USCG–2012–0024]

RIN 1625–AA00

Safety Zone; NOBLE DISCOVERER, Outer Continental Shelf Drillship, Chukchi and/or Beaufort Seas, AK

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a 500-meter safety zone in the navigable waters, from the surface to seabed, around the DRILLSHIP NOBLE DISCOVERER, while anchored or deploying and recovering moorings on location in order to drill exploratory wells at various prospects located in the Chukchi and/or Beaufort Seas Outer Continental Shelf, Alaska, on or about July 1, 2012 through November 30, 2012. See TABLE 1. The purpose of the temporary safety zone is to protect the drillship from vessels operating outside the normal shipping channels and fairways. Placing a safety zone around the drillship will significantly reduce the threat of allisions, which could result in oil spills, and releases of natural gas, and thereby protect the safety of life, property, and the environment. Lawful demonstrations may be conducted outside of the safety zone.

DATES: The temporary safety zone becomes effective on July 1, 2012, and terminates on December 1, 2012, unless sooner terminated by the Commander, Seventeenth Coast Guard District.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2012–0024 and are available online by going to *http://www.regulations.gov,* inserting USCG–2012–0024 in the ''Keyword'' box, and then clicking ''Search.'' This material is also available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Jason Smilie, Seventeenth Coast Guard District (dpi); telephone 907–463–2809, *Jason.A.Smilie@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:

Regulatory Information

On February 23, 2012 the Coast Guard published a notice of proposed rulemaking (NPRM) entitled ''Safety Zone; NOBLE DISCOVERER, Outer Continental Shelf Drillship, Chukchi and Beaufort Seas, Alaska'' in the **Federal Register** (77 FR 10707). The NPRM included a 30-day comment period. We received 3 (three) submissions with comments on the proposed rule. No public meeting was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication because to do otherwise would be contrary to the public interest since immediate action is required to protect mariners, vessels, and the environment from potential harm while the NOBLE DISCOVERER is anchored or deploying and recovering moorings on location.

Basis and Purpose

The legal basis for the rule is 14 U.S.C. 85; 43 U.S.C. 1333; Department of Homeland Security Delegation No. 0170.1. Collectively they provide the authority for the Coast Guard to establish safety zones on the Outer Continental Shelf.

The Coast Guard is establishing a temporary safety zone in the navigable waters, from the surface to seabed, around the DRILLSHIP NOBLE DISCOVERER while anchored or deploying and recovering moorings on location in order to drill exploratory wells in several prospects located in the Chukchi and/or Beaufort Seas during the 2012 drilling season.

The request for the temporary safety zone was made by Shell Exploration & Production Company due to safety concerns for both the personnel aboard the NOBLE DISCOVERER and the environment. Shell Exploration & Production Company indicated that it is highly likely that any allision or inability to identify, monitor or mitigate any risks or threats, including ice-related hazards that might be encountered, could result in a catastrophic event. Incursions into the safety zone by unapproved vessels could degrade the ability to monitor and mitigate such risks. In evaluating this request, the Coast Guard explored relevant safety factors and considered several criteria, including but not limited to: (1) The level of shipping activity around the operation; (2) safety concerns for personnel aboard the vessel; (3) concerns for the environment given the sensitivity of the environmental and subsistence importance to the indigenous population; (4) the lack of any established shipping fairways, fueling and supply storage/operations, and size of the crew increase the likelihood that an allision could result in a catastrophic event; (5) the recent and potential future maritime traffic in the vicinity of the areas; (6) the types of vessels navigating in the vicinity of the area; (7) the structural configuration of the vessel, and (8) the need to allow for lawful demonstrations without endangering the safe operation of the NOBLE DISCOVERER. For any group or individual intending to conduct lawful demonstrations in the vicinity of the NOBLE DISCOVERER, these demonstrations must be conducted outside the safety zone.

Results from a thorough and comprehensive examination of the criteria, IMO guidelines, and existing regulations warrant the establishment of the temporary safety zone. The regulation will significantly reduce the threat of allisions that could result in oil spills, and releases. Furthermore, the regulation will increase the safety of life, property, and the environment in the Chukchi and/or Beaufort Seas by prohibiting entry into the zone unless specifically authorized by the Commander, Seventeenth Coast Guard District, or a designated representative. Due to the remote location and the need to protect the environment, the Coast Guard may use criminal sanctions to enforce the safety zone as appropriate.

The temporary safety zone will be around the NOBLE DISCOVERER while anchored or deploying and recovering moorings on location in order to drill exploratory wells in various locations in the Chukchi and/or Beaufort Seas Outer Continental Shelf, Alaska during the 2012 timeframe.

Shell Exploration & Production Company has ten drill sites within the Burger, Sivulliq and Torpedo prospects of the Chukchi and Beaufort Seas, Alaska (See Table 1).

TABLE 1—PROSPECT LOCATIONS

Prospect	Well	Area	Block	Lease No.	Latitude	Longitude
Burger	A	Posey	6764	OCS–Y–2280	N71°18′30.92″	W163°12′43.17″
Burger	F	Posey	6714	OCS–Y–2267	N71°20′13.96″	W163°12′21.75″
Burger	J	Posey	6912	OCS–Y–2321	N71°10′24.03″	W163°28′18.52″
Burger	R	Posey	6812	OCS–Y–2294	N71°16′06.57″	W163°30′39.44″
Burger	S	Posey	6762	OCS–Y–2278	N71°19′25.79″	W163°28′40.84″
Burger	V	Posey	6915	OCS–Y–2324	N71°10′33.39″	W163°04′21.23″
Sivulliq	G	Flaxman Is	6658	OCS–Y 1805	N70°23′46.82″	W146°01′03.46″
Sivulliq	N	Flaxman Is	6658	OCS–Y 1805	N70°23′29.58″	W145°58′52.53″
Torpedo	H	Flaxman Is	6610	OCS–Y 1941	N70°27′01.62″	W145°49′32.07″
Torpedo	J	Flaxman Is	6559	OCS–Y 1936	N70°28′56.94″	W145°53′47.15″

During the 2012 timeframe, Shell Exploration & Production Company has proposed drilling up to two exploration wells at the identified Chukchi and Beaufort Sea prospects depending on favorable ice conditions, weather, sea state, and any other pertinent factors. Each of these drill sites will be permitted for drilling in 2012 to allow for operational flexibility in the event sea ice conditions prevent access to one of the locations. The number of actual wells that will be drilled will depend on ice conditions and the length of time available for the 2012 drilling season. The predicted ''average'' drilling season, constrained by prevailing ice conditions and regulatory restrictions, is long enough for two to three typical exploration wells to be drilled.

The actual order of drilling activities will be controlled by an interplay between actual ice conditions immediately prior to movement of the NOBLE DISCOVERER, ice forecasts, any regulatory restrictions with respect to the dates of allowed operating windows, whether the planned drilling activity involves only drilling the shallow non-objective section or penetrating potential hydrocarbon zones, the availability of permitted sites having approved shallow hazards clearance, the anticipated duration of each contemplated drilling activity, the results of preceding wells and Marine Mammal Monitoring and Mitigation plan requirements.

The planned exploration drilling in the identified lease blocks will be conducted with the NOBLE DISCOVERER. The NOBLE DISCOVERER is a true drillship, and is a large self-contained drilling vessel that offers full accommodations for up to 124 persons. The hull has been reinforced for ice resistance.

The NOBLE DISCOVERER has a ''persons on board'' capacity of 124, and it is expected to be at capacity for most of its operating period. The NOBLE DISCOVERER's personnel will include its crew, as well as Shell employees, third party contractors, Alaska Native Marine Mammal Observers and possibly Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE) personnel.

While conducting exploration drilling operations, the NOBLE DISCOVERER will be anchored. The NOBLE DISCOVERER uses an anchoring system consisting of an 8-point anchored mooring spread attached to the onboard turret and could have a maximum anchor radius of 3,600 ft (1,100 m). The anchor spread, which radiates from the center of the NOBLE DISCOVERER, may pose a fouling hazard to any vessel attempting to anchor within the anchor spread. Fouling of the NOBLE DISCOVERER anchor lines may endanger the drillship, its 124 persons onboard the third party vessel, persons onboard the third party vessel and the environment.

The center point of the NOBLE DISCOVERER will be positioned within the prospect location in the Beaufort or Chukchi Sea at the coordinates listed below (See Table 1).

The NOBLE DISCOVERER will transit through the Bering Strait on or about July 1, 2012 and onto a prospect location when ice allows. Drilling will be curtailed on or before October 31, 2012. The drillship and support vessels will depart the Chukchi and Beaufort Seas at the conclusion of the 2012 drilling season.

Discussion of Comments and Changes

Three submissions with comments on the proposed rule were received. No public meeting was requested, and none was held.

One comment was received suggesting that the safety zone be issued for a multi-year period similar to safety zones in the Gulf of Mexico. The Coast Guard disagrees. While the Coast Guard understands that the underlying justifications for the safety zone are not likely to change from year to year, we find that there are several operational and permitting variables with respect to these activities to support not continuing the safety zones period beyond the current 2012 drilling season as originally requested. Many of these variables would be considered substantive changes. Some of the factors that dictate a season by season publication of the safety zone include the possibility that a different vessel will be utilized for the exploratory wells; changes in the published prospect/drilling locations and corresponding latitude/longitude coordinates; significant changes in any approved future Outer Continental Shelf Lease Exploration Plans, and the limited timeframe each year (approximately 4 to 5 months) associated with actual on site activity. The nature of this activity as noted above is not currently comparable to the ''manned production facility'' operations in the Gulf of Mexico in that those safety zones are established for year-round operations on permanent structures that are engaged in the exploration and production of sub-sea resources. The Coast Guard will reconsider the temporary nature of these safety zones should the nature of the operations significantly change from solely seasonal exploratory drilling operations.

One comment asked for a clarification with regard to the probability of a catastrophic event resulting from an

incident. The Coast Guard agrees and has amended the ''Basis and Purpose'' section of the Final Rule by changing the word ''would'' to ''could'' as it relates to the outcome of an ''allision or inability to identify, monitor or mitigate ice-related hazards that might be encountered.''

One comment requested flexibility with respect to the effective dates of the temporary safety zone to allow for certain non-drilling demobilization activities. The Coast Guard understands the nature of the post-drilling activity and agrees that the safety zone effective period should be extended to provide that needed flexibility through November 30, 2012, but only while the vessel is on location as listed in Table 1 of the rule. The purpose of this change is to ensure the rule remains effective while the KULLUK completes demobilization activities on location, thereby enhancing the safety of the personnel aboard the OCS facility and the environment. The Coast Guard has amended the final rule to reflect the new effective termination date of December 1, 2012, so long as the vessel is on location and engaged in exploratory drilling demobilization activities until this date.

One comment requested flexibility with respect to dates the drilling rigs will be engaged in exploratory drilling, noting that the commencement of drilling activities may not be on July 1, 2012. The Coast Guard agrees and is amending language relating to the commencement of drilling activity to be ''on or about'' July 1, 2012.

One comment requested flexibility with respect to locations drilling rigs will be operating to state ''Chukchi and/or Beaufort Seas'' as opposed to ''Chukchi and Beaufort Seas,'' to avoid possible confusion. The Coast Guard agrees and is amending the regulation accordingly.

One comment requested the rule be amended to have the safety zone in effect once the vessels is ''on location'' while the mooring system is being deployed or recovered not only when the vessel is anchored. The Coast Guard agrees. The safety factors that were evaluated in determining that a safety zone was warranted while the vessel was anchored on location are substantially similar for when the vessel is on location and the mooring system is in the process of being deployed or recovered. The Coast Guard has amended § 147–T17.0024 to read: ''The navigable waters, from the surface to seabed, within 500 meters (1,640.4 feet) from each point on the outer edge of the vessel, while anchored or deploying and recovering moorings on location, is a safety zone.''

Two comments recommended an extension of the outer boundaries of the safety zone to include the anchor chain extending from the OCS facilities; one comment recommended an extension to 1,500 meters from the vessel, the other recommended the zone extend to 50 meters beyond the anchor marker buoys of the mobile drilling vessel. The safety zone extends the maximum distance permitted as per 33 CFR § 147.15, which establishes the limits of a safety zone at a distance of ''500 meters around the OCS facility.'' Further, the determination that the outer edge of the OCS facility is marked by the physical structure of the drilling rig not to include any area encompassed by the anchor spread is consistent with other safety zones established for other similar OCS facilities operating on the Outer Continental Shelf, which is a 500 meter enforcement radius from the outer edge of the OCS facility structure.

One comment stated the safety zone should be a moving safety zone and that it should be extended to all support and tow vessels involved in the operation and referenced previous safety zones established by the Coast Guard as precedent. The safety zones referenced by the commenter were established under the Ports and Waterways Safety Act (PWSA) (33 U.S.C. 1226(b)), under which the Coast Guard agrees it has the authority to establish moving safety zones for any vessel operating within the U.S. territorial seas. The safety zone encompasses areas outside of the U.S. territorial seas and extends to the maximum extent permitted by 33 CFR 147.10 which provides a maximum enforcement area of 500 meters from the OCS facility. 33 CFR § 147 does not permit establishment of safety zones for non-OCS facilities. With respect to moving safety zones, safety zones may only be enforced while the OCS facility is being constructed, maintained, or operated on the Outer Continental Shelf. The Coast Guard, in conjunction with the Department of State, has determined that this definition does not include times where the OCS facility is in transit and not directly engaged in activity related to the exploration or extraction of mineral resources. Accordingly, the safety zone cannot be implemented or enforced during times where the OCS facility is in transit. With respect to vessel movements within the U.S. territorial seas, the Coast Guard is establishing separate moving safety zones under the PWSA through a separate rulemaking process which will include safety zones for support and tow vessels in addition to OCS facilities during periods of transit within the 12 nautical mile territorial sea in the vicinity of Dutch Harbor, Alaska.

One comment requested specific language granting State and Local officer's enforcement authority under 46 U.S.C. 70118, similar to safety zones established by the Coast Guard for the Columbia and Snake Rivers. Title 46 U.S.C. 70118 provides authority for state or local law enforcement officers to make arrests for safety zones established under the PWSA or Deepwater Port Act of 1974 (DPA) (33 U.S.C. 1509(d)). The PWSA does not apply for safety zones established outside of the territorial seas of the United States, and the DPA does not apply to the drillship to which the safety zone applies. The authority to implement this particular safety zone is based upon the Outer Continental Shelf Lands Act and 33 CFR 147. Accordingly, State and Local law enforcement officers do not have the authority to take law enforcement action due to the location of the safety zone.

One comment stated that the safety zone is overbroad and unnecessarily restricts first amendment rights. We disagree. The safety zones were created to facilitate safe navigation and promote the conduct of safe operations for entities engaging in lawful activities. However, actions taken which may potentially endanger or threaten either the individuals operating within this zone or the OCS facility within this zone will be subject to law enforcement action. There are no prohibitions on persons exercising free speech; however, actions that endanger persons or property within the safety zone are prohibited. Unauthorized vessels operating within this safety zone create an unnecessary risk to all vessels within the zone, including themselves. The Coast Guard determined this to be the best course of action given the complexities in the Arctic, which includes ice management issues, Marine Mammal Monitoring and Mitigation plan requirements, the lack of infrastructure in the Arctic, and a harsh, dynamic offshore environment. These complexities dictate reducing unnecessary risks associated with vessels not engaged in natural resource extraction activities operating near the NOBLE DISCOVERER in order to significantly reduce the threat of allisions and oil spills, and at the same time increase the safety of life, property, and the environment in the Chukchi and Beaufort Seas. The Coast Guard believes that the 500-meter safety zone is ideal because it still provides sufficient area for persons to peacefully assemble or engage in legitimate protest activities outside of the safety zone.

One comment opined that the Coast Guard should be required to prepare an Environmental Assessment (EA) and Environmental Impact Statement (EIS) under NEPA. While safety zones are typically categorically excluded from NEPA analysis, the Coast Guard anticipates that it will have more assets operating in the Arctic than normal due to increased vessel traffic in the Arctic. Consequently, the Coast Guard has undertaken an EA to determine the environmental impacts of its operations in the Arctic during the summer of 2012, and the enforcement of the subject safety zones has been included for consideration of cumulative impacts.

One comment pointed out that a preliminary environmental analysis checklist and categorical exclusion determination were stated to be available in the online record, but was not available. A preliminary determination was not completed. The Coast Guard is not required to provide a preliminary environmental analysis checklist and categorical exclusion determination for a temporary safety zone until publication of the Final Rule. The reasoning is that safety zones are generally categorically excluded, and the Coast Guard wanted to review all public comments before completing the environmental analysis checklist and categorical exclusion determination in order to ensure that it accounted for all concerns. The environmental analysis checklist and categorical exclusion determination for this temporary safety zone is available in the docket, and can be obtained online following the direction provided in the **ADDRESSES** section above.

One comment stated that the safety zones will cause increased air pollution because the air permits issued for the NOBLE DISCOVERER exclude air within the safety zones, and, therefore, the Coast Guard must undertake a ''NEPA analysis'' to determine the affects of any air emissions within the safety zone. The Coast Guard does not have the authority or agency expertise to issue air permits, and, therefore, does not have the authority to determine whether the issuance of those permits is appropriate. The safety zones are being implemented to enhance the safety of vessel operations during a period of increased vessel traffic at locations where any marine casualty will present unique challenges due to the remote locations, lack of infrastructure and unforgiving environmental variables.

One comment supported the determination to prohibit all vessels, irrespective of size from the safety zone. The Coast Guard determined this to be the best course of action given the complexities of this Arctic operation, which includes ice management issues, Marine Mammal and Mitigation plan requirements, and a harsh, dynamic offshore environment. The safety zones will significantly reduce the threat of allisions and oil spills, and at the same time increase the safety of life, property, and the environment in the Chukchi and Beaufort Seas. A change was also made to clarify that the subject safety zones include ''the navigable waters, from the surface to seabed.''

Regulatory Analyses

The Coast Guard developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

This rule is not a significant regulatory action due to the location of the NOBLE DISCOVERER on the Outer Continental Shelf and its distance from both land and safety fairways. Additional considerations were the relatively short period of time that the safety zone will be in effect and the limited size of the safety zone. Vessels traversing waters near the safety zone will be able to safely travel around the zone without incurring additional costs.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), the Coast Guard has considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. This rule could affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in the Sivulliq and Torpedo Prospect of the Beaufort Sea, including Flaxman Island blocks 6610, 6658 and 6659, and Posey Blocks 6714, 6762, 6764, 6812, 6912, and 6915 in the Chukchi Sea. (See Table 1).

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will enforce a temporary safety zone around a drillship facility near Flaxman Island of the Beaufort Sea and/or at the Burger Prospect in the Chukchi Sea, which are both areas not frequented by vessel traffic and are not in close proximity to a safety fairway. Further, vessel traffic can pass safely around the safety zone without incurring additional costs.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

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

Collection of Information

This rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions

that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

The Coast Guard analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves a temporary final rule for a safety zone that will be established for 1 week or longer. An environmental analysis checklist and a categorical exclusion determination are included in the docket, and can be obtained online by following the directions delineated in the ''ADDRESSES'' section above. Nevertheless, while safety zones are typically categorically excluded from NEPA analysis the Coast Guard anticipates that it will have more assets operating in the Arctic Ocean than normal due to increased vessel traffic in the Arctic Ocean. Consequently, the Coast Guard has undertaken an Environmental Assessment (EA) to determine the environmental impacts of its overall operations in the Arctic Ocean during the summer of 2012, and the enforcement of the subject safety zones has been included for consideration of cumulative impacts. Public hearings on the draft EA were held on May 30, 2012, in Anchorage, Alaska, and on May 31, 2012, in Barrow, Alaska.

List of Subjects in 33 CFR Part 147

Continental shelf, Marine safety, Navigation (water).

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 85; 43 U.S.C. 1333; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 147.T17–0024 to read as follows:

§ 147.T17–0024 Safety Zone; NOBLE DISCOVERER, Outer Continental Shelf Drillship, Chukchi and/or Beaufort Seas, Alaska.

(a) *Description.* The NOBLE DISCOVERER will be engaged in exploratory drilling operations at various locations in the Chukchi and/or Beaufort Seas on or about July 1, 2012 through November 30, 2012. The DRILLSHIP will be anchored while conducting exploratory drilling operations with the center point of the vessel located at the coordinates listed in Table 1. These coordinates are based upon [NAD 83] UTM Zone 3.

TABLE 1—PROSPECT LOCATIONS

Prospect	Well	Area	Block	Lease No.	Latitude	Longitude
Burger	A	Posey	6764	OCS–Y–2280	N71° 18′ 30.92″	W163° 12′ 43.17″
Burger	F	Posey	6714	OCS–Y–2267	N71° 20′ 13.96″	W163° 12′ 21.75″
Burger	J	Posey	6912	OCS–Y–2321	N71° 10′ 24.03″	W163° 28′ 18.52″
Burger	R	Posey	6812	OCS–Y–2294	N71° 16′ 06.57″	W163° 30′ 39.44″
Burger	S	Posey	6762	OCS–Y–2278	N71° 19′ 25.79″	W163° 28′ 40.84″
Burger	V	Posey	6915	OCS–Y–2324	N71° 10′ 33.39″	W163° 04′ 21.23″
Sivulliq	G	Flaxman Is	6658	OCS–Y 1805	N70° 23′ 46.82″	W146° 01′ 03.46″
Sivulliq	N	Flaxman Is	6658	OCS–Y 1805	N70° 23′ 29.58″	W145° 58′ 52.53″
Torpedo	H	Flaxman Is	6610	OCS–Y 1941	N70° 27′ 01.62″	W145° 49′ 32.07″

TABLE 1—PROSPECT LOCATIONS—Continued

Prospect	Well	Area	Block	Lease No.	Latitude	Longitude
Torpedo	J	Flaxman Is	6559	OCS–Y 1936	N70° 28′ 56.94″	W145° 53′ 47.15″

(b) The navigable waters, from the surface to seabed, within 500 meters (1,640.4 feet) from each point on the outer edge of the vessel, while anchored or deploying and recovering moorings on location, is a safety zone. Lawful demonstrations may be conducted outside of the safety zone.

(c) *Regulation.* No vessel may enter or remain in this safety zone except the following:

(1) An attending vessel; or

(2) A vessel authorized by the Commander, Seventeenth Coast Guard District, or a designated representative. A ''designated representative'' is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Commander, Seventeenth Coast Guard District to act on his or her behalf.

(d) *Penalties.* Violation of this regulation may result in criminal or civil penalties, or both.

(e) *Effective Period.* This rule is effective from July 1, 2012, and terminates on December 1, 2012, unless sooner terminated by the Commander, Seventeenth Coast Guard District.

Dated: June 13, 2012.

Thomas P. Ostebo,

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

[FR Doc. 2012–15950 Filed 6–28–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0131]

RIN 1625–AA00

Safety Zones; Sellwood Bridge Project, Willamette River; Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary Final Rule.

SUMMARY: The Coast Guard is establishing two safety zones to remain in effect throughout the duration of the construction and renewal of the Sellwood Bridge located on the Willamette River in Portland, Oregon. This action is necessary to ensure the safety of vessels transiting in close proximity to cranes, barges, and temporary structures associated with this construction project. During the effective period, all vessels will be required to remain at the prescribed safe distance from the construction area while transiting in the vicinity of the Sellwood Bridge project; however, the establishment of these safety zones does not entirely close this section of the Willamette River. The section of the Willamette River between the safety zones will remain open for vessel transits, and it will have a minimum channel width of 138 feet at all times.

DATES: This rule is effective from July 1, 2012 until January 31, 2015.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0131 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0131 in the ''Search'' box, and then clicking ''Search.'' They are also available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this Temporary Final Rule, call or email ENS Ian McPhillips, Waterways Management Division, Coast Guard MSU Portland; telephone 503–240–9319, email *msupdxwwm@uscg.mil.* If you have questions on viewing 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

Regulatory History and Information

On May 14, 2012 we published a notice of proposed rulemaking (NPRM) titled Sellwood Bridge Project, Willamette River (77 FR 15009). We received no comments on the proposed rule. There were no requests made for public meeting regarding this rule and none were held. No other documents have been published for this rulemaking.

Basis and Purpose

The Sellwood Bridge project will replace the existing 86 year old bridge that is structurally inadequate and functionally obsolete. The project will renew the bridge with a new deck arch structure compliant with current loading and seismic requirements, upgrade the interchange at Oregon Route 43, and provide substantially improved bicycle and pedestrian facilities. Construction work will continue through January 1, 2015. The project includes the construction of two temporary structures and two new bridge piers which will each require a cofferdam. The temporary structures will be constructed to facilitate the moving of the older bridge. To ensure the safety of construction crews on the barges, temporary structures, and cranes, two safety zones on each side of the river are being established to require vessels in the vicinity of the construction area to remain outside of the two designated safety zones. Additionally, these safety zones will ensure that the vessels operating in the vicinity of the designated area will not be in any dangerous areas near the temporary structures or cranes.

Discussion of the Rule

The rule establishes two safety zones that cover all waters of the Willamette River; however, the establishment of these safety zones does not entirely close this section of the Willamette River. The section of the Willamette River between the safety zones will remain open for vessel transits, and it will have a minimum channel width of 138 feet at all times. The safety zone on the western river bank encompasses all waters of the Willamette River within the following four points:

45–27′53.5″ N	122–40′03.5″ W
45–27′53.5″ N	122–39′58.5″ W
45–27′49.5″ N	122–39′58.5″ W
45–27′49.5″ N	122–40′04.5″ W

The safety zone on the eastern river bank is encompassed within the following four points:

45–27′53.5″ N	122–39′50.5″ W
45–27′53.5″ N	122–39′55.0″ W
45–27′49.5″ N	122–39′55.0″ W
45–27′49.5″ N	122–39′47.0″ W

Geographically this rule covers the waters of the Willamette River for two

zones east and west of the main shipping channel, 100 feet upriver and downriver of the existing Sellwood Bridge, from the edges of the shipping channel outward to the east and west shorelines. The section of the Willamette River between the safety zones will remain open for vessel transits, and it will have a minimum width of 138 feet at all times. These safety zones will ensure the safety of the all vessels and crew that are working and transiting in the construction areas.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

Executive Orders 13563, Improving Regulation and Regulatory Review, and 12866, Regulatory Planning and Review, direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget has not reviewed this regulation under Executive Order 12866. The Coast Guard has made this determination based on the fact that the safety zones created by this rule will not significantly affect the maritime public because vessels may still transit in the vicinity of the safety zones.

Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this 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 and operators of vessels intending to operate in the area covered by the safety zones. The safety zones will not have a significant economic impact on a substantial number of small entities because the area can still be used to transit through this section of the river, which will maintain a minimum width of 138 feet. Other maritime users, such as dragon boats, kayaks, and canoes, will be able to transit around the safety zones or through the open section.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact ENS Ian McPhillips, Waterways Management Division, Marine Safety Unit Portland, Coast Guard; telephone 503–240–9319, email *msupdxwwm@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

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 the people, places or vessels.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have 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. An environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the instruction. This rule involves the creation of two safety zones.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T13–207 to read as follows:

§ 165.T13–207 Safety Zones; Sellwood Bridge project, Willamette River; Portland, OR.

(a) Location. The safety zone on the western river bank encompasses all waters of the Willamette River within the following four points:

45–27′53.5″ N	122–40′03.5″ W
45–27′53.5″ N	122–39′58.5″ W
45–27′49.5″ N	122–39′58.5″ W
45–27′49.5″ N	122–40′04.5″ W

(b) The safety zone on the eastern river bank encompasses all waters of the Willamette River within the following four points:

45–27′53.5″ N	122–39′50.5″ W
45–27′53.5″ N	122–39′55.0″ W
45–27′49.5″ N	122–39′55.0″ W
45–27′49.5″ N	122–39′47.0″ W

(c) Regulations. In accordance with the general regulations in 33 CFR Part 165, subpart C, no person may enter or remain in the safety zones created in this section or bring, cause to be brought, or allow to remain in the safety zones created in this section any vehicle, vessel, or object unless authorized by the Captain of the Port Columbia River or his designated representative. The Captain of the Port Columbia River may be assisted by other federal, state, or local agencies with the enforcement of the safety zones.

(d) Enforcement Period. The safety zones created by this section will be in effect from 11 a.m. on July 1, 2012 through 11:00 p.m. on January 31, 2015.

Dated: June 5, 2012.

B.C. Jones,

Captain, U.S. Coast Guard, Captain of the Port, Columbia River.

[FR Doc. 2012–15951 Filed 6–28–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–1050; FRL–9690–3]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Volatile Organic Compounds; Consumer Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: In this action we are approving into the Indiana State Implementation Plan (SIP) the addition of a new rule that sets volatile organic compound (VOC) emissions limits and other restrictions on consumer products that are sold, supplied, manufactured, or offered for sale in the State of Indiana.

DATES: This rule is effective August 28, 2012, unless EPA receives adverse comments by July 30, 2012. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2010–1050, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: blakley.pamela@epa.gov.*
3. *Fax:* (312) 692–2450.
4. *Mail:* Pamela Blakley, Chief, Control Strategies Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Pamela Blakley, Chief, Control Strategies Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2010–1050. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment

that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Anthony Maietta, Environmental Protection Specialist, at (312) 353–8777 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Anthony Maietta, Environmental Protection Specialist, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8777, *maietta.anthony@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. Background

''Consumer products'' encompass a wide array of sprays, gels, cleaners, adhesives, and other chemically formulated products that are purchased for personal or institutional use and that emit VOCs through their use, consumption, storage, disposal, destruction, or decomposition. On December 7, 2010, the Indiana Department of Environmental Management (IDEM) requested that EPA approve into its SIP the addition of a new rule that limits VOC in consumer products. The rule is located within Title 326 of the Indiana Administrative Code (IAC) Article 8 ''Volatile Organic Compound Rules'' at 326 IAC 8–15. The rule consists of the following nine sections:

(1) Section 1, ''Applicability''
(2) Section 2, ''Definitions''
(3) Section 3, ''Standards''
(4) Section 4, ''Exemptions''
(5) Section 5, ''Innovative products exemption''
(6) Section 6, ''Alternative control plan''
(7) Section 7, ''Administrative requirements''
(8) Section 8, ''Record keeping and reporting requirements''
(9) Section 9, ''Test methods''

A discussion of each section and its approvability is included in section III of this action.

The rule that Indiana adopted and submitted to EPA for approval is based on the model rule developed by the Ozone Transport Commission (OTC) for consumer products. The OTC is a multi-state organization created under section 176A of the Clean Air Act. It is responsible for advising EPA on transport issues and for developing and implementing regional solutions to the ground-level ozone problem in the Northeast and Mid-Atlantic regions.

The OTC has developed this model rule for consumer products which OTC member states have signed a memorandum of understanding to adopt. The OTC model rule that Indiana based its rule on is at least as stringent as, and in most cases is more stringent than, EPA's national consumer products rule, ''National Volatile Organic Compound Emission Standards for Consumer Products,'' 40 CFR part 59, subpart C. It should be noted that Indiana is not an OTC member state. By adopting a rule that mirrors the OTC model rule, however, Indiana is strengthening its SIP through enforceable VOC limits for consumer products with corresponding recordkeeping and reporting requirements.

II. Contents of Indiana's Rule

The following is a summary of each section of 326 IAC 8–15 ''Standards for Consumer and Commercial Products,'' as submitted on November 7, 2010, and a discussion of why each section is approvable into the State's SIP.

326 IAC 8–15–1 ''Applicability''

This section makes 326 IAC 8–15 applicable to any person who sells, supplies, offers for sale, or manufactures consumer products in the State of Indiana on or after June 1, 2011. The applicability for the rule as outlined in this section is congruent with the model OTC language, and therefore is approvable for inclusion in Indiana's SIP.

326 IAC 8–15–2 ''Definitions''

This section provides definitions of products, terms, acronyms, and other language that are unique and/or specific to this rule. This section is congruent with the OTC model rule, and therefore is approvable for inclusion in Indiana's SIP.

326 IAC 8–15–3 ''Standards''

This section codifies VOC standards for each category of consumer products affected by 326 IAC 8–15 and includes additional requirements for certain product categories. Each category of consumer product and its associated VOC limit mirror the OTC model rule as do additional requirements for certain product categories, including:

—A ban on use of air toxics, as classified by the California Code of Regulations, in antiperspirants and deodorants.
—A provision establishing how to determine the VOC content of diluted products.
—Sell-through provisions for affected products that were already manufactured by June 1, 2011.
—An effective date of June 1, 2012, for any products that are covered by 326 IAC 8–15 and also registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
—A restriction on sale of any charcoal lighter material that has not been issued a currently effective certification by either the California Air Resources Board (CARB), or another state air agency in conjunction with EPA.
—Additional requirements for aerosol adhesives, including a ban on the sale or manufacturing of aerosol adhesives containing methylene chloride, perchloroethylene, or trichloroethylene.
—A requirement for floor wax strippers that ensures that product packaging clearly indicates ''light/medium'' and ''heavy'' dilution ratios that correlate with the associated VOC limits for these dilutions.
—Additional requirements for products containing ozone depleting compounds.
—Additional requirements for adhesive removers, contact adhesives, electrical cleaners, electronic cleaners, footwear or leather care products, general purpose degreasers, and graffiti removers that contain methylene

chloride, perchloroethylene, or trichloroethylene.

This section is at least as stringent as the OTC model rule, and therefore is approvable for inclusion in Indiana's SIP.

326 IAC 8–15–4 ''Exemptions''

This section outlines conditions for certain products that may allow them to be exempt from 326 IAC 8–15, including an exemption for products manufactured in the State but meant for sale outside the State. This section also allows a retailer (but not manufacturer) to not be considered in violation of 326 IAC 8–15 if they immediately discontinue sale of the violating product, and make good faith efforts to assure the product met the applicable requirements of 326 IAC 8–15. Finally, this section excludes any products that are regulated under this rule from the administrative requirements of the rule if the products are registered under FIFRA. This section is congruent with the OTC model rule, and therefore is approvable.

326 IAC 8–15–5 ''Innovative Products Exemption''

This section allows for an exemption for products otherwise covered under 326 IAC 8–15, so long as the manufacturer has been granted an innovative products exemption by CARB or the air pollution control agency of another state with an innovative products exemption substantially equivalent to CARB's. This section then outlines additional requirements necessary for Indiana to consider an innovative products exemption to be valid within the State. Finally, this section outlines conditions in which the innovative products exemption can expire or be revoked by the State. This section is congruent with the OTC model rule, and therefore is approvable.

326 IAC 8–15–6 ''Alternative Control Plan''

This section outlines circumstances in which a manufacturer of a product regulated under 326 IAC 8–15 can provide an alternative method to comply with the VOC limits contained in Indiana's rule. Only manufacturers who have been granted an alternative control plan by CARB, or a state air pollution control agency with alternative control plans to consumer product VOC limits that are substantially equivalent to CARB's alternative control plan, may be exempted from the VOC limits in Indiana's rule. The section also outlines circumstances in which an approved alternative control plan can be considered valid, or can be revoked by the State. This section is congruent with the OTC model rule, and therefore is approvable.

326 IAC 8–15–7 ''Administrative Requirements''

This section outlines product dating and labeling requirements for consumer products manufactured or sold in Indiana. This section also defines the most restrictive limit that a product must meet if it is regulated by FIFRA as well as 326 IAC 8–15. This section is congruent with the OTC model rule and therefore is approvable.

326 IAC 8–15–8 ''Record Keeping and Reporting Requirements''

This section outlines the recordkeeping and reporting requirements that manufacturers of products regulated under this rule must meet. Manufacturers must keep and make available to Indiana or EPA information about their product, including:

—The product manufacturer's name and contact information.
—Any claim of confidentiality of the product.
—The product's name, and a description of the product category to which the product belongs.
—Applicable product form or forms listed separately.
—Identification of each product brand name and whether it is a household product, industrial and institutional product, or both.
—Sales of the product in Indiana in pounds per year, as well as the methodology used to achieve the calculation.
—An identification of each company that is submitting relevant data about the product (if it is manufactured using multiple companies).
—Specific net ''percent by weight'' information for certain compounds that may be in the product.
—Specific chemical names of certain compounds used in the product formulation.
—Propellant information, if propellant is used in the product.

This section also specifies which information a company may present to the State if it cannot meet the requirements listed above. Finally, this section contains special reporting requirements for products that contain perchloroethylene or methylene chloride. This section is congruent with the OTC model rule, and therefore is approvable.

326 IAC 8–15–9 ''Test Methods''

This section outlines methods acceptable to the State that manufacturers can use to determine compliance with the VOC content limits outlined in the rule. Manufacturers may use CARB Method 310, a method approved in writing both by the State of Indiana and EPA, or through calculation of the VOC content of constituents used to make the product. This section also includes the approved method to test whether a product is a liquid or solid, and the approved method to determine the distillation points of petroleum distillate-based charcoal lighter materials. This section is congruent with the OTC model rule, and therefore is approvable.

III. What action is EPA taking?

EPA is approving into the Indiana SIP Title 326 IAC Article 8–15 as adopted by the State of Indiana and as submitted to EPA on December 7, 2010. We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective August 28, 2012 without further notice unless we receive relevant adverse written comments by July 30, 2012. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective August 28, 2012.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus,

in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 28, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 11, 2012.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.770 the table in paragraph (c) is amended by adding a new entry in ''Article 8. Volatile Organic Compound Rules'' for ''Rule 15. Standards for Consumer and Commercial Products'' in numerical order to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED INDIANA REGULATIONS

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
*	*	*	*	*
Article 8. Volatile Organic Compound Rules				
*	*	*	*	*
Rule 15. Standards for Consumer and Commercial Products				
8–15–1	Applicability	12/1/2010	6/29/2012, [Insert page number where the document begins].	
8–15–2	Definitions	12/1/2010	6/29/2012, [Insert page number where the document begins].	
8–15–3	Standards	12/1/2010	6/29/2012, [Insert page number where the document begins].	
8–15–4	Exemptions	12/1/2010	6/29/2012, [Insert page number where the document begins].	
8–15–5	Innovative products exemption.	12/1/2010	6/29/2012, [Insert page number where the document begins].	

EPA-APPROVED INDIANA REGULATIONS—Continued

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
8–15–6	Alternative control plan	12/1/2010	6/29/2012, [Insert page number where the document begins].	
8–15–7	Administrative requirements	12/1/2010	6/29/2012, [Insert page number where the document begins].	
8–15–8	Record keeping and reporting requirements.	12/1/2010	6/29/2012, [Insert page number where the document begins].	
8–15–9	Test methods	12/1/2010	6/29/2012, [Insert page number where the document begins].	
*	*	*	*	*

[FR Doc. 2012–15688 Filed 6–28–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 126

[Docket No. USCG–2011–0966]

RIN 1625–AB82

Alternate Tonnage Threshold for Oil Spill Response Vessels

AGENCY: Coast Guard, DHS.

ACTION: Final rule; Interpretation.

SUMMARY: The Coast Guard is establishing an alternate size threshold based on the measurement system established under the International Convention on Tonnage Measurement of Ships, 1969, for oil spill response vessels, which are properly certificated under 46 CFR chapter I, subchapter L. The present size threshold of 500 gross register tons is based on the U.S. regulatory measurement system. This final rule provides an alternative for owners and operators of offshore supply vessels that may result in an increase in oil spill response capacity and capability. This final rule adopts, without change, the interim rule amending 46 CFR part 126 published in the **Federal Register** on Monday, December 12, 2011.

DATES: This final rule is effective June 29, 2012.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2011–0966 and are available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2011–0966 in the ''Keyword'' box, and then clicking ''Search.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this final rule, call or email Mr. Brian T. Ellis, Coast Guard Marine Safety Center; telephone 202–475–5636, email *Brian.T.Ellis@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Abbreviations

DHS Department of Homeland Security
FR **Federal Register**
GT ITC Gross Tonnage International Tonnage Convention, 1969
OSV Offshore Supply Vessel
OSRV Oil Spill Response Vessel
U.S.C. United States Code

II. Regulatory History

On Monday, December 12, 2011, the Coast Guard published an interim rule with request for comments entitled Alternate Tonnage Threshold for Oil Spill Response Vessels in the **Federal Register** (76 FR 77128). We received no comments on the interim rule. No public meeting was requested and none was held. This rule is considered to be an interpretive rule under the Administrative Procedure Act (5 U.S.C. 551 et seq.) and, therefore, the 30-day delay of the effective date is not required under 5 U.S.C. 553(d)(2).

III. Basis and Purpose

The interim final rule published in the **Federal Register** on Monday, December 12, 2011 (76 FR 77128) provides a discussion of the basis and purpose of this rulemaking, but a summary of that discussion follows.

This final rule establishes an alternate tonnage threshold at 6000 Gross Tonnage International Tonnage Convention (GT ITC) for oil spill response vessels (OSRVs) that are also certificated as offshore supply vessels (OSVs). The selected alternate tonnage threshold is consistent with a 6000 GT ITC alternate threshold established for OSVs in 1996.[1] This final rule will allow owners of OSVs regulated under the alternate tonnage framework to also have their vessels certificated as OSRVs, without the need to meet significantly higher standards applicable to tank vessels.

Because this final rule provides for optional use of an alternative approach to meet an existing requirement, there is no mandatory cost to the public. The authority for this final rule is the 1996 Coast Guard Authorization Act (the Act) (Pub. L. 104–324), as codified in 46 U.S.C. 3702(f)(2)(A) and 14104(b).

IV. Background

The interim final rule, published in the **Federal Register** on Monday, December 12, 2011 (76 FR 77128), provides a discussion of the background of this rulemaking. No comments were received on the interim final rule and,

[1] See Offshore Supply Vessels: Alternate Tonnage, 61 FR 66613 (Dec. 18, 1996), amending 46 CFR 125.160.

therefore, this final rule adopts, without change, that interim rule amending 46 CFR part 126.

V. Regulatory Analyses

We developed this final rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 14 of these statutes or executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has reviewed it under that Order.

This final rule establishes a tonnage threshold of 6000 GT ITC for OSRVs under the alternate tonnage framework, which offers a mechanism for the Coast Guard to regulate vessels under tonnages assigned using the convention measurement system, instead of the regulatory measurement system. Therefore, this final rule provides an option to owners of vessels certificated as OSVs (under 46 CFR subchapter L) to seek OSRV certification based on this alternate tonnage threshold. We believe that a vessel owner will opt to use the alternate tonnage framework described in this final rule only if it will be beneficial to the owner's business.

We expect this final rule to be beneficial to the public and to the maritime industry because it provides the opportunity to increase oil spill response capacity and capability.

This final rule provides for optional and voluntary use of an alternative approach to meet an existing requirement. Accordingly, there is no mandatory cost to the public.

B. Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), this rule is considered an interpretive rule and is not subject to the requirement under 5 U.S.C. 553(b) for publication of a general notice of proposed rulemaking. Therefore, under 5 U.S.C. 601, it is not a rule that is subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

The Coast Guard issued this rule as an interpretive rule on December 12, 2011, as authorized by section 702 of the Act (Pub. L. 104–324; October 19, 1996). The Conference Report on the Act (H. Rept. 104–854) states that, because this rule is considered to be an interpretive rule under the Administrative Procedure Act (5 U.S.C. 551 *et seq.*), the notice of proposed rulemaking and comment requirements and the 30-day delay of effective date under 5 U.S.C. 553 would not be required in order to expedite this rulemaking.

This final rule provides for optional and voluntary use of an alternative approach to owners of vessels certificated as OSVs to seek an OSRV certification based on an alternate tonnage threshold. We believe that a vessel owner will opt to use the alternate tonnage framework described in this final rule only if it will be beneficial to the owner's business. We expect this final rule to be beneficial to the public and to the maritime industry because it provides the opportunity to increase the availability and capacity of OSRVs.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Brian T. Ellis, U.S. Coast Guard Marine Safety Center, Tonnage Division, 202–475–5636, *Brian.T.Ellis@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it does not have implications for federalism. It is well settled that States may not establish alternate tonnages for oil spill response vessels pursuant to 46 U.S.C. 3702(f)(2)(A). Therefore, preemption is not an issue under Executive Order 13132.

F. Unfunded Mandates Reform Act

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

G. Taking of Private Property

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

H. Civil Justice Reform

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

I. Protection of Children

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

J. Indian Tribal Governments

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

K. Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order 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.

L. Technical Standards

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

M. Environment

We have analyzed this final 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 (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This final rule is categorically excluded under section 2.B.2, figure 2–1, paragraph (34)(d) of the Instruction. Exclusion under paragraph (34)(d) applies because this final rule pertains to regulations concerning documentation and admeasurement of vessels. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 46 CFR Part 126

Cargo vessels, Marine safety, Reporting and recordkeeping requirements.

PART 126–INSPECTION AND CERTIFICATION

Accordingly, the interim rule amending 46 CFR part 126, which was published at 76 FR 77128 on December 12, 2011, is adopted as a final rule without change.

Dated: May 24, 2012.

F. J. Sturm,

Acting Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2012–15976 Filed 6–28–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 218, 232 and 252

RIN Number 0750–AH40

Defense Federal Acquisition Regulation Supplement: Updates to Wide Area WorkFlow (DFARS Case 2011–D027)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to update policies on the submission of payment requests and receiving reports in electronic format.

DATES: *Effective date:* June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Veronica Fallon, 571–372–6087.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule at 76 FR 71928 on November 21, 2011, to update DFARS policies and procedures for electronic submission of payment requests and receiving reports through Wide Area WorkFlow (WAWF) and TRICARE Encounter Data System (TEDS). WAWF, which electronically interfaces with the primary DoD payment systems, is the accepted DoD system for generating invoices and receiving reports. TEDS is an accepted system for processing payment requests for rendered TRICARE health care services.

The capabilities of WAWF have expanded to enable use in additional environments by a wider variety of users. As such, this rule expands the use of WAWF for submission of payment requests and receiving reports and standardizes processes and instructions on the use of WAWF. The public comment period closed January 20, 2011. Six respondents submitted comments on the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

A. Summary of Significant Changes

Changes to the proposed rule to clarify language were made at 232.7002 Policy, 232.7004 Prescription, and the Payment Clause at 252.232–7003, Electronic Submission of Payment Requests and Receiving Reports. The new payment instruction clause at 252.232–7006, Wide Area WorkFlow Payment Instructions, was changed to more clearly identify WAWF as DoD's method to receive payment requests and receiving reports and clarify language and to clarify instructions for completion of clause fill-ins.

B. Analysis of Public Comments

1. Policies and Procedures

Comment: Several respondents identified an apparent inconsistency with use of the term ''Senior Procurement Executive'' in the Supplementary and Background information and the use of the term ''Service Procurement Executive'' in the proposed change to 232.7002(a)(6).

Response: The correct term is ''Senior Procurement Executive,'' which is incorporated into the final rule.

Comment: A respondent observed that language is confusing to the reader, in both the proposed change to policy at 232.7002(a)(1) and the existing clause at 252.232–7003, Electronic Submission of Payment Requests and Receiving Reports, paragraph (c)(4). Specifically, according to the respondent, the language is unclear that describes what is and is not required to be submitted in electronic form for payment requests and receiving reports when purchases are paid for using a Governmentwide purchase card.

Response: The language of the final rule in both instances noted is revised to reflect clarifying language as suggested by the respondent.

Comment: One respondent requested adding to the rule additional procedures at 232.7003 to allow use of an existing Navy system, PayWeb, for submitting and processing payment requests by universities and nonprofits administered by Office of Naval Research Regional Office.

Response: Consideration of the respondent's comment resulted in no change to the final rule. However, the Department of the Navy plans to issue supplementary guidance to address PayWeb, a front-end system that feeds Electronic Data Interchange to WAWF.

2. Wide Area WorkFlow Payment Instructions Clause

Comment: Three comments addressed paragraph (f)(1) of the clause. One respondent identified that a listed document type is not an allowable document for their office, and that there is a possible conflict in language between this paragraph and the note that follows. Another respondent provided two comments. First, issues were noted with regard to possible scenarios resulting from ambiguous terminology and a lack of identified procedures to address said scenarios. Second, the respondent is unsure the reader will understand the intended use of the note following the paragraph, and requested the note be clarified as to its purpose and intended use.

Response: Regarding the concern of allowable document types, applicable instructions to preclude possible conflicts have been incorporated into the WAWF Web site. A link to the Web site is included in the DFARS clause and in the Procedures Guidance and Information (PGI) text. In addition, since it is the contracting officer who inserts the document type into the clause, there should be no resultant issue. Therefore, no change is made to the language of the rule as a result of this comment.

In response to the concern regarding possible scenarios resulting from ambiguous terminology of the text, the language in question is deleted, leaving a clear statement. Likewise, deletion of this text served to resolve the comment concerning the intended use of the note following the paragraph.

Comment: Two respondents expressed concern with the Routing Data Table at paragraph (f)(3). The respondents indicated that the table may increase the workload of contracting personnel and increase the opportunity for error and inconsistency. Also, the table may not account for all circumstances.

Response: The Routing Data Table along with the instructions for the contracting officer to complete the table is retained in the final rule; however, several of the respondents' suggestions, which clarified a number of table elements, are incorporated into the final rule. DoD retained the Routing Data Table and instructions after considering the following: (1) The possible variation in contract formats and types; (2) the absence of a more acceptable place to identify the local processing office in existing contracts; and (3) in order to increase the ease of use and facilitate contractor compliance.

Comment: One respondent recommended revised language for paragraph (f)(4) to strengthen the rule in consideration of future audits.

Response: The data requirements for documentation to be submitted with specific actions are well defined elsewhere in the regulations (e.g. DFARS Appendix F). Repeating those requirements again in the clause would create redundancy and introduce the possibility of conflict between updates to Appendix F and the clause language.

Comment: Two respondents observed that the clause language for paragraph (g), Payment request follow-up, is not compatible with current systems and does not provide complete information regarding availability of invoice status.

Response: The paragraph (g) clause text is deleted since the capability discussed is now provided for in WAWF. Therefore, inclusion of the paragraph (g) text is not necessary.

Comment: Two respondents noted that paragraph (h), WAWF point of contact, may not be appropriately included; or if included, a better point of contact could be provided.

Response: Former paragraph (h), which is now paragraph (g) in the final rule, is updated to include subparagraphs so that an additional point of contact for technical issues, the WAWF helpdesk, is also listed.

Comment: One respondent identified a disparity between language in the existing clause at 252.232.7003, Electronic Submission of Payment Requests and Receiving Reports, paragraph (b), and the proposed clause paragraph (b) regarding ''preferred method'' versus ''contractor shall''.

Response: WAWF is the DoD system to electronically process payment requests and receiving reports, therefore the word ''preferred'' was deleted in the final rule. Further, in this same paragraph (b); language regarding alternate invoicing methods as agreed to by the parties is also deleted. The remaining language demonstrates DoD's effort to meet the intent of the E–Government Act and the Paperwork Reduction Act in minimizing the number of ways contractors must interact with the Government.

3. Definitions

Comment: The value of the definitions at paragraph (a) of the proposed new clause at 252.232–70XX was questioned. The respondent suggests deleting definitions from the clause as definitions are provided as part of the referenced WAWF training.

Response: Definitions are customarily included in the DFARS clause to ensure immediate understanding of the terminology of the clause. As suggested, the definition of ''local processing office'' has been edited to convey a generic application.

4. Prescription

Comment: Several comments addressed the proposed change to the prescription at 232.7004(a) and following paragraphs (1) through (6). The respondents expressed that paragraphs (1) through (6) as a whole may be confusing to the reader regarding whether and when use of WAWF is required or an exception applies.

Response: To alleviate potential confusion in the prescription at 232.7004(a), the proposed references to subparagraphs are deleted.

5. Web Site Links

Comment: A respondent stated that the Web site links provided were not working for the new proposed clause at 252.232–70XX.

Response: The Web site links included for this final rule are active and accurate.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD expects that this rule may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Therefore, a Final Regulatory Flexibility Analysis has been prepared and is summarized as follows:

The rule incorporates WAWF's new capability of capturing receiving reports for contracts paid with a Governmentwide commercial purchase card and clarifies exceptions to the use of WAWF. The rule also consolidates and standardizes instructions to contractors on how to use the WAWF application. Furthermore, it eliminates locally defined methods that, in some cases, cause confusion and inefficiencies. It also incorporates the use of TEDS for medical services requiring Health Insurance Portability and Accountability Act data not handled by WAWF.

DoD made small business awards to 47,000 companies in Fiscal Year 2011. With the exception of less than 7,000 companies that only received awards paid with a purchase card, this rule will simplify procedures by allowing contractors to use the same payment process and systems for all DoD shipments.

This rule does not impose any new reporting or record keeping requirements.

The rule does not duplicate, overlap, or conflict with any other Federal rules. No significant alternatives have been identified that would accomplish the stated objectives of this rule.

V. Paperwork Reduction Act

This rule does not impose any new information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 218, 232 and 252

Government procurement.

Mary Overstreet,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 218, 232, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 218, 232, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 218—EMERGENCY ACQUISITIONS

■ 2. Section 218.170(j) is revised to read as follows:

218.170 Additional acquisition flexibilities.

* * * * *

(j) *Electronic submission and processing of payment requests.* Exceptions to the use of Wide Area WorkFlow are at 232.7002(a).

* * * * *

PART 232—CONTRACT FINANCING

■ 3. Section 232.7002(a) is revised to read as follows:

232.7002 Policy.

(a)(1) Contractors shall submit payment requests and receiving reports in electronic form, except for—

(i) Classified contracts or purchases when electronic submission and processing of payment requests could compromise the safeguarding of classified information or national security;

(ii) Contracts awarded by deployed contracting officers in the course of military operations, including, but not limited to, contingency operations as defined in 10 U.S.C. 101(a)(13) or humanitarian or peacekeeping operations as defined in 10 U.S.C. 2302(8), or contracts awarded by contracting officers in the conduct of emergency operations, such as responses to natural disasters or national or civil emergencies, when access to Wide Area WorkFlow by those contractors is not feasible;

(iii) Purchases to support unusual or compelling needs of the type described in FAR 6.302–2, when access to Wide Area WorkFlow by those contractors is not feasible;

(iv) Cases in which DoD is unable to receive payment requests or possible acceptance in electronic form;

(v) Cases in which the contracting officer administering the contract for payment has determined, in writing, that electronic submission would be unduly burdensome to the contractor. In those cases, the contracting officer administering the contract shall furnish a copy of the determination to their Senior Procurement Executive; and

(2) When the Governmentwide commercial purchase card is used as the method of payment, only submission of the receiving report in electronic form is required.

* * * * *

■ 4. Section 232.7003 is amended by revising paragraphs (b) and (c) to read as follows:

232.7003 Procedures.

* * * * *

(b) For payment of commercial transportation services provided under a Government rate tender or a contract for transportation services, the use of a DoD-approved electronic third party payment system or other exempted vendor payment/invoicing system (e.g., PowerTrack, Transportation Financial Management System, and Cargo and Billing System) is permitted.

(c) For submitting and processing payment requests and receiving reports for rendered health care services, use of TRICARE Encounter Data System as the electronic format is permitted.

■ 5. Section 232.7004 is revised to read as follows:

232.7004 Contract clauses.

(a) Except as provided in 232.7002(a), use the clause at 252.232–7003, Electronic Submission of Payment Requests and Receiving Reports, in solicitations and contracts.

(b) Use the clause at 252.232–7006, Wide Area WorkFlow Payment Instructions, when 252.232–7003 is used and neither 232.7003 (b) nor (c) apply. See PGI 232.7004 for instructions on completing the clause.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 6. Section 252.232–7003 is amended—

■ a. In the introductory text by removing the reference ''232.7004'' and adding in its place ''232.7004(a)'';

■ b. By removing the clause date ''(MAR 2008)'' and adding in its place ''(JUN 2012)'';

■ c. By adding paragraph (a)(4);

■ d. By removing paragraphs (c)(1) and (2);

■ (e) By redesignating paragraphs (c)(3) and (4) as paragraphs (c)(1) and (2), respectively;

■ (f) By removing the word ''or'' at the end of newly redesignated paragraph (c)(1);

■ (g) By removing the period at the end of newly redesignated paragraph (c)(2) and adding a semicolon in its place; and

■ (h) By adding new paragraphs (c)(3) and (4).

The additions read as follows:

252.232–7003 Electronic Submission of Payment Requests and Receiving Reports.

* * * * *

(a) * * *

(4) ''Receiving report'' means the data required by the clause at 252.246–7000, Material Inspection and Receiving Report.

* * * * *

(c) * * *

(3) DoD makes payment for rendered health care services using the TRICARE Encounter Data System (TEDS) as the electronic format; or

(4) When the Governmentwide commercial purchase card is used as the method of payment, only submission of the receiving report in electronic form is required.

* * * * *

■ 7. Section 252.232–7006 is added to read as follows:

252.232–7006 Wide Area WorkFlow Payment Instructions.

As prescribed in 232.7004(b), use the following clause:

WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (JUN 2012)

(a) *Definitions.* As used in this clause—

Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) *Electronic invoicing.* The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232–7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) *WAWF access.* To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the Central Contractor Registration at *https://www.acquisition.gov;* and

(2) Be registered to use WAWF at *https://wawf.eb.mil/* following the step-by-step procedures for self-registration available at this Web site.

(d) *WAWF training.* The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the ''Web Based Training'' link on the WAWF home page at *https://wawf.eb.mil/.*

(e) *WAWF methods of document submission.* Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) *WAWF payment instructions.* The Contractor must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) *Document type.* The Contractor shall use the following document type(s).

(*Contracting Officer: Insert applicable document type(s). Note: If a ''Combo'' document type is identified but not supportable by the Contractor's business systems, an ''Invoice'' (stand-alone) and ''Receiving Report'' (stand-alone) document type may be used instead.*)

(2) *Inspection/acceptance location.* The Contractor shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

(*Contracting Officer: Insert inspection and acceptance locations or ''Not applicable.''*)

(3) *Document routing.* The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

ROUTING DATA TABLE*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	
Issue By DoDAAC	
Admin DoDAAC	
Inspect By DoDAAC	
Ship To Code	
Ship From Code	
Mark For Code	
Service Approver (DoDAAC)	
Service Acceptor (DoDAAC)	
Accept at Other DoDAAC	
LPO DoDAAC	
DCAA Auditor DoDAAC	
Other DoDAAC(s)	

(**Contracting Officer: Insert applicable DoDAAC information or ''See schedule'' if multiple ship to/acceptance locations apply, or ''Not applicable.''*)

(4) *Payment request and supporting documentation.* The Contractor shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation, as defined in DFARS Appendix F, (e.g. timesheets) in support of each payment request.

(5) *WAWF email notifications.* The Contractor shall enter the email address identified below in the ''Send Additional Email Notifications'' field of WAWF once a document is submitted in the system.

(*Contracting Officer: Insert applicable email addresses or ''Not applicable.''*)

(g) *WAWF point of contact.* (1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(*Contracting Officer: Insert applicable information or ''Not applicable.''*)

(2) For technical WAWF help, contact the WAWF helpdesk at 866–618–5988.

(End of clause)

[FR Doc. 2012–15566 Filed 6–28–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 225 and 252

RIN 0750–AH73

Defense Federal Acquisition Regulation Supplement; Acquisition of Tents and Other Temporary Structures (DFARS Case 2012–D015)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule.

SUMMARY: DoD is issuing an interim rule to implement sections of the National Defense Authorization Act for Fiscal Year 2012 that address the acquisition of tents and other temporary structures.

DATES: *Effective date:* June 29, 2012.

Comment date: Comments are due by August 28, 2012.

ADDRESSES: Submit comments identified by DFARS Case 2012–D015, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by inserting ''DFARS Case 2012–D015'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2012–D015.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2012–D015'' on your attached document.

○ *Email: dfars@osd.mil.* Include DFARS Case 2012–D015 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Amy G. Williams, OUSD(AT&L)DPAP/DARS, Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

SUPPLEMENTARY INFORMATION:

I. Background

This interim rule amends DFARS subpart 225.70 and the associated DFARS clauses at 252.212–7001 and

252.225–7012, in order to implement sections 368 and 821 of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81).

• Section 368 requires award of contracts that provide the best value, when acquiring tents and other temporary structures, regardless of whether purchased by DoD or by another agency on behalf of DoD.

• Section 821 amends 10 U.S.C. 2533a (the ''Berry Amendment''), to extend the restriction requiring acquisition of domestic tents to include the structural components of tents, applicable to acquisitions that exceed the simplified acquisition threshold. There is also an exception for domestic nonavailability (see DFARS 225.7002–2).

The interim rule provides a definition of ''structural component of a tent'' and also provides examples of the type of temporary structures covered by this regulation.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Regulatory Flexibility Act

DoD does not expect this interim rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been prepared and is summarized as follows:

The objectives of this interim rule are to—

• Require that contracts for the acquisition of tents and other temporary structures provide best value, regardless of whether purchased by DoD or by another agency on behalf of DoD; and

• Extend the domestic source restriction of 10 U.S.C. 2533a (the ''Berry Amendment'') to cover the structural components of tents, in order to promote the use of domestic materials and enhance growth of the United States economy.

The legal basis for this interim rule is sections 368 and 821 of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81).

The requirement to award contracts that provide best value to the Government does not have any impact on small business entities, because that is already a general requirement for all acquisitions.

The domestic source restriction on the structural components of tents may affect approximately 40 or less small business concerns at the prime contract level. Review of the Fiscal Year 2011 data on acquisition of items with product or service code 8340 (tents or tarpaulins) identified 49 actions with small business concerns (contracts or orders), estimated value of $48.6 million, of which about 10 percent appeared to be for other than tents (e.g., prefabricated metal buildings and components, metal household furnishings, or electrical equipment). The Federal Procurement Data System does not provide data on components, so it is not known the extent to which the providers of tents currently utilize domestic or foreign structural components. An exception may be granted if a component is domestically nonavailable. However, this rule promotes the use of domestic components, and should, therefore, be favorable to small entities that provide domestic structural components of tents. The requirements of the rule will not apply below the simplified acquisition threshold.

This rule does not impose any reporting or recordkeeping requirements.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD did not identify any significant alternatives that would accomplish the stated objectives of the statute. The rule specifically implements the statutory requirement.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2012–D015) in correspondence.

IV. Applicability

This interim rule does not apply below the simplified acquisition threshold. Section 821 amends 10 U.S.C. 2533a (the ''Berry Amendment''), which specifically exempts acquisitions below the simplified acquisition threshold. The ''Berry Amendment'', implemented at DFARS clause 252.225–7012, Preference for Certain Domestic Commodities, specifically applies to contracts or subcontracts for the acquisition of commercial items that are articles, items, specialty metals, or tools covered by the ''Berry Amendment'' (including tents and components of tents) (see section 8109 of Pub. L. 104–208) and is included in the clause list in DFARS clause 252.212–7001, Contract Terms and Conditions required to Implement Statutes or Executive Orders Applicable to Defense Acquisitions of Commercial Items.

Section 368 only imposes requirements on the internal operating procedures of DoD, and does not address application below the simplified acquisition threshold. Most acquisitions of tents and other temporary structures exceed the simplified acquisition threshold. In accordance with 41 U.S.C. 1901, simplified acquisition procedures are to be used to promote efficiency and economy in contracting to avoid unnecessary burdens for agencies and contractors. Written acquisition plans are not required for acquisitions below the simplified acquisition threshold. Therefore, this rule does not apply to acquisitions of tents and other temporary structures below the simplified acquisition threshold.

V. Paperwork Reduction Act

This rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

VI. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense, that urgent and compelling reasons exist to publish an interim rule prior to affording the public an opportunity to comment. This interim rule implements sections 368 and 821 of the National Defense Authorization Act for Fiscal Year 2012. This requirement became effective upon enactment, December 23, 2011. This action is necessary in order to enable contracting officers to comply with this new requirement, which will promote the use of domestic materials and enhance growth of the United States economy. Pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), comments received in response to this interim rule will be

considered in the formation of the final rule.

List of Subjects in 48 CFR Part 225 and 252

Government procurement.

Ynette R. Shelkin,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 225 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 225 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 225—FOREIGN ACQUISITION

■ 2. Amend section 225.7001 by revising paragraph (e) to read as follows:

225.7001 Definitions.

* * * * *

(e) *Structural component of a tent* is defined in the clause at 252.225–7012, Preference for Certain Domestic Commodities.

■ 3. Amend section 225.7002–1 by revising paragraph (a)(3) to read as follows:

225.7002–1 Restrictions.

* * * * *

(a) * * *

(3) *Tents and the structural components of tents, tarpaulins, or covers.* In addition, in accordance with section 368 of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81)—

(i) When acquiring tents or other temporary structures for use by the Armed Forces, the contracting officer shall award contracts that provide the best value (see FAR 15.101). Temporary structures covered by this paragraph (a)(3)(i) are nonpermanent buildings, including tactical shelters, nonpermanent modular or pre-fabricated buildings, or portable or relocatable buildings, such as trailers or equipment configured for occupancy (see also DFARS 246.270–2)). Determination of best value includes consideration of the total life-cycle costs of such tents or structures, including the costs associated with any equipment, fuel, or electricity needed to heat, cool, or light such tents or structures (see FAR 7.105(a)(3)(i) and PGI 207.105(a)(3)(i)).

(ii) These requirements apply to any agency or department that acquires tents or other temporary structures on behalf of DoD (see FAR 17.503(d)(2)).

* * * * *

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.212–7001 [Amended]

■ 4. Amend section 252.212–7001 in paragraph (b)(9) by removing ''(JUN 2010)'' and adding ''(JUN 2012)'' in its place.

■ 5. Amend section 252.225–7012—

■ a. By removing the clause date ''(JUN 2010)'' and adding ''(JUN 2012)'' in its place;

■ b. In paragraph (a), by removing the numerical designations (1) through (5) from the definitions and adding, in alphabetical order, the definition of ''Structural component of a tent''; and

■ c. By revising paragraph (b)(3).

The addition and revision read as follows:

252.225–7012 Preference for Certain Domestic Commodities.

* * * * *

(a) * * *

Structural component of a tent—

(i) Means a component that contributes to the form and stability of the tent (e.g., poles, frames, flooring, guy ropes, pegs);

(ii) Does not include equipment such as heating, cooling, or lighting.

* * * * *

(b) * * *

(3) Tents and structural components of tents, tarpaulins, and covers.

* * * * *

[FR Doc. 2012–15563 Filed 6–28–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 225 and 252

RIN 0750–AH75

Defense Federal Acquisition Regulation Supplement: New Qualifying Country—Czech Republic (DFARS Case 2012–D043)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to add the Czech Republic as a qualifying country.

DATES: *Effective date:* June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is amending the DFARS to add the Czech Republic as a qualifying country. On April 18, 2012, the Secretary of Defense signed a new reciprocal defense procurement agreement with the Czech Minister of Defense. The agreement removes discriminatory barriers to procurements of supplies and services produced by industrial enterprises of the other country to the extent mutually beneficial and consistent with national laws, regulations, policies, and international obligations. The agreement does not cover construction or construction material.

II. Publication of This Final Rule for Public Comment Is Not Required by Statute

''Publication of proposed regulations'', 41 U.S.C. 1707, is the statute which applies to the publication of the Federal Acquisition Regulation. Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment. Adding the Czech Republic to the list of 21 other countries that have similar reciprocal defense procurement agreements with DoD does not alter the substantive meaning of the basic DoD policy on contracting with qualifying country sources. Accordingly, the change does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, does not have a significant effect beyond the internal operating procedures of DoD, and will not have a significant cost or administrative impact on contractors or offerors.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs

and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

V. Paperwork Reduction Act

This rule affects the certification and information collection requirements in the provisions at DFARS 252.225–7000, 252.225–7020, currently approved under OMB Control Number 0704–0229, titled DFARS Part 225, Foreign Acquisition, and Associated Clauses, in the amount of 57,235 hours, in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The impact, however, is negligible, because it merely shifts the category under which items from the Czech Republic must be listed.

List of Subjects in 48 CFR Parts 225 and 252

Government procurement.

Ynette R. Shelkin,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 225 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 225 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 225—FOREIGN ACQUISITION

225.003 [Amended]

■ 2. Amend section 225.003 in the definition ''Qualifying country'', paragraph (10), by adding ''Czech Republic'' in alphabetical order.

225.872–1 [Amended]

■ 3. Amend section 225.872–1, paragraph (a), by adding ''Czech Republic'' in alphabetical order.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.212–7001 [Amended]

■ 4. Amend section 252.212–7001 in paragraph (b)(12) by removing ''(MAY 2012)'' and adding ''(JUN 2012)'' in its place.

252.225–7001 [Amended]

■ 5. Amend section 252.225–7001, paragraph (a), definition of ''Qualifying country,'' by adding ''Czech Republic'' in alphabetical order.

■ 6. Amend section 252.225–7002 by removing the clause date ''(APR 2003)'' and adding ''(JUN 2012)'' in its place and revising paragraph (a) to read as follows:

252.225–7002 Qualifying Country Sources as Subcontractors.

* * * * *

(a) *Definition. Qualifying country,* as used in this clause, means a country with a reciprocal defense procurement memorandum of understanding or international agreement with the United States in which both countries agree to remove barriers to purchases of supplies produced in the other country or services performed by sources of the other country, and the memorandum or agreement complies, where applicable, with the requirements of section 36 of the Arms Export Control Act (22 U.S.C. 2776) and with 10 U.S.C. 2457. Accordingly, the following are qualifying countries:

Australia
Austria
Belgium
Canada
Czech Republic
Denmark
Egypt
Finland
France
Germany
Greece
Israel
Italy
Luxembourg
Netherlands
Norway
Portugal
Spain
Sweden
Switzerland
Turkey
United Kingdom of Great Britain and Northern Ireland

* * * * *

252.225–7012 [Amended]

■ 7. Amend section 252.225–7012 in paragraph (a)(3) by adding ''Czech Republic'' in alphabetical order.

■ 8. Amend section 252.225–7017 by removing the clause date ''(MAY 2012)'' and adding ''(JUN 2012)'' in its place and by revising the definition of ''Qualifying country,'' in paragraph (a) to read as follows:

252.225–7017 Photovoltaic Devices.

* * * * *

(a) * * *

Qualifying country means a country with a reciprocal defense procurement memorandum of understanding or international agreement with the United States in which both countries agree to remove barriers to purchases of supplies produced in the other country or services performed by sources of the other country, and the memorandum or agreement complies, where applicable, with the requirements of section 36 of the Arms Export Control Act (22 U.S.C. 2776) and with 10 U.S.C. 2457. Accordingly, the following are qualifying countries:

Australia
Austria
Belgium
Canada
Czech Republic
Denmark
Egypt
Finland
France
Germany
Greece
Israel
Italy
Luxembourg
Netherlands
Norway
Portugal
Spain
Sweden
Switzerland
Turkey
United Kingdom of Great Britain and Northern Ireland

* * * * *

252.225–7021 [Amended]

■ 9. Amend section 252.225–7021, paragraph (a), definition of ''Qualifying country,'' by adding ''Czech Republic'' in alphabetical order.

■ 10. Amend section 252.225–7036 by revising the definition of ''Qualifying country,'' in paragraph (a) to read as follows:

252.225–7036 Buy American—Free Trade Agreements—Balance of Payments Program.

* * * * *

(a) * * *

''Qualifying country'' means a country with a reciprocal defense procurement memorandum of understanding or international agreement with the United

States in which both countries agree to remove barriers to purchases of supplies produced in the other country or services performed by sources of the other country, and the memorandum or agreement complies, where applicable, with the requirements of section 36 of the Arms Export Control Act (22 U.S.C. 2776) and with 10 U.S.C. 2457. Accordingly, the following are qualifying countries:

Australia
Austria
Belgium
Canada
Czech Republic
Denmark
Egypt
Finland
France
Germany
Greece
Israel
Italy
Luxembourg
Netherlands
Norway
Portugal
Spain
Sweden
Switzerland
Turkey
United Kingdom of Great Britain and Northern Ireland

* * * * *

[FR Doc. 2012–15564 Filed 6–28–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 110901554–2178–02]

RIN 0648–BB35

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Exempted Fishery for the Southern New England Skate Bait Trawl Fishery

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

ACTION: Final rule.

SUMMARY: This final rule modifies the regulations implementing the Northeast (NE) Multispecies Fishery Management Plan (FMP) to allow vessels issued a Federal skate permit and a Skate Bait Letter of Authorization to fish for skates in a portion of southern New England (SNE) from July 1 through October 31 of each year, outside of the NE multispecies days-at-sea (DAS) program. This action allows vessels to harvest skates in a manner that is consistent with the bycatch reduction objectives of the NE Multispecies FMP.

DATES: Effective July 1, 2012.

ADDRESSES: An environmental assessment (EA) was prepared for the Secretarial Amendment that describes this action and other considered alternatives, and provides an analysis of the impacts of the approved measures and alternatives. Copies of the Secretarial Amendment, including the EA and the Initial Regulatory Flexibility Analysis (IRFA), are available on request from Daniel Morris, Acting Regional Administrator, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930. These documents are also available online at *http://www.nero.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Travis Ford, Fishery Management Specialist, 978–281–9233; fax 978–281–9135; email: *travis.ford@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Current regulations, implemented under Framework Adjustment 9 (60 FR 19364, April 18, 1995) and expanded under Amendment 7 to the FMP (61 FR 27710, May 31, 1996), contain a NE multispecies fishing mortality and bycatch reduction measure that is applied to the Gulf of Maine (GOM), Georges Bank (GB), and SNE Exemption Areas found in 50 CFR § 648.80. A vessel may not fish in these areas unless it is fishing under a NE multispecies or a scallop DAS allocation, is fishing with exempted gear, is fishing under the Small Vessel Handgear (A or B) or Party/Charter permit restrictions, or is fishing in an exempted fishery. The procedure for adding, modifying, or deleting fisheries from the list of exempted fisheries is found in 50 CFR § 648.80. A fishery may be exempted by the Regional Administrator (RA), after consultation with the New England Fishery Management Council (Council), if the RA determines, based on available data or information, that the bycatch of regulated species is, or can be reduced to, less than 5 percent by weight of the total catch and that such exemption will not jeopardize the fishing mortality objectives of the FMP.

Representatives from the NE multispecies sector fleet submitted an exempted fishery request to the RA on April 1, 2011. The petitioners requested that NMFS consider an exempted fishery for trawl vessels using 6.5-inch (16.5-cm) mesh nets and targeting skate bait in a portion of SNE from June through November of each year (referred to in the EA and in this rule as Alternative 2). Northeast Fisheries Observer Program (NEFOP) and at-sea monitoring (ASM) data were compiled and analyzed with reference to groundfish vessels targeting skate in the area and months requested for the exemption. A second alternative was assessed that reduced both the size of the exempted area and the requested season from June through November to July through October (referred to in the EA and in this rule as Alternative 1). The data best supported Alternative 1, revealing that bycatch of regulated species (primarily winter flounder and windowpane flounder) was substantially reduced from the original proposal by reducing the area and contracting the time period.

On April 27, 2012, a proposed rule was published in the **Federal Register** (77 FR 25117) soliciting public comment. The proposed rule and EA discuss these analyses in greater detail. No comments were received during the comment period. In addition, the Council was consulted on June 19, 2012, regarding this final rule. The Council raised no objections. Since no comments were received from the public or the Council, there are no modifications from the proposed measures in this final rule.

Approved Measures

Southern New England Skate Bait Trawl Exemption Area

The RA has determined that an exempted skate bait trawl fishery in a specifically defined portion of SNE meets the exemption requirements in § 648.80(a)(8)(i). Analysis of available data indicate that bycatch of regulated species by vessels targeting skate bait in that portion of SNE is less than 5 percent, by weight, of the total catch. Also, the RA has determined that the exemption will not jeopardize the fishing mortality objectives of the FMP because this exemption does not increase the demand for skate bait and is not expected to increase fishing for skate bait. Due to this exemption, common pool vessels will have more DAS available to target multispecies; however, DAS are not considered a limiting factor in the common pool. Further, Annual Catch Limits (ACLs) for each stock will prevent the overharvest of any species. Based on these determinations, the RA is exempting eligible vessels from the prohibition against fishing while not on a DAS in a portion of SNE from July through

October of each year when the vessels target skates and use 6.5-inch (16.5-cm) mesh trawl gear. The area of this exempted fishery will be referred to as the SNE Skate Bait Trawl Exemption Area.

The SNE Skate Bait Trawl Exemption Area is defined by straight lines connecting the following points in the order stated (copies of a chart depicting the area are available from the RA upon request):

Point	N. lat.	W. long.
SBT 1	Southeastern MA.	71° 00′
SBT 2	41° 00′	71° 00′
SBT 3	41° 00′	72° 05′
SBT 4	Southern CT	72° 05′

As required by existing regulations, vessels participating in the exempted skate fishery will need to hold a Federal skate permit and a valid Skate Bait Letter of Authorization (LOA) from the RA containing an exemption from the skate wing possession limits, which will allow them to land whole skates for use as bait. A participating vessel may possess and land up to 25,000 lb (9,072 kg) of whole skates of less than 23 inches (59 cm) total length. In addition, vessels will be limited by the skate bait Total Allowable Landings (TAL) that is divided into three seasons to help maintain a supply of bait throughout the fishing year. When 90 percent of the seasonal quota is landed in either Season 1 or 2, or when 90 percent of the annual skate bait TAL is landed, the RA will close the directed fishery by reducing the skate bait possession limit to the whole weight equivalent of the skate wing possession limit in effect at that time (either 5,902 lb (2,677 kg); 9,307 lb (4,222 kg); or 1,135 lb (515 kg)).

For additional details regarding the SNE Skate Bait Trawl Exemption Area, please see the proposed rule for this action.

Comments and Responses

No comments were received.

Changes From the Proposed Rule

There are no changes from the proposed measures in this final rule.

Classification

NMFS has determined that this final rule is consistent with the FMP and the Magnuson-Stevens Fishery Conservation and Management Act and other applicable laws.

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

Administrative Procedure Act

The Assistant Administrator, NMFS, finds that a waiver of the 30-day delay in the rule's effectiveness is justified under 5 U.S.C. 553(d)(1) because this rule ''recognizes an exemption or relieves a restriction[.]'' Currently, vessels fishing for skates in the SNE must use a groundfish DAS. This rule creates an exemption to the DAS requirement and allows vessels fishing in a portion of the SNE with 6.5 inch (16.5-cm) net mesh during part of the year to fish without using a DAS. As a result, more DAS will be available to vessels to fish specifically for groundfish rather than have them used on skate trips that catch very small amounts of groundfish. Because this rule recognizes an exemption and relieves a restriction by eliminating the requirement that vessels use NE Multispecies DAS while targeting skate bait in SNE, the 30-day delay in effectiveness may be waived pursuant to 5 U.S.C. 553(d)(1).

The Assistant Administrator also finds that there is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay because such a delay would be contrary to the public interest by potentially preventing sector members from realizing the full potential savings in discards and DAS. The exemption would ordinarily be in effect from July 1 to October 31, but the 30-day delay in effectiveness would reduce the duration of the exemption in 2012 by nearly 25 percent. Currently, sector members in the SNE area have an elevated groundfish discard rate applied to skate trips fished under groundfish DAS. The elevated discard rate applied to skate trips and use of DAS on skate trips costs sector members approximately $24,000 each year. Delaying the effective date of this rule could prevent the sector members from obtaining the full amount of cost savings. Further, waiving the 30-day delay in effectiveness will not cause any hardship for regulated entities because this rule does not create any new obligations or otherwise require trawl operators to make modifications to equipment or processes. Therefore, the primary rationale for the 30-day delay—to provide regulated entities with time to prepare for new rules—does not apply to this rule.

Regulatory Flexibility Act

Pursuant to 5 U.S.C. 603, a Final Regulatory Flexibility Analysis (FRFA) has been prepared, which describes the economic impacts that this rule will have on small entities. The FRFA incorporates the economic impacts and analysis summarized in the Initial Regulatory Flexibility Analysis (IRFA) for the proposed rule for this action, and the corresponding economic analyses prepared for this action in the EA and the Regulatory Impact Review (RIR). The contents of these documents are not repeated in detail here. Copies of the IRFA, the RIR, and the EA are available upon request (see **ADDRESSES**). A description of the reasons for this action, the objectives of the action, and the legal basis for this final rule are found in the preamble to the proposed and final rules.

There are no Federal rules that duplicate, overlap, or conflict with this rule. This action does not include any new reporting, recordkeeping, or other compliance requirements. This rule creates a new skate bait trawl exemption area for trawl vessels targeting skate bait in SNE. This action was compared to two different alternatives for the exemption. Alternatives to the selected exemption include exempting a larger portion of SNE for a longer period of time, from June through November, and the No Action alternative, which would continue to require vessels targeting skate bait in this area to be on a declared NE multispecies trip from July through October.

Description and Estimate of the Number of Small Entities to Which This Final Rule Would Apply

The Small Business Administration (SBA) defines a small commercial fishing entity as a firm with gross receipts not exceeding $4 million. In Rhode Island, there are two major dealers involved in the skate bait market. One reports supplying skate bait to 100 lobster businesses located in Point Judith, Wickford, Newport, Westerly, and Jamestown, RI, along with businesses scattered throughout Connecticut and Massachusetts. The company buys skate bait from 12–15 vessels throughout the year. The lobster businesses supplied by the company employ between two and four crewmembers per vessel. The other major skate dealer in Rhode Island supplies local Newport, Sakonnet, and New Bedford, MA, vessels and numerous offshore lobster vessels fishing in the Gulf of Maine. Skates are supplied to this dealer from draggers working out of Newport and Tiverton, RI, and New Bedford, MA.

Due to direct, independent contracts between draggers and lobster vessels, landings of skates are estimated to be under-documented. While skate bait is always landed (rather than transferred at sea), it is not always reported because it can be sold directly to lobster vessels by non-federally permitted vessels, which

are not required to report as dealers. A more complete description of the skate bait fishery can be found in Amendment 3 to the NE Skate Complex FMP, available from the Council (*http://www.nefmc.org*).

Economic Impacts of This Action

This action is expected to benefit the local fishing communities that have historically depended on the skate bait fishery in SNE. This exemption was requested by members of the NE multispecies fishing industry, specifically members of a sector that fishes in the SNE area. The cost of fishing for skate bait has become increasingly high primarily due to the deduction of calculated discards from each vessel's sector's Annual Catch Entitlement (ACE) when fishing under a groundfish DAS. This exemption will allow vessels to target skate bait outside of the DAS program, which will prevent the discards being deducted from their sector's ACE at a higher rate than is actually occurring. The EA for this action estimates that the exemption could save the fleet approximately $24,489.79 a year in discards and DAS alone.

With the elimination of these low discard trips from the sector's discard stratum, the overall discard rate for the sector will likely increase because skate bait trips that were observed were keeping the discard rate for trips targeting groundfish artificially low. While this change will result in an increase of the discard rate for the skate bait vessel's original discard stratum, the increase will not represent a significant cost to the SNE sector vessels that are not participating in the exemption and is outweighed by the benefit of the exemption. In addition, the calculated discard rates for both groundfish vessels and skate bait vessels will be more accurate as a result of the exemption; more accurate discards are not expected to have an economic effect on the fishing community as a whole. Further, participation in this exemption is voluntary. A vessel may still choose to target skate bait during the exemption while on a DAS should they feel it is to their benefit.

Economic Impacts of Alternatives to the Action

The impacts of Alternative 2, which extends the exemption an additional 2 months over a larger area, would be expected to be similar to the impacts of Alternative 1, but the expanded area and time would allow more vessels a greater opportunity to participate in the exempted fishery. The EA for this action estimates that Alternative 2 would save the industry an additional $ 3,739.37 compared to Alternative 1, for a total savings of $28,229.16. However, the months of June and November showed an increased number of trips that caught over 5 percent groundfish, and a large portion of the area could not be evaluated because there were no observer or ASM data available. Providing an exemption for trips that caught over 5 percent groundfish, or for areas for which no data are available, would be contrary to the current regulations. Therefore, this alternative was not selected.

The No Action Alternative would have a negative economic impact on SNE skate bait vessels relative to Alternative 1. This exemption was requested because of the economic burden that the cost of DAS and calculated discards had on sector fishermen targeting skate bait. As described above, it is estimated that this exemption could save the fleet approximately $24,489.79 a year in discards and DAS alone compared to the No Action alternative. Under the No Action Alternative, sector fishermen targeting skate bait would continue fishing on DAS only to be charged a higher than observed groundfish discard rate for their trip targeting skate bait. The skate bait fishery is a valuable resource to those fishing in SNE. The groundfish discards that are attributed to these trips come directly out of the vessel's sector's ACE, which takes away the opportunity to catch these fish in the future.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule. As part of this rulemaking process, NMFS prepared a small entity compliance guide, which will be sent to all holders of permits issued for the NE skate fishery. In addition, copies of this final rule and guide (i.e., permit holder letter) are available from the Regional Administrator (see **ADDRESSES**).

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: June 26, 2012.

Samuel D. Rauch III,

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

For the reasons stated in the preamble, 50 CFR part 648 is amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.14, paragraph (k)(5)(i) is revised to read as follows:

§ 648.14 Prohibitions.

* * * * *

(k) * * *

(5) * * *

(i) Violate any of the provisions of § 648.80, including paragraphs (a)(5), the Small-mesh Northern Shrimp Fishery Exemption Area; (a)(6), the Cultivator Shoal Whiting Fishery Exemption Area; (a)(9), Small-mesh Area 1/Small-mesh Area 2; (a)(10), the Nantucket Shoals Dogfish Fishery Exemption Area; (a)(11), the GOM Scallop Dredge Exemption Area; (a)(12), the Nantucket Shoals Mussel and Sea Urchin Dredge Exemption Area; (a)(13), the GOM/GB Monkfish Gillnet Exemption Area; (a)(14), the GOM/GB Dogfish Gillnet Exemption Area; (a)(15), the Raised Footrope Trawl Exempted Whiting Fishery; (a)(16), the GOM Grate Raised Footrope Trawl Exempted Whiting Fishery; (a)(18), the Great South Channel Scallop Dredge Exemption Area; (b)(3), exemptions (small mesh); (b)(5), the SNE Monkfish and Skate Trawl Exemption Area; (b)(6), the SNE Monkfish and Skate Gillnet Exemption Area; (b)(8), the SNE Mussel and Sea Urchin Dredge Exemption Area; (b)(9), the SNE Little Tunny Gillnet Exemption Area; (b)(11), the SNE Scallop Dredge Exemption Area; or (b)(12), the SNE Skate Bait Trawl Exemption Area. Each violation of any provision in § 648.80 constitutes a separate violation.

* * * * *

■ 3. In § 648.80, paragraph (b)(2)(vi) is revised, and paragraph (b)(12) is added to read as follows:

§ 648.80 NE Multispecies regulated mesh areas and restrictions on gear and methods of fishing.

* * * * *

(b) * * *

(2) * * *

(vi) *Other restrictions and exemptions.* A vessel is prohibited from fishing in the SNE Exemption Area, as

defined in paragraph (b)(10) of this section, except if fishing with exempted gear (as defined under this part) or under the exemptions specified in paragraphs (b)(3), (b)(5) through (9), (b)(11), (b)(12), (c), (e), (h), and (i) of this section; or if fishing under a NE multispecies DAS; or if fishing on a sector trip; or if fishing under the Small Vessel or Handgear A permit specified in § 648.82(b)(5) and (6), respectively; or if fishing under a Handgear B permit specified in § 648.88(a); or if fishing under a scallop state waters exemption specified in § 648.54; or if fishing under a scallop DAS in accordance with paragraph (h) of this section; or if fishing under a General Category scallop permit in accordance with paragraphs (b)(11)(i)(A) and (B) of this section; or if fishing pursuant to a NE multispecies open access Charter/Party or Handgear permit specified in § 648.88; or if fishing as a charter/party or private recreational vessel in compliance with the regulations specified in § 648.89. Any gear on a vessel, or used by a vessel, in this area must be authorized under one of these exemptions or must be stowed as specified in § 648.23(b).

* * * * *

(12) *SNE Skate Bait Trawl Exemption Area.* Vessels issued an open access skate permit and a skate bait Letter of Authorization as specified in § 648.322(c) that have declared out of the DAS program as specified in § 648.10, or that have used up their DAS allocations, may fish in the SNE Skate Bait Trawl Exemption Area as defined under paragraph (b)(12)(i) of this section, when not under a NE multispecies or scallop DAS, provided the vessel complies with the requirements specified in paragraph (b)(1)(ii) of this section.

(i) *Area definition.* The SNE Skate Bait Trawl Exemption Area is defined by the straight lines connecting the following points in the order stated (copies of a chart depicting the area are available from the Regional Administrator upon request):

SNE Skate Bait Trawl Exemption Area

[July 1 through October 31]

Point	N. lat.	W. long.
SBT 1	Southeastern MA.	71°00′
SBT 2	41°00′	71°00′
SBT 3	41°00′	72°05′
SBT 4	Southern CT	72°05′

(ii) *Requirements.* (A) A vessel fishing in the SNE Skate Bait Trawl Exemption Area specified in this paragraph (b)(12) may not fish for, possess on board, or land any NE regulated species.

(B) Vessels must use trawl gear, as specified in § 648.80(b)(2)(i).

(C) Vessels must possess an active skate bait letter of authorization issued by the Regional Administrator, as specified in § 648.322(c) and fish pursuant to the terms of authorization.

(D) Fishing may only occur from July 1 through October 31 of each fishing year.

* * * * *

[FR Doc. 2012–16013 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 77, No. 126
Friday, June 29, 2012

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC–2011–0087]

RIN 3150–AI96

Non-Power Reactor License Renewal

AGENCY: Nuclear Regulatory Commission.

ACTION: Preliminary draft regulatory basis; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is making available a preliminary draft regulatory basis for a proposed rulemaking that would amend the NRC's regulations concerning the license renewal requirements for non-power reactors. This contemplated rulemaking would also make conforming changes to address technical issues in existing non-power reactor regulations. The NRC is seeking input from the public, licensees, certificate holders, and other stakeholders on the preliminary draft regulatory basis.

DATES: Submit comments by July 31, 2012. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may access information and comment submissions related to this preliminary draft regulatory basis, which the NRC possesses and are publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2011–0087. You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2011–0087. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov*.
- *Email comments to: Rulemaking.Comments@nrc.gov*. If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Duane Hardesty, Project Manager, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation, Mail Stop: O12–E20, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3724; email: *Duane.Hardesty@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2011–0087 when contacting the NRC about the availability of information for this preliminary draft regulatory basis. You may access information related to this preliminary draft regulatory basis, which the NRC possesses and are publicly available, by any of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2011–0087.
- *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 document (if that document is available in ADAMS) is provided the first time that a document is referenced. The preliminary draft regulatory basis is available in ADAMS under Accession No. ML12167A383.
- *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–2011–0087 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* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

In response to Commission direction in a Staff Requirements Memorandum for SECY–08–0161 (ADAMS Accession Nos. ML082550140 and ML090850159), the NRC has developed a preliminary draft regulatory basis for a proposed rulemaking regarding non-power reactor licenses. The preliminary draft regulatory basis document describes the NRC's overall objectives, conceptual approaches, potential solutions, integration with the NRC's strategic goals, and related technical and

regulatory clarity issues for the proposed rulemaking. The NRC is soliciting comments on this preliminary draft regulatory basis document from the public, licensees, and other stakeholders to confirm that an adequate regulatory basis exists to proceed with rulemaking to issue amended license renewal regulations for non-power reactors. The NRC conducted public meetings and Webinars on September 13 (ML112710285), and December19, 2011 (ML113630166), and on June 20, 2012 (ML12177A334), to discuss the regulatory basis and to facilitate the public's and stakeholders' submission of informed comments.

The NRC is issuing this notice to solicit public comments on the preliminary draft regulatory basis to streamline non-power reactor license renewal. After the NRC staff considers public comments, it will make a determination regarding issuance of the final regulatory basis. Any subsequent versions of the regulatory basis will be posted on *www.regulations.gov* in Docket ID NRC–2011–0087. Regulations.gov allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder, NRC–2011–0087; (2) click the ''Email Alert'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly or monthly).

Dated at Rockville, Maryland, this 25th day of June, 2012.

For the Nuclear Regulatory Commission.

Jessie F. Quichocho,

Chief, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–16115 Filed 6–28–12; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2008–BT–STD–0005]

RIN 1904–AB57

Energy Efficiency Program for Consumer Products: Energy Conservation Standards for Battery Chargers and External Power Supplies

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

ACTION: Reopening of comment period.

SUMMARY: This document announces a reopening of the comment period for 15 days in order to consider comments previously submitted after the close of the earlier comment period and to allow interested parties to submit comments on the notice of proposed rulemaking to establish energy conservation standards for battery chargers and external power supplies.

DATES: Comments must be submitted no later than July 16, 2012.

ADDRESSES: Any comments submitted must identify the subject matter (''Notice of Proposed Rulemaking to Establish Energy Conservation Standards for Battery Chargers and External Power Supplies'') and provide the appropriate docket number (EERE–2008–BT–STD–0005) and/or RIN number (1904–AB57). Comments may be submitted using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: BC&EPS_ECS@ee.doe.gov.* Include docket number EERE–BT–STD–0005 and/or RIN number 1904–AB57 in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mail-stop EE–2J, Notice of Propsed Rulemaking to Establish Energy Conservation Standards for Battery Chargers and External Power Supplies, docket number EERE–2008–BT–STD–0005 and/or RIN number 1904–AB57, 1000 Independence Avenue SW., Washington, DC 20585–0121. Please submit one signed paper original.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586–2945. Please submit one signed paper original.

FOR FURTHER INFORMATION CONTACT:

Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *Jeremy.Dommu @ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

For information on how to submit or review public comments, contact Ms. Brenda Edwards, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–2945. Email: *Brenda.Edwards@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: On March 27, 2012, the U.S. Department of Energy (DOE) published in the **Federal Register** a Notice of Proposed Rulemaking (NOPR) that would establish energy conservation standards for battery chargers and amend those that currently apply to Class A external power supplies (EPSs). (77 FR 18478) That notice also proposed to establish standards for non-Class A EPSs and possible labeling requirements for battery chargers and EPSs. The comment period for this NOPR closed on May 29, 2012.

Recently, after the closing of the comment period, DOE has received comments on this rulemaking from interested parties. These comments submit additional information for DOE to consider as part of its evaluation of potential standards for battery chargers and EPSs. In order to consider comments previously submitted after the close of the earlier comment period and to allow interested parties to submit comments on the NOPR, DOE has determined that a re-opening of the comment period in this rulemaking is appropriate and is hereby doing so. DOE will consider any comments received between March 27, 2012 and July 16, 2012 to be timely submitted.

Further Information on Submitting Comments

Under 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit two copies: one copy of the document including all the information believed to be confidential, and one copy of the document with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include (1) a description of the items, (2) whether and why such items are customarily treated as confidential within the industry, (3) whether the information is generally known by or available from other sources, (4) whether the information has previously been made available to others without obligation concerning its confidentiality, (5) an explanation of the competitive injury to the submitting person which would result from public disclosure, (6) when such information might lose its confidential character due to the

passage of time, and (7) why disclosure of the information would be contrary to the public interest.

Issued in Washington, DC on June 25, 2012.

Kathleen Hogan,

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

[FR Doc. 2012–15987 Filed 6–28–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0689; Directorate Identifier 2009–SW–065–AD]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft-Manufactured Model S–64F Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) for the Sikorsky Aircraft Corporation-manufactured Model S–64F helicopters, now under the Erickson Air-Crane Incorporated (Erickson) Model S–64F type certificate. That AD currently requires inspections, rework, and replacement, if necessary, of the main gearbox (MGB) second stage lower planetary plate (plate). Since we issued that AD, the manufacturer has conducted a configuration review and analysis, and a review of the service history of certain components. The proposed actions are intended to establish life limits for certain components, remove various parts from service, and require consistency in the part numbers of certain four bladed tail rotor (T/R) assemblies to prevent fatigue cracking, failure from static overload, and subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by August 28, 2012.

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

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

Examining the AD Docket

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

For service information identified in this proposed AD, contact Erickson Air-Crane Incorporated, ATTN: Chris Erickson/Compliance Officer, 3100 Willow Springs Rd, P.O. Box 3247, Central Point, OR 97502, telephone (541) 664–5544, fax (541) 664–2312, email address *cerickson@ericksonaircrane.com.* You may review a copy of this service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Michael Kohner, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Certification Office, Fort Worth, Texas 76137, telephone (817) 222–5170, email *7-avs-asw-170@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Discussion

On May 9, 1997, we issued AD 97–10–15, Amendment 39–10028 (62 FR 28321, May 23, 1997), for the Sikorsky Aircraft-manufactured Model S–64F helicopters (now under the Erickson Model S–64F helicopter type certificate) with a plate, P/N 6435–20516–101, with 2,000 or more hours time-in-service (TIS). That AD requires, before the first flight of each day, inspecting the MGB main oil filter for magnesium contamination, and if magnesium contamination is present, replacing the MGB assembly. That AD also requires inspecting the MGB assembly within 100 hours TIS, and thereafter at intervals not to exceed 500 hours TIS, and if necessary, replacing the MGB assembly. Finally, that AD requires, at the next overhaul of the MGB assembly, inspecting and reworking the plate. That action was prompted by two incidents in which the plate was found cracked. The requirements of that AD are intended to prevent failure of the plate due to fatigue cracking, which could lead to failure of the MGB and subsequent loss of control of the helicopter.

Actions Since Existing AD Was Issued

Since we issued AD 97–10–15, Erickson has performed additional analysis as a part of a configuration review and has also reviewed the service history of certain components. Erickson determined that certain life-limits and other maintenance requirements need to be revised, and released Erickson Service Bulletin (SB) No. 64F General-1, Revision 17, dated August 17, 2010 (SB No. 64F General-1, Rev. 17). We have reviewed this SB and have determined that the retirement lives of certain parts need to be revised. We have also determined that certain parts, including the plate, P/N 6435–20516–101, which is the subject of the existing AD, should be removed from service and should no longer be eligible for installation on these helicopters.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or

develop in other products of the same type design.

Related Service Information

SB No. 64F General-1, Rev. 17, contains the Airworthiness Limitations Schedule for the Model S–64F helicopter and lists the parts and assemblies with their specified retirement lives.

Proposed AD Requirements

This AD proposes to reduce or establish the life limits for certain flight-critical components, remove other parts with service difficulties from service, and require that T/R blade assembly P/N 65160–00001–048 be installed only as a set of four and not be installed with another part-numbered blade. The requirements in current AD 97–10–15 would be superseded and the part-numbered planetary plate, which is the subject of that AD, would be removed from service. This proposed AD would require, before further flight, a change in the life-limit for the following components:

- Main Rotor (M/R) Blade Assembly, P/N 6415–20601–045;
- Main Transmission Support Beam Assembly, LH, P/N 6420–62363–045;
- Main Transmission Support Beam Assembly, RH, P/N 6420–62363–046;
- Left Splice Fitting (Transition Fitting), Rotary, Rudder Boom, P/N 6420–66341–101;
- Right Splice Fitting (Transition Fitting), Rotary, Rudder Boom, P/N 6420–66341 102;
- M/R Drive Shaft, P/N 6435–20536–101;
- Pressure Plate Assembly, Rotary Wing Head, P/N 65101–11016–042;
- Horn and Liner Assembly, P/N 65102–11047–041;
- Lower Hub Plate Assembly, P/N 65103–11009–041;
- Horizontal Hinge Pin, Rotary Wing Head, P/N 65103–11020–103;
- Damper Bracket Assembly, Rotary Wing Head, P/N 65103–11032–043;
- Hub Subassembly, Rotary Wing, P/N 65103–11310–043;
- Shaft Assembly, Pitch Control Tail Gearbox, P/N 65358–07035–043; and
- Rod End Assembly, Primary Servo Assembly, P/N 65652–11212–041.

In addition to proposing new or revised life limits for certain flight-critical components, this AD also proposes to remove the following components from service due to service difficulties:

- Spindle Assembly, Rotary Rudder, P/N 6410–30302–041;
- MGB Second Stage Lower Planetary Plate, P/N 6435–20516–101 or 6435–20516–102;
- Bracket Assembly, Main Servo, P/N 6435–20527–041 or 6435–20527–042;
- Primary Servo Link Assembly, Tandem Servo, M/R, P/N 6465–62161–042;
- Shoulder Bolt, T/R, P/N 65111–07001–102; and
- T/R Blade Assembly, P/N 65161–00001–041.

This proposed AD contains only a portion of the life-limited parts for this model helicopter, and is not an all-inclusive list.

Costs of Compliance

We estimate that this proposed AD would affect 7 helicopters of U.S. Registry and estimate, at an average labor rate of $85 per hour, the following costs for removing from service the parts listed in Table 2 of this proposed AD action:

- Reviewing helicopter records to determine if an affected part is installed will require approximately 2 work-hours, for a cost per helicopter of $170 and a fleet cost of $1,190.
- Replacing the rotary rudder spindle assembly will require 10 work-hours and a parts cost of $2,787, for a cost per helicopter of $3,637 and a fleet cost of $25,459.
- Replacing the plate will require 40 work-hours and a parts cost of $43,750, for a cost per helicopter of $47,150 and a fleet cost of $330,050.
- Replacing the main servo bracket assembly will require 2 work-hours and a parts cost of $5,223, for a cost per helicopter of $5,393 and a fleet cost of $37,751.
- Replacing the primary servo link assembly of the M/R tandem servo will require 10 work-hours and a parts cost of $14,533, for a cost per helicopter of $15,383 and a fleet cost of $107,681.
- Replacing the T/R shoulder bolt will require 10 work-hours and a parts cost of $571, for a cost per helicopter of $1,421 and a fleet cost of $9,947.
- Replacing the T/R Blade Assembly will require 8 work-hours and a parts cost of $125,765 for a cost per helicopter of $126,445 and a fleet cost of $885,115.
- The total cost to replace the parts that are proposed to be removed from service is estimated to be $199,599 per helicopter and a fleet cost of $1,397,193.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing Amendment 39–10028 (62 FR 28321, May 23, 1997), and adding the following new AD:

ERICKSON AIR–CRANE INCORPORATED:

Docket No. FAA–2012–0689; Directorate Identifier 2009–SW–065–AD.

(a) Applicability

This AD applies to Sikorsky Aircraft Corporation-manufactured Model S–64F helicopters, now under the Erickson Air-Crane Incorporated Model S–64F type certificate, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a fatigue crack in a flight critical component. This condition could result in component failure from static overload and subsequent loss of control of the helicopter.

(c) Other Affected ADs

This AD supersedes AD 97–10–15, Amendment 39–10028 (62 FR 28321, May 23, 1997).

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless accomplished previously.

(e) Required Actions

(1) Before further flight:

(i) Remove from service any part with a number of hours time-in-service (TIS) equal to or greater than the part's retirement life as stated in following Table 1 of this AD.

TABLE 1—PARTS WITH NEW OR REVISED LIFE LIMITS

Part name	Part No. (P/N)	Retirement life
Main Rotor (M/R) Blade Assembly	6415–20601–045	13,280 hours TIS.
Main Transmission Support Beam Assembly, LH	6420–62363–045	9,300 hours TIS.
Main Transmission Support Beam Assembly, RH	6420–62363–046	9,300 hours TIS.
Left Splice Fitting (Transition Fitting), Rotary, Rudder Boom	6420–66341–101	8,300 hours TIS.
Right Splice Fitting (Transition Fitting), Rotary, Rudder Boom	6420–66341–102	8,300 hours TIS.
M/R Drive Shaft	6435–20536–101	2,200 hours TIS.
Pressure Plate Assembly, Rotary Wing Head	65101–11016–042	8,800 hours TIS.
Horn and Liner Assembly	65102–11047–041	1,140 hours TIS.
Lower Hub Plate Assembly	65103–11009–041	15,500 hours TIS.
Horizontal Hinge Pin, Rotary Wing Head	65103–11020–103	5,100 hours TIS.
Damper Bracket Assembly, Rotary Wing Head	65103–11032–043	20,000 hours TIS.
Hub Subassembly, Rotary Wing	65103–11310–043	21,600 hours TIS.
Shaft Assembly, Pitch Control Tail Gearbox	65358–07035–043	9,400 hours TIS.
Rod End Assembly, Primary Servo Assembly	65652–11212–041	20,800 hours TIS.

Note to Table 1: The list of parts in Table 1 of this AD contains only a portion of the life-limited parts for this model helicopter and is not an all-inclusive list.

(ii) Revise the retirement life of each part as shown in Table 1 of this AD by making pen and ink changes or by inserting a copy of this AD into the Airworthiness Limitations section of the maintenance manual.

(iii) Record on the component history card or equivalent record the retirement life for each part as shown in Table 1 of this AD.

(2) Before further flight, remove from service any part with a P/N listed in the following Table 2 of this AD, regardless of the part's TIS. The P/Ns listed in Table 2 of this AD are not eligible for installation on any helicopter.

TABLE 2—PARTS TO BE REMOVED FROM SERVICE

Part name	P/N
Spindle Assembly, Rotary Rudder	6410–30302–041.
Main Gearbox Second Stage Lower Planetary Plate	6435–20516–101 or 6435–20516–102.
Bracket Assembly, Main Servo	6435–20527–041 or 6435–20527–042.
Primary Servo Link, Tandem Servo, M/R	6465–62161–042.
Shoulder Bolt, Tail Rotor (T/R)	65111–07001–102.
T/R Blade Assembly	65161–00001–041.

(3) Before further flight, if a T/R blade assembly, P/N 65160–00001–048, is installed, remove any of the other three T/R blade assemblies that have a different P/N and replace it with a T/R blade assembly, P/N 65160–00001–048. The T/R blade assembly, P/N 65160–00001–048, must be installed in sets of four only.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Rotorcraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Michael Kohner, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Certification Office, Fort Worth, Texas, 76137, telephone (817) 222–5170, email *7-avs-asw-170@faa.gov.*

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

(g) Additional Information

Erickson Service Bulletin No. 64F General-1, Revision 17, dated August 17, 2010, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Erickson Air-Crane Incorporated, ATTN: Chris Erickson/Compliance Officer, 3100 Willow Springs Rd, PO Box 3247, Central Point, OR 97502, telephone (541) 664–5544, fax (541) 664–2312, email address *cerickson@ericksonaircrane.com.* You may review a copy of this information at the FAA,

Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6300: Main Rotor Drive System and 6400: Tail Rotor System.

Issued in Fort Worth, Texas, on June 21, 2012.

M. Monica Merritt,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–15978 Filed 6–28–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 234 and 235

[Docket No. DOT–OST–2010–0211]

RIN 2105–AE07

Reports by Air Carriers on Incidents Involving Animals During Air Transport

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Department is proposing to amend its existing rule regarding the reporting of incidents involving animals during air transport, 14 CFR 234.13, to expand the reporting requirement to U.S. carriers that operate scheduled service with at least one aircraft with a design capacity of more than 60 seats, to expand the definition of ''animal'' to include all cats and dogs transported by the carrier, regardless of whether the cat or dog is transported as a pet by its owner or as part of a commercial shipment (e.g., shipped by a breeder), and to require all covered carriers to provide in their December reports the total number of animals that were lost, injured, or died during air transport. We also seek comment on requiring carriers to report the total number of animals transported in the calendar year in the December reports.

DATES: Comments should be filed by August 28, 2012. Late-filed comments will be considered to the extent practicable.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2010–0211 by any of the following methods:

- *Federal eRulemaking Portal:* go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

Instructions: You must include the agency name and docket number DOT–OST–2010–0211 or Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comment. All comments will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, a business, a 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), or you may visit *http://DocketsInfo.dot.gov*.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Vinh Q. Nguyen, Trial Attorney, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202–366–9342 (phone), 202–366–7152 (fax), *vinh.nguyen@dot.gov*. You may also contact Blane A. Workie, Deputy Assistant General Counsel, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202–366–9342 (phone), 202–366–7152 (fax), *blane.workie@dot.gov*.

SUPPLEMENTARY INFORMATION:

Background

The current rule regarding reporting of incidents involving animals during air transport derives from the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century or ''AIR–21'' (Pub. L. 106–181), which was signed into law on April 5, 2000. It included section 710, ''Reports by Carriers on Incidents Involving Animals During Air Transport,'' and was codified as 49 U.S.C. 41721. Section 41721 contains the following provisions:

(a) *In General.*—An air carrier that provides scheduled passenger air transportation shall submit monthly to the Secretary a report on any incidents involving the loss, injury, or death of an animal (as defined by the Secretary of Transportation) during air transport provided by the air carrier. The report shall be in such form and contain such information as the Secretary determines appropriate.

* * * * *

(d) *Publication of Data.*—The Secretary shall publish data on incidents and complaints involving the loss, injury, or death of an animal during air transport in a manner comparable to other consumer complaint and incident data.

(e) *Air Transport.*—For purposes of this section, the air transport of an animal includes the entire period during which an animal is in the custody of an air carrier, from check-in of the animal prior to departure until the animal is returned to the owner or guardian of the animal at the final destination of the animal.

On August 11, 2003, DOT, through its Federal Aviation Administration (FAA), issued a final rule implementing section 710 of AIR–21. *See* 68 FR 47798. The rule required air carriers that provide scheduled passenger air transportation to submit a report to the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) on any incident involving the loss, injury, or death of an animal during air transportation provided by the air carrier. Under the rule, the reports would then be shared with DOT, which would publish the data, as required by AIR–21, in a format similar to the manner in which it publishes data on consumer complaints and other incidents. However, issues arose regarding whether APHIS had the capability to accept such information directly from the carriers and pass it on to DOT. In order to resolve any such issues, on February 14, 2005, DOT made a technical change in the rule to require reporting airlines to submit the required information directly to DOT's Aviation Consumer Protection Division (ACPD) rather than APHIS and to make the rule part of DOT's economic regulations. *See* 70 FR 7392. The rule is codified at 14 CFR 234.13.

Section 234.13 requires air carriers that provide scheduled passenger air transportation to submit a report to the ACPD on any incidents involving the loss, injury, or death of an animal during air transportation within 15 days of the end of the month during which the incident occurred. It defines ''animal'' as any warm- or cold-blooded animal which, at the time of transportation, is being kept as a pet in a family household in the United States. The air transport of an animal covers the

entire period during which an animal is in the custody of an air carrier, from check-in or delivery of the animal to the carrier prior to departure until the animal is returned to the owner or guardian of the animal at the final destination of the animal. Section 234.13 also lists the information that is to be included in each report (e.g., carrier and flight number, date and time of the incident). However, because section 234.13 is contained in Part 234 of Title 14 and that part applies only to the domestic scheduled passenger flights of carriers that account for at least 1 percent of domestic scheduled passenger revenue (''reporting carriers''), there has been confusion regarding which entities are required to submit a report to the ACPD on incidents involving loss, injury, or death on an animal during air transportation as well as which flights are covered (i.e., only domestic scheduled passenger flights, or all scheduled passenger flights, including international flights).

On August 10, 2010, Senators Richard Durbin, Robert Menendez, and Joseph Lieberman wrote to the Secretary of Transportation urging the Department to amend the rule so that airlines would be required to report all incidents involving the loss, injury, or death of cats and dogs that occur while they are traveling in an airline's care, custody, or control, regardless of whether the cat or dog is being transported as a pet by its owner or as part of a commercial shipment. In addition to the letter, the Department received a petition for rulemaking on this matter from the Animal Legal Defense Fund (ALDF), an advocacy group which works to protect the lives and advance the interest of animals through the legal system. In its petition, ALDF requests that the Department's regulation requiring the reporting of loss, injury, or death of animals in air transport be revised to require airlines to report any such incident involving animals they carry. It contends that the data that are currently collected by the Department capture only incidents affecting pets, even though pets make up only part of the total number of animals transported by airlines. The ALDF's proposal would apply to all species of animals, not just cats and dogs.

Notice of Proposed Rulemaking

This NPRM proposes to expand the applicability of the rule to require all U.S. carriers that operate scheduled service with at least one aircraft with a design capacity of more than 60 passenger seats to submit a report to the ACPD on any incidents involving the loss, injury, or death of an animal during air transportation within 15 days after the end of the month during which the incident occurred. Under the current rule, most of the reports on incidents involving animals during air transport have been submitted by ''reporting carriers,'' as defined in 14 CFR 234.2. At the present time, there are 15 ''reporting carriers.'' These airlines account for the vast majority of domestic traffic. Nevertheless, we believe that it is important to expand the requirement to all carriers that operate scheduled service with at least one aircraft with a design capacity of more than 60 seats to provide consumers and other interested parties a more complete picture of the treatment of animals on scheduled passenger flights. By expanding the applicability from the reporting carriers (i.e., U.S. carriers that account for at least 1 percent of domestic scheduled passenger revenue) to U.S. carriers that operate domestic or international scheduled passenger service with at least one aircraft with more than 60 seats, we would be requiring reports of loss, injury or death of an animal from 36 carriers instead of only 15 carriers. These 36 carriers carry about 99.6 percent of domestic passengers and 98 percent of international passengers that travel on U.S. airlines.

Consistent with section 605 of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA), we are not proposing to expand this rule to carriers that operate scheduled service with only aircraft that have a design capacity of 60 seats or less as these carriers are considered small businesses.[1] We invite comment on whether there is any benefit to expanding the applicability of the rule any further to encompass more U.S. carriers. We are not considering expanding the requirement to report on the loss, injury or death of animals to foreign air carriers that operate flights to and from the U.S. or to charter flights, as Congress mandated the reporting of such information only by U.S.-flag airlines that operate scheduled passenger service. However, we are aware of an indirect cargo air carrier operating under the provisions of Part 296 of the Department's regulations that specializes in providing air transportation only to pets. We seek comment on whether the reporting requirements should apply to such entities.

The existing rule defines an animal as a pet in a family household. The NPRM proposes to expand this definition to include cats and dogs that are part of a commercial shipment. More specifically, the NPRM proposes to retain that portion of the definition of ''animal'' that refers to any warm- or cold-blooded animal which, at the time of transportation, is being kept as a pet in a family household in the United States and add to this definition ''and any dog or cat which, at the time of transportation, is shipped as part of a commercial shipment on a scheduled passenger flight.''

We are proposing this expansion in the definition of an animal because dogs and cats that are being shipped on scheduled passenger flights other than as pets by their owners are likely being transported for the purpose of being sold as a pet in a family household in the United States. Moreover, based on the data we collected of loss, injury or death of household pets transported in commercial aviation from May 2005 to November 2011, we found that virtually all of the reports of deaths (95%), injuries (100%), and loss (98%) involved cats and dogs. Nevertheless, we seek comment on whether the definition of an animal should be expanded further to include not only dogs and cats in commercial shipments but all species of animals in commercial air transportation. We are seeking comment, rather than proposing specific language, on expanding the definition of an animal to apply to all species of animals, as suggested by the Animal Legal Defense Fund. We are not proposing language at this time for two reasons. First, the overwhelming majority of losses, injuries, and deaths of household pets reported to DOT by airlines have involved cats and dogs. Second, the legislative history of AIR–21 does not appear to show an intent to require reporting of incidents involving commercial shipment of animals such as fish and birds that are being shipped from breeders/wholesalers to retailers. The rule would continue not to cover animals that accompany a passenger at his or her seat in the cabin as the air carrier does not take custody of such animals. In any event, the likelihood of the loss, injury, or death of such animals is very minimal.

We further propose in this NPRM to require each covered carrier to provide in its December report a summary of the total number of animal losses, injuries, and deaths and the total number of

[1] DOT defines small carriers based on the standard published in 14 CFR 399.73: ''For the purposes of the Department's implementation of chapter 6 of title 5, United State Code (Regulatory Flexibility Act), a direct air carrier or foreign air carrier is a small business if it provides air transportation only with small aircraft as defined in § 298.3 of this chapter (up to 60 seats/18,000 pound payload capacity).''

animals transported for the calendar year. Thus, each covered carrier would be required to file a report for the month of December even if the carrier did not experience any incidents involving animals and/or carried no animals during that month or even that year. We seek comment on requiring carriers to report the total number of animals transported during that year. We believe the additional requirement of reporting the number of animals transported may be important for providing a complete picture of a covered carrier's animal transport record, as the number of animals transported by each airline may vary widely. If we were to gather this data from the airlines, we would use it to calculate rates of animal loss, injury and death per unit of animals transported for each airline (e.g., 1.04 deaths per 10,000 animals transported) and include this information in our published animal incident reports. Without this information, consumers and others will not be able to compare the rate of animal incidents from one carrier to another or one year to another.

We ask commenters to provide the following information to assist our consideration of the question of requiring carriers to report the total number of animals transported. How many cats, dogs and other household pets are currently transported per year on scheduled flights of U.S. air carriers? Has this number been increasing or decreasing in recent years? Are current procedures for tracking animal incidents adequate for tracking the total number of animals transported? If yes, then what additional annual costs would be involved for tracking the total number of animals transported? If not, what new procedures would need to be put in place? What exactly would be involved? In terms of costs: What are the set-up costs for such a system? What are annual costs of running it? Are the annual costs fixed or do they depend on the number of animals transported? Please describe capital costs, labor hours, and other costs separately.

In order to limit the burden on the covered carriers, we seek comment on whether we should require covered carriers to report only once per year in the December reports on the total number of animals transported during the previous year, or whether the total number of animals transported should be reported each month. We also solicit comment on whether carriers should be required to file negative reports even if the carrier did not have any incidents involving the loss, injury, or death of an animal during a particular month or year —i.e., reporting ''0'' for any reporting category where there were no such incidents. Negative reports would require carriers to affirmatively certify that there were no reportable animal incidents during that period; they are an additional incentive to ensure that the reports are complete and accurate. We also invite interested persons to comment on whether the Department should continue not requiring carriers to file negative monthly reports of animal incidents (i.e., not requiring reports stating there were no incidents of death, loss, or injury of an animal).

The Department is seeking comment on these issues. Our final action will be based on the comments and supporting evidence filed in this docket and on our own analysis.

Regulatory Analyses and Notices

A. Executive Order 13563 and 12866 and DOT Regulatory Policies and Procedures

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This action has been determined not to be significant under Executive Order 12866 and DOT's Regulatory Policies and Procedures and was not reviewed by the Office of Management and Budget (OMB). The costs associated with this rule would be minimal.

1. Cost of Monthly Reports Other Than December Report

The cost of filing monthly reports would be minimal. Aside from the December report, a carrier would be required to report only during the months where the carrier experiences a reportable animal incident. Currently, 15 of the 36 carriers that would be affected are already required to collect information on incidents involving the loss, injury, or death of an animal. For these 15 carriers, who account for approximately 90 percent of the domestic market, there would be no additional costs. For the 21 other carriers who do not currently have to report, the cost would vary depending on whether or not there is a reportable incident during any given month. For example, if a carrier experiences no reportable incidents all year, then the recurrent cost of filing monthly reports for January to November is $0. However, if the carrier experiences a reportable incident every month of the year, the cost would be $401.52. This is based on our estimate that it would take a Paralegal working in scheduled air transportation making $33.46 (the average wage rate plus benefits) one hour to prepare and submit one monthly report. So, if all 21 carriers, who do not currently have to report, each experience a reportable incident every month of the year, the total cost would be $8,431.92. Therefore, the cost of monthly reports would be between $0 and $8,431.92 per year depending on the number of reportable incidents. Even the high estimate would still be a minimal cost.

2. Cost of the December Report

All covered carriers would be required to submit a December report. However, the burden on covered carriers to submit a December report that includes the total number of animals that were lost, injured, or died during air transport would be minimal. This report would merely be an arithmetic total of the values in any report that a covered carrier filed throughout the year.

3. Cost of Expanded Definition of an Animal

The cost of the proposed expanded definition of an animal would impact airlines, but the cost would still be minimal. Since 2006, the average number of reported incidents per year is 46. If we were to assume that it takes a Paralegal one hour to prepare and submit a report per incident, then we have estimated that the cost to the industry is $1540 per year. This is based on our estimate of a Paralegal's salary discussed above. Various trade sources indicate that dogs and cats transported as part of a commercial shipment may account for as much as half of all dogs, cats, and other household pets that are transported by covered carriers. If we were to assume that expanding the definition to include dogs and cats transported as part of a commercial shipment would result in an additional 46 reported incidents per year (i.e., a total of 92 incidents), the additional cost of $1540 is still minimal.

The benefits of the rule, while difficult to quantify, exceed the costs. Good data are not immediately available as to the total number of animals that air carriers currently transport. Neither trade associations for animal transportation providers nor airlines collect data on the number of animals transported annually by air. Trade association (e.g., pet transportation

firms) and industry (airlines) sources estimate the actual number of pets that carriers transport annually at up to 800,000. This proposal would provide consumers with a fuller picture of the safety record of airlines in the transportation of animals. If the benefit of expanding reporting requirements to dogs and cats transported as a commercial shipment were as little as a cent per animal shipped, the benefits of the rule would exceed the costs.

A copy of the preliminary regulatory evaluation has been placed in the docket. We invite comment on the quantification of costs and benefits for this proposed requirement, as well as the methodology used to develop our cost and benefit estimates. We also seek comment on how unquantified costs and benefits could be measured.

B. Regulatory Flexibility Act

Pursuant to section 605 of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA), I certify that this rulemaking would not have a significant economic impact on a substantial number of small entities. The NPRM would impose no new duties or obligations on small entities. As discussed above, consistent with the RFA, as amended by the SBREFA, we are not proposing to expand this rule to carriers that operate scheduled service with only aircraft that have a design capacity of 60 seats or less as these carriers are considered small businesses.

C. Executive Order 13132 (Federalism)

This action 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, and therefore will not have federalism implications.

D. Executive Order 13084

This notice has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Because the provision on which we are seeking comment would not significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13084 do not apply.

E. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 49 U.S.C. 3501 et seq.), the Department is seeking to renew with change the information collection titled ''Reports by Carriers on Incidents Involving Animals During Air Transport'' (OMB No. 2105–055). This information collection expired on June 6, 2011. This NPRM proposes to modify the information collection requirement. Under the Paperwork Reduction Act, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing notice of the proposed collection of information and a 60-day comment period, and must otherwise consult with members of the public and affected agencies concerning the proposed collection.

The collection of information proposed in the NPRM is a requirement that U.S. carriers that operate scheduled passenger service with at least one aircraft having a designed seating capacity of more than 60 passenger seats report to the Department's ACPD any incidents involving the loss, injury, or death during air transport of cats and dogs that were part of a commercial shipment. (Cats and dogs that were being kept as a household pet at the time of such a loss, injury, or death are already required to be reported by these airlines.) As discussed above, this requirement would expand the reporting requirement from 15 carriers to 36 carriers, an increase of 21 carriers. We also propose to require covered carriers to state in their report for the month of December the total number of animals that were lost, injured, or died during air transport. We solicit comment on whether we should also require carriers to provide information about the total number of animals transported in the calendar year.

Title: Reports by Carriers on Incidents Involving Animals During Air Transport.

OMB Control Number: 2105–0552.

Type of Request: Modification of expired Information Collection Request.

Respondents: U.S. carriers that operate scheduled passenger service with at least one aircraft having a designed seating capacity of more than 60 seats (36).

Frequency: For each respondent, one information set for the month of December, plus one information set during some months (1 to 12).

Estimated Annual Burden on Respondents: 36 to 432 hours (Respondents [36] × Frequency [1 to 12 per year]).

Comments are invited on: (1) The necessity and utility of the information collection, (2) the accuracy of the estimate of the burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) ways to minimize the burden of collection without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized or included, or both, in the request for OMB approval of these information collections.

F. Unfunded Mandates Reform Act

The Department has determined that the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply to this rulemaking.

Issued this 22nd day of June 2012, in Washington, DC.

Robert S. Rivkin,

General Counsel.

List of Subjects in Parts 234 and 235

Air carrier, Animal incidents, Consumer protection, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Transportation proposes to amend 14 CFR chapter II as follows:

PART 234—AIRLINE SERVICE QUALITY PERFORMANCE REPORTS

1. The authority citation for part 234 continues to read as follows:

Authority: 49 U.S.C. 329 and Sections 41708 and 41709.

2. Section 234.13 is removed.

§ 234.13 [Removed]

3. A new part 235 is added to read as follows:

PART 235—REPORTS BY AIR CARRIERS ON INCIDENTS INVOLVING ANIMALS DURING AIR TRANSPORT

Sec.

Authority: 49 U.S.C. 41721.

§ 235.1 Definitions.

For the purposes of this part:

Air transport includes the entire period during which an animal is in the custody of an air carrier, from the time that the animal is tendered to the air carrier prior to departure until the air carrier tenders the animal to the owner, guardian or representative of the shipper of the animal at the animal's final destination. It does not include animals that accompany a passenger at his or her seat in the cabin and of which the air carrier does not take custody.

Animal means any warm or cold blooded animal which, at the time of

transportation, is being kept as a pet in a family household in the United States and any dog or cat which, at the time of transportation, is shipped as part of a commercial shipment on a scheduled passenger flight, including shipments by trainers and breeders.

§ 235.2 Applicability.

This part applies to the scheduled domestic and international passenger service of any U.S. air carrier that operates such service with at least one aircraft having a designed seating capacity of more than 60 passenger seats.

§ 235.3 Reports by air carriers on incidents involving animals during air transport.

(a) Each covered carrier shall, within 15 days after the end of the month to which the information applies, submit to the United States Department of Transportation's Aviation Consumer Protection Division a report on any incidents involving the loss, injury, or death of an animal during air transport provided by the air carrier, including incidents on flights by that carrier that are operated with aircraft having 60 or fewer seats. The report shall be made in the form and manner set forth in reporting directives issued by the Deputy General Counsel for the U.S. Department of Transportation and shall contain the following information:

(1) Carrier and flight number;

(2) Date and time of the incident;

(3) Description of the animal, including name, if applicable;

(4) Name and contact information of the owner(s), guardian and/or shipper of the animal;

(5) Narrative description of the incident;

(6) Narrative description of the cause of the incident;

(7) Narrative description of any corrective action taken in response to the incident; and

(8) Name, title, address, and telephone number of the individual filing the report on behalf of the air carrier.

(b) Within 15 days after the end of December of each year, each covered carrier shall submit the following information (this information may be included in any report that the carrier may file for the loss, injury, or death of animals during the month of December):

(1) The total number of incidents involving an animal during air transport provided by the air carrier for the entire calendar year, including incidents on flights by that carrier that are operated with aircraft having 60 or fewer seats. The report shall include subtotals for loss, injury, and death of animals. Report ''0'' for any category for which there were no such incidents. If the carrier had no reportable incidents for that calendar year, it shall report ''0'' in each category.

(2) The December report must contain the following certification signed by your authorized representative: ''I, the undersigned, do certify that this report has been prepared under my direction in accordance with the regulations in 14 CFR Part 235. I affirm that, to the best of my knowledge and belief, this is a true, correct and complete report.''

[FR Doc. 2012–16024 Filed 6–28–12; 8:45 am]

BILLING CODE 4910–9X–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2012–0037]

16 CFR Part 1500

Codification of Animal Testing Policy

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed Statement of Policy on Animal Testing

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) proposes to codify its statement of policy on animal testing, as amended, which was previously published in the **Federal Register**. The amended statement of policy on animal testing is intended for manufacturers of products subject to the Federal Hazardous Substances Act (FHSA) to find alternatives to animal testing and reduce the number of animal tests under the FHSA.

DATES: Written comments and submissions in response to this notice must be received by September 12, 2012.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2012–0037, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (email) except through *www.regulations.gov.*

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this proposed statement of animal testing policy. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Leslie E. Patton, Ph.D., Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7848; *lpatton@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

The Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261–1278, requires appropriate cautionary labeling on certain hazardous household products to alert consumers to the potential hazards that a product may present. Among the hazards addressed by the FHSA are products that are toxic, corrosive, irritants, flammable, combustible, or strong sensitizers. The FHSA and the Commission regulations at 16 CFR part 1500 provide certain test methods related to testing on animals to determine the existence of the hazards addressed by the FHSA.

On May 30, 1984, the Commission adopted an animal testing policy that minimized the number of test animals required for toxicity testing and clarified when animal testing might be needed (1984 Policy) published in the **Federal Register** on May 30, 1984 (49 FR 22522). These guidelines advised product manufacturers to use alternatives to animal testing whenever possible, including: (1) Prior human experience, (2) existing animal or limited human test results, and (3) expert opinion. The 1984 Policy stated:

It is important to keep in mind that neither the FHSA nor the Commission's regulations require any firm to perform animal tests. The statute and its implementing regulations only require that a product be labeled to reflect the

hazards associated with that product. While animal testing may be necessary in some cases, Commission policy supports limiting such tests to the lowest feasible number and taking every feasible step to eliminate or reduce the pain or discomfort that can be associated with such tests* * *.The Commission resorts to animal testing only when the other information sources have been exhausted. Furthermore, the FHSA regulations, at 16 CFR 1500.4, clearly state that reliable human experience shall take precedence over different results from animal data.

Id. at 22523. The 1984 Policy also stated that if non-animal test systems for prediction of toxicity and irritancy are accepted by the scientific community as adjuncts or alternatives to whole-animal testing, ''[The CPSC Directorate for] Health Sciences will incorporate the techniques into the Commission's compliance program to the extent feasible and will recommend any changes to the Commission's statutes or regulations that may become appropriate as the result of advances in testing methods that are developed.'' *Id.*

Since the 1984 Policy, there have been new methods accepted by the scientific community as replacements or adjuncts to animal tests for predictions of toxicity and irritancy. Such developments in testing have been made in recent years, particularly since the National Institutes of Health Revitalization Act was passed in 1993 (Pub. L. 103–43, Section 1301), directing the National Institute of Environmental Health Sciences (NIEHS) to establish a method and criteria for the validation and regulatory acceptance of alternative testing methods. The NIEHS created the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM; *http://iccvam.niehs.nih.gov/home.htm*), which was made permanent by the ICCVAM Authorization Act of 2000, Public Law 106–545. The duties of ICCVAM are to review, optimize, and validate new, revised, or alternative test methods that encourage the reduction, refinement, or replacement of the use of animals in testing. ICCVAM has representatives from 15 federal regulatory and research agencies, including the CPSC. These agencies generate, use, or provide information from toxicity test methods for risk assessment purposes. In addition, ICCVAM provides test recommendations to federal agencies and other stakeholders to facilitate appropriate interagency and international harmonization of toxicological test protocols.

ICCVAM submits recommendations for a test method to federal agencies that require or recommend acute or chronic toxicological testing. According to Public Law 106–545, these agencies should promote and encourage the development and use of alternatives to animal test methods for regulatory purposes, and ensure that any new or revised acute or chronic toxicity test method is valid for its proposed use. Federal agencies have 180 days from the time of submission to identify any relevant test methods for which the ICCVAM test recommendations may be added or substituted, review such test recommendations, and notify ICCVAM if they will adopt the ICCVAM test recommendations. Since 2003, the Commission has approved, where applicable, the recommendations made by ICCVAM to reduce and refine animal testing applicable to test methods under the FHSA. In order to make the ICCVAM recommendations and Commission's animal testing policy more accessible and transparent to interested parties, the Commission proposes to update its regulations on animal testing at 16 C.F.R. part 1500, published elsewhere in this **Federal Register**, and establish a Web page on the CPSC's Web site at *http://www.cpsc.gov/businfo/animaltesting.html* regarding the ICCVAM recommendations and new developments in test methods that further reduce or refine animal testing.

In addition, the Commission proposes to update its statement on animal testing policy to reflect the ICCVAM recommendations that have been reviewed and adopted by the CPSC as being appropriate tests for assessing hazards under the FHSA. In order to make this statement of policy more accessible and transparent to interested parties, the Commission proposes to codify the policy at 16 CFR 1500.232.

Since this is a statement of policy, a delayed effective date is not required. 5 U.S.C. 553(d)(2). A delayed effective date is not required for the additional reason that this policy is not a substantive rule. 5 U.S.C. 553(d)(3). Accordingly, this codification will become effective upon the publication of a final policy statement in the **Federal Register**.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, Reporting and recordkeeping requirements, and Toys.

For the reasons given above, the Commission proposes to amend 16 CFR part 1500 as follows:

PART 1500—[AMENDED]

1. The authority for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261–1278, 122 Stat. 3016; the Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, § 104, 122 Stat. 3016 (August 14, 2008).

2. Add a new section 1500.232 to read as follows:

§ 1500.232 Statement on Animal Testing Policy.

(a) Summary

(1) The U.S. Consumer Product Safety Commission issues this statement of policy on animal testing and alternatives to animal testing of hazardous substances regulated under the Federal Hazardous Substances Act (FHSA). The FHSA requires appropriate cautionary labeling on certain household products to alert consumers to the potential hazard(s) that the products may present. Among the hazards addressed by the FHSA are toxicity, corrosivity, sensitization, and irritation.

(2) In order to determine the appropriate cautionary labeling, it is necessary to have objective criteria by which the existence of each hazard can be determined. Hazards such as toxicity, tissue corrosiveness, eye irritancy, and skin irritancy result from the biological response of living tissue and organs to the presence of the hazardous substance. One means of characterizing these hazards is to use animal testing as a proxy for the human reaction. In fact, the FHSA defines the hazard category of ''*highly toxic*'' in terms of animal toxicity when groups of 10 or more rats are exposed to specified amounts of the substance. The Commission's regulations under the FHSA concerning toxicity and irritancy allow the use of animal tests to determine the presence of the hazard when human data or existing animal data are not available.

(3) Neither the FHSA nor the Commission's regulations *require* animal testing. The FHSA and its implementing regulations only require that a product be labeled to reflect the hazards associated with that product. While animal testing may be necessary in some cases, Commission policy supports limiting such tests to a minimum number of animals, and the policy also advocates measures that eliminate or reduce the pain or discomfort to animals that can be associated with such tests. The Commission has prepared this statement of policy with respect to animal testing to encourage the manufacturers subject to the FHSA to follow a similar policy.

(4) In making the appropriate hazard determinations, manufacturers of products subject to the FHSA should use existing alternatives to animal testing whenever possible. These include prior human experience, literature sources that record the results of prior animal testing or limited human tests, and expert opinion. The Commission recommends resorting to animal testing only when the other information sources have been exhausted. At this time, the Commission recommends use of the most humane procedures with the fewest animals possible to achieve reliable results. Recommended procedures are summarized in the following statement and can be accessed on the Commission's Web page at: *http://www.cpsc.gov/businfo/animaltesting.html.*

(b) Statement of Policy on Animal Testing.

(1) The Commission reviews staff recommendations on alternative test methods developed by the scientific and regulatory communities. Current descriptions of test method recommendations approved by the Commission can be accessed via the Internet at: *http://www.cpsc.gov/businfo/animaltesting.html.* Overall, the Commission prefers test methods that reduce stress and suffering in test animals and that use none or fewer animals while maintaining scientific integrity. The Commission strongly supports the use of validated alternatives to animal testing. The following parts of this section outline some of these alternatives. Testing laboratories and other interested persons requiring assistance interpreting the results obtained when a substance is tested in accordance with the methods described here, or in following the testing strategies outlined in this statement of policy and the regulations under 16 CFR part 1500, should refer to the Commission's animal testing Web page at *http://www.cpsc.gov/businfo/animaltesting.html*.

(a) Acute toxicity—The traditional FHSA animal test for acute toxicity determines the median lethal dose (LD_{50}) or lethal concentration (LC_{50}), the dose or concentration that is expected to kill half the test animals. Procedures for determining the median LD_{50}/LC_{50} are described in section 2(h)(1) of the FHSA and supplemented in § 1500.3(c)(1) and (2) and the test method outlined in § 1500.40. The Commission recommends using modifications of the traditional LD_{50}/LC_{50} test during toxicity testing that reduce the number of animals tested, whenever possible. Approved modifications are identified on the Web site at: *http://www.cpsc.gov/businfo/animaltesting.html* and include:

(i) *In vitro* and *in vivo* test methods that have been scientifically validated and approved for use in toxicity testing by the Commission;

(ii) Valid *in vitro* methods to estimate a starting dose for an acute *in vivo* test;

(iii) A sequential version of the traditional LD_{50}/LC_{50} tests described in § 1500.3(c)(1) and (2) and the test method described in § 1500.40, in which dose groups are run successively rather than simultaneously;

(iv) A limit-dose test, where the LD_{50}/LC_{50} is determined as a point estimate, which can still be used to categorize a hazard, although it gives no information on hazard dose response.

(b) Dermal irritation/corrosivity—A weight-of-evidence analysis is recommended to evaluate existing information before *in vivo* dermal irritation testing is considered to determine appropriate cautionary labeling. This analysis should incorporate any existing data on humans and animals, validated *in vitro* test results (valid tests are identified on the Commission's animal testing Web site at: *http://www.cpsc.gov/businfo/animaltesting.html*), the substance's dermal toxicity, evidence of corrosivity/irritation of one or more structurally related substances or mixtures of such substances, data demonstrating low or high pH (≤ 2 or ≥ 11.5) of the substance, and any other relevant physicochemical properties that indicate the substance might be a dermal corrosive or irritant. If there is any indication from this analysis that the substance is either corrosive or irritating to the skin, the substance should be labeled appropriately. If the substance is not corrosive *in vitro,* but no data exist regarding its irritation potential, human patch testing should be considered. If *in vitro* data are unavailable, and human patch testing is not an option, a tiered *in vivo* animal test is recommended.

(i) In a tiered *in vivo* dermal study, a single rabbit is tested initially. If the outcome is positive for corrosivity, testing is stopped, and the substance is labeled appropriately. If the substance is not corrosive, two more rabbits should be patch-tested to complete the assessment of skin irritation potential.

(ii) If a tiered test is not feasible, the Commission recommends the test method described in § 1500.41. Note that in any *in vivo* dermal irritation test method, the Commission recommends using a semi-occlusive patch to cover the animal's test site, and eliminating the use of stocks for restraint during the exposure period, thereby allowing the animal free mobility and access to food and water.

(c) Ocular irritation—A weight-of-evidence analysis is recommended to evaluate existing information before any *in vivo* ocular irritation testing is considered. This analysis should incorporate any existing data on humans and animals, validated *in vitro* test data (identified on the Commission's animal testing Web site at: *http://www.cpsc.gov/businfo/animaltesting.html*), the substance's dermal corrosivity/irritation (primary skin irritants and corrosives are also usually eye irritants, and therefore, do not need to be tested in the eye), evidence of ocular irritation of one or more structurally related substances or mixtures of such substances, data demonstrating high acidity or alkalinity of the substance, and any other relevant physicochemical properties that indicate that the substance might be a dermal corrosive or irritant or ocular irritant.

(i) When the weight-of-evidence is insufficient to determine a substance's ocular irritation, a Commission-approved *in vitro* assay for ocular irritancy should be run to assess eye irritation potential and determine labeling. Valid *in vitro* assays are identified at: *http://www.cpsc.gov/businfo/animaltesting.html.* If no valid *in vitro* test exists, the test strategy for determining dermal corrosion/irritation outlined in section (b)(ii) above can be followed to determine ocular irritation.

(ii) If the dermal test strategy outlined in section (b)(ii) leads to a conclusion of *not corrosive,* a tiered *in vivo* ocular irritation test should be performed, in which a single rabbit is exposed to the substance initially. If the outcome of this initial test is positive, testing is stopped, and the substance is labeled an eye irritant. If the outcome of this initial test is negative, one to two more rabbits are tested for ocular irritation, and the outcome of this test will determine the label. If a tiered test is not feasible, the Commission recommends the test method described in § 1500.42.

(iii) When any ocular irritancy testing on animals is considered necessary, including the method described in § 1500.42, the Commission recommends a threefold plan to reduce animal suffering: (1) The use of preemptive pain management, including topical anesthetics and systemic analgesics that eliminate or reduce suffering that may occur as a result of the application process or from the test substance itself; (2) post-treatment with systemic analgesics for pain relief; and (3) implementation of humane endpoints, including scheduled observations,

monitoring, and recording of clinical signs of distress and pain, and recording the nature, severity, and progression of eye injuries. The specific techniques that have been approved by the Commission can be found at: *http://www.cpsc.gov/businfo/animaltesting.html.*

Dated: June 25, 2012.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2012–15883 Filed 6–28–12; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. CPSC–2012–0036]

16 CFR Part 1500

Hazardous Substances and Articles; Administration and Enforcement Regulations: Notice of Proposed Rulemaking; Revisions to Animal Testing Regulations

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Consumer Product Safety Commission (CPSC or Commission) proposes to amend and to update regulations on the CPSC's animal testing methods under the Federal Hazardous Substances Act (FHSA).

DATES: Written comments must be received by September 12, 2012.

ADDRESSES: You may submit comments identified by Docket No. CPSC–2012–0036, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (email) except through *www.regulations.gov.*

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Leslie E. Patton, Ph.D., Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7848; *lpatton@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261–1278, requires appropriate cautionary labeling on certain hazardous household products to alert consumers to the potential hazards that a product may present. Among the hazards addressed by the FHSA are products that are toxic, corrosive, irritants, flammable, combustible, or strong sensitizers. The FHSA and the Commission regulations at 16 CFR part 1500 provide certain test methods related to testing on animals to determine the existence of the hazards addressed by the FHSA.

On May 30, 1984, the Commission adopted an animal testing policy that minimized the number of test animals required for toxicity testing and clarified when animal testing might be needed (1984 Policy) (49 FR 22522). These guidelines advised product manufacturers to use alternatives to animal testing whenever possible, including: (1) Prior human experience, (2) existing animal or limited human test results, and (3) expert opinion. The 1984 Policy stated:

> It is important to keep in mind that neither the FHSA nor the Commission's regulations require any firm to perform animal tests. The statute and its implementing regulations only require that a product be labeled to reflect the hazards associated with that product. While animal testing may be necessary in some cases, Commission policy supports limiting such tests to the lowest feasible number and taking every feasible step to eliminate or reduce the pain or discomfort that can be associated with such tests. * * * The Commission resorts to animal testing only when the other information sources have been exhausted. Furthermore, the FHSA regulations, at 16 CFR 1500.4, clearly state that reliable human experience shall take precedence over different results from animal data.

Id. at 22523. The 1984 Policy also stated that if non-animal test systems for prediction of toxicity and irritancy are accepted by the scientific community as adjuncts or alternatives to whole-animal testing, ''[The CPSC Directorate for] Health Sciences will incorporate the techniques into the Commission's compliance program to the extent feasible and will recommend any changes to the Commission's statutes or regulations that may become appropriate as the result of advances in testing methods that are developed.'' *Id.*

Since the 1984 Policy, there have been new methods accepted by the scientific community as replacements or adjuncts to animal tests for predictions of toxicity and irritancy. Such developments in testing have been made in recent years, particularly since the National Institutes of Health Revitalization Act was passed in 1993 (Pub. L. 103–43, Section 1301), directing the National Institute of Environmental Health Sciences (NIEHS) to establish a method and criteria for the validation and regulatory acceptance of alternative testing methods. The NIEHS created the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM; *http://iccvam.niehs.nih.gov/home.htm*), which was made permanent by the ICCVAM Authorization Act of 2000, Public Law 106–545. The duties of ICCVAM are to review, optimize, and validate new, revised, or alternative test methods that encourage the reduction, refinement, or replacement of the use of animals in testing. ICCVAM has representatives from 15 federal regulatory and research agencies, including the CPSC. These agencies generate, use, or provide information from toxicity test methods for risk assessment purposes. In addition, ICCVAM provides test recommendations to federal agencies and other stakeholders to facilitate appropriate interagency and international harmonization of toxicological test protocols.

ICCVAM submits recommendations for a test method to federal agencies that require or recommend acute or chronic toxicological testing. According to Public Law 106–545, these agencies should promote and encourage the development and use of alternatives to animal test methods for regulatory purposes, and ensure that any new or revised acute or chronic toxicity test method is valid for its proposed use. Federal agencies have 180 days from the

time of submission to identify any relevant test methods for which the ICCVAM test recommendations may be added or substituted, review such test recommendations, and notify ICCVAM if they will adopt the ICCVAM test recommendations. Since 2003, the Commission has approved, where applicable, the recommendations made by ICCVAM to reduce and refine animal testing applicable to test methods under the FHSA. In order to make the ICCVAM recommendations and Commission's animal testing policy more accessible and transparent to interested parties, the Commission proposes to codify its updated animal testing policy at 16 CFR 1500.232, published elsewhere in this **Federal Register**, and establish a Web page on the CPSC's Web site at *http://www.cpsc.gov/businfo/animaltesting.html* regarding the ICCVAM recommendations and new developments in test methods that further reduce or refine animal testing.

In addition, to reflect more accurately the ICCVAM recommendations and updated test methods approved by the Commission, this proposed rule amends the Commission's regulations that interpret, supplement, or provide alternatives to definitions on animal test methods used to aid in the classification of hazardous substances under the FHSA.

B. Proposed Amendments

All of the proposed amendments to 16 CFR part 1500 clarify or add language to explain that alternative test methods exist that avoid or reduce animal testing, which have been approved by the Commission.

1. Definition of Highly Toxic

Currently, the test methods in section 1500.3(c)(1)(ii) A–C, used in the definitions of oral, inhalation, and dermal toxicity, respectively, each describe a method for defining a substance as *highly toxic.* The definition of highly toxic is:

(i) A substance determined by the Commission to be highly toxic on the basis of human experience; and/or (ii) A substance that produces death within 14 days in half or more than half of a group of: (A) White rats (each weighing between 200 and 300 grams) when a single dose of 50 milligrams or less per kilogram of body weight is administered orally; (B) White rats (each weighing between 200 and 300 grams) when a concentration of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter by volume or less of mist or dust, is inhaled continuously for 1 hour or less, if such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; and/or (C) Rabbits (each weighing between 2.3 and 3.0 kilograms) when a dosage of 200 milligrams or less per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours or less by the method described in § 1500.40. The number of animals tested must be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices.

The proposed amendment makes clear that the animal tests are not the only means to test or define a product's toxicity under the FHSA, nor are they the only methods used by the CPSC to assess product toxicity. Because there are other Commission-approved test methods that may be used by CPSC staff or the public for toxicity testing and defining a substance as highly toxic, as reflected in the ICCVAM recommendations and outlined in the CPSC'statement of policy on animal testing published elsewhere in this **Federal Register**, the proposed rule adds language under new section 1500.3(c)(1)(iii) as follows: *A substance that produces a result of 'highly toxic' in any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.*

2. Definition of Toxic

Currently, the test methods in section 1500.3(c)(2)(i) A–C, used in the definitions of oral, inhalation, and dermal toxicity, respectively, each describe a method for defining a substance as *toxic.* The definition of toxic is:

(i) Any substance that produces death within 14 days in half or more than half of a group of: (A) White rats (each weighing between 200 and 300 grams) when a single dose of 50 milligrams to 5 grams per kilogram of body weight is administered orally. Substances falling in the toxicity range between 500 milligrams and 5 grams per kilogram of body weight will be considered for exemption from some or all of the labeling requirements of the act, under § 1500.82, upon a showing that such labeling is not needed because of the physical form of the substances (solid, a thick plastic, emulsion, etc.), the size or closure of the container, human experience with the article, or any other relevant factors; and/or (B) White rats (each weighing between 200 and 300 grams) when a concentration of more than 200 parts per million but not more than 20,000 parts per million by volume of gas or vapor, or more than 2 but not more than 200 milligrams per liter by volume of mist or dust, is inhaled continuously for 1 hour or less, if such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; and/or (C) Rabbits (each weighing between 2.3 and 3.0 kilograms) when a dosage of more than 200 milligrams but not more than 2 grams per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours by the method described in § 1500.40. The number of animals tested must be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices.

The proposed amendment makes clear that the animal tests are not the only means to test or define a product's toxicity under the FHSA, nor are they the only methods used by the CPSC to assess product toxicity. Because there are other Commission-approved test methods that may be used by CPSC staff or the public for toxicity testing and defining a substance as *toxic,* as reflected in the ICCVAM recommendations, and outlined in the CPSC's statement of policy on animal testing published elsewhere in this **Federal Register**, the proposed rule adds language under new section 1500.3(c)(2)(iii) as follows: *Toxic also applies to any substance that can be labeled as such, based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.*

3. Definition of Corrosive

16 CFR 1500.3(c)(3) currently states that: Corrosive means a substance that causes visible destruction or irreversible alterations in the tissue at the site of contact. A test for a corrosive substance is whether, by human experience, such tissue destruction occurs at the site of application. A substance would be considered corrosive to the skin if, when tested on the intact skin of the albino rabbit by the technique described in § 1500.41, the structure of the tissue at the site of contact is destroyed or changed irreversibly in 24 hours or less. Other appropriate tests should be applied when contact of the substance with other than skin tissue is being considered.

The method of testing described in § 1500.41 is a test for acute dermal toxicity. The proposed rule amends this definition to make explicit that the animal testing is not the only testing method used or accepted by the CPSC, or the preferred method. Accordingly, the proposed rule adds the following text (in underline) to section 16 CFR 1500.3(c)(3):

Corrosive means a substance that causes visible destruction or irreversible alterations in the tissue at the site of contact. A test for a corrosive substance is whether, by human experience, such tissue destruction occurs at the site of application. A substance would be considered corrosive to the skin *if a weight-of-evidence analysis suggests that it is corrosive or if, when tested by the in vivo* technique described in § 1500.41, the structure of the tissue at the site of contact is destroyed or changed irreversibly in 24

hours or less. Other appropriate tests should be applied when contact of the substance with other than skin tissue is being considered. *A substance could also be labeled corrosive based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.*

4. Definition of Irritant, Primary Irritant, and Eye Irritant

Currently, 16 CFR 1500.3(c)(4) provides that the test methods for *irritant, primary irritant,* and *eye irritant* reference 16 CFR 1500.41 and 1500.42, which each describe a specific animal test method and outcome. For example, 16 CFR 1500.41 states that primary irritation to the skin is measured by a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. A minimum of six subjects are used in the skin tests. To test for eye irritants, 16 CFR 1500.42 requires the use of six albino rabbits. Such tests require the test material be placed in one eye of each animal, while the other eye remains untreated, to serve as a control to assess the grade of ocular reaction.

The proposed rule clarifies that the method for testing for irritant substances should not be based solely on these specific animal tests because there are other scientifically valid ways of testing for irritants, including methods that do not use animals. Accordingly, the proposed rule adds the following text (in underline) to section 1500.3(c)(4):

The definition of irritant in section 2(j) of the act (restated in paragraph (b)(8) of this section) is supplemented by the following: *Irritant* includes primary irritant to the skin, as well as substances irritant to the eye or to mucous membranes. *Primary irritant* means a substance that is not corrosive and that human experience data indicate is a primary irritant; and/or means a substance that results in an empirical score of five or more when tested by the method described in 1500.41; *and/or a substance that can be considered a primary irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232. Eye irritant* means a substance that human experience data indicate is an irritant to the eye; and/or means a substance for which a positive test is obtained when tested by the method described in 1500.42; *and/or means a substance that can be considered an eye irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.*

5. Method of Testing Toxic Substances

The method of testing toxic substances is set forth under 16 CFR 1500.40. This method details an acute dermal toxicity assay using rabbits. The method is referenced in § 1500.3(c)(1)(ii)(C) and § 1500.3(c)(2)(C). Although the method described in § 1500.40 is one way of assessing a substance's acute dermal toxicity, this method is not mandatory, and it is not the only or preferred method for evaluating dermal toxicity. Accordingly, the proposed rule adds the following text (in underline) to § 1500.40 immediately after the heading titled, ''Method of testing toxic substances'':

Guidelines for testing the toxicity of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before in vivo tests are considered. This analysis, when deemed necessary to carry out, should include any of the following: existing human and animal data, in vitro data, structure activity relationships, physicochemical properties, and chemical reactivity. When in vivo testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals.

6. Method of Testing Primary Irritant Substances

The method of testing primary irritant substances is set forth under 16 CFR 1500.41. This method details an acute dermal toxicity assay using rabbits. The method is referenced in §§ 1500.3(c)(3) and 1500.3(c)(4). Although the method described in § 1500.41 is one way of assessing a substance's dermal irritation/corrosivity, this method is not mandatory, and it is not the only or preferred method for evaluating a substance's dermal irritation/corrosivity. Accordingly, the proposed rule adds the following text (in underline) to § 1500.41 immediately after the heading titled, ''Method of testing primary irritant substances'':

Guidelines for testing the dermal irritation and corrosivity properties of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before in vivo tests are considered. This analysis should include all of the following that are available: human and animal data, structure activity relationships, physicochemical properties, and dermal toxicity. When in vivo testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals. The method of testing the dermal corrosivity and primary irritation of substances referred to in §§ 1500.3(c)(3) and (4), respectively, is a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair * * *

7. Test for Eye Irritants

Section 1500.42 of 16 CFR provides a detailed animal test for eye irritation. The method is referenced in § 1500.3(c)(4), which defines *irritation.* Although the method described in § 1500.42 is one way of assessing a substance's properties of ocular irritation, this method is not mandatory, and it is not the only or preferred method of assessing a substance's properties of ocular irritation. Accordingly, the proposed rule adds the following text (in underline) to § 1500.42 immediately after the heading titled, ''Test for eye irritants'':

Guidelines for in vivo and in vitro testing of ocular irritation of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before in vivo tests are considered. This analysis should include any of the following: existing human and animal data on ocular or dermal irritation, structure activity relationships, physicochemical properties, and chemical reactivity. When in vivo testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals. Additionally, the routine use of topical anesthetics, systemic analgesics, and humane endpoints to avoid or minimize pain and distress in ocular safety testing is recommended.

(a)(1) *In the method of testing the ocular irritation of a substance referred to in § 1500.3(c)(4),* six albino rabbits are used for each test substance * * *

8. Editorial Changes

The proposed rule eliminates the reference in § 1500.42(c) to the ''Illustrated Guide for Grading Eye Irritation by Hazardous Substances,'' and the accompanying note. The referenced guide is out of print, and photocopies are rare. Instead, the proposed rule amends § 1500.42(c) to reference guidelines from the U.S. Environmental Protection Agency (EPA) and the Organisation for Economic Co-operation and Development (OECD) as follows:

To assist testing laboratories and others interested in interpreting ocular irritation test results, the CPSC animal testing policy Web page at *http://www.cpsc.gov/businfo/animaltesting.html* will contain the scoring system defined in the U.S. EPA's Test Guideline, OPPTS 870.2400: Acute Eye Irritation [1] or the OECD Test Guideline 405: Acute Eye Irritation/Corrosion.[2]

[1] EPA. 1998. Health Effects Test Guidelines, OPPTS 870.2400 Acute Eye Irritation. EPA 712–C–98–195. Washington, DC: U.S. Environmental Protection Agency. (Available: *http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/EPA/EPA_870_2400.pdf*).

[2] OECD. 2002. OECD Guideline for the Testing of Chemicals 405: Acute Eye Irritation/Corrosion. Paris: Organisation for Economic Co-operation and Development. (Available: *http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECDtg405.pdf*).

C. Impact on Small Businesses

Under the Regulatory Flexibility Act (RFA), when an agency issues a proposed rule, it generally must prepare an initial regulatory flexibility analysis describing the impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of amending the regulations on animal testing. That assessment found that there would be little or no effect on small businesses and other entities because the proposed amendments will not result in product modifications in order to comply, and they will not result in additional testing or recordkeeping burdens. Based on the foregoing assessment, the Commission preliminarily finds that the proposed rule would not have a significant impact on a substantial number of small entities.

D. Environmental Considerations

Generally, CPSC rules are considered to ''have little or no potential for affecting the human environment,'' and environmental assessments and environmental impact statements are not usually prepared for these rules (see 16 CFR 1021.5(c)(1)). The Commission does not expect the proposed rule to have any adverse impact on the environment under this categorical exclusion.

E. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of regulations such as this proposed rule is stated in section 18 of the FHSA. 15 U.S.C. 1261n.

F. Paperwork Reduction Act

This rule would not impose any information collection requirements. Accordingly, this rule is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501–3520.

G. Effective Date

The Administrative Procedure Act generally requires that a substantive rule be published not less than 30 days before its effective date, unless the agency finds, for good cause shown, that a lesser time period is required. 5 U.S.C. 553(d)(3). We propose that the rule would take effect 30 days after publication of a final rule in the **Federal Register**.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, Reporting and recordkeeping requirements, and Toys.

Accordingly, 16 CFR part 1500 is proposed to be amended as follows:

PART 1500—[AMENDED]

1. The authority citation for part 1500 continues to reads as follows:

Authority: 15 U.S.C. 1261–1278, 122 Stat. 3016; the Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, § 104, 122 Stat. 3016 (August 14, 2008).

2. Amend section 1500.3 by adding new paragraphs (c)(1)(iii) and (c)(2)(iii) and revise paragraphs (c)(3) and (c)(4), to read as follows:

§ 1500.3 Definitions.

* * * * *

(c) * * *

(1) * * *

(iii) A substance that produces a result of 'highly toxic' in any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.

(2) * * *

(iii) *Toxic* also applies to any substance that can be labeled as such, based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.

(3) Corrosive means a substance that causes visible destruction or irreversible alterations in the tissue at the site of contact. A test for a corrosive substance is whether, by human experience, such tissue destruction occurs at the site of application. A substance would be considered corrosive to the skin if a weight-of-evidence analysis suggests that it is corrosive or if, when tested by the *in vivo* technique described in § 1500.41, the structure of the tissue at the site of contact is destroyed or changed irreversibly in 24 hours or less. Other appropriate tests should be applied when contact of the substance with other than skin tissue is being considered. A substance could also be labeled corrosive based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.

(4) The definition of irritant in section 2(j) of the act (restated in paragraph (b)(8) of this section) is supplemented by the following: *Irritant* includes primary irritant to the skin, as well as substances irritant to the eye or to the mucous membranes. *Primary irritant* means a substance that is not corrosive and that human experience data indicate is a primary irritant; and/or means a substance that results in an empirical score of five or more when tested by the method described in § 1500.41; and/or a substance that can be considered a primary irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232. *Eye irritant* means a substance that human experience data indicate is an irritant to the eye; and/or means a substance for which a positive test is obtained when tested by the method described in § 1500.42; and/or means a substance that can be considered an eye irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.

* * * * *

3. Amend section 1500.40 by revising the introductory text to read as follows:

§ 1500.40 Method of testing toxic substances.

Guidelines for testing the toxicity of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before *in vivo* tests are considered. This analysis, when deemed necessary to carry out, should include any of the following: existing human and animal data, *in vitro* data, structure activity relationships, physicochemical properties, and chemical reactivity. When *in vivo* testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals. The method of testing the toxic substances referred to in § 1500.3(c)(1)(ii)(C) and (2)(iii) is as follows:

* * * * *

4. In § 1500.41, add five sentences at the start of the introductory text to read as follows:

§ 1500.41 Method of testing primary irritant substances.

Guidelines for testing the dermal irritation and corrosivity properties of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include all of the following that are available: Human and animal data, structure activity relationships, physicochemical properties, and dermal

toxicity. When *in vivo* testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals. The method of testing the dermal corrosivity and primary irritation of substances referred to in §§ 1500.3(c)(3) and (4), respectively, is a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. * * *

5. Amend section 1500.42 by adding introductory text, adding a sentence at the beginning of paragraph (a)(1), and revising paragraph (c) to read as follows:

§ 1500.42 Test for eye irritants.

Guidelines for *in vivo* and *in vitro* testing of ocular irritation of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include any of the following: Existing human and animal data on ocular or dermal irritation, structure activity relationships, physicochemical properties, and chemical reactivity. When *in vivo* testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals. Additionally, the routine use of topical anesthetics, systemic analgesics, and humane endpoints to avoid or minimize pain and distress in ocular safety testing is recommended.

(a)(1) In the method of testing the ocular irritation of a substance referred to in § 1500.3(c)(4), six albino rabbits are used for each test substance * * * * * * * * * *

(c) To assist testing laboratories and others interested in interpreting ocular irritation test results, the CPSC animal testing policy Web page at *http://www.cpsc.gov/businfo/animaltesting.html* will contain the scoring system defined in the U.S. EPA's Test Guideline, OPPTS 870.2400: Acute Eye Irritation [3] or the OECD Test Guideline 405: Acute Eye Irritation/Corrosion.[4]

[3] EPA. 1998. Health Effects Test Guidelines, OPPTS 870.2400 Acute Eye Irritation. EPA 712–C–98–195. Washington, DC: U.S. Environmental Protection Agency. (Available: *http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/EPA/EPA_870_2400.pdf*).

[4] OECD. 2002. OECD Guideline for the Testing of Chemicals 405: Acute Eye Irritation/Corrosion. Paris: Organisation for Economic Co-operation and Development. (Available: *http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECDtg405.pdf*).

Dated: June 25, 2012.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2012–15882 Filed 6–28–12; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 5

[Docket No. TTB–2012–0002; Notice No. 127A; Re: Notice No. 127]

RIN 1513–AB33

Proposed Amendment to the Standards of Identity for Distilled Spirits; Comment Period Extension

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) is extending the comment period for Notice No. 127, Proposed Amendment to the Standards of Identity for Distilled Spirits, for an additional 10 days. In Notice No. 127, a notice of proposed rulemaking published in the **Federal Register** on April 30, 2012, TTB proposes to amend the standards of identity regulations for distilled spirits to include ''Cachaça'' as a type of rum distinctive to Brazil.

DATES: Written comments on Notice No. 127 are now due on or before July 9, 2012.

ADDRESSES: You may send comments on Notice No. 127 to one of the following addresses:

- *http://www.regulations.gov:* To submit comments via the Internet, use the comment form for Notice No. 127 as posted within Docket No. TTB–2012–0002 on ''Regulations.gov,'' the Federal e-rulemaking portal;
- *U.S. Mail:* Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044–4412.
- *Hand Delivery/Courier in Lieu of Mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200–E, Washington, DC 20005.

See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of all rulemaking documents, supporting materials, and any comments related to this proposal within Docket No. TTB–2012–0002 at *http://www.regulations.gov.* A link to the docket is posted on the TTB Web site at *http://www.ttb.gov/regulations_laws/all_rulemaking.shtml* under Notice No. 127. You also may view copies of all related rulemaking documents, supporting materials, and any comments related to this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. Please call 202–453–2270 to make an appointment.

FOR FURTHER INFORMATION CONTACT: Christopher M. Thiemann, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200E, Washington, DC 20005; telephone 202–453–1039, ext. 138.

SUPPLEMENTARY INFORMATION: In Notice No. 127, published in the **Federal Register** on April 30, 2012, at 77 FR 25382, the Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to amend its regulations concerning the standards of identity for distilled spirits at 27 CFR 5.22 to include ''Cachaça'' as a type of rum and as a distinctive product of Brazil. TTB undertook this rulemaking action in response to a petition from the Government of Brazil, and in response to an agreement between the United States and Brazil setting out a procedure that could lead each party to recognize certain distinctive distilled spirits produced in the other party's territory. The agreement provides in part that if, following the publication of a notice of proposed rulemaking, the United States publishes a final rule that lists Cachaça as a type of rum distinctive to Brazil, then Brazil, within 30 days thereafter, will recognize Bourbon Whiskey and Tennessee Whiskey as distinctive products of the United States.

The 60-day comment period for Notice No. 127 originally was set to close on June 29, 2012. On June 15, 2012, TTB received a comment from the European Union requesting an extension of the comment period ''in order to have time to analyze and prepare comments'' on the proposal (see Comment 4 within Docket No. TTB–2012–0002). In response to this request, TTB is extending the comment period for an additional 10 days, and, therefore, comments on Notice No. 127 are now due on or before July 9, 2012.

Drafting Information

Michael D. Hoover of the Regulations and Rulings Division drafted this notice.

Signed: June 26, 2012.

John J. Manfreda,

Administrator.

[FR Doc. 2012–16087 Filed 6–28–12; 8:45 am]

BILLING CODE 4810–31–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 381

[Docket No. 2011–2 CRB NCEB II]

Determination of Reasonable Rates and Terms for Noncommercial Broadcasting

Correction

In proposed rule document 2012–15538, appearing on pages 38022–38024, in the issue of Tuesday, June 26, 2012, make the following correction:

§ 381.8 [Corrected]

1. On page 38023, column three, § 381.8 is being reprinted in its entirety for corrections to (b)(1)(i) and (ii).

§ 381.8 Terms and rates of royalty payments for the use of published pictorial, graphic, and sculptural works.

* * * * *

(b) *Royalty rate.* (1) The following schedule of rates shall apply to the use of works within the scope of this section:

(i) For such uses in a PBS-distributed program:

	2013–2017
(A) For featured display of a work	$70.75
(B) For background and montage display	34.50
(C) For use of a work for program identification or for thematic use	139.46
(D) For the display of an art reproduction copyrighted separately from the work of fine art from which the work was reproduced irrespective of whether the reproduced work of fine art is copyrighted so as to be subject also to payment of a display fee under the terms of the schedule	45.82

(ii) For such uses in other than PBS-distributed programs:

	2013–2017
(A) For featured display of a work	$45.82
(B) For background and montage display	23.48
(C) For use of a work for program identification or for thematic use	93.65
(D) For the display of an art reproduction copyrighted separately from the work of fine art from which the work was reproduced irrespective of whether the reproduced work of fine art is copyrighted so as to be subject also to payment of a display fee under the terms of the schedule	23.49

* * * * *

[FR Doc. C1–2012–15538 Filed 6–28–12; 8:45 am]

BILLING CODE 1505–01–D

POSTAL SERVICE

39 CFR Part 111

New Pallet Preparation Standards for Periodicals

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: The Postal Service is proposing to revise the *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®), to align pallet preparation standards for Periodicals with those currently required for Periodicals prepared in sacks and similar containers.

DATES: Submit comments on or before July 30, 2012.

ADDRESSES: Mail or deliver written comments to the manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW., Room 4446, Washington, DC 20260–5015. You may inspect and photocopy all written comments at USPS® Headquarters Library, 475 L'Enfant Plaza SW., 11th Floor North, Washington, DC, by appointment only between the hours of 9 a.m. and 4 p.m., Monday through Friday. Call 1–202–268–2906 in advance for an appointment. Email comments, containing the name and address of the commenter, may be sent to: *MailingStandards@usps.gov,* with a subject line of ''Periodicals Pallet Standards.'' Faxed comments are not accepted.

FOR FURTHER INFORMATION CONTACT: Craig Vance at 202–268–7595, or Kevin Gunther at 202–268–7208.

SUPPLEMENTARY INFORMATION: Prior to January 22, 2012, mailers were required to prepare bundles of flat-size Periodicals in mixed area distribution center (ADC) sacks (or similar containers), labeled according to labeling list L009; and in origin mixed ADC (OMX) sacks (or similar containers), labeled according to labeling list L201. These standards assured that the OMX and the mixed ADC separations were always made, and the sacks that were prepared could then be presented directly for acceptance or placed on pallets in accordance with DMM 705.8.10.2.

The separation of mail destinating within the ''OMX'' surface reach of the mailer's plant (or entry point) from the remaining mixed ADC mail is crucial for maintaining acceptable service performance, for the benefit of both Periodicals customers and USPS® processing operations.

On January 22, 2012, the Postal Service revised DMM 705.8.10.2 to allow mailers to place bundles of flat-size Periodicals directly onto mixed area distribution center (ADC) and origin mixed ADC (OMX) pallets, but retained the existing language describing these pallet levels as optional. The long-standing language that required the mixed ADC pallet to be labeled in accordance with labeling list L004 was also retained. As a result of this change, some mailers have discontinued the practice of making the mixed ADC and OMX separations when placing bundles of flat-size Periodicals directly on pallets.

It was not the intent of the January 22, 2012 revision to eliminate the requirement to perform the OMX and mixed ADC separations. The Postal Service therefore proposes to revise DMM 705.8.10.2 to provide the option for mailers to prepare both the OMX and mixed ADC pallet at no minimum volume threshold. The Postal Service proposes to require the preparation of both pallets at volumes of 100 pounds or more, and require sacking of these separations if the mailer elects not to form either pallet level below the 100-pound threshold. The Postal Service also proposes that the mixed ADC pallet will be prepared in accordance with labeling list L009 instead of L004, as is currently required. If these new standards are adopted, they will be effective January 28, 2013.

Although these changes are intended to be effective January 28, 2013, to provide for the most expeditious processing of their mixed ADC and OMX Periodicals mailpieces in USPS® networks, mailers are strongly encouraged to begin using these new standards immediately.

Although the Postal Service is exempted by 39 U.S.C. 410(a) from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C 553(b), (c)), we invite public comments on the following proposed revisions to *Mailing Standards of the United States*

Postal Service, Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations. See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is proposed to be amended as follows:

PART 111—[AMENDED]

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

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

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

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

* * * * *

700 Special Standards

* * * * *

705 Advanced Preparation and Special Postage Payment Systems

* * * * *

8.0 Preparing Pallets

* * * * *

8.10 Pallet Presort and Labeling

* * * * *

8.10.2 Periodicals—Bundles, Sacks, or Trays

* * * * *

[Revise the introductory paragraph of 8.10.2j as follows:]

j. *Origin Mixed ADC (OMX), optional for sacks and trays;* allowed with no minimum and required at 100 pounds for bundles of flats. Bundles of flats totaling less than 100 pounds in weight must be sacked if not palletized. Pallet may contain carrier route, automation price, and presorted price mail. Labeling:

* * * * *

[Revise the introductory paragraph and line 1 of 8.10.2k as follows:]

k. *Mixed ADC,* optional for sacks and trays; allowed with no minimum and required at 100 pounds for bundles of flats. Bundles of flats totaling less than 100 pounds in weight must be sacked if not palletized. Pallet may contain carrier route, automation price, or presorted price mail. Pallets must not contain sacks, trays or bundles that should be properly placed on the origin mixed ADC (OMX) pallet. Labeling:

1. Line 1: ''MXD'' followed by the city, state, and ZIP Code information for facility serving 3-digit ZIP Code prefix of entry Post Office as shown in L009, Column A.

* * * * *

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes if the proposal is adopted.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2012–15927 Filed 6–28–12; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50, 51, 52, 53, and 58

[EPA–HQ–OAR–2007–0492; FRL–9693–7]

RIN 2060–AO47

National Ambient Air Quality Standards for Particulate Matter; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; correction.

SUMMARY: In the Proposed Rules section of today's **Federal Register**, the EPA is proposing to revise the national ambient air quality standards (NAAQS) for particulate matter (PM). This action corrects a typographical error in one table contained in the preamble.

FOR FURTHER INFORMATION CONTACT: Questions concerning the ''National Ambient Air Quality Standards for Particulate Matter'' proposed rule should be addressed to Ms. Beth Hassett-Sipple, U.S. EPA, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, (C504–06), Research Triangle Park, NC 27711, telephone number (919) 541–4605, email *hassett-sipple.beth@epa.gov.* Questions related to the Regulatory Impact Analysis for the proposed revisions to the PM NAAQS should be addressed to Ms. Lillian Bradley, U.S. EPA, Office of Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, (C439–02), Research Triangle Park, NC 27711, telephone number (919) 541–5694, email *bradley.lillian@epa.gov.*

SUPPLEMENTARY INFORMATION: In today's **Federal Register**, a proposed rule titled, ''National Ambient Air Quality Standards for Particulate Matter,'' with the same RIN as this correction (RIN 2060–AO47) was published. This correction corrects a typographical error in section X.A, Table 4 of the preamble. This correction will make a change to the summary of the potential costs and benefits of attaining several alternative $PM_{2.5}$ standards as presented in the Regulatory Impact Analysis (RIA). In NAAQS rulemaking, the RIA is done for informational purposes only, and the proposed decisions announced in today's **Federal Register** are not in any way based on consideration of the information or analyses in the RIA. Specifically, the net benefits presented in Table 4 (3% discount rate) for alternative $PM_{2.5}$ standard levels of 11/35 $\mu g/m^3$ (annual and 24-hour standards) were incorrectly identified as $8,900 to $2300 million in the proposed rule. The correct estimates are $8,900 to $23,000 million. Table 4 is corrected to read as follows:

TABLE 4—TOTAL COSTS, MONETIZED BENEFITS AND NET BENEFITS IN 2020 [a] (MILLIONS OF 2006$) [b] FULL ATTAINMENT

Alternate $PM_{2.5}$ standards (annual/24-hour, in $\mu g/m^3$)	Total costs		Monetized benefits [b]		Net benefits [b]	
	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate [c]	7% Discount rate
13/35	$2.9	$2.9	$88 to $220	$79 to $200	$85 to $220	$76 to $200
12/35	69	69	2,300 to $5,900	2,100 to $5,400	2,300 to $5,900	2,000 to $5,300
11/35	270	270	9,200 to $23,000	8,300 to $21,000	8,900 to $23,000	8,000 to $21,000
11/30	390	390	14,000 to $36,000	13,000 to $33,000	14,000 to $36,000	13,000 to $33,000

[a] Values are rounded to two significant figures. Using a 2010$ year increases estimated costs and benefits by approximately 8%.

[b] 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.

[c] Due to data limitations, we were unable to discount compliance costs for all sectors at 3%. As a result, the net benefit calculations at 3% were computed by subtracting the monetized benefits at 3% minus the costs at 7%.

Dated: June 25, 2012.

Gina McCarthy,

Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2012–16044 Filed 6–28–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–1050; FRL–9690–4]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Volatile Organic Compounds; Consumer Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this action we are proposing to approve into the Indiana State Implementation Plan (SIP) the addition of a new rule that sets volatile organic compound (VOC) emissions limits and other restrictions on consumer products that are sold, supplied, manufactured, or offered for sale in the State.

DATES: Comments must be received on or before July 30, 2012.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2010–1050, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: blakley.pamela@epa.gov.*
3. *Fax:* (312) 692–2450.
4. *Mail:* Pamela Blakley, Chief, Control Strategies Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Pamela Blakley, Chief, Control Strategies Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Anthony Maietta, Environmental Protection Specialist, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8777 *maietta.anthony@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register,** EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register.**

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 11, 2012.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2012–15689 Filed 6–28–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 11–206; RM–11634; DA 12–980]

Radio Broadcasting Services; Pike Road, AL

AGENCY: Federal Communications Commission.

ACTION: Proposal rule; dismissal.

SUMMARY: The Audio Division dismisses the petition for rulemaking filed by Alatron Corporation, Inc., proposing the allotment of Channel 228A at Pike Road, Alabama, as the community's second local service, and the associated new FM application, File No. 20110504ACT. No comments or counterproposals were received by any parties. Petitioner did not file comments expressing a continuing interest in the proposed Pike Road allotment. It is the Commission's policy to refrain from making an allotment to a community absent an expression of interest. We will not allot Channel 228A at Pike Road, Alabama.

ADDRESSES: Secretary, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

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

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 11–206, adopted June 21, 2012, and released June 22, 2012. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW., Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractors, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or via email *www.BCPIWEB.com.* This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. This document is not subject to the Congressional Review Act. (The Commission is not required to submit a copy of this Report and Order to Government Accountability Office, pursuant to the Congressional Review

Act, *see* 5 U.S.C. 801(a)(1)(A) since the proposed petition for rule making is dismissed).

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 2012–15990 Filed 6–28–12; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS–R3–ES–2012–N103; FX3ES11130300000D2–123–FF03E00000]

Endangered and Threatened Wildlife and Plants; 5-Year Status Reviews of Seven Listed Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service, are initiating 5-year status reviews under the Endangered Species Act of 1973, as amended (Act), of seven animal and plant species. We conduct these reviews to ensure that our classification of each species on the Lists of Endangered and Threatened Wildlife and Plants as threatened or endangered is accurate. A 5-year review assesses the best scientific and commercial data available at the time of the review. We are requesting the public to send us any information that has become available since the most recent status reviews on each of these species. Based on review results, we will determine whether we should change the listing status of any of these species.

DATES: To ensure consideration, please send your written information by August 28, 2012. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For how and where to send comments or information, see ''VIII. Contacts'' under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: To request information, see ''VIII. Contacts'' under **SUPPLEMENTARY INFORMATION**. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8337 for TTY (telephone typewriter or teletypewriter) assistance.

SUPPLEMENTARY INFORMATION:

I. Why do we conduct 5-year reviews?

Under the Act (16 U.S.C. 1531 *et seq.*), we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the Act requires us to review each listed species' status at least once every 5 years. Then, under section 4(c)(2)(B), we determine whether to remove any species from the List (delist), to reclassify it from endangered to threatened, or to reclassify it from threatened to endangered. Any change in Federal classification requires a separate rulemaking process.

In classifying, we use the following definitions, from 50 CFR 424.02:

(A) *Species* includes any species or subspecies of fish, wildlife, or plant, and any distinct population segment of any species of vertebrate, that interbreeds when mature;

(B) *Endangered species* means any species that is in danger of extinction throughout all or a significant portion of its range; and

(C) *Threatened species* means any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

We must support delisting by the best scientific and commercial data available, and only consider delisting if data substantiate that the species is neither endangered nor threatened for one or more of the following reasons (50 CFR 424.11(d)):

(A) The species is considered extinct;

(B) The species is considered to be recovered; or

(C) The original data available when the species was listed, or the interpretation of data, were in error.

Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing the species we are reviewing.

II. What species are under review?

This notice announces our active 5-year status reviews of the species in the following table.

SPECIES UNDER 5-YEAR REVIEW

Common name	Scientific name	Status	Where listed	Final listing rule publication date and citation
Animals				
Warbler (wood), Kirtland's	*Dendroica kirtlandii*	Endangered	U.S.A. (principally MI), Canada, West Indies—Bahama Islands.	March 11, 1967 (32 FR 4001).
Darter, Niangua	*Etheostoma nianguae*	Threatened	U.S.A. (MO)	June 12, 1985 (50 FR 24649).
Catspaw, white (pearlymussel).	*Epioblasma obliquata perobliqua.*	Endangered	U.S.A. (IN, MI, OH)	June 14, 1976 (41 FR 24064).
Dragonfly, Hine's emerald	*Somatochlora hineana*	Endangered	U.S.A. (AL, IL, IN, MI, MO, OH, WI).	January 26, 1995 (60 FR 5273).
Plants				
Dwarf lake iris	*Iris lacustris*	Threatened	U.S.A. (MI, WI), Canada (Ont.).	September 28, 1988 (53 FR 37972).
Eastern prairie fringed orchid.	*Platanthera leucophaea*	Threatened	U.S.A. (AR, IA, IL, IN, ME, MI, MO, NE, NJ, NY, OH, OK, PA, VA, WI), Canada (Ont., N.B.).	September 28, 1989 (54 FR 39863).
Houghton's goldenrod	*Solidago houghtonii*	Threatened	U.S.A. (MI), Canada (Ont.)	July 18, 1988 (53 FR 27134).

III. What do we consider in our review?

We consider all new information available at the time we conduct a 5-year review. We consider the best scientific and commercial data that have become available since our current listing determination, or most recent status review that is accessible from our Web site *http://www.fws.gov/midwest/Endangered/recovery/5yr_rev/completed5yrs.html,* such as:

(A) Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

(B) Habitat conditions, including but not limited to amount, distribution, and suitability;

(C) Conservation measures that have been implemented that benefit the species;

(D) Threat status and trends (see five factors under heading ''How Do We Determine Whether a Species Is Endangered or Threatened?''); and

(E) Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

IV. How do we determine whether a species is endangered or threatened?

Section 4(a)(1) of the Act requires that we determine whether a species is endangered or threatened based on one or more of the five following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

Under section 4(b)(1) of the Act, we must base our assessment of these factors solely on the best scientific and commercial data available.

V. What could happen as a result of our review?

For each species under review, if we find new information that indicates a change in classification may be warranted, we may propose a new rule that could do one of the following:

(A) Reclassify the species from threatened to endangered (uplist);

(B) Reclassify the species from endangered to threatened (downlist); or

(C) Remove the species from the List (delist).

If we determine that a change in classification is not warranted, then the species remains on the List under its current status.

VI. Request for New Information

To ensure that a 5-year review is complete and based on the best available scientific and commercial information, we request new information from all sources. See ''What Information Do We Consider in Our Review?'' for specific criteria. If you submit information, support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

Submit your comments and materials to the appropriate U.S. Fish and Wildlife Service office listed under ''VIII. Contacts.''

Submit all electronic information in Text or Rich Text format to *FW3MidwestRegion_5YearReview@fws.gov.* Please send information for each species in a separate email. Provide your name and return address in the body of your message, and include the following identifier in your email subject line: Information on 5-year review for [NAME OF SPECIES].

VII. Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the offices where the comments are submitted.

VIII. Contacts

Send your comments and information on the following species, as well as requests for information, to the corresponding contacts. You may view information we receive in response to this notice, as well as other documentation in our files, at the following locations by appointment, during normal business hours.

Species	Contact person, phone, email	Contact address
Kirtlands's warbler	Dan Elbert, (517) 351–7261, *daniel_elbert@fws.gov*	East Lansing Field Office, U.S. Fish and Wildlife Service, 2651 Coolidge Road, Suite 101, East Lansing, MI 48823–6316.
Niangua darter	Rick Hansen, (573) 234–2132, extension 106, *rick_hansen@fws.gov*.	Columbia Missouri Field Office, U.S. Fish and Wildlife Service, 101 Park DeVille Drive, Suite A, Columbia, MO 65203–0007.
White catspaw	Angela Boyer, (614) 416–8993, extension 22, *angela_boyer@fws.gov*.	Columbus Ohio Field Office, U.S. Fish and Wildlife Service, 4625 Morse Road, Suite 104, Columbus, OH 43230.
Hine's emerald dragonfly	Kris Lah, (847) 381–2253, extension 15, *kristopher_lah@fws.gov*.	Chicago Illinois Field Office, U.S. Fish and Wildlife Service, 1250 South Grove Avenue, Suite 103, Barrington, IL 60010–5010.
Dwarf lake iris	Barbara Hosler, (517) 351–6326, *barbara_hosler@fws.gov*.	East Lansing Field Office, U.S. Fish and Wildlife Service, 2651 Coolidge Road, Suite 101, East Lansing, MI 48823–6316.
Eastern prairie fringed orchid	Cathy Pollack, (847) 381–2253, extension 28, *cathy_pollack@fws.gov*.	Chicago Illinois Field Office, U.S. Fish and Wildlife Service, 1250 South Grove Avenue, Suite 103, Barrington, IL 60010–5010.
Houghton's goldenrod	Tameka Dandridge, (517) 351–8315, *tameka_dandridge@fws.gov*.	East Lansing Field Office, U.S. Fish and Wildlife Service, 2651 Coolidge Road, Suite 101, East Lansing, MI 48823–6316.

IX. Authority

We publish this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: May 21, 2012.

Lynn M. Lewis,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2012–14941 Filed 6–28–12; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 77, No. 126
Friday, June 29, 2012

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

Notice of Intent To Revise a Currently Approved Information Collection

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Office of Management and Budget (OMB) Paperwork Reduction Act of 1995, this notice announces the National Institute of Food and Agriculture's (NIFA) intention to revise a currently approved information collection entitled, ''Cooperative State Research, Education, and Extension Service Grant Application.'' NIFA also intends to rename the information collection, ''NIFA Grant Application.''

DATES: Written comments on this notice must be received by August 28, 2012 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments concerning this notice and requests for copies of the information collection may be submitted by any of the following methods: Email: *gmendez@nifa.usda.gov;* Fax: 202–720–0857; Mail: Office of Information Technology (OIT), NIFA, USDA, STOP 2216, 1400 Independence Avenue SW., Washington, DC 20250–2216.

FOR FURTHER INFORMATION CONTACT: Gidel Mendez; Email: *gmendez@nifa.usda.gov.*

SUPPLEMENTARY INFORMATION: *Title:* NIFA Grant Application.

OMB Number: 0524–0039.

Expiration Date of Current Approval: August 31, 2012.

Type of Request: Revise a currently approved information collection.

Abstract: The National Institute of Food and Agriculture (NIFA) sponsors ongoing agricultural research, extension, and education programs under which competitive, formula, and special awards of a high-priority nature are made. Before awards can be made, certain information is required from applicants as part of an application process.

The nature of the competitive, peer-reviewed process makes it important that information from applicants be available in a standardized format to ensure equitable treatment. Each year, request for applications are issued for various research, education, and extension areas targeted for support. Applicants submit applications for these targeted areas following formats outlined in the application guidelines accompanying each program's solicitation. These applications are evaluated by peer review panels, undergo other merit review processes, and are subsequently awarded. The forms and narrative information are mainly used for application evaluation and administration purposes. While some of the information is used to respond to inquiries from Congress and other government agencies, the forms are not designed to be statistical surveys.

NIFA requires submission of grant applications electronically through Grants.gov. The application processes through Grants.gov leverages several standard forms from the research and related form family. In addition to Grants.gov's standard forms, NIFA must collect some additional information for the proper evaluation and processing of applications. NIFA is also proposing some minor revisions to select forms as noted in each description. These forms include:

Supplemental Information Form—This form is used in all grant application packages and collects the program name and program code to which the applicant is applying, additional applicant type information, key words, and the conflict of interest information as an attached file. NIFA is proposing to revise this form to add the collection of the organizations Commercial and Government Entity (CAGE) code to assist in the validation of the organizational identity. NIFA also requests to replace the collection of the HHS account code (which is no longer used) with the Automated Standard Application for Payments (ASAP) Recipient ID.

Application Type Form—This form is used principally by the Agriculture and Food Research Initiative Competitive Grants Program to collect the specific type of application being submitted. This form is being revised to change the application type names and some business rules associated with the form.

Application Modification Form—This form is used to indicate the forms or narrative portions of an application that an applicant has changed or corrected from a previously submitted application. No changes to this form are proposed.

Form NIFA–2008, Assurance Statement(s)—This form is used in formula grant programs and provides required assurances of compliance with regulations involving the protection of human subjects, animal welfare, and recombinant DNA research.

Form NIFA–2010—Fellowships/Scholarships Entry/Annual Update/Exit Form: This form will only apply to recipients of a NIFA award to appoint each student beneficiary, report student progress, and the exit of each beneficiary of fellowship or scholarship support towards a higher education degree in food and agricultural sciences. The form will be used for fellowship and scholarships to document pertinent demographic data on the fellows/scholars, documentation of the progress of the fellows/scholars under the program, and performance outcomes of the student beneficiaries. The form name will change to replace CSREES with NIFA.

Summary of USDA/1890 Cooperation Form—NIFA will be eliminating this form from the collection as it is no longer required.

Respondents: Non-profit institutions, State, local, or Tribal governments, and a limited number of for-profit institutions and individuals.

Estimated Number of Responses by Form

Supplemental Information: 6,200.
Application Type: 2,200.
Application Modification: 0.
Form NIFA–2008 Assurance Statement(s): 2,000.
NIFA–2010 Fellowships/Scholarships Entry/Exit: 150.

The individual form burden is as follows (calculated based on a survey of grant applicants conducted by NIFA):

Supplemental Information: 2 hours.

Application Type: 15 minutes.

Application Modification: 5 minutes.

Form NIFA–2008 Assurance Statement(s): 30 minutes.

NIFA–2010 Fellowships/Scholarships Entry/Annual Update/Exit: 3 hours.

Estimated Total Annual Burden on Respondents: The annual total burden on the public for all forms is estimated to be 14,400 hours.

Frequency of Respondents: Annually.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments should be sent to the address stated in the preamble.

All responses to this notice will be summarized and included in the request for OMB approval. All comments also will become a matter of public record.

Done in Washington, DC, this 25th day of June 2012.

Catherine E. Woteki,

Under Secretary, Research, Education, and Economics.

[FR Doc. 2012–16058 Filed 6–28–12; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF COMMERCE

International Trade Administration

Proposed Information Collection; Comment Request; International Client Life-Cycle Multi-Purpose Forms

AGENCY: International Trade Administration.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act (PRA) of 1995.

DATES: Written comments must be submitted on or before August 28, 2012.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Suzan Winters—Phone: (202) 482–6042, *Suzan.Winters@trade.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The International Trade Administration's U.S. Commercial Service (CS) is seeking approval to revise this information collection by combining with other collections, OMB control numbers: 0625–0065, 0625–0130, 0625–0143, 0625–0151, 0625–0215, 0625–0220, 0625–0228, and 0625–0238. These collections include all client intake, events/activities and export success forms. This comprehensive information collection will cover all aspects of an international organization's life-cycle with CS.

CS is mandated by Congress to help U.S. organizations, particularly but not limited to small and medium-sized organizations, export their products and services to global markets. As part of its mission, the CS provides market entry/expansion services and trade events to U.S. organizations. The International Client Life-cycle Multi-Purpose Forms, previously titled Export Assistance Center Internet Web Site Forms, are needed to collect information to enable U.S. organizations to efficiently and effectively enhance their ability to determine which international organizations are most suited for their exporting expansion efforts.

The key to effectively and efficiently assisting U.S. organizations export is identifying and verifying potential international buyers of U.S. goods and services.

1. Create an all inclusive and flexible client life-cycle information collection. The proposed categories of questions are: Contact information, organization information, organization type, agreements and confirmations, objectives, products and services, exporting experience, marketing, events and activities, trade fair/show, certified trade missions, trade missions, advocacy, environment, and education. CS asks only those questions that provide the required information to assist CS in fulfilling a client's objective for a requested service and/or event/activity.

2. Provide CS with the flexibility to create forms from the above approved categories and their questions. Client benefits include customizing questions, forms, and services to address their specific needs and objectives. Without this flexibility, CS is impeded from collecting pertinent client information in an effective and efficient manner.

Therefore, with increased flexibility, and the ability to immediately ascertain key information, U.S. organizations are productively positioned to achieve their exporting and expansion goals.

3. Reduce client burden through forms' flexibility and technology. CS seeks increased forms flexibility to ensure that CS asks and captures only the specific information needed for a particular event, thereby continuing to reduce client burdens as CS utilizes pre-populated information for clients who have previously registered with CS. As CS moves forward, we understand the importance and need for strategic planning and integration of future technology and initiatives that relate to CS programs and metrics with the types of information collected from clients to conduct those programs.

Additionally, the most important positive impact is the ability to quickly change and ask pertinent questions to assist clients with their exporting needs regarding matchmaking services, organization promotions, trade missions, market research and other trade promotional activities.

II. Method of Collection

The information will be collected through Export.gov or sent via email and then completed by client electronically.

III. Data

OMB Control Number: 0625–0237.

Form Number(s): NA.

Type of Review: Regular submission (revision of a currently approved collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 70,000.

Estimated Time per Response: 5–25 minutes.

Estimated Total Annual Burden Hours: 29,167.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance

of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: June 26, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–15999 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Rulings

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

DATES: *Effective Date:* June 29, 2012.

SUMMARY: The Department of Commerce (''Department'') hereby publishes a list of scope rulings completed between October 1, 2011, and December 31, 2011. In conjunction with this list, the Department is also publishing a list of requests for scope rulings and anticircumvention determinations pending as of December 31, 2011. We intend to publish future lists after the close of the next calendar quarter.

FOR FURTHER INFORMATION CONTACT: Julia Hancock, AD/CVD Operations, China/NME Group, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: 202–482–1394.

SUPPLEMENTARY INFORMATION:

Background

The Department's regulations provide that the Secretary will publish in the **Federal Register** a list of scope rulings on a quarterly basis. *See* 19 CFR 351.225(o). Our most recent notification of scope rulings was published on June 1, 2012. *See Notice of Scope Rulings,* 77 FR 32568 (June 1, 2012). This current notice covers all scope rulings and anticircumvention determinations completed by Import Administration between October 1, 2011, and December 31, 2011, inclusive. As described below, subsequent lists will follow after the close of each calendar quarter.

Scope Rulings Completed Between October 1, 2011, and December 31, 2011:

People's Republic of China

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: Sapa Extrusions; shower door kits containing at the time of importation all of the parts necessary to assemble a complete shower door, including glass panels, without further fabrication are not within the scope of the antidumping and countervailing duty orders; November 7, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: Tri Vantage; retractable awning mechanisms that, at the time of importation do not contain the fabric awning, are within the scope of the antidumping and countervailing duty orders; October 14, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: Skyline Displays Inc.; banner stands and back wall kits containing at the time of importation all of the parts necessary to assemble a complete banner stand or back wall, without further fabrication, are not within the scope of the antidumping and countervailing duty orders; October 19, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: Rubbermaid; cleaning system product lines (frames, handles, and mop handles) composed of aluminum extrusions that do not, at the time of importation, contain all of the parts necessary to comprise a final finished product, are within the scope of the antidumping and countervailing duty orders; October 25, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: Rubbermaid; non-extruded aluminum decorative waste containers are not within the scope of the antidumping and countervailing duty orders; October 28, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: Peak Products America Inc.; certain modular aluminum railing system components are within the scope of the antidumping and countervailing duty orders; October 31, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: Moss Holding Company; its EZ fabric wall display systems are not within the scope of the antidumping and countervailing duty orders; November 9, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: American Fence Manufacturing; aluminum fence sections, posts and gates are within the scope of the antidumping and countervailing duty orders; December 6, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: IAP Enclosure Systems LLC; window kits containing at the time of importation all of the parts necessary to assemble a complete window, including the glass, without further fabrication are not within the scope of the antidumping and countervailing duty orders; December 6, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: Origin Point Brands; certain fence posts, panels, and gates are within the scope of the antidumping and countervailing duty orders; December 13, 2011.

A–570–967; C–570–968: Aluminum Extrusions from the People's Republic of China

Requestor: Ameristar Fence Products; certain aluminum individual fence parts (*i.e.,* posts, rails, and pickets, whether packed in bulk or individually) are within the scope of the antidumping and countervailing duty orders; December 13, 2011.

A–570–864: Pure Magnesium in Granular Form from the People's Republic of China

Requestor: US Magnesium LLC; granular magnesium ground in a third-country, such as Mexico for this inquiry, from pure magnesium ingots produced in the People's Republic of China is

within the scope of the antidumping duty order; October 28, 2011.

A–570–864: Pure Magnesium in Granular Form from the People's Republic of China

Requestor: ESM Group Inc.; its United States-origin pure magnesium ingots exported to the People's Republic of China for atomization and re-exported to the United States are not within the scope of the antidumping duty order; October 28, 2011.

A–570–918: Steel Wire Garment Hangers from the People's Republic of China

Requestor: Robert H. Ham Associates Ltd.; its retail display hangers are not within the scope of the antidumping duty order; December 1, 2011.

A–570–890: Wooden Bedroom Furniture from the People's Republic of China

Requestor: University Loft Company; twin-sized Metropolitan (item number 50211SKD) and full-sized Metropolitan (item number 50205SKD) slat beds are not within the scope of the antidumping duty order, while twin-sized (item number 50470–12) and full-sized (item number 50480–12) metal bed headboards and the Upperclassman 2 shelf nightstand (item number 50568–152) are within the scope of the antidumping duty order; December 13, 2011.

A–570–890: Wooden Bedroom Furniture from the People's Republic of China

Requestor: Delta Enterprise Corporation; its Delta Venetian changing table is outside of the scope of the antidumping duty order; December 27, 2011.

Multiple Countries

A–533–838/C–533–839/A–570–892: Carbazole Violet Pigment 23 from India and the People's Republic of China

Requestor: Nation Ford Chemical Co. and Sun Chemical Corp.; finished carbazole violet pigment exported from Japan, made from crude carbazole violet pigment from India and/or the People's Republic of China, is within the scope of the antidumping duty and countervailing duty orders; October 14, 2011.

Anticircumvention Determinations Completed Between October 1, 2011, and December 31, 2011:

A–570–918: Steel Wire Garment Hangers from the People's Republic of China

Requestor: M&B Metal Products Inc.; imports of steel wire garment hangers from the Socialist Republic of Vietnam exported by Angang Clothes Rack Manufacture Co., Ltd. and Quyky Yanglei International Co., Ltd. are circumventing the antidumping duty order through means of third country assembly or completion of merchandise imported from the People's Republic of China; October 28, 2011.

Scope Inquiries Terminated Between October 1, 2011 and December 31, 2011:

None.

Interested parties are invited to comment on the completeness of this list of pending scope and anticircumvention inquiries. Any comments should be submitted to the Deputy Assistant Secretary for AD/CVD Operations, Import Administration, International Trade Administration, 14th Street and Constitution Avenue NW., APO/Dockets Unit, Room 1870, Washington, DC 20230.

This notice is published in accordance with 19 CFR 351.225(o).

Dated: June 19, 2012.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–15995 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Smart Grid Advisory Committee

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The Smart Grid Advisory Committee (SGAC or Committee) will hold a meeting via teleconference on Friday, July 27, 2012 from 11 a.m. to 2 p.m. Eastern Time (ET). The primary purposes of this meeting are to review updates on the Smart Grid Interoperability Panel transition plan, review the status of the research subcommittee and the August Smart Grid Workshop in Boulder, Colorado, and plan for a fall meeting. Interested members of the public will be able to participate in the meeting from remote locations by calling into a central phone number.

DATES: The SGAC will hold a meeting via teleconference on Friday, July 27, 2012, from 11 a.m. until 2 p.m. Eastern Time (ET).

ADDRESSES: Questions regarding the meeting should be sent to Office of the National Coordinator for Smart Grid Interoperability, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8200, Gaithersburg, MD 20899–8200. For instructions on how to participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Dr. George W. Arnold, National Coordinator for Smart Grid Interoperability, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8200, Gaithersburg, MD 20899–8200; telephone 301–975–2232, fax 301–975–4091; or via email at *nistsgfac@nist.gov*.

SUPPLEMENTARY INFORMATION: The Committee was established in accordance with the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Background information on the Committee is available at *http://www.nist.gov/smartgrid/committee.cfm*.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the SGAC will hold a meeting via teleconference on Friday, July 27, 2012, from 11 a.m. until 2 p.m. Eastern Time (ET). There will be no central meeting location. The public is invited to participate in the meeting by calling in from remote locations. The primary purposes of this meeting are to review updates on the Smart Grid Interoperability Panel transition plan, review the status of the research subcommittee and the August Smart Grid Workshop in Boulder, Colorado, and plan for a fall meeting.

All participants of the meeting are required to pre-register to be admitted. Anyone wishing to participate must register by close of business on Friday, July 20, 2012, in order to be admitted. Please submit your name, email address, and phone number to Cuong Nguyen at *cuong.nguyen@nist.gov* or (301) 975–2254. After registering, participants will be provided with detailed instructions on how to dial in from a remote location in order to participate.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's affairs are invited to request detailed instructions on how to dial in from a remote location to participate in the meeting by contacting Cuong Nguyen at *cuong.nguyen@nist.gov* or (301) 975–2254 no later than July 20, 2012. Approximately fifteen minutes will be reserved from 1:45 p.m.–2 p.m. Eastern Time (ET) for public comments, and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about 3 minutes each. Questions from the public will not be considered during this period. Speakers

who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated, and those who were unable to participate are invited to submit written statements to the Office of the National Coordinator for Smart Grid Interoperability, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8200, Gaithersburg, MD 20899–8200, via fax at 301–975–4091, or electronically by email to *nistsgfac@nist.gov.*

Dated: June 26, 2012.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2012–16012 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

97th Annual Meeting of the National Conference on Weights and Measures

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: The 97th Annual Meeting of the National Conference on Weights and Measures (NCWM) will be held July 15–19, 2012. This notice contains information about significant items on the NCWM Committee agendas which will be considered at the meetings, but does not include all agenda items. As a result, the items are not consecutively numbered.

DATES: The meeting will be held on July 15–19, 2012.

ADDRESSES: The meeting will be held at the Holiday Inn by the Bay, 88 Spring Street, Portland, Maine 04101.

FOR FURTHER INFORMATION CONTACT: Ms. Carol Hockert, Chief, NIST, Office of Weights and Measures, 100 Bureau Drive, Stop 2600, Gaithersburg, MD 20899–2600; by telephone (301) 975–5507; or by email at *Carol.Hockert@nist.gov.* The meetings are open to the public, but a paid registration is required. Please see NCWM Publication 16 ''National Conference on Weights and Measures Committee Reports for the 97th Annual Meeting'' on the Web (*http://www.ncwm.net* or *http://www.nist.gov/pml/wmd*) to view the meeting agendas, registration forms, and hotel information.

SUPPLEMENTARY INFORMATION: Publication of this notice on the NCWM's behalf is undertaken as a public service; NIST does not endorse, approve, or recommend any of the proposals contained in this notice or in the publications of the NCWM.

The NCWM is an organization of weights and measures officials of the states, counties, and cities of the United States, federal agencies, and private sector representatives. These meetings bring together government officials and representatives of business, industry, trade associations, and consumer organizations on subjects related to the field of weights and measures technology, administration and enforcement. NIST participates to promote uniformity among the states in laws, regulations, methods, and testing equipment that comprise the regulatory control of commercial weighing and measuring devices.

The following are brief descriptions of some of the significant agenda items that will be considered at the NCWM Annual Meeting. Comments will be taken on these during several public comment sessions. At this stage, the items are proposals. This meeting also includes work sessions in which the Committees may also accept oral or written comments, and where they will finalize recommendations for NCWM consideration and possible adoption at its voting sessions, which are scheduled for July 18–19, 2012. The Committees may withdraw or carryover items that need additional development.

The Specifications and Tolerances Committee (S&T Committee) will consider proposed amendments to NIST Handbook 44, ''Specifications, Tolerances, and other Technical Requirements for Weighing and Measuring Devices.'' Those items address weighing and measuring devices used in commercial applications, that is, devices that are used to buy from or sell to the public or used for determining the quantity of product sold among businesses. Issues on the agenda of the NCWM Laws and Regulations Committee (L&R Committee) relate to proposals to amend NIST Handbook 130, ''Uniform Laws and Regulations in the area of Legal Metrology and Engine Fuel Quality'' and NIST Handbook 133, ''Checking the Net Contents of Packaged Goods.''

NCWM Specifications and Tolerances Committee

The following items are proposals to amend NIST Handbook 44:

Item 320–4, UR.1.2. Grain Hopper Scales

The Committee will consider a proposal to add language to NIST Handbook 44 to clarify the requirement that hopper scales manufactured as of January 1, 1986, used to weigh grain, must be Accuracy Class III weighing devices. The submitter of this proposal believes that this revision is needed to help ensure that weights and measures officials uniformly apply the handbook's tolerances and other technical and use requirements to grain hopper scales.

Item 321–1, Belt-Conveyor Scale Systems

The Committee will consider a proposal to add language to NIST Handbook 44 to add a new specification requiring these scales to have an automatic zero ready indicating device. The proposal also includes a requirement that users maintain equipment in accordance with the manufacturer's instructions and that a zero balance condition be established immediately prior to weighing a commodity for a commercial transaction.

Liquid Measuring Devices

Some gasoline and fuel retailers offer a variety of discounts to consumers on fuel prices in connection with marketing services and dispensing product. The Committee will consider the following proposal to modify Section 3.30. Liquid-Measuring Devices. The intent of this proposal is to require that retailers provide consumers with adequate transaction information to assist them in making value comparisons and ensure transparency when fuel purchases are discounted after a delivery.

Item 330–1 includes seven proposed requirements:

S.1.6.4.1. Unit Price

This proposal would modify device specifications to recognize current marketing practices of offering pre or post delivery discounts on fuel prices and require the final unit price information to be displayed.

S.1.6.5.4. Selection of Unit Price

This proposal would allow device manufacturers greater flexibility in the design and operation of customer operated controls on motor-fuel dispensers by recognizing the use of new technology in the selection of a unit price.

S.1.6.6. Agreement Between Indications

This proposal would exempt ''total money values'' displays on the dispenser and auxiliary equipment (such as the display on a remote control console in an operator's kiosk) from agreement requirements when retailers

offer post delivery discounts for a fuel sale.

S.1.6.7. Recorded Representations

This proposal would ensure that, except in fleet sales or under price contracts or where post-delivery discounts are provided, fuel dispensers will provide receipts with sufficient price and other information to allow customers to understand and verify the accuracy of price discounts. The requirement will also recognize the use of either digitally transmitted or printed receipts.

S.1.6.8. Recorded Representations for Transactions Where a Post-Delivery Discount(s) Is Provided

In cases where post delivery discounts on fuel purchases are offered, this proposal would require specific information be printed on receipts made available to consumers so they can verify the accuracy of the transaction and receive a printed record.

UR.3.2. Unit Price and Product Identity

This proposal is intended to clarify the requirements for displaying or posting the final unit price of a fuel offered at a discount and periods where the highest unit price shall be displayed.

UR.3.3. Computing Device

This proposal would require that customer receipts include adequate information to allow the customer to understand and verify any post delivery discounts the retailer provides in connection with a fuel sale.

Electronic Livestock, Meat and Poultry Carcass Evaluation Systems

Item 359–1, Tentative Status of Code 5.59. Electronic Livestock, Meat, and Poultry Evaluation Systems and/or Devices

The Committee will consider the adoption of a proposal to make tentative Code 5.59. in Handbook 44 enforceable so that it can be used to control the accuracy and the use of electronic carcass evaluation equipment. The equipment in this code is used commercially in livestock procurement operations to determine the value of the animals being purchased. Currently, there is no independent, third party verifying the accuracy of these devices. In 2010, 106.9 million hogs weighing 21.8 billion pounds with a total value of $15.7 billion were commercially purchased. Of these purchases, about 80 percent were made on a carcass yield weight basis using an electronic carcass evaluation device. In addition, electronic evaluation devices are used to measure composition or quality constituents in individual cuts of meat for further sale to consumers. Studies have shown that improper use of electronic carcass evaluation equipment can change the value of livestock, meat, and poultry.

NCWM Laws and Regulations Committee

The following items are proposals to amend NIST Handbook 130 or NIST Handbook 133:

Uniform Regulation for the Method of Sale of Commodities

Item 232–1, Method of Sale Regulation—Section 2.13.4. Declaration of Weight (Polyethylene)

The Committee will consider a proposal to revise the density values used to calculate the net weights on packages of polyethylene products to recognize that heavier density plastics are now used in the manufacture of some sheeting and bags. (See also Item 260–4, Handbook 133, Chapter 4.7. Polyethylene Sheeting—Test Procedure—Footnote to Step 3.)

Item 232–2, Method of Sale Regulation—Section 2.19. Kerosene

The Committee will consider a proposal to require that kerosene sold from bulk storage at the retail level be solely on the basis of the gallon or liter (note: Kerosene sold in packaged form is already required under packaging and labeling regulations to be sold by fluid volume).

Item 232–4, Method of Sale Regulation—Section 2.33. Vehicle Motor Oil

The Committee will consider a proposal to adopt a method of sale that includes product labeling, invoicing, and other requirements for motor oil sold to consumers as part of the oil change service. (See also Item 237–4, Handbook 130 Uniform Engine Fuels and Automotive Lubricants Regulation, Section 3.13.1. Labeling of Vehicle Motor Oil.)

Item 232–6, Packaged Printer Ink and Toner Cartridges

A newly formed task group will develop proposals for methods of sale, labeling requirements and test procedures for packaged printer ink and toner cartridges. The NCWM has assigned the group the task of developing proposed regulations that would require manufacturers of these products to declare net weight statements on both toner and packaged printer ink cartridges. The goal in developing these requirements is to provide consumers with information on the net quantity of contents of these products so that value comparisons can be made, and the stated quantities can be verified by weights and measures officials. The task group will meet on Sunday, July 15, 2012, at the NCWM Annual Meeting.

Uniform Engine Fuels and Automotive Lubricants Regulation

Item 237–9, Requirements for Hydrogen, and Item 237–10, Definition for Hydrogen Fuel for Internal Combustion Engines and Fuel Cell Vehicles

The Committee will consider two proposals to adopt a national quality standard for commercial hydrogen fuel and to add hydrogen related definitions to the uniform engine fuel regulation. Both proposals would apply to hydrogen fuel sold through dispensing equipment for use in fuel cells and internal combustion engine vehicles. The first proposal would adopt the most recent version of SAE International's Standard J2719 ''Hydrogen Fuel Quality for Fuel Cell Vehicles'' by reference to establish quality requirements for hydrogen fuel, and the second proposal would define the hydrogen-related terms of ''fuel cell,'' ''hydrogen fuel,'' and ''internal combustion engine.'' (see also Item 232–7, Handbook 130 Uniform Regulation for the Method of Sale Commodities, Section 2.32.1. Definitions for Hydrogen Fuel.)

Dated: June 23, 2012.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2012–16014 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Notice of Consortium on ''nSoft Consortium''

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: On June 3, 2011, the National Institute of Standards and Technology (NIST) held a public meeting on its campus to explore the feasibility of establishing a NIST/Industry Consortium on Neutron Metrology for Soft Materials Manufacturing. The notice stated the membership fees would be on the order of Twenty Thousand ($20,000) per year. The initial term of the consortium was intended to be three years. As a result of the October 3, 2011, public meeting, revisions have

been made to the membership fee structure and the initial period of time for the consortium. Also, the consortium is open to a limited number of for-profit and not-for-profit institutions.

DATES: This notice is effective on June 29, 2012.

ADDRESSES: Questions about joining the consortium should be sent to Ronald Jones at the National Institute of Standards and Technology; 100 Bureau Drive; MS 8615; Gaithersburg, MD 20899–8615.

FOR FURTHER INFORMATION CONTACT: Ronald L. Jones, Eric K. Lin, or Dan Neumann National Institute of Standards and Technology, 100 Bureau Drive, Stop 8514, Gaithersburg, MD 20899–8514, USA; (301) 975–4624; Fax (301) 975–3928; Email: *ronald.jones@nist.gov, eric.lin@nist.gov, dan.neumann@nist.gov.*

SUPPLEMENTARY INFORMATION: NIST will form the ''nSoft Consortium'' to advance and transfer neutron based measurement methods for soft materials manufacturing. The goals of nSoft are to develop neutron-based measurements that address critical needs for manufacturers of soft materials such as polymers, complex fluids, and protein-based materials. Advances in neutron-based measurement science are anticipated through the development of sample environments that closely mimic manufacturing processes, measurement methods to probe and analyze complex mixtures, and data analysis models that support routine measurements with high information content. The consortium will be supervised and administered by NIST. Consortium research and development will be conducted by NIST staff members along with at least one technical representative from each participating member company.

Each member of the consortium will be required to sign a Cooperative Research and Development Agreement (''CRADA'') with NIST. Membership is limited to 40 for-profit institutions and 15 not-for-profit institutions. For-profit membership fees are Twenty Thousand ($20,000) per year, payable by Member to NIST at the time of CRADA execution and annually in August thereafter. For-profit membership fees for members who join in the second half of the year (February through July) will be Ten Thousand ($10,000), payable at the time of CRADA execution. Subsequent membership payments of Twenty Thousand ($20,000) shall be paid each year in August thereafter. Non-profit organizations in lieu of membership fees will contribute personal expertise and materials that are mutually acceptable to NIST and Member. The consortium is designated to last for an initial period of two years.

Dated: June 25, 2012.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2012–16015 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Prospective Grant of Exclusive Patent License

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of prospective grant of exclusive patent license.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the National Institute of Standards and Technology (''NIST''), U.S. Department of Commerce, is contemplating the grant of an exclusive license in the United States of America, its territories, possessions and commonwealths, to NIST's interest in the invention embodied in U.S. Patent Application No. 13/346,999 titled ''Chirped-Pulse Terahertz Spectroscopy for Broadband Trace Gas Sensing,'' NIST Docket No. 11–016 to TerBAT Inc., having a place of business at 2400 Trade Centre Ave, Longmont, CO 80503. The grant of the license would be for the field of use of medical diagnostic devices and environmental/industrial monitoring devices.

FOR FURTHER INFORMATION CONTACT: Cathy Cohn, National Institute of Standards and Technology, Technology Partnerships Office, 100 Bureau Drive, Stop 2200, Gaithersburg, MD 20899, (301) 975–6691, *cathleen.cohn@nist.gov.*

SUPPLEMENTARY INFORMATION: The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen days from the date of this published Notice, NIST receives written evidence and argument which establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

U.S. Patent Application No. 13/346,999 is co-owned by the U.S. government, as represented by the Secretary of Commerce and the University of Massachusetts Amherst. The invention comprises Terahertz spectroscopy methods that are fast and have excellent spectral resolution and that do not require background correction of the instrument response without sample are disclosed. In one instance, the methods include phase coherent chirp pulse generation and phase coherent detection.

Dated: June 25, 2012.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2012–16016 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Prospective Grant of Exclusive Patent License

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of prospective grant of exclusive patent license.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the National Institute of Standards and Technology (''NIST''), U.S. Department of Commerce, is contemplating the grant of an exclusive license in the United States of America, its territories, possessions and commonwealths, to NIST's interest in the invention embodied in U.S. Patent No. 6,393,566 titled ''Timestamp Service for the National Information Network,'' NIST Docket No. 95–022 to RSIP LLC, having a place of business at 8 East Figueroa, Suite 220, Santa Barbara, California 93101. The grant of the license would be for the field of use of Digital Timestamping.

FOR FURTHER INFORMATION CONTACT: Cathy Cohn, National Institute of Standards and Technology, Technology Partnerships Office, 100 Bureau Drive, Stop 2200, Gaithersburg, MD 20899, Phone 301–975–6691, *cathleen.cohn@nist.gov.*

SUPPLEMENTARY INFORMATION: The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen days from the date of this published Notice, NIST receives written evidence and argument which establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

U.S. Patent No. 6,393,566 is owned by the U.S. government, as represented by the Secretary of Commerce. The invention is a system and method for

time-stamping and signing a digital document by an authenticating party and returning the signed stamped document to the originator or his designated recipient. Messages may be received by a first ''public'' machine over a network, by fax, or through input mediums such as diskettes. The clock of the first machine is synchronized with Universal Coordinated Time (UTC) and can be checked for accuracy by anyone on the network. A second ''private'' machine, not connected to any network, receives the time-stamped message, applies a hashing procedure and provides a signature using a private key. The signed hashed time-stamped message is then returned. A verify procedure is made widely available to check the genuineness of a document by rehashing the document and applying a public key. The result should match the signed time-stamped message returned by the authenticating party.

Dated: June 25, 2012.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2012–16018 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Prospective Grant of Exclusive Patent License

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of prospective grant of exclusive patent license.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the National Institute of Standards and Technology (''NIST''), U.S. Department of Commerce, is contemplating the grant of an exclusive license in the United States of America, its territories, possessions and commonwealths, to NIST's interest in the invention embodied in U.S. Patent No. 7,709,807 (Application No. 12/116,522), titled ''Magneto-Optical Trap Ion Source,'' NIST Docket No. 07–015 and U.S. Patent Application No. 13/369,008 titled ''Charged Particle Source from a Photoionized Cold Atom Beam,'' NIST Docket No. 11–018 to LoTIS Technologies LLC, having a place of business at 18026 Royal Bonnet Circle, Montgomery Village, Maryland 20886. The grant of the license would be for the field: Devices that produce or include a focused beam of electrons and/or ions.

FOR FURTHER INFORMATION CONTACT: Cathy Cohn, National Institute of Standards and Technology, Technology Partnerships Office, 100 Bureau Drive, Stop 2200, Gaithersburg, MD 20899, (301) 975–6691, *cathleen.cohn@nist.gov.*

SUPPLEMENTARY INFORMATION: The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen days from the date of this published Notice, NIST receives written evidence and argument which establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

U.S. Patent No. 7,709,807 and U.S. Patent Application No. 13/369,008 are owned by the U.S. government, as represented by the Secretary of Commerce. U.S. Patent No. 7,709,807 describes a system and method for producing a source of ions, and particularly, a focused ion beam. The system and method use a magneto-optical trap (MOT) to produce a population of neutral atoms. A laser is then utilized to ionize atoms and produce a population of ions. An extraction element is then used to transfer the ions so that they can be used in a wide array of applications. U.S. Patent Application No. 13/369,008 describes a system for producing a charged particle beam from a photoionized cold atom beam. A vapor of neutral atoms is generated. From these atoms, an atom beam having axial and transverse velocity distributions controlled by the application of laser light is produced. The produced atom beam is spatially compressed along each transverse axis, thus reducing the cross-sectional area of the produced beam and reducing a velocity spread of the produced beam along directions transverse to the beam's direction of propagation. Laser light is directed onto at least a portion of the neutral atoms in the atom beam, thereby producing ions and electrons. An electric field is generated at the location of the produced ions and electrons, thereby producing a beam of ions traveling in a first direction and electrons traveling in substantially the opposite direction. A vacuum chamber contains the atom beam, the ion beam and the electron beam.

Dated: June 25, 2012.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2012–16020 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–BA75

Atlantic Highly Migratory Species; Electronic Dealer Reporting System Workshop

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

ACTION: Notice of public workshops.

SUMMARY: On June 28, 2011, NMFS published a proposed rule that considered requiring, among other things, Federal Atlantic swordfish, shark, and tunas dealers (except for dealers reporting Atlantic bluefin tuna) to report commercially-harvested Atlantic sharks, swordfish, and bigeye, albacore, yellowfin, and skipjack (BAYS) tunas through one centralized electronic reporting system. This electronic reporting system will allow dealers to submit Atlantic sharks, swordfish, and BAYS tuna data on a more real-time basis and more efficiently, which will reduce duplicative data submissions from different regions. We proposed to delay the effective date of the electronic reporting requirements until 2013 in order to give sufficient time for dealers to adjust to implementation of the new system and the additional requirements. On December 14, 2011, we conducted an initial training workshop in the Caribbean area in order to introduce the new reporting system to HMS dealers. In this notice, we announce the date and location for additional training workshops in the Caribbean, Gulf of Mexico and Atlantic regions in order to continue introducing HMS dealers to the new electronic system.

DATES: Training workshops for the new electronic dealer system will be held from July through September 2012. See **SUPPLEMENTARY INFORMATION** for meeting dates, times, and locations.

ADDRESSES: Workshops will be held in Mayagüez, Puerto Rico; St. Croix, United States Virgin Islands (U.S.V.I.); Belle Chase, Louisiana; Dulac, Louisiana; Panama City, Florida; Port Orange, Florida; Seminole, Florida; Fort Lauderdale, Florida; and Marathon, Florida Keys. See **SUPPLEMENTARY INFORMATION** for dates, times, and locations.

FOR FURTHER INFORMATION CONTACT: Delisse Ortiz or Karyl Brewster-Geisz at (301) 427–8503 (phone), or Jackie Wilson at (240) 338–3936, or (301) 713–

1917 (fax), or *http://www.nmfs.noaa.gov/sfa/hms/index.htm*.

SUPPLEMENTARY INFORMATION: Atlantic HMS are managed under the dual authority of the Magnuson-Stevens Fishery Conservation and Management Act (MSA), 16 U.S.C. 1801 *et seq.,* and the Atlantic Tunas Convention Act (ATCA), 16 U.S.C. 971 *et seq.* Under the MSA, NMFS must ensure consistency with the National Standards and manage fisheries to maintain optimum yield, rebuild overfished fisheries, and prevent overfishing. ATCA authorizes the Secretary of Commerce to promulgate regulations, as may be necessary and appropriate, to implement the recommendations adopted by the International Commission for the Conservation of Atlantic Tunas (ICCAT). The authority to issue regulations under MSA and ATCA has been delegated from the Secretary to the Assistant Administrator for Fisheries, NOAA. The implementing regulations for Atlantic HMS are at 50 CFR part 635.

Background

The current regulations and infrastructure of the Atlantic HMS quota-monitoring systems result in a delay of several weeks or more before NMFS receives dealer data. This can affect management and monitoring of small Atlantic HMS quotas and short fishing seasons. As such, on June 28, 2011 (76 FR 37750), we published a proposed rule in the **Federal Register** that considered requiring, among other things, Federal Atlantic swordfish, shark, and tunas dealers (except for dealers reporting Atlantic bluefin tuna) to report commercially-harvested Atlantic sharks, swordfish, and BAYS tunas through one centralized electronic reporting system. Under this new system, dealers would submit HMS data electronically (instead of in a paper format) and include additional information that is necessary for management of HMS (*e.g.,* vessel and logbook information). The electronic submission of data will eliminate the delay associated with mailing in hardcopy reports. In this manner, HMS landings data will be submitted on a more real-time basis, allowing for timely and efficient data collection for management of Atlantic HMS.

In order to give sufficient time for dealers to adjust to implementation of the new system and the additional requirements, we proposed delaying implementation of the new HMS electronic reporting system for all federally-permitted HMS dealers until 2013. Additionally, we decided to conduct outreach to HMS dealers to train them how to use the new system and help ease the transition from the current paper format to the new HMS electronic reporting system. We conducted an initial training workshop for HMS dealers in St. Thomas, U.S.V.I. on December 14, 2011, and in this notice we are announcing additional training workshops in the Gulf of Mexico, Atlantic, and Caribbean regions. However, we are not holding a training workshop in St. Thomas, U.S.V.I. at this time; we are working on scheduling an additional training session in St. Thomas, U.S.V.I. in the future.

Date	Time	Meeting locations	Address
July 17, 2012	4:30–7:30 p.m.	Centro de Recursos para la Información y Educación Marina.	Universidad de Puerto Rico, Recinto de Mayagüez, Edificio de Física, Salón 310, Mayagüez, PR 00681.
July 19, 2012	5:00–8:00 p.m.	Center for Marine and Environmental Studies	University of the Virgin Islands, RR#1 Box 10,000, Evans Center, Theater/Room EVC 401, Kingshill, VI 00850–9781.
August 7, 2012	5:00–8:00 p.m.	Belle Chasse Auditorium	8398 HWY. 23, Belle Chasse, LA 70037.
August 8, 2012	5:00–8:00 p.m.	Grand Caillou Recreation Center	106 Badou Drive, Dulac, LA 70353.
August 15, 2012	1:30–4:30 p.m.	Bay County Government Center	840 W. 11th Street, Room #1030, Panama City, FL 32401.
August 21, 2012	3:30–6:30 p.m.	Port Orange Regional Library	1005 City Center Circle, Port Orange, FL 32129.
August 22, 2012	4:30–7:30 p.m.	Seminole Community Library	9200 113th Street N., Seminole, FL 33772.
August 23, 2012	4:30–7:30 p.m.	Tyrone Bryant Branch Library	2230 NW 21st Avenue, Fort Lauderdale, FL 33311.
September 5, 2012	6:30–9:30 p.m.	Marathon Government Center	2798 Overseas Highway, Milemarker 48.5, EOC BOCC Meeting Room, 2nd Floor, Marathon, FL 33050.

These workshops will be physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Delisse Ortiz at (301) 425–8503 or Jackie Wilson at (240) 338–3936 at least 7 days prior to the workshop date. The public is reminded that NMFS expects participants at the workshop to conduct themselves appropriately. At the beginning of each workshop, a representative of NMFS will explain the ground rules (e.g., alcohol is prohibited from the hearing room; each attendee will have an opportunity to ask questions; and attendees should not interrupt one another). Attendees are expected to respect the ground rules; if they do not, they will be asked to leave the workshop.

Dated: June 26, 2012.

Emily H. Menashes,

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

[FR Doc. 2012–16061 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of committee meeting.

SUMMARY: The North Pacific Fishery Management Council's (Council) Steller Sea Lion Mitigation Committee (SSLMC) will meet July 16–17, 2012, in

Seattle, WA, 9 a.m. through 5 p.m. Pacific time.

ADDRESSES: The meeting will be held at the Alaska Fishery Science Center, 7600 Sand Point Way NE., Seattle, WA.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Steve MacLean, North Pacific Fishery Management Council; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: This public meeting will occur during the scoping period for the Steller Sea Lion Protection Measures EIS (77 FR 22750, April 17, 2012). Information on EIS development, potential alternatives, and issues for analysis may be discussed. The public is encouraged to attend in this meeting, however, comments specific to the EIS should be submitted in writing to NMFS before the close of the scoping period on October 15, 2012. More information on the EIS scoping process and instructions for submitting written public comments are available on the NMFS Alaska Region Web site at *http://alaskafisheries.noaa.gov/sustainablefisheries/sslpm/eis/default.htm.*

Additional information is posted on the Council Web site: *http://www.alaskafisheries.noaa.gov/npfmc/*.

The meeting will be webcast at *https://npfmc.webex.com/npfmc/onstage/g.php?t=a&d=991631167.*

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens 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 sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, (907) 271–2809, at least 5 working days prior to the meeting date.

Dated: June 26, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–15949 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XB160

Marine Mammals; File No. 16193

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Todd Robeck, D.V.M, Ph.D., Sea World Parks and Entertainment Corp, 500 Sea World Drive, San Diego, CA 92109, has applied in due form for a permit to receive, import, and export specimens of marine mammals for scientific research.

DATES: Written, telefaxed, or email comments must be received on or before July 30, 2012.

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. 16193 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 Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562) 980–4001; fax (562) 980–4018.

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. 16193 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: Jennifer Skidmore 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), 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).

The applicant is requesting authorization to receive, import, and export an unlimited number of cetacean and pinniped specimens (from several species of dolphin, pilot whales, beluga whales, killer whales, South American sea lions, Steller sea lions, and Hawaiian monk seals) including but not limited to reproductive cells and organs, urine, feces, teeth, skin, saliva, ocular and nasal secretions, and whole blood taken from dead or captive individuals to study reproductive physiology, including endocrinology, gamete biology, and cryophysiology.

Specimens from dead animals, located solely within the jurisdiction of the U.S.A. or Canada, would be collected under the following circumstances: Legal subsistence harvesting; killed incidentally to fishing or other operations; found dead at sea or beached; or that died of natural causes. No specimens would be imported from animals killed during high seas driftnet fisheries or during a direct fishery. From dead animals, samples from not more than 40 animals per species are anticipated to be collected per year. For captive animals, specimens would be collected from animals that are being housed in countries or situations where such activity is legal and from animals that have been behaviorally conditioned for specimen donation or during normal USDA approved animal husbandry procedures. For live animals, unlimited specimens would be collected for import or export from not more than 20 individual animals per species per year. Specimens may be taken at anytime of the year and in all areas worldwide where pinnipeds and cetaceans are found. The requested duration of the permit is five years.

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.

Dated: June 26, 2012.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–16062 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC042

Schedules for Atlantic Shark Identification Workshops and Protected Species Safe Handling, Release, and Identification Workshops; Correction

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

ACTION: Notice of public workshops; correction.

SUMMARY: NMFS announces that the date of the Atlantic Shark Identification workshop originally scheduled for August 9, 2012, in Rosenberg, TX, has been changed to August 16, 2012. This workshop notice originally published on June 4, 2012. The August 16, 2012, workshop will be held from 12 p.m. to 4 p.m. at LaQuinta Inn & Suites, 28332 SW Freeway 59, Rosenberg, TX 77471. The July and September workshop dates remain unchanged. Atlantic Shark Identification workshops are mandatory for Atlantic Shark Dealer permit holders or their proxies. Additional free workshops will be held in 2012, and announced in the **Federal Register.**

DATES: The Atlantic Shark Identification Workshop scheduled for August 9, 2012, in Rosenberg, TX, has been rescheduled for August 16, 2012. See **SUPPLEMENTARY INFORMATION** for further details.

ADDRESSES: The location of the rescheduled workshop has not changed. See **SUPPLEMENTARY INFORMATION** for further details.

FOR FURTHER INFORMATION CONTACT: Richard A. Pearson of the Highly Migratory Species Management Division at (727) 824–5399.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of June 4, 2012, in FR Doc. 2012–13466, on page 32950, in the third column, the second Atlantic Shark Identification workshop listed under the heading ''Workshop Dates, Times, and Locations'' is corrected to read as follows:

Workshop Dates, Times, and Locations

2. August 16, 2012, from 12 p.m.–4 p.m., LaQuinta Inn & Suites, 28332 SW Freeway 59, Rosenberg, TX 77471.

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

Dated: June 26, 2012.

Emily H. Menashes,

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

[FR Doc. 2012–16017 Filed 6–28–12; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities and to delete products previously furnished by such agencies.

DATES: *Comments must be received on or before:* 7/30/2012.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

NSN: 8415–MD–001–0268—Sack, Compression Stuff, Extreme Cold Weather (ECW CSS) US Marine Corps, One size fits all.
NPA: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, WA.
Contracting Activity: Dept of the Army, W6QK ACC–APG Natick, Natick, MA.
Coverage: C-List for 100% of the requirement of the U.S. Marine Corps, as aggregated by the Army Contracting Command—Aberdeen Proving Ground, Natick Contracting Division, Natick, MA.

NSN: 8950–01–E61–8129—Spice, Oregano Leaf, Whole, 6/5 oz Containers.
NSN: 8950–01–E61–8133—Spice, Oregano Leaf, Whole, 3/24 oz Containers.
NSN: 8950–01–E61–0664—Spice, Thyme, Ground, 6/12 oz Containers.
NSN: 8950–01–E61–8136—Spice, Thyme, Leaf, Whole, 6/6 oz Containers.
NSN: 8950–01–E62–2182—Spice, Basil, Leaf, Whole 3/1.62 lb Containers.
NSN: 8950–01–E60–9314—Spice, Basil, Ground, 6/12 oz Containers.
NSN: 8950–01–E60–9311—Spice, Blend, Poultry, 6/12 oz Containers.
NSN: 8950–01–E62–0115—Spice, Blend, Curry, Powder, No MSG, 6/16 oz Containers.
NSN: 8950–01–E62–0116—Spice, Blend, Santa Fe, 6/16 oz Containers.
NSN: 8950–01–E62–2187—Spice, Onion, Granulated, 6/18 oz Containers.
NSN: 8950–01–E62–0149—Spice, Bay Leaf,

Whole, 6/2 oz Containers.
NSN: 8950–00–NSH–0234—Spice, Blend, Cajun, 6/22 oz Containers.
NSN: 8950–01–E61–6697—Spice, Blend, Italian Seasoning, 6/6.25 oz Containers.
NSN: 8950–01–E62–2190—Spice, Blend, Italian Seasoning, 3/28 oz Containers.
NSN: 8950–01–E62–2191—Spice, Pepper, Red, Crushed, 3/3.25 lb Containers.
NPA: CDS Monarch, Webster, NY.
Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA.
Coverage: C-List for 100% of the requirement of the Department of Defense, as aggregated by the Defense Logistics Agency Troop Support, Philadelphia, PA.

Services

Service Type/Locations: Operation Support Service, Aberdeen Proving Ground, MD, National Ground Intelligence Center (NGIC).
Rivanna Station Complex, 2055 Boulders Road, Charlottesville, VA.
NPA: The Chimes, Inc., Baltimore, MD.
Contracting Activity: Dept of the Army, 0002 MI CTR Contract DODAAC, Charlottesville, VA.
Service Types/Location: Grounds Maintenance Service, National Aeronautics and Space Administration, Goddard Space Flight Center, Wallops Flight Facility, Bldg. E105, Room 319, Wallops Island, VA.
NPA: Didlake, Inc., Manassas, VA.
Contracting Activity: National Aeronautics and Space Administration, Goddard Space Flight Center, Greenbelt, MD.
Service Types/Location: Custodial Service, National Aeronautics and Space Administration, Goddard Space Flight Center, Wallops Flight Facility, Bldg. E105, Room 319, Wallops Island, VA.
NPA: The ARC of the Virginia Peninsula, Inc., Hampton, VA.
Contracting Activity: National Aeronautics and Space Administration, Goddard Space Flight Center, Greenbelt, MD.
Service Type/Location: Mess Attendant Services, 121st Air Refueling Wing, 7370 Minuteman Way, Redtail Dining Facility, Bldg. 917, Columbus, OH.
NPA: First Capital Enterprises, Inc., Chillicothe, OH.
Contracting Activity: Dept of the Army, W7NU USPFO Activity OH ARNG, Columbus, OH.

Mess Attendant Services tasks are defined in the Performance Work Statement and include replenishing tableware and table items, cleaning dining room tables and chairs or benches as needed, including spills, after each meal service, providing cashier services; cleaning and sanitizing food service equipment and utensils; washing, rinsing, and drying tableware, cookware, and kitchen and serving line utensils; cleaning tops and sides of dining tables, monitoring the cleanliness of the Salad Bar area during meal periods, and serving food on the line throughout the duration of the meal period.

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. If approved, the action may result in authorizing small entities to furnish the products to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products proposed for deletion from the Procurement List.

End of Certification

The following products are proposed for deletion from the Procurement List:

Products

Binder, Loose-leaf, 3-Ring
NSN: 7510–01–484–1760.
NSN: 7510–01–484–1752.
NSN: 7510–01–484–1750.
NSN: 7510–01–484–1751.
NSN: 7510–01–484–1748.
NSN: 7510–01–484–1749.
NPA: South Texas Lighthouse for the Blind, Corpus Christi, TX.
Contracting Activity: General Services Administration, New York, NY.

Bag, Sleeping, Firefighter's
NSN: 8465–00–081–0798.
NPAs: Blind Industries & Services of Maryland, Baltimore, MD.
RLCB, Raleigh, NC.
Contracting Activity: General Services Administration, Fort Worth, TX.

NSN: M.R. 552—Nitrile Disposable Gloves.
NSN: M.R. 553—Latex Disposable Gloves.
NPA: New York City Industries for the Blind, Inc., Brooklyn, NY.
Contracting Activity: Military Resale-Defense Commissary Agency, Fort Lee, VA.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2012–15983 Filed 6–28–12; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Reestablishment of the Agricultural Advisory Committee

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Federal Advisory Committee Reestablishment.

SUMMARY: The Commodity Futures Trading Commission has determined to reestablish the charter of its Agricultural Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Gail B. Scott, Committee Management Officer, at 202–418–5139. Written comments should be submitted to David A. Stawick, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581. Electronic comments may be submitted to *dstawick@cftc.gov.*

Comments may also be submitted by any of the following methods:

The agency's Web site, at *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

Hand Delivery/Courier: Same as mail above.

Please submit your comments using only one method and identity that it is for the reestablishment of the Agricultural Advisory Committee.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

SUPPLEMENTARY INFORMATION: The Commodity Futures Trading Commission (''Commission'') has determined to reestablish its Agricultural Advisory Committee. The Commission has determined that reestablishing the advisory committee is in the public interest in connection with the duties imposed on the Commission by the Commodity Exchange Act, 7 U.S.C. 1–26, as amended. The Agricultural Advisory Committee will operate for two years from the date of renewal unless, before the expiration of that time period, its charter is renewed in accordance with section 14(a)(2) of the Federal Advisory Committee Act, or the Chairman of the Commission, with the concurrence of the other Commissioners, shall direct that the advisory committee terminate on an earlier date.

The purpose of the Agricultural Advisory Committee is to conduct public meetings and submit reports and recommendations to assist the

[1] *See* 17 CFR 145.9.

Commission in assessing issues affecting agricultural producers, processors, lenders and others interested in or affected by the agricultural commodity, futures, and swaps markets.

Meetings of the Agricultural Advisory Committee are open to the public.

The Commission may reestablish the Agricultural Advisory Committee by filing the reestablishment charter with the Commission; the Senate Committee on Agriculture, Nutrition and Forestry; the House Committee on Agriculture; the Library of Congress; and the General Services Administration's Committee Management Secretariat at least fifteen (15) calendar days after this notice of reestablishment appears in the **Federal Register**. A copy of the reestablishment charter will also be posted on the Commission's Web site at *www.cftc.gov.*

Issued in Washington, DC, on June 25, 2012 by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. 2012–16006 Filed 6–28–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 12–28]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 12–28 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: June 26, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUN 18 2012

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 12-28, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Morocco for defense articles and services estimated to cost $1.015 billion. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

William E. Landay III
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided under Separate Cover)

BILLING CODE 5001–06–C

Transmittal No. 12–28

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Morocco

(ii) *Total Estimated Value:*

Major Defense Equipment*.	$.074 billion.
Other	.941 billion.
Total	1.015 billion.

* As defined in Section 47(6) of the Arms Export Control Act.

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* enhancement and refurbishment of 200 M1A1 Abrams tanks, provided as part of a grant Excess Defense Article (EDA) transfer notified to Congress on 27 April 2011, to the M1A1 Special Armor (SA) configuration. The proposed sale also includes 150 AN/VRC–87E and 50 AN/VRC–89E Exportable Single Channel Ground and Airborne Radio Systems (SINCGARS), 200 M2 Chrysler Mount Machine Guns, 400 7.62MM M240 Machine Guns, 12,049,842 Ammunition Rounds (including 1400 C785 SABOT, 1800 CA31 HEAT, and 5400 AA38 SLAP–T), 200 M250 Smoke Grenade Launchers, support equipment, spare and repair parts, personnel training and training equipment, publications and technical data, communication support, U.S. Government and contractor

technical assistance, and other related logistics support.

(iv) *Military Department:* Army (USQ)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See attached Annex

(viii) *Date Report Delivered to Congress:* 18 June 2012

POLICY JUSTIFICATION

Kingdom of Morocco—M1A1 SA Abrams Tank Enhancement, Support and Equipment

The Government of the Kingdom of Morocco has requested a possible enhancement and refurbishment of 200 M1A1 Abrams tanks, provided as part of a grant Excess Defense Article (EDA) transfer notified to Congress on 27 April 2011, to the M1A1 Special Armor (SA) configuration. The possible sale will also provide 150 AN/VRC–87E and 50 AN/VRC–89E Exportable Single Channel Ground and Airborne Radio Systems (SINCGARS), 200 M2 Chrysler Mount Machine Guns, and 400 7.62MM M240 Machine Guns. The possible sale also includes 12,049,842 Ammunition Rounds (including 1400 C785 SABOT, 1800 CA31 HEAT, and 5400 AA38 SLAP–T), 200 M250 Smoke Grenade Launchers, support equipment, spare and repair parts, personnel training and training equipment, publications and technical data, communication support, U.S. Government and contractor technical assistance, and other related logistics support. The estimated cost is $1.015 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a major Non-NATO ally that continues to be an important force for political stability and economic progress in Africa.

This package of M1A1 tank enhancements will contribute to the modernization of Morocco's tank fleet, enhancing its ability to meet current and future threats. These tanks will contribute to Morocco's goal of updating its military capability while further enhancing interoperability with the U.S. and other allies.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be General Dynamics Land Systems in Sterling Heights, Michigan. Refurbishment work will be performed at Anniston Army Depot in Anniston, Alabama and the Joint Systems Manufacturing Center in Lima, Ohio. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require annual trips to Morocco involving up to 64 U.S. Government and 13 contractor representatives for a period of up to five years to manage the fielding and training for the program.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 12–28

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The M1A1 Abrams Tanks components considered to contain sensitive technology in the proposed program are as follows:

a. The M1A1 Thermal Imaging System (TIS) 2nd Gen Forward Looking Infrared (FLIR) constitutes a target acquisition system which, when operated with other tank systems, gives the tank crew a substantial advantage over the potential threat. The TIS provides the M1A1 crew with the ability to effectively aim and fire the tank main armament system under a broad range of adverse battlefield conditions. The hardware itself is Unclassified. The engineering design and manufacturing data associated with the detector and infrared (IR) optics and coatings are considered sensitive. The technical data package is Unclassified with the exception of the specifications for target acquisition range (Confidential), nuclear hardening (Confidential, restricted data) and laser hardening (Secret).

b. The M1A1 Tank Special Armor and other special armors used in the hull and turret are classified at the Secret level. Major components of Special Armor are fabricated in sealed modules and in serialized removable subassemblies. Special Armor components and associated vulnerability data for both chemical and kinetic energy rounds are classified Secret.

c. The use of the Advanced Gas Turbine-1500 (AGT–1500) Gas Turbine Propulsion System in the MlA1 is a unique application of armored vehicle power pack technology. The hardware is composed of the AGT–1500 engine and transmission, and is Unclassified. Manufacturing processes associated with the production of turbine blades, recuperator, bearings and shafts, and hydrostatic pump and motor, are proprietary and therefore commercially competition sensitive.

d. A major survivability feature of the Abrams Tank is the compartmentalization of fuel and ammunition. Compartmentalization is the positive separation of the crew and critical components from combustible materials. In the event that the fuel or ammunition is ignited or deteriorated by an incoming threat round, the crew is fully protected by the compartmentalization. Sensitive information includes the performance of the ammunition compartments as well as the compartment design parameters.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

[FR Doc. 2012–15988 Filed 6–28–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Notice of Availability of Draft Environmental Impact Statement for the Proposed Mather Specific Plan Project, Sacramento County, CA, Corps Permit Application Number SPK–2002–561

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD.

ACTION: Notice of availability.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers (USACE), Sacramento District has prepared a Draft Environmental Impact Statement (DEIS) to analyze the potential direct, indirect and cumulative effects of implementing the No Action alternative and three large-scale, mixed-use development alternatives in the approximately 5,749-acre Mather Specific Plan area, Sacramento County, California (note that approximately 2,554 acres of the Plan area contains existing development, primarily Mather Airport, a Commerce Center, a residential subdivision, lake and golf course).

The purpose of the DEIS is to provide decision-makers and the public with information pertaining to the Applicant's Preferred Alternative and alternatives, and to disclose environmental impacts and identify mitigation measures to reduce impacts. The DEIS documents the existing

condition of resources in the Specific Plan area, concentrating on those areas proposed for development, and analyzes the potential impacts to resources as a result of implementing the alternatives. The alternatives considered in detail are: (A) Applicant's Preferred Alternative; (B) 2006 Conceptual Land Use Plan Alternative; (C) Multiple Preserves Alternative; and (D) No Action/No USACE Permit Alternative.

DATES: All written comments must be postmarked on or before August 13, 2012.

ADDRESSES: Comments may be submitted in writing to: Kathleen Dadey, U.S. Army Corps of Engineers, Sacramento District, Regulatory Division; 1325 J Street, Room 1350, Sacramento, CA 95814–2922, or via email to Kathleen.A.Dadey@usace.army.mil.

FOR FURTHER INFORMATION CONTACT: Kathleen Dadey at 916–557–5250, or via email at *Kathleen.A.Dadey@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Sacremento County Office of Economic Development and Marketing (applicant) is seeking authorization from USACE for the placement of dredged or fill material into waters of the United States pursuant to Section 404 of the Clean Water Act to develop portions of the Mather Specific Plan area. The overall project purpose is a large scale, mixed use development to promote economic and wetland conservation opportunities within the Mather Specific Plan area. All of the build alternatives include the following land uses: airport commercial, commercial development, parks and recreation, aggregate extraction, university village/residential, regional sports park and infrastructure, including roadways.

Alternative A, the Applicant's Preferred Alternative, includes approximately 1,910 acres of development a 1,272-acre Preserve and a 13-acre riparian buffer area. The applicant proposes to fill a total of 40.25 acres of waters of the U.S., including seasonal wetlands, vernal pools and swales, channels and drainage ditches. The preserved areas would provide protection for wetlands (including vernal pools) and endangered species, including vernal pool fairy shrimp, vernal pool tadpole shrimp, and legenere. The Preserve would also protect federally listed critical habitat.

Alternative B is based on a land use plan for the Mather Specific Plan area that was conceptually endorsed by the Sacramento County Board of Supervisors in February 2006. Alternative B includes a 1,064-acre Preserve and 27 acre riparian buffer area which would provide protection for wetlands and endangered species. This alternative anticipates development of approximately 2,011 acres. Alternative B also includes four ''avoidance areas'' totaling 93 acres within the parks and recreation and university village/residential areas. Impacts to waters of the U.S. associated with Alternative B would 39.64 acres.

Alternative C proposes land uses identical to Alternative A with the addition of three smaller Preserves within the commercial development and university village/residential areas, with a total of 33.65 acres of fill into waters of the U.S. Alternative C would develop approximately 1,836 acreas and includes 1,346 acres of Preserve and 13 acres of riparian buffer area. Preserve areas would provide protection for wetlands and endangered species.

Alternative D, No Action/No USACE permit, avoids the placement of dredged or fill material into waters of the United States, including wetlands. A reduced amount of future development could occur without Department of the Army authorization, including infill development at Mather Airport and aggregate extraction in the southwestern corner of the project site. Because this alternative does not anticipate substantial economic development and related revenue to fund active management of a Preserve, however, the level of protection and management of wetland resources, listed species and their habitat is unknown.

Comments on the DEIS must be submitted to USACE by August 13, 2012. The public and affected Federal, State and local agencies, Native American Tribes, and other organizations and parties are invited to comment. An electronic copoy of the DEIS may be found on the USACE Web site at: *http://www.spk.usace.army.mil/Missions/Regulatory/Overview/EnvironmentalImpactStatements.aspx.* A hard copy of the DEIS is available for review at the USACE office during normal business hours. To schedule a time to view the hard copy, please contact Kathleen Dadey.

The USACE will conduct a public meeting for the DEIS on July 25, 2012 from 4:00 p.m. to 7:00 p.m. in Main Conference Room A at 10590 Armstrong Avenue, Mather, California 95655. Interested parties can provide oral and written comments at this meeting.

In addition to this **Federal Register** notice, USACE will issue public notices advising interested parties of the availability of the DEIS. Interested parties may register for USACE public notices at: *http://www.spk.usace.army.mil/Media/RegulatoryPublicNotices.aspx.*

Dated: June 20, 2012.

Braden G. LeMaster,

Lieutenant Colonel, Corps of Engineers, Deputy District Engineer.

[FR Doc. 2012–15965 Filed 6–28–12; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Proposed Reduction in Hours of Operation at the Mississippi River Twin Cities Locks Located in Minneapolis, MN

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD.

ACTION: Notice.

SUMMARY: The three locks in the Twin Cities (Upper St. Anthony Falls, Lower St. Anthony Falls, and Lock and Dam 1) located in Minneapolis, MN, on the Mississippi River, currently operate at Service Level 1 (24 hours per day/7 days per week) during the navigation season. It is proposed that these three locks and dams transition to Service Level 2 for the 2013 navigation season and beyond. The navigation season on the Upper Mississippi normally begins in March, depending on river conditions. Under Service Level 2, the locks will operate from 7:00 a.m. to 2:00 a.m. and will be closed to lockages between 2:00 a.m. and 7:00 a.m.

Constrained funding has led to reduced Operations and Maintenance funding within the Corps' Inland Marine Transportation System (IMTS). The intended effect of the proposed change reduces operational costs and aligns lock availability with existing levels of lock usage. The Twin Cities locks have less than 1000 commercial lockages per year. Based on guidance adopted by the IMTS Board of Directors, locks operating at Service Level 1 should pass more than 1,000 commercial lockages per year. Pool levels will not be affected by change of operating hours.

DATES: Submit written comments by August 30, 2012, to Mr. Kevin Baumgard, Deputy Chief, Operations Division, U.S. Army Corps of Engineers, 180 Fifth Street East, Suite 700, St. Paul, MN 55101–1678, or by email at *kevin.l.baumgard@usace.army.mil.* Written comments will also be accepted at the public meeting.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Kidby at Corps of Engineers

Headquarters in Washington, DC, by phone at 202–761–0250.

SUPPLEMENTARY INFORMATION: Public meeting: August 7, 2012, from 7:00 p.m. to 8:00 p.m. at the Minneapolis Park and Recreation Board Headquarters, 2117 West River Road Minneapolis, MN.

The legal authority for the regulation governing the use, administration, and navigation of the Twin Cities locks is Section 4 of the River and Harbor Act of August 18, 1894 (28 Stat. 362), as amended, which is codified at 33 U.S.C. Section 1. This statute requires the Secretary of the Army to ''prescribe such regulations for the use, administration, and navigation of the navigable waters of the United States'' as the Secretary determines may be required by public necessity. Reference 33 CFR 207.300, Mississippi River below mouth of Ohio River, including South and Southwest Passes; use, administration, and navigation.

Brenda S. Bowen,

Army Federal Liaison Officer.

[FR Doc. 2012–15967 Filed 6–28–12; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Naval Base Coronado Coastal Campus and To Announce Public Scoping Meetings

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969, as implemented by the Council on Environmental Quality Regulations, the Department of the Navy (DoN) announces its intent to prepare an Environmental Impact Statement (EIS) to evaluate the potential environmental effects of developing an academic campus on Naval Base Coronado (NBC) to support the current and future operational readiness of personnel with the Naval Special Warfare Command (NSWC). The proposed campus would include a mix of instructional and administrative facilities that would provide for indoor classroom and tactical training instruction, and equipment use, maintenance, and storage. Specific proposed actions within the Coastal Campus proposal are: (1) Evaluation of current land use and available facilities; (2) augmentation by design and construction of new facilities to support logistics, equipment use and maintenance training, classroom and tactical skills instruction, storage, and administration; and, (3) design and build of related site improvements that may include upgraded utilities, fencing, roads, and parking. An EIS is considered the appropriate document for comprehensively analyzing the potential environmental impacts of implementing this proposed action.

Dates and Addresses: DoN is initiating a 30-day public scoping process to identify community interests and specific issues to be addressed in the EIS. This public scoping process starts with the publication of this Notice of Intent (NOI). Two public scoping meetings will be held to receive oral and/or written comments on issues to be addressed in the EIS:

1. Tuesday, July 17, 2012, 6:00 p.m. to 8:00 p.m., Marina Vista Community Center, 1075 Eighth Street, Imperial Beach, California, 91932.

2. Wednesday, July 18, 2012, 6:00 p.m. to 8:00 p.m., Winn Room, Coronado Public Library, 640 Orange Avenue, Coronado, California, 92118.

Additional information concerning meeting times and locations is available on the EIS Web site at *www.nbccoastalcampuseis.com.* Public scoping meeting dates, times, and locations are also being announced in the local news media, including a local Spanish language newspaper.

Public scoping meetings will include open house sessions, with information stations staffed by the DoN representatives. Comments, both written and oral, will be collected at each of the two public scoping meetings, and written comments may also be made electronically on the project Web site. Spanish translation will be available at the public meetings and the project Web site accommodates Spanish language users.

FOR FURTHER INFORMATION CONTACT: Naval Base Coronado Coastal Campus EIS Project Manager, Attn: Ms. Teresa Bresler, 2730 McKean Street, Bldg 291, San Diego, California 92136.

SUPPLEMENTARY INFORMATION: NSWC is the maritime component of United States Special Operations Command (USSOCOM). Based at NAB Coronado, California, NSWC's mission is to organize, train, man, equip, educate, sustain, maintain combat readiness, and deploy Naval Special Warfare (NSW) forces to carry out special operations missions worldwide. NSW forces operate independently or in conjunction with other special operations forces (SOF), joint forces, allied units, and coalition forces.

NSWC currently conducts administrative and extensive logistics support, equipment use and maintenance training and classroom and tactical skills instruction on the Silver Strand Training Complex-North (SSTC–N) and Silver Strand Training Complex South (SSTC–S), Naval Amphibious Base (NAB) Coronado, Naval Air Station North Island (NASNI), and Naval Outlying Landing Field Imperial Beach (NOLFIB), and Camp Michael Monsoor. Although all of the facilities currently used by NSWC are located on components of NBC, they are over-utilized as well as widely dispersed and not conveniently co-located.

To support Congressionally-mandated growth of NSWC and to meet its current and anticipated mission requirements, the DoN is proposing a Coastal Campus at NBC. The proposed Coastal Campus would support future operational readiness by augmenting available NSWC facilities and reducing fragmentation and space deficiencies, while providing an integrated campus that accommodates primacy and privacy, characteristics of learning required for the development of these skill sets.

The proposed Coastal Campus would augment the current facilities used by NSWC. Specific proposed actions within the Coastal Campus proposal are as follows.

(1) Evaluation of current land use and available facilities.

(2) Augmentation by design and construction of new facilities to support logistics, equipment use and maintenance training, classroom and tactical skills instruction, storage, and administration.

(3) Design and build of related site improvements that may including utilities, fencing, roads, and parking. Due to the functional linkages and the geographic proximity of the components, the proposed Coastal Campus could be sited at SSTC–S, SSTC–N including NAB Coronado, NASNI, or NOLFIB, or a combination of these locations, all within the footprint of NBC.

Purpose and Need for the Action: The Global War on Terror has resulted in Congressionally-mandated personnel growth and increased training and operational readiness requirements for NSWC. However, current NSWC operational support, classroom and tactical skills instruction and administrative facilities, primarily located at NAB Coronado, are inadequate to meet existing and future mission requirements. Moreover, expansion potential at this location is limited. To accommodate NSWC's projected growth requires additional logistics and operational support

buildings, classrooms, storage and administrative facilities.

Accordingly, the purpose of the Proposed Action is to provide adequate facilities to support growth of NSWC and to maintain the required levels of operational readiness of special warfare forces, as mandated by Title 10 of U.S.C. Section 167 and Section 5062. The need for the proposed action is the lack of sufficient facilities and space to support NSWC's administrative, logistics, and classroom and tactical instruction functions. The Proposed Action would meet this need by optimizing both facilities and use of space, including synchronistic site improvements, within the existing NBC footprint. This would allow NSWC to support fluctuating organizational structure and mandated mission requirements.

The specific arrangement of built assets, number of buildings and required space would be developed and refined during the NEPA process based on scoping, impacts analysis and results of resource surveys. The DoN proposes 25 projects on NBC over a period of approximately ten years. Each of these projects would be refined as they are studied and evaluated during the Coastal Campus EIS process. The Coastal Campus EIS, when completed, would provide an analytic baseline from which each successive NSWC project may be optimally designed in terms of land use, facilities and infrastructure, and impacts to resources found within the study area.

Alternatives to be Considered: The EIS proposes to address four alternatives, including the No Action Alternative. The alternatives have been designed to study land use patterns, existing infrastructure and resource impacts, as an analytical baseline for receipt of future NSWC Military Construction (MILCON) Program projects. The alternatives would include:

(1) Alternative 1 (SSTC–S Alternative) consists of:

○ Consolidation of the necessary NSWC facilities to one location on the northern half of SSTC–S.

○ Design and construction of logistical support buildings, equipment use and maintenance training facilities, classroom and tactical skills instruction buildings, storage and administrative facilities, utilities, fencing, roads, and parking.

○ Construction of a new entry controlled point providing immediate access to SSTC–S from State Route 75, utilizing sustainable design for all facilities as is practicable.

(2) Alternative 2 (SSTC–S Design II expanded footprint Alternative) would include all of the components of Alternative 1, but the design footprint would increase by expanding the footprint down to the southern fence line of the SSTC–S boundary.

(3) Alternative 3 (Multi-Installation Alternative) would site necessary NSWC facilities at more than one location to include NAB Coronado, NASNI, NOLFIB, and SSTC–S incorporating sustainable design into all facilities as is practicable.

(4) Alternative 4 (No Action Alternative) would maintain existing land uses and training facilities as currently utilized at NBC. No new improvements would occur. Current programmed levels of use (type, tempo, location), including requirements for planned force growth, would continue. As a result, NSWC would continue to have limited space for current and future training support, as well as an inability to cope with Congressionally-mandated expanding training needs. Without consolidation of classroom and support facilities, NSWC personnel would continue to transit between SSTC–N/NAB Coronado, SSTC–S, and NOLFIB. This would continue inefficiency and fragmentation of training and increased expenses, and the environmental consequences would persist (e.g., air emissions and energy consumption of vehicle miles traveled). By limiting facilities and land use support to accommodate NSWC growth and expansion, Alternative 4—No Action Alternative would not achieve the mission of NSWC; however, it will be studied as a baseline of current land and facilities use.

Environmental Issues and Resources to be Examined: Environmental issues that will be addressed in the EIS will include, but are not limited to: Air quality, biological resources (including threatened and endangered species), cultural resources (including historic properties and archaeological resources), geology and soils, hazardous materials and hazardous waste management, health and safety, noise, visual resources, coastal resources, land use, recreation, socioeconomics (including environmental justice and protection of children), transportation and circulation, water resources, and public access. Measures that would avoid or mitigate environmental effects will also be analyzed. Additionally, the DoN will undertake any consultations required by the Endangered Species Act, Coastal Zone Management Act, National Historic Preservation Act, Clean Water Act, and any other applicable law or regulation.

Submitting Comments: The DoN encourages interested persons to submit comments concerning the alternatives proposed for study and environmental impacts to be analyzed. Federal, State and local agencies, Tribal governments, and interested persons are encouraged to provide oral and/or written comments to the DoN to identify specific environmental issues or topics of environmental concern that the DoN should consider when developing the Draft EIS. The DoN will prepare the Draft EIS, incorporating issues identified by the commenting public. All comments received, whether written, oral, on-line, at the public scoping meetings or provided to the DoN during the public scoping period, will receive consideration during Draft EIS preparation.

Written comments on the scope of the EIS should be postmarked no later than July 30, 2012. Comments may be mailed to the EIS Project Manager (Attn: Ms. Teresa Bresler), 2730 McKean Street, Bldg. 291, San Diego, California, 92136. Comments may also be submitted via the EIS Web site at *www.nbccoastalcampuseis.com.*

Dated: June 19, 2012.

L.R. Almand,

Office of the Judge Advocate General, U.S. Navy, Alternate **Federal Register** *Liaison Officer.*

[FR Doc. 2012–15979 Filed 6–28–12; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2012–0010]

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to add a system of records.

SUMMARY: The Department of the Navy proposes to add a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The blanket (k)(1) exemption applies to this systems of records to accurately describe the basis for exempting disclosure of classified information that is or may be contained in the records.

DATES: This proposed action will be effective on July 30, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Patterson, Department of the Navy, DNS–36, 2000 Navy Pentagon, Washington, DC 20350–2000 or call at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in *FOR FURTHER INFORMATION CONTACT.* The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on June 21, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: June 26, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

N07250–1

SYSTEM NAME:

Navy Cash® Financial System.

SYSTEM LOCATION:

Navy Cash is installed on all Navy ships with a Disbursing Officer. Official mailing addresses are published in the Standard Navy Distribution List, which is available as an appendix to the Navy's compilation of system of records notices and may be obtained from the System Manager.

The Navy Cash back-end ashore is operated by a U.S. Department of the Treasury Financial Agent, JPMorgan Chase, Treasury Services, 10430 Highland Manor Drive, Tampa, FL 33610–9128.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy and Marine Corps Active and Reserve military members, civilian employees, and contractors and civilians assigned to duty or visiting on board Navy ships.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, military branch or company name, Social Security Number (SSN), rate, rank, title, pay grade, date of birth, mother's maiden name or keyword, military duty address, residence/permanent address, work telephone number, cell telephone phone, email address, bank or credit union name, city, state, and zip code, ABA routing number, account number, name on account, account type, Navy Cash/Marine Cash card number, electronic signature (future capability), Automated Clearing House (ACH) Electronic Fund Transfer (EFT) requests, returned EFT requests, collections of debts, collections of payments, account balances, transaction history, and purchase history.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters Marine Corps; 31 U.S.C. 321, General Authority of the Secretary of the Treasury; Pub. L. 104–134, Debt Collection Improvement Act of 1996, as amended; Department of Defense Financial Management Regulation (DoDFMR) 7000.14–R, as amended; 5 U.S.C. 5514, Installment deduction for indebtedness to the United States; 31 U.S.C. 1322, Payments of unclaimed trust fund amounts and refund of amounts erroneously deposited; 31 U.S.C. 3720, Collection of payments; 31 U.S.C. 3720A, Reduction of tax refund by amount of debt; 31 U.S.C. 7701, Taxpayer indentifying number; 37 U.S.C. 1007, Deductions from pay; 31 CFR 210, Federal Government Participation in the Automated Clearing House; 31 CFR 285, Debt Collection Authorities under the Debt Collection Improvement Act of 1996; and E.O. 9397 (SSN), as amended.

PURPOSE(S):

To provide an electronic cash management application that replaces bills and coins for purchases on the ship; provides Sailors and Marines on board ship with electronic access to their Navy Cash accounts and a portion of pay each pay day (Split Pay Option), 24/7 offline access to bank and credit union accounts ashore, and the ability to move money electronically to and from Navy Cash accounts and bank and credit union accounts; and provides access off the ship to funds in Navy Cash accounts at merchants and ATMs worldwide.

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. Section 552(a)(b) of the Privacy Act of 1974, as amended, these records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the U.S. Department of the Treasury, Fiscal and Financial Agents, and their contractors involved in providing Navy Cash services.

The DoD 'Blanket Routine Uses' published at the beginning of the Department of the Navy's compilation of system of records notices may apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper file folders and electronic storage media.

RETRIEVABILITY:

Name, Social Security Number (SSN), and Navy Cash/Marine Cash card number.

SAFEGUARDS:

Paper and electronic records on board ship are maintained in controlled areas accessible only to authorized personnel, e.g., the Disbursing Office or Sales Office. Physical entry is restricted by the use of locks and administrative procedures. Access to personal information is restricted to those who require the records in the performance of their official duties. Access to personal information stored electronically is further restricted by the use of user names and passwords (current) and Common Access Card (CAC) (future). All individuals granted access will have received Information Assurance and Privacy Act training.

RETENTION AND DISPOSAL:

Records are maintained for 6 years and 3 months after the period covered by the individual accounts and then destroyed by burning or shredding or by degaussing, erasing, deleting, or overwriting.

SYSTEM MANAGER AND ADDRESS:

Commander, Naval Supply Systems Command, Navy Cash Program Office (N3/4), 5450 Carlisle Pike, Building 309, Mechanicsburg, PA 17055–0791.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to Commander, Naval Supply Systems Command, Navy Cash Program Office (N3/4), 5450 Carlisle Pike, Building 309, Mechanicsburg, PA 17055–0791.

The request should be signed and include full name, last four digits of Social Security Number (SSN), rate/rank, and a complete mailing address. The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to Commander, Naval Supply Systems Command, Navy Cash Program Office (N3/4), 5450 Carlisle Pike, Building 309, Mechanicsburg, PA 17055–0791.

The request should be signed and include full name, last four digits of Social Security Number (SSN), rate/rank, and a complete mailing address. The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

An exemption rule for this system has been promulgated in accordance with the requirements of 5 U.S.C. 553(b)(1), (2) and (3)(c) and (e) and it published at 32 CFR part 701.

[FR Doc. 2012–15953 Filed 6–28–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests; Federal Student Aid; Federal Perkins Loan Program/NDSL Assignment Form

SUMMARY: The Federal Perkins Loan Program allows for assignment of certain defaulted loans from schools to continued collection efforts when the school has exhausted all of its efforts in recovering an outstanding loan. The Perkins Assignment Form serves as the transmittal document in the assignment of such loans to the Federal Government.

DATES: Interested persons are invited to submit comments on or before August 28, 2012.

ADDRESSES: Written comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 04886. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Perkins Loan Program/NDSL Assignment Form.

OMB Control Number: 1845–0048.

Type of Review: Extension.

Total Estimated Number of Annual Responses: 14,055.

Total Estimated Number of Annual Burden Hours: 7,028.

Abstract: Schools participating in the Federal Perkins Loan Program, formerly the National Direct/Defense Student Loan Program (NDSL), currently use this form to assign defaulted loans to the U.S. Department of Education (the Department) for collection. These defaulted loans may, as outlined in 20 U.S.C. 1087cc and under program regulations 34 CFR 674.50, be assigned to the Federal government (i.e., U.S. Department of Education) for collection when the school has exhausted all efforts in the recovery of the outstanding loan. In addition, schools use this form to assign loans for which a school has approved a total and permanent disability discharge request, in accordance with 34 CFR 674.61(b) (2) (v).

Dated: June 26, 2012.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2012–15996 Filed 6–28–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications, Reports, and Other Records for the 2011–2012 Award Year: Student Assistance General Provisions, Federal Supplemental Educational Opportunity Grant, Federal Work-Study, Federal Perkins Loan, Federal Pell Grant, etc.

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

Overview Information

Catalog Federal Domestic Assistance (CFDA) Numbers: 84.007

Federal Supplemental Educational Opportunity Grant Program; 84.033 Federal Work-Study Programs; 84.038 Federal Perkins Loan Program; 84.063 Federal Pell Grant Program; 84.268 William D. Ford Federal Direct Loan Program; 84.379 Teacher Education Assistance for College and Higher Education Grant Program; 84.408 Iraq and Afghanistan Service Grant Program.

SUMMARY: The Secretary announces deadline dates for the receipt of documents and other information from institutions and applicants for the Federal student aid programs authorized under Title IV of the Higher Education Act of 1965, as amended, for the 2011–2012 award year. The Federal student aid programs include the Federal Supplemental Educational Opportunity Grant (FSEOG), Federal Work-Study (FWS), Federal Perkins Loan, Federal Pell Grant, William D. Ford Federal Direct Loan (Direct Loan), Teacher Education Assistance for College and Higher Education (TEACH) Grant, and the Iraq and Afghanistan Service Grant programs.

These programs, administered by the U.S. Department of Education (Department), provide financial assistance to students attending eligible postsecondary educational institutions to help them pay their educational costs.

Deadline and Submission Dates: See Tables A, B, and C at the end of this notice.

Table A—Deadline Dates for Application Processing and Receipt of Institutional Student Information Records (ISIRs) or Student Aid Reports (SARs) by Institutions for the 2011–2012 Award Year

Table A provides information and deadline dates for application processing, including receipt of the Free Application for Federal Student Aid (FAFSA) and corrections to and signatures for the FAFSA, receipt of ISIRs and SARs, and receipt of verification documents.

The deadline date for the receipt of a FAFSA by the Department's Central Processing System is June 30, 2012, regardless of the method that the applicant uses to submit the FAFSA. The deadline date for the receipt of a signature page for the FAFSA (if required), corrections, changes of addresses or schools, or requests for a duplicate SAR is September 21, 2012. Verification documents must be received by the institution no later than the earlier of 120 days after the student's last date of enrollment or September 28, 2012. As a reminder, verification is not required for unsubsidized Direct Stafford Loans and PLUS Loans, TEACH Grants, and Iraq and Afghanistan Service Grants.

For all Federal student aid programs except Direct PLUS Loans made to parent borrowers, an ISIR or SAR with an official expected family contribution must be received by the institution no later than the earlier of the student's last date of enrollment for the 2011–2012 award year or September 28, 2012. For Direct PLUS Loans made to parent borrowers, FAFSA information processed by the Secretary must be received by the institution no later than the earlier of the student's last date of enrollment for the 2011–2012 award year or September 28, 2012. For purposes of only the Federal Pell Grant Program, a valid ISIR or a valid SAR for a student not meeting the conditions for a late disbursement must be received no later than the earlier of the student's last date of enrollment or September 28, 2012. A valid ISIR or valid SAR for a student meeting the conditions for a late disbursement under the Federal Pell Grant, FSEOG, FWS, Federal Perkins Loan or Direct Subsidized Loan programs must be received according to the deadline dates provided in Table A.

In accordance with the regulations in 34 CFR 668.164(g)(4)(i), an institution may not make a late disbursement later than 180 days after the date of the institution's determination that the student withdrew, as provided in 34 CFR 668.22, or for a student who did not withdraw, 180 days after the date the student otherwise became ineligible. Table A provides that an institution must receive a valid ISIR or valid SAR no later than 180 days after its determination of a student's withdrawal or, for a student who did not withdraw, 180 days after the date the student otherwise became ineligible, but not later than September 28, 2012.

Table B—Federal Pell Grant Program and Iraq and Afghanistan Service Grant Program Submission Dates for Disbursement Information by Institutions for the 2011–2012 Award Year

Table B provides the earliest submission and deadline dates for institutions to submit Federal Pell Grant and Iraq and Afghanistan Service Grant disbursement records to the Department's Common Origination and Disbursement (COD) System and deadline dates for requests for administrative relief if the institution cannot meet the established deadline for specified reasons.

In general, an institution must submit Federal Pell Grant or Iraq and Afghanistan Service Grant disbursement records no later than 30 days after making a Federal Pell Grant or Iraq and Afghanistan Service Grant disbursement or becoming aware of the need to adjust a student's previously reported Federal Pell Grant or Iraq and Afghanistan Service Grant disbursement. In accordance with the regulations in 34 CFR 668.164, we consider that Federal Pell Grant and Iraq and Afghanistan Service Grant funds are disbursed on the date that the institution: (a) Credits those funds to a student's account at the institution or (b) pays those funds to a student directly. We consider that Federal Pell Grant and Iraq and Afghanistan Service Grant funds are disbursed even if an institution uses its own funds in advance of receiving program funds from the Department. An institution's failure to submit disbursement records within the required 30-day timeframe may result in an audit or program review finding. In addition, the Secretary may initiate an adverse action, such as a fine or other penalty for such failure, in accordance with subpart G of part 668.

Table C—William D. Ford Federal Direct Loan (Direct Loan) Program and Teacher Education Assistance for College and Higher Education (TEACH) Grant Program Submission Dates for Disbursement Information by Institutions for the 2011–2012 COD Processing Year

Table C provides the earliest submission and deadline dates for institutions to submit Direct Loan and TEACH Grant disbursement records to the Department's COD System.

In general, an institution must submit Direct Loan or TEACH Grant disbursement records no later than 30 days after making a Direct Loan or TEACH Grant disbursement or becoming aware of the need to adjust a student's previously reported Direct Loan or TEACH Grant disbursement. In accordance with the regulations in 34 CFR 668.164, we consider that Direct Loan and TEACH Grant funds are disbursed on the date that the institution: (a) Credits those funds to a student's account at the institution, or (b) pays those funds to a student directly. We consider that Direct Loan and TEACH Grant funds are disbursed even if an institution uses its own funds in advance of receiving program funds from the Department. An institution's failure to submit disbursement records within the required 30-day timeframe may result in an audit or program review finding. In addition, the Secretary may initiate an adverse action, such as a fine or other penalty for such failure.

Other Sources for Detailed Information

We publish a detailed discussion of the Federal student aid application process in the following publications:

- *2011–2012 Funding Education Beyond High School.*
- *2011–2012 Counselors and Mentors Handbook.*
- *2011–2012 ISIR Guide.*

• *2011–2012 Federal Student Aid Handbook.*

Additional information on the institutional reporting requirements for the Federal Pell Grant Program, Iraq and Afghanistan Service Grant Program, Direct Loan Program, and TEACH Grant Program is contained in the 2011–2012 *COD Technical Reference.*

You may access these publications by selecting the ''Publications'' link at the Information for Financial Aid Professionals Web site at: *www.ifap.ed.gov.*

Applicable Regulations: The following regulations apply:

(1) Student Assistance General Provisions, 34 CFR part 668,

(2) Federal Pell Grant Program, 34 CFR part 690,

(3) William D. Ford Direct Loan Program, 34 CFR part 685, and

(4) Teacher Education Assistance for College and Higher Education Grant Program, 34 CFR part 686.

FOR FURTHER INFORMATION CONTACT: Ian Foss, U.S. Department of Education, Federal Student Aid, 830 First Street, NE., Union Center Plaza, Room 114I1, Washington, DC 20202–5345. Telephone: (202) 377–3681. Email: *Ian.Foss@ed.gov.*

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

Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

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.

Program Authority: 20 U.S.C. 1070a, 1070a–1, 1070b–1070b–4, 1070g, 1070h, 1087a–1087j, and 1087aa–1087ii; 42 U.S.C. 2751–2756b.

Dated: June 26, 2012.

James W. Runcie,

Chief Operating Officer, Federal Student Aid.

TABLE A—DEADLINE DATES FOR APPLICATION PROCESSING AND RECEIPT OF INSTITUTIONAL STUDENT INFORMATION RECORDS (ISIRS) OR STUDENT AID REPORTS (SARS) BY INSTITUTIONS FOR THE 2011–2012 AWARD YEAR

Who submits?	What is submitted?	Where is it submitted?	What is the deadline date for receipt?
Student	Free Application for Federal Student Aid (FAFSA)—''FAFSA on the Web'' (original or renewal).	Electronically to the Department's Central Processing System (CPS).	June 30, 2012.[1]
	Signature Page (if required)	To the address printed on the signature page.	September 21, 2012.
Student through an Institution.	An electronic FAFSA (original or renewal).	Electronically to the Department's CPS	June 30, 2012.[1]
Student	A paper original FAFSA	To the address printed on the FAFSA or envelope provided with the form.	June 30, 2012.
Student	Electronic corrections to the FAFSA using ''Corrections on the Web''.	Electronically to the Department's CPS	September 21, 2012.[1]
	Signature Page (if required)	To the address printed on the signature page.	September 21, 2012.
Student through an Institution.	Electronic corrections to the FAFSA	Electronically to the Department's CPS	September 21, 2012.[1]
Student	Paper corrections to the FAFSA using a SAR, including change of mailing and email addresses or institutions.	To the address printed on the SAR	September 21, 2012.
Student	Change of mailing and email addresses, change of institutions, or requests for a duplicate SAR.	To the Federal Student Aid Information Center by calling 1–800–433–3243.	September 21, 2012.
Student	SAR with an official expected family contribution (EFC) calculated by the Department's CPS (except for Parent Direct PLUS).	To the institution	The earlier of: —the student's last date of enrollment; or —September 28, 2012.[2]
Student through CPS.	ISIR with an official EFC calculated by the Department's CPS (except for Parent Direct PLUS).	To the institution from the Department's CPS.	The earlier of: —the student's last date of enrollment; or —September 28, 2012.[2]
Student	Valid SAR (Pell Grant Only)	To the institution	Except for a student meeting the conditions for a late disbursement under 34 CFR 668.164(g), the earlier of: —the student's last date of enrollment; or —September 28, 2012.[2]
Student through CPS.	Valid ISIR (Pell Grant Only)	To the institution from the Department's CPS.	

TABLE A—DEADLINE DATES FOR APPLICATION PROCESSING AND RECEIPT OF INSTITUTIONAL STUDENT INFORMATION RECORDS (ISIRS) OR STUDENT AID REPORTS (SARS) BY INSTITUTIONS FOR THE 2011–2012 AWARD YEAR—Continued

Who submits?	What is submitted?	Where is it submitted?	What is the deadline date for receipt?
Student Student through CPS.	Valid SAR Valid ISIR	To the institution To the institution from the Department's CPS.	For a student receiving a late disbursement under 34 CFR 668.164(g)(4)(i), the earlier of: —180 days after the date of the institution's determination that the student withdrew or otherwise became ineligible; or —September 28, 2012.[2]
Student	Verification documents	To the institution	The earlier of:[3] —120 days after the student's last date of enrollment; or —September 28, 2012.[2]

[1] The deadline for electronic transactions is 11:59 p.m. (Central Time) on the deadline date. Transmissions must be completed and accepted before 12:00 midnight to meet the deadline. If transmissions are started before 12:00 midnight but are not completed until after 12:00 midnight, those transmissions do not meet the deadline. In addition, any transmission submitted on or just prior to the deadline date that is rejected may not be reprocessed because the deadline will have passed by the time the user gets the information notifying him/her of the rejection.

[2] The date the ISIR/SAR transaction was processed by CPS is considered to be the date the institution received the ISIR or SAR regardless of whether the institution has downloaded the ISIR from its SAIG mailbox or when the student submits the SAR to the institution.

[3] Although the Secretary has set this deadline date for the submission of verification documents, if corrections are required, deadline dates for submission of paper or electronic corrections and, for a Federal Pell Grant and applicants selected for verification, the submission of a valid SAR or valid ISIR to the institution must still be met. An institution may establish an earlier deadline for the submission of verification documents for purposes of the campus-based programs and the Federal Direct Loan Program, but no later than this deadline date.

TABLE B—FEDERAL PELL GRANT PROGRAM AND IRAQ AND AFGHANISTAN SERVICE GRANT PROGRAM SUBMISSION DATES FOR DISBURSEMENT INFORMATION BY INSTITUTIONS FOR THE 2011–2012 AWARD YEAR

Who submits?	What is submitted?	Where is it submitted?	What are the earliest disbursement, submission, and deadline dates for receipt?
Institutions	At least one acceptable disbursement record must be submitted for each Federal Pell Grant recipient and Iraq and Afghanistan Service Grant recipient at the institution.	For the Federal Pell Grant Program only using the Student Aid Internet Gateway (SAIG); or, for the Federal Pell Grant Program or the Iraq and Afghanistan Service Grant, to the Common Origination and Disbursement (COD) System using the COD Web site at: www.cod.ed.gov.	Earliest Disbursement Date: February 1, 2011. Earliest Submission Dates: An institution may submit anticipated disbursement information as early as February 21, 2011. An institution may submit actual disbursement information as early as February 21, 2011, but no earlier than: (a) 7 calendar days prior to the disbursement date under the advance payment method; (b) 7 calendar days prior to the disbursement date under the Cash Monitoring #1 payment method; or (c) The date of disbursement under the Reimbursement or Cash Monitoring #2 payment methods. Deadline Submission Dates: Except as provided below, an institution is required to submit disbursement information no later than the earlier of: (a) 30 calendar days after the institution makes a disbursement or becomes aware of the need to make an adjustment to previously reported disbursement data; or (b) October 1, 2012.[1] An institution may submit disbursement information after October 1, 2012, only: (a) for a downward adjustment of a previously reported award or disbursement;

TABLE B—FEDERAL PELL GRANT PROGRAM AND IRAQ AND AFGHANISTAN SERVICE GRANT PROGRAM SUBMISSION DATES FOR DISBURSEMENT INFORMATION BY INSTITUTIONS FOR THE 2011–2012 AWARD YEAR—Continued

Who submits?	What is submitted?	Where is it submitted?	What are the earliest disbursement, submission, and deadline dates for receipt?
			(b) based upon a program review or initial audit finding per 34 CFR 690.83; (c) for reporting a late disbursement under 34 CFR 668.164(g); or (d) for reporting disbursements previously blocked as a result of another institution failing to post a downward adjustment.
Institutions	Request for administrative relief based on a natural disaster or other unusual circumstances, or an administrative error made by the Department.	Via COD Web site at: www.cod.ed.gov	The earlier of: —a date designated by the Secretary after consultation with the institution; or —February 1, 2013.
Institutions	Request for administrative relief if a student reenters the institution within 180 days after initially withdrawing and the institution is reporting a disbursement for the student within 30 days of the student's reenrollment but after October 1, 2012[2].	Via COD Web site at: www.cod.ed.gov	The earlier of: —30 days after the student reenrolls; or —May 3, 2013.

[1] The deadline for electronic transactions is 11:59 p.m. (Eastern Time) on October 1, 2012. Transmissions must be completed and accepted before 12:00 midnight to meet the deadline. If transmissions are started before 12:00 midnight but are not completed until after 12:00 midnight, those transmissions will not meet the deadline. In addition, any transmission submitted on or just prior to the deadline date that is rejected may not be reprocessed because the deadline will have passed by the time the user gets the information notifying him/her of the rejection.

[2] Applies only to students enrolled in clock-hour and nonterm credit-hour educational programs.

Note: The COD System must accept origination data for a student from an institution before it accepts disbursement information from the institution for that student. Institutions may submit origination and disbursement data for a student in the same transmission. However, if the origination data is rejected, the disbursement data is rejected.

TABLE C—WILLIAM D. FORD FEDERAL DIRECT LOAN (DIRECT LOAN) PROGRAM AND TEACHER EDUCATION ASSISTANCE FOR COLLEGE AND HIGHER EDUCATION (TEACH) GRANT PROGRAM SUBMISSION DATES FOR DISBURSEMENT INFORMATION BY INSTITUTIONS FOR THE 2011–2012 COD PROCESSING YEAR[1]

Who submits?	What is submitted?	Where is it submitted?	What are the earliest submission and deadline dates for receipt?
Institutions	At least one acceptable disbursement record must be submitted for each Direct Loan and TEACH Grant recipient at the institution.	To the Student Aid Internet Gateway (SAIG) or to the Common Origination and Disbursement (COD) System using the COD Web site at: *www.cod.ed.gov*.	Earliest Disbursement Date: June 21, 2008. Earliest Submission Dates: An institution may submit anticipated disbursement information as early as February 21, 2011. An institution may submit actual disbursement information as early as February 21, 2011, but no earlier than: (a) 7 calendar days prior to the disbursement date under the advance payment method; (b) 7 calendar days prior to the disbursement date under the Cash Monitoring #1 payment method; or (c) The date of disbursement under the Reimbursement or Cash Monitoring #2 payment methods. Deadline Submission Dates:

TABLE C—WILLIAM D. FORD FEDERAL DIRECT LOAN (DIRECT LOAN) PROGRAM AND TEACHER EDUCATION ASSISTANCE FOR COLLEGE AND HIGHER EDUCATION (TEACH) GRANT PROGRAM SUBMISSION DATES FOR DISBURSEMENT INFORMATION BY INSTITUTIONS FOR THE 2011–2012 COD PROCESSING YEAR [1]—Continued

Who submits?	What is submitted?	Where is it submitted?	What are the earliest submission and deadline dates for receipt?
			An institution is required to submit disbursement information no later than 30 calendar days after the institution makes a disbursement or becomes aware of the need to make an adjustment to previously reported disbursement data.

[1] A COD Processing Year is a period of time in which institutions are permitted to submit Direct Loan and TEACH Grant records to the COD System that are related to a given award year. For a Direct Loan, the period of time includes loans that have a loan period covering any day in the 2011–2012 award year. For a TEACH Grant, the period of time includes an award for a payment period that includes any day in the 2011–2012 award year.

Note: The COD System must accept origination data for a student from an institution before it accepts disbursement information from the institution for that student. Institutions may submit origination and disbursement data for a student in the same transmission. However, if the origination data is rejected, the disbursement data is rejected.

[FR Doc. 2012–16034 Filed 6–28–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Availability of Draft Waste Incidental to Reprocessing Evaluation for the Concentrator Feed Makeup Tank and Melter Feed Hold Tank at the West Valley Demonstration Project for West Valley, NY

AGENCY: Office of Environmental Management, U.S. Department of Energy.

ACTION: Notice of availability.

SUMMARY: The Department of Energy (DOE) announces the availability of a draft evaluation which shows that the concentrator feed makeup tank and melter feed hold tank (the vessels) which were used in conjunction with vitrifying waste from reprocessing of spent nuclear fuel and certain treatment material at the West Valley Demonstration Project (WVDP), located at the Western New York Service Center in West Valley, New York, are waste incidental to reprocessing and thus are not high-level radioactive waste (HLW) and may be managed and disposed of offsite as low-level waste (LLW). DOE prepared the draft evaluation pursuant to DOE Manual 435.1–1, *Radioactive Waste Management Manual.* DOE is consulting with the Nuclear Regulatory Commission (NRC) before finalizing this evaluation. Although it is not required by DOE Manual 435.1–1, DOE is making the draft evaluation available for public and state review and comment during the NRC consultative review period. DOE will make its final evaluation and determination as to whether the vessels are HLW, or are waste incidental to reprocessing which can be managed and disposed of as LLW, after consideration of any public, state, and NRC comments on this draft evaluation.

DATES: The comment period will end August 13, 2012. Comments received after that time will be considered to the extent practicable.

ADDRESSES: The draft waste evaluation is available on the Internet at *http://www.wv.doe.gov/Document_Index/vessels.pdf*, and is publicly available for review at the following location: U.S. Department of Energy, West Valley Demonstration Project Public Reading Room located at the Ashford Office Complex, 9030 US Route 219, Ashford, NY 14171–9799, during the office hours of Monday through Thursday, 8:00 a.m.–5:00 p.m., phone: (716) 942–4601. Written comments should be submitted to: Mr. Daniel Sullivan, U.S. Department of Energy, West Valley Demonstration Project, 10282 Rock Springs Road, West Valley, New York 14171–9799. Alternatively, comments may also be filed electronically by email to *vessels@wv.doe.gov* or by fax at (716) 942–4703.

FOR FURTHER INFORMATION CONTACT: For further information about this draft waste evaluation, please contact Mr. Daniel Sullivan at the mailing address or Web site listed in **ADDRESSES**.

SUPPLEMENTARY INFORMATION: The vessels were used in the vitrification process to prepare and temporarily store pre-treated HLW slurry supplied to the vitrification melter. They were used as part of the process to solidify the HLW which had been generated by commercial reprocessing of spent nuclear fuel at the Western New York Nuclear Service Center in West Valley, New York, by Nuclear Fuel Services, Inc., from 1966 through 1972. DOE undertook the solidification activities pursuant to DOE's responsibilities under the WVDP Act. To solidify the waste, DOE vitrified the waste (combined it at a high temperature with borosilicate glass) and transferred the molten glass-waste mixture into specially developed stainless steel canisters where the mixture hardened into a solid glass waste form.

DOE operated the vitrification system between 1996 and 2002. In 2002, prior to shut down, the vessels were flushed with high pressure demineralized water so as to remove key radionuclides to the maximum extent technically and economically practical. The vessels with their remaining residual waste were characterized for radioactivity and determined to have radionuclide concentrations that do not exceed concentration limits for Class C LLW. They were removed from the vitrification cell in 2004 and are presently safely stored at the WVDP in transportation containers that meet Department of Transportation Industrial Package 2 requirements. The vessels were further stabilized by filling them with cement grout. As explained in the draft evaluation, they would be disposed of at a suitable off-site LLW waste disposal facility, either the Area 5 Radioactive Waste Management Site at DOE's Nevada National Security Site (NNSS) in Nevada or the Waste Control Specialists Federal Facility Waste Disposal Facility near Andrews, Texas. DOE would dispose of the vessel waste packages in accordance with applicable waste acceptance criteria using specific waste profile documentation.

DOE Manual 435.1–1, which implements DOE Order 435.1, *Radioactive Waste Management,* contains a rigorous evaluation process

which DOE uses to determine whether or not certain waste from the reprocessing of spent nuclear fuel is incidental to reprocessing and therefore is not HLW and can be managed as LLW. This process, in relevant part, requires demonstrating that:

(1) Key radionuclides have been removed to the maximum extent that is technically and economically practical;

(2) The waste will be managed to meet safety requirements comparable to the performance objectives set out in 10 Code of Federal Regulations (CFR) part 61, subpart C, *Performance Objectives;* and

(3) The waste will be managed, pursuant to DOE's authority under the *Atomic Energy Act of 1954,* as amended, and in accordance with the provisions of Chapter IV of DOE Manual 435.1–1*,* provided the waste will be incorporated in a solid physical form at a concentration that does not exceed the applicable concentration limits for Class C LLW as set out in 10 CFR 61.55, *Waste Classification.*

The draft waste-incidental-to-reprocessing evaluation summarizes DOE's analysis and shows that the vessels:

(1) Have had key radionuclides removed to the maximum extent technically and economically practical;

(2) Will be managed to meet safety requirements comparable to the NRC performance objectives at 10 CFR part 61, subpart C; and

(3) Will be in a solid physical form that does not exceed concentration limits for Class C LLW and will be managed and disposed of pursuant to DOE's authority under the Atomic Energy Act of 1954, as amended, and in accordance with applicable provisions of Chapter IV of DOE Manual 435.1–1.

Accordingly, the draft evaluation demonstrates using the waste-incidental-to-reprocessing evaluation process that the West Valley vessel waste packages may be managed and disposed of as LLW. The vessel waste packages will meet the applicable waste acceptance criteria for the selected offsite LLW disposal facility, either the NNSS Area 5 Radioactive Waste Management Site or the Waste Control Specialists Federal Facility Waste Disposal Facility in Texas. The vessel waste packages have been approved for disposal by the NNSS in case a final decision is made to send the waste package to that site for disposal.

DOE is consulting with the NRC before finalizing this evaluation. Although not required by DOE Manual 435.1–1, DOE is making the draft evaluation available for public and state review and comment during the NRC consultative review period. DOE plans to issue a final determination as to whether the vessels are HLW or can be managed and disposed of as LLW following review and consultation with the NRC and consideration of public and state comments.

DOE's decision on the disposal site to be used is not within the scope of this draft evaluation. Any DOE decision on the facility to which the vessel waste packages would be sent would be made after the final DOE evaluation and determination, following consideration of NRC and public comments on this draft evaluation, and after DOE confers with appropriate State officials in the state where the waste packages may be disposed.

Issued in Washington, DC, on June 20, 2012.

Frank Marcinowski,

Deputy Assistant Secretary for Waste Management, Office of Environmental Management.

[FR Doc. 2012–15986 Filed 6–28–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket Nos. 12–21–NG; 12–43–NG; 12–48–LNG]

Noble Americas Gas & Power Corp., LNG Development Company, LLC, LNG Development Company, LLC (d/b/a Oregon LNG); Notice of Orders Granting Authority To Import and Export Natural Gas and Liquefied Natural Gas During May 2012

AGENCY: Office of Fossil Energy, Department of Energy (DOE).

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during May 2012, it issued Orders granting authority to import and export natural gas and liquefied natural gas. These Orders are summarized in the attached appendix and may be found on the FE Web site at *http://www.fossil.energy.gov/programs/gasregulation/authorizations/Orders-2012.html.* They are also available for inspection and copying in the Office of Fossil Energy, Office of Natural Gas Regulatory Activities, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on June 25, 2012.

John A. Anderson,

Manager, Natural Gas Regulatory Activities, Office of Oil and Gas Global Security and Supply, Office of Fossil Energy.

APPENDIX

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

Order No.	Date Issued	FE Docket No.	Authorization Holder	Description of Action
3098	05/03/12	12–21–NG	Noble Americas Gas & Power Corp.	Order granting blanket authority to import/export natural gas from/to Canada/Mexico, and to import LNG from various international sources by vessel.
3099	05/31/12	12–43–NG	LNG Development Company, LLC.	Order granting blanket authority to import natural gas from Canada.
3100	05/31/12	12–48–LNG	LNG Development Company, LLC (d/b/a Oregon LNG).	Order granting long-term multi-contract authority to export LNG by vessel from the proposed LNG Terminal in Warrenton, Clatsop County, Oregon to Free Trade Agreement nations.

[FR Doc. 2012–16032 Filed 6–28–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Proposed Agency Information Collection

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

ACTION: Notice and request for OMB review and comment.

SUMMARY: The Department of Energy (DOE) has submitted to the Office of Management and Budget (OMB) for clearance, a proposal for collection of information under the provisions of the Paperwork Reduction Act of 1995. The proposed collection will enable a user-based evaluation of submitted entries to the Bright Tomorrow Lighting Competition (L Prize®) competition. The L Prize competition was authorized to encourage development and deployment of highly energy efficient solid-state lighting products. The proposed collection will assist in evaluating the entries in a real-world environment to insure that winning products do not exhibit undesirable or poor qualities that are not identified from formal laboratory testing by the DOE. These undesirable attributes could be a hindrance to sales of the winning product and could negatively impact the energy reduction potential of the competition. Additionally, the DOE wishes to gauge program success by periodically obtaining quantitative data about the effectiveness of the promotions and campaigns which are directly tied to L Prize winners. The quantitative data will be a survey asking five qualitative questions about the occupant's overall satisfaction of the lights. The brief assessments will be collected by the site's partner sponsor and returned, along with the entrant lamps, to DOE at the conclusion of the field assessment.

DATES: Comments regarding this collection must be received on or before July 30, 2012. 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, please advise the DOE Desk Officer at OMB of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4650.

ADDRESSES: Written comments should be sent to the DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW., Washington, DC 20503.

And to

James R. Brodrick, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585 or by email at *James.Brodrick@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: James R. Brodrick, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585 or by email at *James.Brodrick@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. New; (2) Information Collection Request Title: Bright Tomorrow Lighting Competition (L Prize®): Field Assessment and Post Prize Monitoring; (3) Type of Request: New collection; (4) Purpose: The Bright Tomorrow Lighting Competition was authorized in the Energy Independence and Security Act of 2007 (EISA), Subtitle E, Section 655, to encourage development and deployment of highly energy efficient solid-state lighting (SSL) products to replace several of the most common lighting products currently used in the United States. Field assessments contribute to the evaluation of L Prize entries in a wide range of lighting applications.

The field assessments evaluate energy use of the installed product, the lighting system performance compared to the existing technology, and user feedback. The objective of field testing is to obtain installation data and user acceptance, in order to evaluate the product and determine its potential to be declared a winner. Additionally, DOE plans to monitor the impact of the L Prize competition through post-prize monitoring of incentive programs, educational campaigns, and retail promotions. This monitoring will include measuring the number of customers reached, bulbs sold, energy savings, and other tangible benefits.; (5) Annual Estimated Number of Respondents: 526; (6) Annual Estimated Number of Total Responses: 526; (7) Annual Estimated Number of Burden Hours: 115; (8) Response Obligation: Voluntary. (9) Annual Estimated Reporting and Recordkeeping Cost Burden: $0.

Statutory Authority: 42 U.S.C. 17243.

Issued in Washington, DC on June 25, 2012.

Kathleen B. Hogan,

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

[FR Doc. 2012–15984 Filed 6–28–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–1645–001.
Applicants: ITC Midwest LLC.
Description: Withdrawal of Agreement to be effective 7/1/2012.
Filed Date: 6/20/12.
Accession Number: 20120620–5042.
Comments Due: 5 p.m. ET 7/11/12.

Docket Numbers: ER12–2071–000.
Applicants: Verde Energy USA New York, LLC.
Description: MBR Application to be effective 8/20/2012.
Filed Date: 6/20/12.
Accession Number: 20120620–5033.
Comments Due: 5 p.m. ET 7/11/12.

Docket Numbers: ER12–2072–000.
Applicants: Michigan Electric Transmission Company, LLC.
Description: Filing of Amended and Restated Interconnection Agreement to be effective 6/21/2012.
Filed Date: 6/20/12.
Accession Number: 20120620–5039.
Comments Due: 5 p.m. ET 7/11/12.

Docket Numbers: ER12–2073–000.
Applicants: Public Service Company of Colorado.
Description: 2012–6–20_321–PSCo_HLYCRS_CAA to be effective 4/11/2012.
Filed Date: 6/20/12.
Accession Number: 20120620–5086.
Comments Due: 5 p.m. ET 7/11/12.

Docket Numbers: ER12–2074–000.
Applicants: The Connecticut Light and Power Company.
Description: United Illuminating 2012 O&M Agreement to be effective 12/31/9998.
Filed Date: 6/20/12.
Accession Number: 20120620–5093.
Comments Due: 5 p.m. ET 7/11/12.

Docket Numbers: ER12–2075–000.
Applicants: Atlantic Renewable Projects II LLC.
Description: Tariff Revisions to be effective 6/30/2012.
Filed Date: 6/20/12.
Accession Number: 20120620–5115.
Comments Due: 5 p.m. ET 7/11/12.

Docket Numbers: ER12–2076–000.
Applicants: Barton Windpower LLC.
Description: Tariff Revisions to be effective 6/30/2012.
Filed Date: 6/20/12.
Accession Number: 20120620–5116.
Comments Due: 5 p.m. ET 7/11/12.

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: June 21, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–15945 Filed 6–28–12; 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: ER11–4044–004.

Applicants: Gratiot County Wind, LLC.

Description: Change in Status Notice of Gratiot County Wind, LLC.

Filed Date: 6/22/12.

Accession Number: 20120622–5084.

Comments Due: 5 p.m. ET 7/13/12.

Docket Numbers: ER12–2090–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc.'s Notice of Cancellation.

Filed Date: 6/22/12.

Accession Number: 20120622–5091.

Comments Due: 5 p.m. ET 7/13/12.

Docket Numbers: ER12–2091–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc.'s Notice of Cancellation.

Filed Date: 6/22/12.

Accession Number: 20120622–5099.

Comments Due: 5 p.m. ET 7/13/12.

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 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: June 22, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–15947 Filed 6–28–12; 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: EC12–113–000.

Applicants: Ingenco Wholesale Power, L.L.C.

Description: Section 203 Application of Ingenco Wholesale Power, L.L.C.

Filed Date: 6/21/12.

Accession Number: 20120621–5136.

Comments Due: 5 p.m. ET 7/12/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2860–002.

Applicants: TC Ravenswood, LLC.

Description: Market-Based Sale of Capacity, Energy and Ancillary Services to be effective 11/22/2010.

Filed Date: 6/21/12.

Accession Number: 20120621–5110.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2051–001.

Applicants: SPS Alpaugh 50, LLC.

Description: Amended Application for Market-Based Rate Authority to be effective 8/20/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5133.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2052–001.

Applicants: SPS Alpaugh North, LLC.

Description: Amended Application for Market-Based Rate Authority to be effective 8/20/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5139.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2077–000.

Applicants: Buffalo Ridge I LLC.

Description: Tariff Revisions to be effective 6/30/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5000.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2078–000.

Applicants: Buffalo Ridge II LLC.

Description: Tariff Revisions to be effective 6/30/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5001.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2079–000.

Applicants: El Paso Electric Company.

Description: Arlington Valley Solar I IA to be effective 5/24/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5094.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2080–000.

Applicants: Genon Power Midwest, LP.

Description: Revised Rate Schedule FERC No. 2 to be effective 9/1/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5096.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2081–000.

Applicants: Elm Creek Wind, LLC.

Description: Tariff Revisions to be effective 6/30/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5104.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2082–000.

Applicants: Arizona Public Service Company.

Description: Palo Verde Bay 10 Construction Agreement to be effective 8/30/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5105.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2083–000.

Applicants: Elm Creek Wind II LLC.

Description: Tariff Revisions to be effective 6/30/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5109.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2084–000.

Applicants: Farmers City Wind, LLC.

Description: Tariff Revisions to be effective 6/30/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5112.

Comments Due: 5 p.m. ET 7/12/12.

Docket Numbers: ER12–2085–000.

Applicants: PJM Interconnection, L.L.C.

Description: Amendments to Schedule 12–Appendix re RTEP approved by PJM Board May 17, 2012 to be effective 9/19/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5143.

Comments Due: 5 p.m. ET 7/23/12.

Docket Numbers: ER12–2086–000.

Applicants: Flying Cloud Power Partners, LLC.

Description: Tariff Revisions to be effective 6/30/2012.

Filed Date: 6/21/12.

Accession Number: 20120621–5144.

Comments Due: 5 p.m. ET 7/12/12.

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: June 22, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–15946 Filed 6–28–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL12–77–000]

Grand Valley Rural Power Lines, Inc., Yampa Valley Electric Association, Inc., Intermountain Rural Electric Association, Tri-State Generation and Transmission Association, Inc. v. Public Service Company of Colorado; Notice of Complaint

Take notice that on June 21, 2012, pursuant to sections 201, 206, and 306 of the Federal Power Act; 16 U.S.C. 824, 824(e) and 825 (2010) and Rules 206 and 212 of the Rules of Practice and Procedure of the Federal Energy Regulatory Commission (Commission); 18 CFR 385.206 and 385.212 (2011), Grand Valley Rural Power Lines, Inc., Yampa Valley Electric Association, Inc., Intermountain Rural Electric Association, and Tri-State Generation and Transmission Association, Inc. (collectively, Complainants) filed a formal complaint against the Public Service Company of Colorado (Respondent), alleging that the 10.25 percent ''Return on Equity'' assessed by the Respondent in the formula rate is unjust and unreasonable.

The Complainants state that a copy of the Complaint has been served on the contact for the Respondent as listed on the Commission list of Corporate Officials.

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. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

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 July 11, 2012.

Dated: June 25, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–15974 Filed 6–28–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP12–469–000]

Northern Natural Gas Company; Notice of Intent To Prepare an Environmental Assessment for the Proposed A-Line Abandonment Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the A-Line Abandonment Project (Project) which would include the abandonment of facilities by Northern Natural Gas Company (Northern) in Ochiltree, Hansford, Hutchinson, and Carson Counties, Texas; Beaver County, Oklahoma; and Kiowa and Clark Counties, Kansas. This EA will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. Your input will help the Commission staff determine what issues need to be evaluated in the EA. Please note that the scoping period will close on July 25, 2012. Further details on how to submit written comments are provided in the Public Participation section of this notice.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives are asked to notify their constituents of this planned project and encourage them to comment on their areas of concern.

Summary of the Proposed Project

Northern proposes to abandon in by sale to DKM Enterprises, LLC (DKM) for salvage about 126 miles of its A-line consisting of two segments of 24-inch-diameter pipeline. One segment (the Skellytown to Spearman A-line) is about 38 miles long and extends from Northern's abandoned Skellytown Station near Skellytown, Carson County, Texas, to Northern's Spearman Compressor Station in Spearman, Ochiltree County, Texas. The second segment (the Beaver to Mullinville A-line) is about 88 miles long and extends from Northern's Beaver Compressor Station near Beaver, Oklahoma, to its Mullinville Compressor Station near Mullinville, Kansas. Activities Northern would conduct related to the

abandonment would include disconnecting the abandoned A-line from its other facilities that would be retained by cutting and capping the pipeline at valve settings or compressor stations at eight locations. After abandonment of the subject A-line by sale to DKM, DKM would salvage the 126 miles of pipeline subject to the terms of its purchase and sales agreement with Northern and applicable regulations and permits.

The general locations of the project facilities are shown in the maps in Appendix 1.[1]

Land Requirements for Construction

Northern proposes abandoning these facilities by sale to DKM and states that all of its abandonment and DKM's salvage activities would be conducted within Northern's existing right-of-way which Northern would retain. Therefore, there would be no new land use requirements.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping''. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. All comments received will be considered during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the proposed abandonment project under these general headings:

- Land use;
- Water resources, fisheries, and wetlands;
- Cultural resources;
- Vegetation and wildlife;
- Endangered and threatened species;
- Public safety; and
- Cumulative impact.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through the Commission's eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before we make our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section beginning on page 4.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this project to formally cooperate with us in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations, we are using this notice to solicit the views of the public on the project's potential effects on historic properties.[4] We will document our findings on the impacts on cultural resources and summarize the status of consultations under section 106 of the National Historic Preservation Act in our EA.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. 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 your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC, on or before July 25, 2012.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the project docket number (CP12–469–000) with your submission. The Commission encourages electronic filing of comments and has expert eFiling staff available to assist you at (202) 502–8258 or *efiling@ferc.gov*.

(1) You can file your comments electronically using the eComment feature located on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the eFiling feature located 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 may file a paper copy of your comments at the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned project. If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you wish to receive no further mailings

[1] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] ''We'', ''us'', and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are found at title 40 of the Code of Federal Regulations, part 1501.6.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Historic properties are defined in those regulations as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register for Historic Places.

concerning environmental review of Northern's A-Line Abandonment Project, please use the return mailer attached as appendix 2 to notify us and you will be deleted from the environmental mailing list.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the ''e-filing'' link on the Commission's Web site.

Additional Information

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., CP12–469–000). 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.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: June 25, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–15973 Filed 6–28–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL12–78–000]

Gerry E. Greenfield Jr. v. *Benton County, WA;* Notice of Petition To Enforce PURPA

Take notice that on June 21, 2012, pursuant to section 210(h) of the Public Utility Regulatory Policies Act of 1978 (PURPA),[1] Gerry E. Greenfield Jr. filed a petition requesting that the Federal Energy Regulatory Commission (Commission) initiate enforcement action against Benton County, Washington, regarding the operation of a 25 KW Net Metering 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 p.m. Eastern Time on July 12, 2012.

[1] 16 U.S.C. 824a–3(h) (2006).

Dated: June 25, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–15972 Filed 6–28–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14426–000]

Dolores Water Conservancy District; Notice of Competing Preliminary Permit Application Accepted for Filing and Soliciting Comments and Motions To Intervene

On May 10, 2012, Dolores Water Conservancy District, Colorado, filed an application, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Plateau Creek Pumped Storage Project to be located on Plateau Creek, near the town of Dolores, Montezuma County, Colorado. The project affects federal lands administered by the Forest Service (San Juan National Forest). All filings submitted pursuant to the original June 6, 2012 notice will continue to be considered and do not need to be resubmitted.

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 new facilities: (1) An upper reservoir, formed by a 130-foot-high by 6,500-foot-long, roller-compacted concrete (RCC) or embankment dam, with a total storage capacity of 8,000 acre-feet and a water surface area of 275 acres at full pool elevation; (2) a lower reservoir, formed by a 270-foot-high by 800-foot-long dam, having a total storage capacity of 9,500 acre-feet and a water surface area of 200 acres at full pool elevation; (3) two 15-foot-diameter steel penstocks consisting of a surface penstock, a vertical shaft, and an inclined tunnel; (4) two 27-foot-diameter tailrace tunnels that would be 850-feet-long; (5) an underground powerhouse containing two reversible pump-turbines totaling 500 megawatts (MW) (2 units × 250 MW) of generating capacity; and (6) a 7-mile-long, 230 kilovolt (kV) transmission line that would connect the switchyard with an existing 230 kV interconnection east of the project area. The project's annual

energy output would vary between 600 and 1,500 gigawatthours.

Applicant Contact: Mr. Kenneth W. Curtis III, Dolores Water Conservancy District, 60 S. Cactus, P.O. Box 1150, Cortez, CO 81321; phone (970) 565–7562.

FERC Contact: Brian Csernak; phone: (202) 502–6144.

Competing Application: This application competes with Project No. 14328 filed December 1, 2011. Competing applications had to be filed on or before May 14, 2012.

Deadline for filing comments and motions to intervene: 60 days from the issuance of this notice. Comments and motions to intervene 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 the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14426) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: June 25, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–15969 Filed 6–28–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 485–063—Georgia and Alabama]

Georgia Power Company; Bartletts Ferry Hydroelectric Project; Notice of Revised Restricted Service List for a Programmatic Agreement

Rule 2010 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.2010, provides that, to eliminate unnecessary expense or improve administrative efficiency, the Secretary may establish a restricted service list for a particular phase or issue in a proceeding. The restricted service list should contain the names of persons on the service list who, in the judgment of the decisional authority establishing the list, are active participants with respect to the phase or issue in the proceeding for which the list is established.

The Commission staff is consulting with the Georgia State Historic Preservation Officer (SHPO), the Alabama SHPO, and the Advisory Council on Historic Preservation (Advisory Council) pursuant to the Advisory Council's regulations, 36 CFR part 800, implementing section 106 of the National Historic Preservation Act, *as amended,* (16 U.S.C. section 470f), to prepare a programmatic agreement for managing properties included in, or eligible for inclusion in, the National Register of Historic Places that could be affected by issuance of a new license for the Bartletts Ferry Hydroelectric Project No. 485.

The programmatic agreement, when executed by the Commission, the Georgia SHPO, the Alabama SHPO, and the Advisory Council would satisfy the Commission's section 106 responsibilities for all individual undertakings carried out in accordance with the license until the license expires or is terminated (36 CFR section 800.13(e)).

On April 28, 2011, the Commission staff established a restricted service list for the Bartletts Ferry Hydroelectric Project. On June 14, 2012, the Kialegee Tribal Town requested a revision to the restricted service list. The revision is:

''Henry Harjo'' is replaced with ''Kelly Davis or Representative.''

On June 14 and June 19, 2012, the Alabama-Quassarte Tribal Town and the United Keetoowah Band of Cherokee Indians in Oklahoma, respectively, requested to be added to the restricted service list. The restricted service list is supplemented to include:

''Augustine Asbury or Representative, Alabama-Quassarte Tribal Town, P.O. Box 187, Wetumka, OK 74883;''

''Lisa LaRue-Baker, Acting THPO, or Representative, United Keetoowah Band of Cherokee Indians in Oklahoma, P.O. Box 748, Tahlequah, OK 74465.''

Dated: June 25, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–15970 Filed 6–28–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2203–013—Alabama]

Alabama Power Company; Holt Hydroelectric Project; Notice of Revised Restricted Service List for a Programmatic Agreement

Rule 2010 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR section 385.2010, provides that, to eliminate unnecessary expense or improve administrative efficiency, the Secretary may establish a restricted service list for a particular phase or issue in a proceeding. The restricted service list should contain the names of persons on the service list who, in the judgment of the decisional authority establishing the list, are active participants with respect to the phase or issue in the proceeding for which the list is established.

The Commission staff is consulting with the Alabama State Historic Preservation Officer (Alabama SHPO) and the Advisory Council on Historic Preservation (Advisory Council) pursuant to the Advisory Council's regulations, 36 CFR part 800, implementing section 106 of the National Historic Preservation Act, *as amende*d, (16 U.S.C. section 470f), to prepare a programmatic agreement for managing properties included in, or eligible for inclusion in, the National Register of Historic Places that could be affected by issuance of a new license for the Holt Hydroelectric Project No. 2203.

The programmatic agreement, when executed by the Commission, the Alabama SHPO, and the Advisory Council, would satisfy the Commission's section 106 responsibilities for all individual undertakings carried out in accordance with the license until the license expires or is terminated (36 CFR section 800.13(e)). On August 30, 2011, the Commission staff established a

restricted service list for the Holt Hydroelectric Project.

On June 21, 2012, the Choctaw Nation of Oklahoma requested a revision to the restricted service list. The revision is: ''Terry Cole, THPO'' is replaced with ''Dr. Ian Thompson, THPO, or Representative''.

Dated: June 25, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–15971 Filed 6–28–12; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R01–OW–2012–0201, FRL–9695–8]

Massachusetts Marine Sanitation Device Standard—Notice of Determination

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Determination.

SUMMARY: The Regional Administrator of the Environmental Protection Agency—New England Region, has determined that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the state waters of Vineyard and Nantucket Sounds and the Islands collectively termed Southern Cape Cod.

ADDRESSES: *Docket:* All documents in the docket are listed in the *www.regulations.gov index.* Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ann Rodney, U.S. Environmental Protection Agency—New England Region, Office of Ecosystem Protection, Oceans and Coastal Protection Unit, Five Post Office Square, Suite 100, OEP06–1, Boston, MA 02109–3912. Telephone: (617) 918–1538. Fax number: (617) 918–0538. Email address: *rodney.ann@epa.gov.*

SUPPLEMENTARY INFORMATION: On April 26, 2012, EPA published a notice that the Commonwealth of Massachusetts had petitioned the Regional Administrator, Environmental Protection Agency, to determine that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the waters of Southern Cape Cod. Eight comments were received on this petition and all endorsed this designation. The response to comments can be obtained using the above contact information.

The petition was filed pursuant to Section 312(f)(3) of Public Law 92–500, as amended by Public Laws 95–217 and 100–4, for the purpose of declaring these waters a No Discharge Area (NDA).

Section 312(f)(3) states: After the effective date of the initial standards and regulations promulgated under this section, if any State determines that the protection and enhancement of the quality of some or all of the waters within such State require greater environmental protection, such State may completely prohibit the discharge from all vessels of any sewage, whether treated or not, into such waters, except that no such prohibition shall apply until the Administrator determines that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for such water to which such prohibition would apply.

This Notice of Determination is for the waters of Southern Cape Cod. The NDA boundaries are as follows:

Waterbody/general area	Latitude	Longitude
West of the Elizabeth Islands	41°24′35.11″ N	70°56′54.62″ W
West of the Elizabeth Islands	41°22′30.32″ N	70°59′51.57″ W
West of the Elizabeth Islands	41°24′17.81″ N	71°02′06.69″ W

The upper-eastern area of the NDA is bound by the Outer Cape NDA:

Waterbody/general area	Latitude	Longitude
South of Monomoy Island	41°32′29.79″ N	70°00′36.28″ W
South of Monomoy Island	41°29′14.59″ N	70°00′10.93″ W

The small triangle of Commonwealth waters at the mouth of Buzzards Bay will be bound by the following coordinates along the Federal/State boundary line:

Waterbody/general area	Latitude	Longitude
Mouth of Buzzards Bay	41°24′50.40″ N	71°02′48.61″ W
Mouth of Buzzards Bay	41°25′25.66″ N	71°03′31.78″ W
Mouth of Buzzards Bay	41°25′18.57″ N	71°04′18.47″ W

The two temporarily undesignated areas will be bound by the following coordinates:

Area 1:

Waterbody/general area	Latitude	Longitude
Vineyard Sound	41°30′33.61″ N	70°40′06.67″ W

Waterbody/general area	Latitude	Longitude
Vineyard Sound	41°30′49.20″ N	70°39′19.65″ W
Vineyard Sound	41°30′59.29″ N	70°39′02.76″ W
Vineyard Sound	41°30′03.08″ N	70°33′54.78″ W
Vineyard Sound	41°28′22.57″ N	70°33′27.72″ W
Vineyard Sound	41°28′44.74″ N	70°35′18.74″ W
Vineyard Sound	41°29′08.60″ N	70°35′32.38″ W

Area 2:

Waterbody/general area	Latitude	Longitude
Nantucket Sound	41°34′27.90″ N	70°16′48.99″ W
Nantucket Sound	41°34′27.90″ N	70°15′00.99″ W
Nantucket Sound	41°33′20.36″ N	70°14′39.33″ W
Nantucket Sound	41°31′41.73″ N	70°12′27.06″ W
Nantucket Sound	41°31′07.88″ N	70°15′32.25″ W

The boundaries were chosen to maximize the area designated, give larger vessels a temporary window in which to comply with this proposed regulation, and generally represent all navigational waters. The Southern Cape Cod NDA will encompass the state waters of Vineyard and Nantucket Sounds and the Islands.

The information submitted to EPA by the Commonwealth of Massachusetts certifies that there are 29 pumpout facilities available to the boating public. The location, contact information, hours of operation, and water depth are provided at the end of this notice.

Based on the examination of the petition and its supporting documentation, and information from site visits conducted by EPA New England staff, EPA has determined that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the area covered under this determination.

This determination is made pursuant to Section 312(f)(3) of Public Law 92–500, as amended by Public laws 95–217 and 100–4.

PUMPOUT FACILITIES WITHIN PROPOSED NO DISCHARGE AREA

Name	Location	Contact information	Hours of operation	Depth (ft)
Menemsha Harbor	Chilmark	508–645–2846, VHF 9,16	8 a.m.–4 p.m.	4
Vineyard Haven Harbor/Tashmoo Pond	Tisbury	508–696–4249, VHF 9	9 a.m.–4 p.m.	NA
Tisbury Wharf Co.	144 Beach Road, P.O. Box 1317, Tisbury	508–693–9300, VFH 9	9 a.m.–4 p.m.	4
Oak Bluffs Harbor	Oak Bluffs	508–693–4355, VHF 71	9 a.m.–4 p.m.	NA
Oak Bluffs Harbor Marina	Box 1327, Oak Bluffs	508–693–4355, VHF 71	9 a.m.–4 p.m.	6
Edgartown Marina	1 Morse Street Edgartown	508–627–4746, VHF 9, 74	8 a.m.–4 p.m.	6
Edgartown Harbor	1 Morse Street Edgartown	508–627–4746, VHF 9, 74	8 a.m.–4 p.m.	NA
Falmouth Marine Inner Harbor	278 Scranton Avenue, Falmouth	508–548–4600, VHF 9, 16	9 a.m.–5 p.m.	6
McDougall's Inner Harbor	145 Falmouth Heights Road, Falmouth	508–548–3146, VHF 9, 16	9 a.m.–5 p.m.	NA
Falmouth Town Dock	Falmouth	508–457–2550, VHF 9, 16	9 a.m.–5 p.m.	6
Green Pond Marina	70 Green Harbor Road, East Falmouth	508–457–9283, VHF 9, 16	9 a.m.–4 p.m.	3
Bosun's Marine	1209 East Falmouth Highway, Route 28, Falmouth.	508–548–2216, VHF 9, 16	9 a.m.–4 p.m.	3
Waquoit Bay/Inner Harbor	Falmouth	508–457–2550, VHF 9, 16	9 a.m.–5 p.m.	NA
Popponessett Bay	Mashpee	508–539–1450, VHF 9, 16	9 a.m.–4 p.m.	NA
Oyster Harbor Marine	122 Bridge Street, Osterville	508–428–2017, VHF 9, 79	9 a.m.–4 p.m.	6
Crosby Yacht Yard	72 Crosby Circle Osterville, MA	508–428–6900 VHF 9	9 a.m.–5 p.m.	6
Centerville Harbor/3 Bays	Barnstable	508–790–6273, VHF 9, 16	9 a.m.–4 p.m.	NA

PUMPOUT FACILITIES WITHIN PROPOSED NO DISCHARGE AREA—Continued

Name	Location	Contact information	Hours of operation	Depth (ft)
Bismore Park (Hyannis)	180 Ocean Street Hyannis	508–790–6273, VHF, 9, 16	9 a.m.–5 p.m.	6
Hyannis Marine	1 Willow Street, Hyannis	508–790–4000, VHF 9, 72	9 a.m.–5 p.m.	6
Lewis Bay/Hyannis Harbor/Bass River	Yarmouth	508–760–4800, VHF 66	9 a.m.–4 p.m.	NA
Bass River	Packet Landing, Water Street. Yarmouth	508–760–4800, VHF 66	9 a.m.–4 p.m.	3
Bass River Marina	140 Main Street, West Dennis	508–394–8341, VHF 71	8 a.m.–5 p.m.	3
Saquatucket, Allen & Wychmere Harbors (Within existing NDA).	Harwich	508–430–7532, VHF 68	9:30 a.m.–3:30 p.m.	NA
Saquatucket, fuel dock (Within existing NDA).	Harwich	508–430–7532, VHF 68	9 a.m.–5 p.m.	5
Stage Harbor (Within existing NDA)	Chatham	508–945–5185, VHF 16, 66	7 a.m.–6 p.m.	5.5
Madaket Marine (Within Existing NDA)	Nantucket	508–228–1163, VHF 9, 16	9 a.m.–5 p.m.	3
Nantucket Boat Basin (Within Existing NDA).	Nantucket	508–325–1350, VHF 9, 11	9 a.m.–5 p.m.	6
Nantucket Harbor (Within Existing NDA)	Nantucket	508–228–7261, VHF 9, 14	9 a.m.–4 p.m.	6
Nantucket Harbor (Within Existing NDA)	Nantucket	508–228–7261, VHF 9, 14	9 a.m.–4 p.m.	NA

Dated: June 20, 2012.

H. Curtis Spalding,

Regional Administrator, New England Region.

[FR Doc. 2012–16057 Filed 6–28–12; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

[Docket ID No. EPA–HQ–ORD–2012–0459; FRL–9695–1]

Draft Toxicological Review of 1,2,3-, 1,2,4-, and 1,3,5-Trimethylbenzene: In Support of the Summary Information in the Integrated Risk Information System (IRIS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period and listening session.

SUMMARY: EPA is announcing a 60-day public comment period and a public listening session for the external review draft human health assessment titled ''Toxicological Review of 1,2,3-, 1,2,4-, and 1,3,5-Trimethylbenzene: In Support of Summary Information on the Integrated Risk Information System (IRIS)'' (EPA/635/R–11/012A). The draft assessment was prepared by the National Center for Environmental Assessment (NCEA) within the EPA Office of Research and Development (ORD). EPA is releasing this draft assessment for the purposes of public comment and peer review. This draft assessment is not final as described in EPA's information quality guidelines, and it does not represent and should not be construed to represent Agency policy or views.

EPA's Science Advisory Board (SAB) will convene an expert panel for independent external peer review of the draft assessment. The EPA SAB is a body established under the Federal Advisory Committee Act with a broad mandate to advise the Agency on scientific matters. The public comment period and the SAB peer review are separate processes that provide opportunities for all interested parties to comment on the document. The SAB will schedule one or more public peer review meetings, which will be announced in the **Federal Register** at a later date.

EPA is also announcing a listening session to be held on Wednesday, August 1, 2012, during the public comment period. The purpose of the listening session is to allow all interested parties to present scientific and technical comments on the draft IRIS health assessment to EPA and other interested parties attending the listening session. EPA welcomes the scientific and technical comments that will be provided to the Agency by the listening session participants. The comments will be considered by the Agency as it revises the draft assessment after the independent external peer review.

DATES: The public comment period begins, June 29, 2012, and ends August 28, 2012. Technical comments should be in writing and must be received by EPA by August 28, 2012.

The listening session on the draft IRIS health assessment for 1,2,3-, 1,2,4-, and 1,3,5-Trimethylbenzene (TMB) will be held on August 1, 2012, beginning at 9 a.m. and ending at 4 p.m., Eastern Time, or when the last presentation has been completed. If you would like to make a presentation at the listening session, you should register by July 25, 2012, following the detailed instructions below under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The draft ''Toxicological Review of 1,2,3-, 1,2,4-, and 1,3,5-Trimethylbenzene: In Support of Summary Information on the Integrated Risk Information System (IRIS)'' is available primarily via the Internet on the NCEA home page under the Recent Additions and Publications menus at *http://www.epa.gov/ncea.* A limited number of paper copies are available from the Information Management Team, NCEA; telephone: 703–347–8561; facsimile: 703–347–8691. If you request a paper copy, please provide your name, mailing address, and the document title.

The listening session on the draft assessment of TMB will be held at the EPA offices at Two Potomac Yard (North Building), 7th Floor, Room 7100, 2733 South Crystal Drive, Arlington, Virginia, 22202. There are two buildings at Potomac Yard, please be sure you go to Building Two, the North Building. Please note that to gain entrance to this EPA building, attendees must register at

the guard's desk in the lobby and present photo identification. The guard will retain your photo identification and provide you with a visitor's badge. At the guard's desk, attendees should give the name Christine Ross and the telephone number, 703–347–8592, to the guard on duty. The guard will contact Ms. Ross who will meet you in the reception area to escort you to the meeting room. When you leave the building, please return your visitor's badge to the guard and you will receive your photo identification.

A teleconference line will also be available for registered attendees/speakers. The teleconference number is 866–299–3188 and the access code is 926–378–7897, followed by the pound sign (#). The teleconference line will be activated at 8:45 a.m., and you will be asked to identify yourself and your affiliation at the beginning of the call.

Information on Services for Individuals with Disabilities: EPA welcomes public attendance at the TMB Listening Session and will make every effort to accommodate persons with disabilities. For information on access or services for individuals with disabilities, please contact Christine Ross at 703–347–8592 or *IRISListeningSession@epa.gov*. To request accommodation of a disability, please contact Ms. Ross, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

SUPPLEMENTARY INFORMATION:

I. Information about IRIS

IRIS is a database that contains potential adverse human health effects information that may result from chronic (or lifetime) exposure to specific chemical substances found in the environment. The database (available on the Internet at *http://www.epa.gov/iris*) contains qualitative and quantitative health effects information for more than 540 chemical substances that may be used to support the first two steps (hazard identification and dose-response evaluation) of a risk assessment process. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Combined with specific exposure information, IRIS data are used by government and private entities to help characterize public health risks of chemical substances in site-specific situations and thereby support risk management decisions designed to protect public health.

II. How To Register for the Listening Session

To attend the August 1, 2012, listening session, register by July 25, 2012, by sending an email to *IRISListeningSession@epa.gov* (subject line: TMB Listening Session); by calling Christine Ross at 703–347–8592; or by faxing a registration request to 703–347–8689. Please reference the ''TMB Listening Session'' and include your name, title, affiliation, sponsoring organization, if any, full address, and contact information. To present at the listening session, indicate in your registration that you would like to make oral comments and provide the length of your presentation. When you register, please indicate if you will need audio-visual aid (e.g., lap top and slide projector). In general, each presentation should be no more than 30 minutes. If, however, there are more requests for presentations than the allotted time allows, then the time limit for each presentation will be adjusted. A copy of the agenda for the listening session will be available at the meeting. If no speakers have registered by July 25, 2012, the listening session will be cancelled and EPA will notify those registered of the cancellation.

III. How To Submit Technical Comments to the Docket at *http://www.regulations.gov*

Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2012–0459 by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: ORD.Docket@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* Office of Environmental Information (OEI) Docket (Mail Code: 28221T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460. The phone number is 202–566–1752.
- *Hand Delivery:* The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center's 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. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by mail or hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions for submitting comments to the EPA Docket: Direct your comments to Docket ID No. EPA–HQ–ORD–2012–0459. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *http://www.regulations.gov,* including any personal information provided, unless a 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 *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

FOR FURTHER INFORMATION CONTACT: For information on the federal docket, contact the Office of Environmental Information Docket; telephone: 202–566–1752; facsimile: 202–566–9744; or email: *ORD.Docket@epa.gov.*

For information on the public listening session, please contact Christine Ross, IRIS Staff, National Center for Environmental Assessment, (8601P), U.S. EPA, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: 703–347–8592; facsimile: 703–347–8689; or email: *IRISListeningSession@epa.gov.*

If you have questions about the document, contact Allen Davis, National Center for Environmental Assessment (NCEA); telephone: 919–541–3789; facsimile: 919–541–0245; or email: *[FRN_Questions@epa.gov].*

Dated: June 12, 2012.

Darrell A. Winner,

Director, National Center for Environmental Assessment.

[FR Doc. 2012–16027 Filed 6–28–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9003–7]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/*

Weekly receipt of Environmental Impact Statements

Filed 06/18/2012 Through 06/22/2012 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

SUPPLEMENTARY INFORMATION: EPA is seeking agencies to participate in its e-NEPA electronic EIS submission pilot. Participating agencies can fulfill all requirements for EIS filing, eliminating the need to submit paper copies to EPA Headquarters, by filing documents online and providing feedback on the process. To participate in the pilot, register at: *https://cdx.epa.gov.*

EIS No. 20120197, Draft EIS, USFS, ID, Golden Hand No. 1 and No. 2 Lode Mining Claims Project, Krassel Ranger District, Payette National Forest, Valley and Idaho Counties, ID, Comment Period Ends: 08/13/2012, Contact: Jeff Hunteman 208–634–0434.

EIS No. 20120198, Draft EIS, FHWA, TX, Grand Parkway (State Highway 99) Segment B, Construction, from SH–288 to IH–45, USACE Section 404 Permit, Brazoria and Galveston Counties, TX, Comment Period Ends: 09/26/2012, Contact: Gregory Punske 512–536–5960.

EIS No. 20120199, Final EIS, RUS, MS, ADOPTION—Kemper County Integrated Gasification Combined Cycle Project, To Provide Financial Assistance, Kemper County, MS, Review Period Ends: 07/30/2012, Contact: Emily Orler 202–720–1414.

EIS No. 20120200, Final EIS, USFS, MT, Stillwater Mining Reused Water Management Plans and Boe Ranch LAD, USACE Section 404 Permit, Beartooth Ranger District, Stillwater County, MT, Review Period Ends: 07/30/2012, Contact: Pat Pierson 406–255–1441.

EIS No. 20120201, Draft Supplement, USACE, IN, Indianapolis North Flood Damage Reduction, Modifications to Project Features and Realignment of the South Warfleigh Section, Marion County, IN, Comment Period Ends: 08/13/2012, Contact: Michael Turner 502–315–6900.

EIS No. 20120202, Final EIS, FAA, NM, Taos Regional Airport Layout Plan, Improvements, Construction and Operation of Various Improvements, Town of Taos, Taos County, NM, Review Period Ends: 07/30/2012, Contact: Dean McMath 817–222–5617.

EIS No. 20120203, Final EIS, BLM, WY, Visual Resource Management (VRM) Plan, Amendment, Class Designation, Carbon County, WY, Review Period Ends: 07/30/2012, Contact: Pamela Murdock 307–775–6259.

EIS No. 20120204, Final EIS, BLM, WY, Chokecherry and Sierra Madre Wind Energy Project, Development of a Wind Farm, Carbon County, WY, Review Period Ends: 07/30/2012, Contact: Pamela Murdock 307–775–6259.

EIS No. 20120205, Draft EIS, BLM, CA, Alta East Wind Project, Development of a 318-megawatt Wind Energy Facility, Kern County, CA, Comment Period Ends: 09/26/2012, Contact: Jeffery Childers 951–697–5308.

EIS No. 20120206, Final EIS, NPS, AK, Denali Park Road Final Vehicle Management Plan, Implementation, Denali National Park and Preserve, AK, Review Period Ends: 07/30/2012, Contact: Miriam Valentine 907–733–9102.

EIS No. 20120207, Final EIS, USACE, LA, Mississippi River Gulf Outlet Ecosystem Restoration, To Develop a Comprehensive Ecosystem Restoration Plan to Restore the Lake Borgne Ecosystems, LA and MS, Review Period Ends: 07/30/2012, Contact: Tammy Gilmore 504–862–1002.

EIS No. 20120208, Final EIS, USFS, MT, Troy Mine Revised Reclamation Plan, Approval of a Reclamation Plan and Permits, Kootenai National Forest, Lincoln County, MT, Review Period Ends: 07/30/2012, Contact: Bobbie Lacklen 406–283–7681.

EIS No. 20120209, Draft EIS, USN, FL, Naval Air Station Key West Airfield Operations, To Support and Conduct Aircraft Training Operations, Florida Keys, Monroe County, FL, Comment Period Ends: 08/13/2012, Contact: John Conway 904–542–6870.

EIS No. 20120210, Final EIS, BIA, WI, Menominee Casino-Hotel 223-Acre Fee-to-Trust Transfer and Casino Project, Implementation, NPDES Permit, Kenosha County, WI, Review Period Ends: 07/30/2012, Contact: Scott Doig 612–725–4514 This document is available on the Internet at: *www.kenoshaeis.com.*

EIS No. 20120211, Draft EIS, USFWS, OH, Proposed Habitat Conservation Plan and Incidental Take Permit for the Indiana Bat (Myotis sodalis) for the Buckeye Wind Power Project, Application, Champaign County, OH, Comment Period Ends: 09/27/2012, Contact: Megan Seymour 614–416–8993, ext. 16.

Amended Notices

EIS No. 20120150, Draft EIS, FHWA, CA, Interchange 5/State Route 56 Interchange Project, Connection between southbound I–5 to eastbound SR–56 and northbound SR 56 to northbound I–5, San Diego County, CA, Comment Period Ends: 07/17/2012, Contact: Manuel E. Sanchez 619–699–7336. Revision to FR Notice Published 05/18/2012, Extending Comment Period from 07/02/2012 to 07/17/2012.

EIS No. 20120152, Draft EIS, FHWA, CA, San Diego Freeway (I–405) Improvement Project, between State Route 73 and Interstate 605, USACE Section 404 Permit, Orange and Los Angeles Counties, CA, Comment Period Ends: 07/17/2012, Contact: Tay Dam 213–605–2013. Revision to FR Notice Published 5/15/2012; Comment Period Extended from 07/02/2012 to 07/17/2012.

EIS No. 20120192, Final EIS, NMFS, CA, Authorization for Incidental Take and Implementation of Fruit Growers

Supply Multispecies Habitat Conservation Plan, Siskiyou County, CA, Review Period Ends: 08/06/2012, Contact: Lisa Roberts, 707–825–5178 NMFS, Yreka Office 530–842–5763 ext. 109 USFWS. Revision to FR Notice Published 6/22/2012; Change Review Period from 7/23/2012 to 8/6/2012.

Dated: June 26, 2012.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2012–16031 Filed 6–28–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9695–3]

Notification of Closed Meeting of the Science Advisory Board's Scientific and Technological Achievement Awards Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency's (EPA), Science Advisory Board (SAB) Staff Office announces a meeting of the SAB's Scientific and Technological Achievement Awards (STAA) Committee to discuss SAB recommendations regarding the Agency's 2012 STAA recipients. The SAB meeting will be closed to the public.

DATES: The SAB meeting dates are Monday and Tuesday, July 23 and 24, 2012, from 8:00 a.m. to 6:00 p.m. (Eastern Time).

ADDRESSES: The closed SAB meeting will be held at the EPA Potomac Yard Conference Center, South Building, 2777 S. Crystal Drive, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain further information regarding this announcement may contact Mr. Edward Hanlon, Designated Federal Officer, by telephone: (202) 564–2134 or email at *hanlon.edward@epa.gov.* The SAB Mailing address is: U.S. EPA Science Advisory Board (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460. General information about the SAB concerning the SAB meeting announced in this notice may be found on the SAB Web site at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Summary: Pursuant to Section 10(d) of the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2, and section (c)(6) of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6), EPA has determined that the SAB meeting will be closed to the public. The purpose of the SAB meeting is for the Committee to discuss recommendations for the SAB regarding the recipients of the Agency's 2012 Scientific and Technological Achievement Awards. These awards are established to honor and recognize EPA employees who have made outstanding contributions in the advancement of science and technology through their research and development activities, as exhibited in publication of their results in peer reviewed journals. I have determined that the SAB meeting will be closed to the public because it is concerned with selecting employees deserving of awards. In making these recommendations, the Agency requires full and frank advice from the SAB. This advice will involve professional judgments on the relative merits of various employees and their respective work. Such personnel matters involve the discussion of information that is of a personal nature and the disclosure of which would be a clearly unwarranted invasion of personal privacy and, therefore, are protected from disclosure by section (c)(6) of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6). Minutes of the SAB meeting will be kept and certified by the Chair.

Dated: June 22, 2012.

Lisa P. Jackson,

Administrator.

[FR Doc. 2012–16048 Filed 6–28–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9695–2]

Proposed CERCLA Administrative Cost Recovery Settlement; Standex International Corporation

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: Notice is hereby given of a proposed administrative settlement for recovery of past response costs concerning the Trinity Superfund Site in Cleveland, Ohio, with the following settling party: Standex International Corporation. The settlement requires the settling party to pay $110,000 to the Hazardous Substance Superfund. The settlement includes a covenant not to sue the settling party pursuant to Section 107(a) of CERCLA. For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement.

DATES: Comments must be submitted on or before July 30, 2012.

ADDRESSES: The proposed settlement is available for public inspection at the U.S. Environmental Protection Agency, Region 5, 77 West Jackson Blvd., Chicago, Illinois 60604. A copy of the proposed settlement may be obtained from Catherine Garypie, U.S. Environmental Protection Agency, 77 W. Jackson Boulevard (C–14J), Chicago, IL 60604, (312) 886–5825. Comments should reference the Trinity Superfund Site in Cleveland, Ohio and EPA Docket No. V–W–12–C–999 and should be addressed to LaDawn Whitehead, U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance, 77 W. Jackson Boulevard, Chicago, IL 60604, (312) 886–3713.

SUPPLEMENTARY INFORMATION: In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past response costs concerning the Trinity Superfund Site in Cleveland, Ohio, with the following settling party: Standex International Corporation. The settlement requires the settling party to pay $110,000 to the Hazardous Substance Superfund. The settlement includes a covenant not to sue the settling party pursuant to Section 107(a) of CERCLA, 42 U.S.C. 9607(a). For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at the U.S. EPA Records Center, Room 714, 77 W. Jackson Boulevard, Chicago, IL 60604.

FOR FURTHER INFORMATION CONTACT: Catherine Garypie, U.S. Environmental Protection Agency, 77 W. Jackson Boulevard (C–14J), Chicago, IL 60604, (312) 886–5825.

Dated: June 20, 2012.

Richard C. Karl,

Director, Superfund Division, Region 5.

[FR Doc. 2012–16050 Filed 6–28–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9695–7]

Request for Nominations to the Great Lakes Advisory Board (GLAB)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for nominations to the Great Lakes Advisory Board (GLAB).

SUMMARY: The U.S. Environmental Protection Agency (EPA) is seeking nominations from a diverse range of qualified candidates to be considered for appointment as members of its Great Lakes Advisory Board (GLAB). The GLAB will provide advice and recommendations to the EPA Administrator, in her capacity as Chair of the Great Lakes Interagency Task Force, on matters pertaining to Great Lakes restoration and protection. Vacancies are expected to be filled by September 2012. Sources in addition to this **Federal Register** Notice may be used in the solicitation of nominees.

DATES: Nominations must be postmarked by July 30, 2012.

ADDRESSES: Submit nominations electronically with the subject line ''GLAB Nomination 2012'' to *cestaric.rita@epa.gov.* You may also submit nominations by mail to: Rita Cestaric, Designated Federal Officer, US Environmental Protection Agency, Great Lakes National Program Office, 77 W. Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Rita Cestaric, Designated Federal Officer, US Environmental Protection Agency, 77 W. Jackson, Chicago, IL 60604; email address: *cestaric.rita@epa.gov;* telephone number: (312) 886–6815.

SUPPLEMENTARY INFORMATION: On May 31, 2012, EPA published in the **Federal Register** a notice of intent to establish the GLAB under the authority of the Federal Advisory Committee Act (FACA), Public Law 92–463. The GLAB will provide advice and recommendations to the EPA Administrator, in her capacity as Chair of the Great Lakes Interagency Task Force, on matters pertaining to Great Lakes restoration and protection. The GLAB will conduct business in accordance with FACA and related regulations.

The GLAB will be composed of approximately 15 members appointed by the EPA Administrator. In selecting members, EPA will consider candidates representing or serving as liaison to a broad range of interests across the Great Lakes, that may include, but are not limited to, environmental groups, business, agricultural groups, youth groups, foundations, environmental justice groups, academia and state, local and tribal governments. Members will be appointed for two year terms and are eligible for reappointment.

The GLAB will meet approximately two times a year. Additionally, members may be asked to participate in teleconference meetings. The average workload for members will be approximately 4 to 6 hours per month. We are unable to provide honoraria or compensation for service on the GLAB. However, you may receive travel and per diem allowances where appropriate and according to applicable federal travel regulations.

Nominations: The EPA welcomes and values diversity. In an effort to obtain nominations of diverse candidates, the agency encourages nominations of women and men of all racial and ethnic groups. All nominations will be fully considered, but applicants need to be aware of the specific representation sought as outlined in the **SUPPLEMENTARY INFORMATION** section above.

Other criteria used to evaluate nominees will include:

- The background and experiences that would help members contribute to the diversity of perspectives on the GLAB (e.g., economic, social, cultural, educational background, professional affiliations and other considerations);
- Demonstrated experience with Great Lakes issues;
- Leadership experience in Great Lakes organizations, businesses and workgroups;
- Excellent interpersonal and consensus-building skills;
- Ability to volunteer time to attend approximately two in-person meetings a year, participate in teleconference meetings, attend listening sessions with senior-level federal officials, develop policy recommendations and prepare reports and letters of advice; and
- Willingness to commit time to the committee and demonstrated ability to work constructively and effectively on committees.

How to Submit Nominations: Any interested person or organization may nominate qualified persons to be considered for appointment to the GLAB. Individuals may self-nominate. Nominations can be submitted in electronic format (preferred) or in hard copy format (see **ADDRESSES** section above). To be considered, nominations should include:

- Current contact information for the nominee, including the nominee's name, organization (and position within that organization), current business address, email address and daytime phone number;
- Brief statement describing the nominee's interest in serving on the GLAB;
- Resume and a short biography (no more than two paragraphs) describing the professional and educational qualifications of the nominee, including a list of relevant activities and any current or previous service on advisory committees; and
- Letter(s) of recommendation from a third party supporting the nomination. Letter(s) should describe how the nominee's experience and knowledge will bring value to the work of the GLAB.

To help the Agency in evaluating the effectiveness of its outreach efforts, please tell us how you learned of this opportunity.

Dated: June 21, 2012.

Susan Hedman,

Great Lakes National Program Manager.

[FR Doc. 2012–16056 Filed 6–28–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[AU Docket No. 12–25; DA 12–990]

Mobility Fund Phase I Auction Updated Data For Auction 901

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Wireless Telecommunications and Wireline Competition Bureaus (Bureaus) announce updated data files of census blocks eligible for the Mobility Fund Phase I support to be offered in Auction 901, which is to be held on September 27, 2012.

DATES: Short-form applications to participate in Auction 901 are due prior to 6:00 p.m. on July 11, 2012.

FOR FURTHER INFORMATION CONTACT: Wireless Telecommunications Bureau, Auctions and Spectrum Access Division: Lisa Stover at (717) 338–2868.

SUPPLEMENTARY INFORMATION: This is a summary of the *Auction 901 Data Files Public Notice* released on June 22, 2012. The *Auction 901 Data Files Public*

Notice and its associated attachment as well as related Commission documents may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc. (BCPI), 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 202–488–5300, fax 202–488–5563, or you may contact BCPI at its Web site: *http://www.BCPIWEB.com.* When ordering documents from BCPI, please provide the appropriate FCC document number, for example, DA 12–990. The *Auction 901 Data Files Public Notice* and related documents also are available on the Internet at the Commission's Web site: *http://wireless.fcc.gov/auctions/901/* or by using the search function for AU Docket No. 12–25 on the Commission's Electronic Comment Filing System (ECFS) Web page at *http://www.fcc.gov/cgb/ecfs/.*

1. The *Auction 901 Data Files Public Notice* announces the availability of certain files that have been updated to conform to decisions previously announced by the Wireless Telecommunications Bureau and Wireline Competition Bureau (Bureaus). In the *Auction 901 Procedures Public Notice,* 77 FR 32092, May 31, 2012, the Bureaus described how they identified census blocks eligible for the Mobility Fund Phase I support to be offered in Auction 901. With the *Auction 901 Procedures Public Notice,* the Bureaus released Attachment A, a summary of the final list of eligible census blocks, and they concurrently provided more detailed Attachment A files in electronic format only. Subsequent to the release of the *Auction 901 Procedures Public Notice,* the Bureaus provided updates to some of the Attachment A files in two public notices. The Bureaus have since found that they need to correct some of these files to accurately reflect the determinations made in the *Auction 901 Procedures Public Notice.* Accordingly, the Bureaus are releasing a new Attachment A to replace the one released with the *Auction 901 Procedures Public Notice,* and they are updating some of the corresponding Attachment A files.

2. The files for which the Bureaus now announce updates are available via the link for Attachment A Files at *http://wireless.fcc.gov/auctions/901/.* Specifically, the All Eligible Census Blocks file; the Biddable Items file; and the state spreadsheet files for Maryland, Oklahoma, and Nevada have been updated. Interested parties should use these files instead of previously-released versions.

3. Concurrent with the release of *Auction 901 Procedures Public Notice,* the Bureaus released an interactive map of the eligible census blocks. The map is a visual representation of data from the Attachment A files, which contain more information and generally more detail than is displayed on the map. The Bureaus subsequently released geographic information system (GIS) formats of the data shown in the interactive map. The interactive map and the related GIS data formats will be updated in the near future to match the corrections in the Attachment A files. Once updated, the link for the map and each of the GIS data links will be displayed with a notation of when they were updated.

Federal Communications Commission.

Gary D. Michaels,

Deputy Chief, Auctions and Spectrum Access Division, WTB.

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FEDERAL COMMUNICATIONS COMMISSION

[WC Docket Nos. 10–90 and 05–337; DA 12–911]

Wireline Competition Bureau Seeks Comment on Model Design and Data Inputs for Phase II of the Connect America Fund

AGENCY: Federal Communications Commission.

ACTION: Notice; solicitation of comments.

SUMMARY: In this document, the Wireline Competition Bureau (the Bureau) seeks comment on a number of threshold decisions regarding the design of and data inputs to the forward looking cost model, and on other assumptions in the cost models currently in the record.

DATES: Comments are due on or before July 9, 2012 and reply comments are due on or before July 23, 2012.

ADDRESSES: Interested parties may file comments on or before July 9, 2012 and reply comments on or before July 23, 2012. All pleadings are to reference WC Docket Nos. 10–90 and 05–337. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies, by any of the following methods:

- *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 four copies 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.
- *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).

FOR FURTHER INFORMATION CONTACT: Ted Burmeister, Wireline Competition Bureau at (202) 418–7389 or TTY (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Public Notice in WC Docket Nos. 10–90, 05–337; DA 12–911, released June 8, 2012. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone (800) 378–3160 or (202) 863–2893, facsimile (202) 863–2898, or via the Internet at *http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.bcpiweb.comhttp://www.bcpiweb.com.*

I. Introduction

1. In the Public Notice (Notice), the Wireline Competition Bureau (Bureau) identifies several significant threshold model design decisions and seeks comment on specific proposals for the design of the model and data inputs to be used. This is not an exhaustive list of such issues, but represents the next step in the open, deliberative process to determine the design of the model the Bureau will ultimately adopt. The Bureau also seeks comment on commenters' identification of additional issues that need to be developed in the record of this proceeding.

2. The Notice first seeks comment on what wireline network technology and design the model should use to calculate costs. This question includes the important threshold matters of whether the model should presume green-field or brown-field deployment and whether the model should estimate the costs of Fiber-to-the-Premises (FTTP) or Digital Subscriber Line (DSL) (including Fiber-to-the-Node (FTTN)) technology. Closely related is the question of what terminal value to assign to the modeled network—book

value, economic value, or zero value. The Notice then seeks comment on whether the model should estimate the total costs of serving the entire service area so that shared costs may be distributed between areas that are eligible and ineligible for support or estimate only the standalone costs of areas eligible for support. Next, the Notice seeks comment on how shared network costs should be distributed to the census-block (or smaller) area. The Notice also asks whether the model should calculate support for areas to which broadband has already been deployed or only for unserved areas. Finally, this Notice seeks comment on what benchmarks should be used to identify areas with costs that are too low, or too high (and therefore subject to support under the Remote Areas Fund), to receive support pursuant to CAF Phase II.

3. In addition, to expedite the model development process, the Bureau also initiates comment on data inputs—specifically, on data sources relating to geography and carrier plant. The geographic information systems (GIS) inputs on which this Notice seeks comment include the definitions of existing wire center boundaries and broadband footprints, and the locations of business and residential customers. Plant-related data questions raised in this Notice relate to plant mix (*i.e.,* mix of aerial, underground, and buried plant), the location and age of existing plant, the gauge of existing twisted-pair copper wires, and validating other cost inputs to the model.

4. Finally, the Bureau seeks comment on the models submitted by the ABC Coalition and ACS. Specifically, the Bureau asks that commenters identify model design decisions, inputs, or other assumptions included in those models that require further analysis and record development.

5. The Bureau presents and seeks comment on several approaches for addressing each of the model design issues summarized above. The Bureau encourages commenters to address in depth how to address the potential limitations of some approaches or to propose additional alternatives, including hybrid approaches that bring the benefits of multiple methodologies. Similarly, although the Bureau references the models filed by the ABC Coalition and ACS, and encourages commenters to address those models specifically, commenters should not be constrained by the assumptions contained in those models.

6. Commenters should explain in detail why the positions they argue for are preferable to others, supporting their positions with arguments grounded in economic principles, data and analysis. Commenters are encouraged to take a position on each of the issues addressed herein, and explain how those positions, in combination, establish a reasonable approach to modeling and are consistent with the requirements set forth in the *USF/ICC Transformation Order,* 76 FR 73830, November 29, 2011. The Bureau is particularly interested in understanding how specific choices impact the model with respect to (1) precision (*i.e.,* the granularity of the model at a geographic or other level); (2) accuracy (aligning modeled costs with the forward-looking costs of an efficient provider); (3) simplicity (reducing the computational complexity); (4) accessibility (ease with which the public can evaluate and comment on the model); (5) administrative feasibility (the burden on carriers, the Commission, or other interested parties and the time necessary to implement), and (6) the cost of implementation. Commenters are invited to suggest additional criteria that the Bureau should use to evaluate different model choices.

II. Discussion

A. Model Design

1. What wireline network technology and design should the model use to calculate costs, and how should the model calculate the terminal value of the network?

7. The choices of network technology (*e.g.,* FTTP or DSL) and design (green-field or brown-field deployment)—along with terminal value of the network (book value, economic value, or zero value) are likely to be major drivers of cost. Insofar as both issues relate to the timeframe over which network costs are evaluated, there may be a logical interrelationship among these choices.

8. The Bureau emphasizes that model design choices will not obligate providers to deploy the modeled technology—providers can deploy any technology that meets the obligations laid out in the *USF/ICC Transformation Order.* The requirements laid out in the *USF/ICC Transformation Order* focus on the services delivered, not the technology used.

9. Consistent with the *USF/ICC Transformation Order,* the model must incorporate the most appropriate approach to determining an efficient provider's forward-looking costs. Accordingly, the Bureau is focusing on technologies and designs that, together, would align the modeled costs as closely as possible with the forward-looking costs of the wireline providers who have a statewide option to accept or decline support.

10. Several interdependent issues need to be resolved regarding network technology, design, and valuation: (1) How much of the network the model assumes to pre-exist, (2) whether the model assumes the connection to the customer location is wholly fiber or some mixture of fiber and copper wire, and (3) how the model should calculate the value of the network at the end of the modeling period.

(i) Network Design: Green-field vs. Brown-field

11. The first issue is the amount of the modeled network that the model assumes will be newly built. Because the two approaches to resolving this embedded issue are aligned with either the green-field or brown-field approach, this Notice discusses the issues together.

12. One approach (''green-field'') is to model costs assuming that the entire network, from the local central office to each end-user location, is newly built. The network is assumed to be built in its entirety, typically along roads or other rights of way. A green-field model may retain central offices in their existing locations and hold wire center boundaries constant (scorched node). This is the approach taken in the ABC Coalition model.

13. Another approach (brown-field) is to assume that only a part of the network will be built, and to therefore model only the costs associated with those network upgrades. This approach relies on existing assets as part of the modeled network. Some parts of the network are upgraded as necessary to achieve the necessary levels of connectivity. Other existing network assets, typically twisted-pair copper, are retained because, with the other upgrades, they provide sufficient connectivity.

(ii) Network Design: FTTP vs. DSL or FTTN

14. The second issue is whether the Bureau should model the costs associated with fiber-to-the-premises (FTTP) technology, or with technology that relies in part on twisted-pair copper like digital subscriber line (DSL) or fiber to the node (FTTN). The choice of what technology to model does not obligate providers to deploy that technology. The requirements laid out in the *USF/ICC Transformation Order* focus on the services delivered, not the technology used.

15. As the name suggests, in an FTTP network, fiber optic cables are run from the central office to each end-user location. This example assumes the use

of a Passive Optical Network (PON) for modeling purposes, placing passive splitters throughout the network. There are other approaches to FTTP, including architectures where each end-user location has a dedicated fiber connected back to the central office, or where there are active electronics in the field. Given that companies deploying FTTP today typically rely on PON architectures, however, the Bureau believes it is appropriate to limit the model's approach to PON. Commenters who believe other architectures are appropriate, or who wish to advocate for a particular PON architecture are encouraged to explain the specific basis for their position.

16. A DSL network that relies on the twisted-pair infrastructure includes both fiber-optic and twisted-pair copper connections. DSL Access Multiplexers (DSLAMs) are placed so that the longest copper loop between the DSLAM and end-user location is shorter than some maximum length like 5,000 or 12,000 feet, as necessary to achieve the modeled level of connectivity. These DSLAMs are presumed to be connected to the central office by fiber optic cable. The ABC Coalition model estimates the cost of a DSL network.

(iii) Terminal Value: Book value vs. Economic Value vs. Zero Value

17. The third issue is how the model should calculate the terminal value of the network at the end of the modeling period.

18. Some network assets are particularly long-lived, with accounting lifetimes of 20 or more years, and economic lifetimes that are even longer (*i.e.,* these assets can continue to operate and provide value even after they are fully depreciated, and their book value is zero). Depending on the type of network, these long-lived assets may represent a significant fraction of the total cost of deployment.

19. The *USF/ICC Transformation Order* provides that price cap carriers accepting a state-level commitment will receive funding for five years. At the end of the five-year term, the *USF/ICC Transformation Order* contemplates a market-based mechanism will be used to set support going forward. Thus, recipients of model-based support over the next five years may continue to receive support, or a competitor may receive support instead. On the other hand, if a market-based mechanism is not implemented by the end of the five-year period, ETCs accepting the state-level commitment ''will be required to continue providing broadband * * * in exchange for ongoing CAF Phase II [model-determined] support.''

20. The extent to which the model includes costs that reflect the value of longer-lived assets is likely to be a large driver of support amounts. A green-field FTTP deployment would likely have significant commercial value after five years, even in high-cost areas, given that it scales more readily to higher-speed services than DSL and would have many years of depreciable life (and possibly even more actual) remaining. The commercial value and remaining life of a brown-field DSL deployment is less clear.

21. *Book value.* The model would determine the residual value of the network by the book value of the assets at end of the modeling period. This is a regulatory accounting calculation that the Bureau expects would be relatively simple to implement. Book value may overstate the terminal value, however, if there is a lack of a business case for continuing to provide service without ongoing support. The ABC Coalition model adopts the approach of using book value as the residual network value.

22. *Commercial (or economic) value.* The model would determine the residual value of the network by the value the business can generate (profitability) at end of the modeling period. This approach best reflects the ability of the network to generate profit from end-user revenue against ongoing costs at the end of the five-year period. It may be difficult, however, to forecast revenue and profit, especially if it is unknown whether the carrier will continue to receive support after five years. If, for example, a competitor won support for that area under a subsequent market-based mechanism, the model-support recipient's market share and revenue could fall.

23. *Zero value.* Under this approach, the model would assume zero value of assets at the end of the modeling period, either through an assumption that the assets have zero revenue-producing ability or an assumption of accelerated five-year depreciable life for all assets. This would provide certainty for the carriers that they would not be left with unrecovered investment when CAF Phase II ends. However, the approach may create a significant excess support for carriers if they are able to generate revenue on assets at the end of the modeling period or if modeled support continues beyond the expected five-year period.

24. The decisions regarding network technology, design, and terminal value together define a possible model approach. As discussed below, the Bureau proposes two approaches: green-field FTTP paired with book value; or brown-field DSL paired with zero value. The Bureau also seeks comment on the ABC Coalition's proposal to use a green-field DSL model. The Bureau seeks public input on its analysis as set forth below.

25. To the extent that parties support alternative model designs not discussed here, including other variants of networks that use both fiber- and copper-based connections, such as hybrid-fiber coax (HFC) networks, the Bureau asks that the parties use their comments to justify those alternatives. The parties should address how their favored alternatives meet the criteria set forth above—precision, accuracy, simplicity, accessibility, administrative feasibility, and the cost of implementation—as well as any other criteria the parties believe relevant to the choice of model designs.

26. *Green-field FTTP paired with Book Value.* Under this proposal, the Bureau would model the costs of a wholly new FTTP network, with fiber connectivity to the end user. The primary advantage of a green-field FTTP model is that it would calculate the forward-looking, total long-run incremental cost of an efficient provider. This would be consistent with prior modeling efforts and the *USF/ICC Transformation Order and FNPRM,* 76 FR 73830, November 29, 2011/76 FR 78384, December 16, 2011. The operating costs of a green-field FTTP network are likely lower than for networks with active electronics in the outside plant, such as DSL networks.

27. However, a green-field FTTP model would also make annual cost and support levels highly dependent on the terminal value, because the explicit modeling period is much shorter than the lifetime of many of the assets in the model. Given the degree of uncertainty associated with estimating commercial value, it may be inappropriate to use commercial value to determine the terminal value. However, because the commercial value is likely to be significant, using zero terminal value with the green-field FTTP approach would likely provide an excessive benefit. The Bureau therefore proposes to use book value as the terminal value, if a green-field FTTP approach is adopted.

28. A green-field FTTP approach may have drawbacks as well. Relative to a brown-field model, a green-field model using any technology is likely to calculate higher costs and require higher support levels per location (*i.e.,* fewer locations covered for a fixed sum of funding). A green-field FTTP model in particular is not likely to represent providers' actual expenditures to

provide broadband over the five-year modeling period. Specifically, it would provide support for construction of parts of the existing network that are unlikely to be replaced during the modeling period. In addition, the green-field FTTP approach ignores the cost savings that some providers may achieve by shortening loops only as customer demand requires, or the additional revenues that some providers may achieve by deploying a wireless network from which they can derive both fixed and mobile revenue. The Bureau seeks comment on this analysis.

29. *Brown-field DSL paired with Zero Value.* The second proposal is to model the cost of a network upgrade, shortening loops to a maximum of, for example, 12,000 or 5,000 feet, relying on the existing copper plant for the last several thousand feet of connectivity. The choice of maximum loop length is a major driver of cost and connectivity because shorter loops will provide higher speeds at greater costs. A brown-field DSL model is most likely consistent with providers' actual costs (at least for those providers who deploy DSL) and aligns modeled costs with demand (*i.e.,* loops can be shortened, and costs incurred, only as demand warrants).

30. There are likely to be disadvantages associated with a brown-field DSL approach, however. The ability of a given loop length to deliver desired speed depends on age and quality of existing plant, and on the gauge of the copper wires. It is unclear if the necessary data for existing copper deployments are available. As a result, the brown-field approach may require modeling existing networks and assets or making sweeping generalizations about average conditions. In addition, increasing offered broadband speed (*e.g.,* if the Commission increases the minimum requirement) in the future will require additional investment, and presumably additional support. In addition, the brown-field approach ignores sunk costs associated with the existing plant (part of total cost of building, operating and maintaining in a given area), and so arguably will not provide sufficient funds to meet universal service goals over the long run. Finally, a DSL approach is likely to have higher operating cost than FTTP (though these higher costs may be small relative to excluded sunk costs).

31. The Bureau also notes that the use of a brown-field model makes the availability of some data sets more important (*e.g.,* age and gauge of copper plant, location of existing fiber) because the cost of a brown-field deployment cannot be reasonably estimated without them. A lack of reliable data sets to address these needs would undermine the development of a brown-field model.

32. The brown-field DSL model also would need to capture costs associated with exhaust of capacity in existing aggregation facilities that is driven by the addition of new served locations. Although the brown-field DSL approach likely results in lower costs and support per location, this is dependent on terminal value calculation. Under the brown-field DSL approach, the Bureau proposes that the model would assume that, at the end of the modeling period, assets would have zero value. A DSL network with only limited upgrades could have small commercial value, especially if another service provider receives support under a program subsequent to CAF Phase II, but estimating actual commercial value is difficult and uncertain. For that reason, using a terminal value of zero could reasonably approximate the value of the network without the added complexity of estimating commercial value. This approach would ensure that calculated costs reflect the entire cost of network upgrades, including possible impairment of value in an unfavorable commercial environment. The Bureau seeks comment on this analysis.

33. *Green-field DSL.* Under this approach, the Bureau would model the cost of a wholly new network where the last several thousand feet of the connection is provided by newly installed twisted-pair copper. The green-field DSL approach calculates the total long-run incremental cost, in most locations, of the current telephone and broadband network. This is the approach initially proposed by the ABC Coalition.

34. There appear to be significant disadvantages of a green-field DSL approach. First, it is only forward looking from the perspective of decisions made a decade or more in the past (*i.e.,* DSL does not currently represent the most efficient, forward-looking choice of technology). Second, relative to a green-field FTTP approach, a green-field DSL approach is less efficient because it has higher expected operating expenses and is more likely to require significant additional investment to make faster broadband offerings available. It also may not be representative of providers' actual investment to provide broadband over the five-year modeling period (in other words, it would likely provide support for construction of parts of existing network that are unlikely to be replaced during the modeling period). As a result, this approach may not represent either forward-looking costs nor the costs providers are likely to actually incur. In addition, given these concerns, a green-field DSL approach may have an especially high error rate with respect to identifying the highest cost areas for the purpose of the Remote Areas Fund.

2. Should the model estimate the total costs of serving the entire service area (and allocate shared costs to supported areas) or only the standalone costs of areas eligible for support?

35. The Commission concluded in the *USF/ICC Transformation Order* that it would use a forward-looking model capable of determining ''on a census block or smaller basis, areas that will be eligible for CAF Phase II support.'' Specifically, the Commission ''will use the model to identify those census blocks where the cost of service is likely to be higher than can be supported through reasonable end-user rates alone'' and ''identify, from among these, a small number of extremely high-cost census blocks that should receive funding specifically set aside for remote and extremely high-cost areas'' (*i.e.,* the Remote Areas Fund). The Commission also concluded that ''it would be appropriate to exclude any area serviced by an unsubsidized competitor that meets our initial performance requirements.''

36. Most costs in a network are shared costs. For example, feeder cabling is shared among all end-users served by that feeder; even cabling in the distribution plant is often shared among multiple end user locations. The method used to attribute the costs of shared plant to individual end users or to census block or smaller areas will affect the relative cost of serving different areas.

37. The Bureau thus must determine how to estimate network costs consistent with the requirement in the *USF/ICC Transformation Order* that support will only be provided in areas outside the footprint of an unsubsidized competitor. As proposed in the ABC Coalition model, the Bureau proposes to use a method in which the model would calculate the costs of a network that serves the entire service territory area and then allocate the shared costs between eligible and ineligible areas.

38. A simplified example of this issue: In a given area served by a single central office, most of the homes served are clustered together in a small area. These homes are served by an unsubsidized cable company and are in a census block (or smaller area) that is ineligible for CAF support. Three remaining homes are in a different census block outside the footprint of the

unsubsidized competitor. Only these three homes are in an area that is eligible for support.

39. *Model Entire Network.* One approach to modeling the cost of the area eligible for support (the three homes) is to calculate the cost of the entire network, including those areas in the footprint of the subsidized competitor, and then determine the share of costs for the eligible and ineligible areas in a later step. In this approach, parts of the network serve both the eligible and ineligible areas and the associated costs will be shared in some way between the homes that are ineligible for support and the three homes, which are in an area eligible for support. The costs associated with network infrastructure serving only ineligible areas are excluded entirely from the analysis, and the costs associated with network plant serving only eligible areas are included entirely. This approach assumes that any service provided by carriers in areas ineligible for support will continue. The specific method for determining the share of costs for network facilities that serve both eligible and ineligible areas is essential to this approach, and is discussed immediately below.

40. *Standalone Cost of Serving Eligible Areas.* An alternative approach would be to model only the network needed to connect the locations in eligible areas (in the previous example, only the three homes). In the example above, this approach means modeling only the parts of the network that serve supported areas, whether they would otherwise be shared with unsupported areas or not, which has the effect of attributing a greater amount of costs to the eligible areas.

41. Modeling the costs associated with a complete network (*i.e.,* including both eligible and ineligible areas) and then assigning shared costs between the eligible and ineligible areas appears to have significant benefits. First, it more accurately depicts an economically efficient network and provider. In an economically efficient network, buildout would cover all or most locations in a given area, rather than only serving a small subset of locations that lack broadband. This is particularly true in areas where building out the network to the unserved could enable very low cost service to homes served by a competitive provider, as in the example above. An economically efficient provider would not generally cede a large fraction of customers to competition.

42. Second, in the *USF/ICC Transformation Order,* the Commission ''weigh[ed] the fact that incumbent LECs generally continue to have carrier of last resort obligations for voice services.'' Modeling the entire network would be consistent with these obligations and the treatment of incumbent price cap carriers. In addition, this approach will generally lead to lower per-location costs and therefore lower per-location support levels in areas that receive support, which, depending on how the low- and high-end cost thresholds are set for CAF Phase II, may maximize the number of locations that would be supported pursuant to CAF Phase II. In contrast, the primary advantage of modeling the standalone cost of serving eligible areas is that the cost of serving eligible areas is not dependent on maintaining service to locations in ineligible areas.

43. For these reasons, the Bureau proposes to model the entire network and assign shared costs between eligible and ineligible areas to determine support amounts. The Bureau seeks comment on this proposal and on its analysis of the relative attributes of each alternative.

3. What specific methodology should be used to assign shared costs?

44. A related question is how to allocate costs consistent with the requirement in the *USF/ICC Transformation Order* that the model be capable of determining ''on a census block or smaller basis, areas that will be eligible for CAF Phase II support.''

45. *Subtractive method.* Under the first approach, the model would estimate only those costs needed to serve supported areas that are over and above the costs that would be required to serve unsupported areas (*i.e.,* the marginal or incremental costs of the supported areas). The Bureau would calculate these costs by comparing the cost of networks modeled with and without those areas. Specifically, the model would estimate the cost of a network serving both supported and unsupported areas and then subtract the cost of a network serving only the unsuppored areas to determine the costs associated with the supported areas.

46. An example of how this calculation would be performed: Assume a service area that includes two areas, X and Y. Area X represents an area (*i.e.* a census block) that is commercially viable for the carrier and for which the carrier will not receive support. Area Y is a high-cost area (i.e. a different census block) for which costs must be estimated. By calculating the cost of a network serving the entire area (cost (X + Y)) and then subtracting the cost of serving area X (cost (X)), the model would estimate costs associated solely with serving area Y, *i.e.,* the incremental cost of serving area Y. The cost of serving area Y may include the incremental cost associated with upgrading to larger-capacity feeder links within area X; but would *not* include any costs incurred in area X necessary to serve customers in area X if area Y is not served.

47. Two related issues complicate this scenario. The Bureau needs to (1) determine how to maximize the number of locations served with the $1.8 billion budget, and (2) determine the threshold for which locations will be served by the Remote Areas Fund designed to ensure service to the most costly locations. As a result, the model needs to determine not just the cost of a single incremental addition to the network, but the cost of building out many areas—when the cost of each area can affect the cost of the others.

48. A slightly more complicated example highlights the challenges associated with such a calculation. In addition to the commercially viable Area X, there are three areas that are eligible for support: A, B and C. In this simplified example, those three areas hold individual homes, but they could also be groups of homes.

49. The cost of serving each of these areas depends in part on whether the other areas are served. For example, if a provider builds network to area A, then the cost for building to areas B and C could be lower; similarly if network is built to area B, the cost to serve area C could be lower. Determining the cost of building each area then depends on what other areas eventually get service. Therefore a model would need to calculate cost (X), cost (X + A), cost (X + B), cost (X + C), cost (X + A + B), cost (X + A + C), cost (X + B + C) and cost (X + A + B + C). After the Bureau determines which areas are to be included (i.e., which areas are eligible for support instead of being moved into the Remote Area Fund), then calculating the incremental costs of those areas would be straightforward. Note that this method effectively averages the costs of areas are included: In the above example, determining the cost (A + B) by calculating the cost (X + A + B) and subtracting cost (X) averages the cost of areas A and B together.

50. The subtraction methodology may be a computationally difficult method of allocating costs. There are hundreds of thousands of unserved census blocks in the country, meaning a multiple of that many permutations; this, in turn, will require many more model runs than an allocation approach. In addition, the approach presumes the Bureau has determined which areas are sufficiently

low cost so as not to qualify for support (area X in the example above). It also may be difficult to determine the subsidy required to maintain services in areas that require support (*i.e.,* areas that would be unserved but for existing high-cost support). It will also be necessary to determine which areas are extremely high-cost for Remote Areas Fund purposes using only this methodology (*i.e.,* there may need to be a way to determine which areas to exclude before calculating costs).

51. *Pro Rata or Formula method.* Costs could be allocated to various areas within a service area on a pro rata basis or using some other formula. For example, one could allocate costs based on the number of end-user locations, the amount of bandwidth throughput (typically in Mbps) each user is assumed to buy, or the amount of bandwidth each user is assumed to consume (typically in GB per month). This method is consistent with the current FCC High-Cost Proxy Model, the model submitted by the ABC Coalition and the National Broadband Plan modeling.

52. The Bureau proposes to use a subtractive approach, provided that a computationally tractable method can be found, because the subtractive approach ensures that only the costs that would not otherwise be incurred are attributed to each area, which the Bureau believes provides the best estimate of the economic costs of serving an area. The Bureau seeks comment on this proposal.

53. The main advantage of the pro-rata or other formula approach is that it involves straightforward calculations without the computational complexity of the subtraction approach. However, a pro-rata or other formula-based approach may not estimate the economic costs of serving any area with a high degree of accuracy. Moreover, it may not capture that an area is commercially viable without a subsidy (*e.g.,* where there is a large institutional customer for whom fiber would be run into a neighborhood in any circumstance).

54. The Bureau seeks comment on its proposal and analysis of alternatives. With respect to the pro rata or formula approach, the Bureau seeks comment on which formula or method of allocating costs could or should be used and the advantages or disadvantages of each.

4. Should the model calculate support levels for locations already served?

55. High-cost areas are likely to include a mix of both served and unserved locations. Some locations in areas with high long-run incremental costs may already have broadband because they had previously been subject to other forms of regulation (such as rate-of-return regulation) that compensated carriers' costs on a different basis, because they had received legacy high-cost support, or because the existence of commercially viable service areas nearby reduced the incremental cost of providing broadband such that there was a business case to invest. Should the model include and calculate support for high-cost areas that are already served?

56. *Include existing areas.* Under this approach, areas that meet a certain cost threshold would receive support regardless of existing broadband deployment. Otherwise, some carriers might be worse off for having aggressively deployed broadband service, perhaps using legacy high-cost support, prior to the implementation of CAF Phase II. Including areas already served with broadband is consistent with the green-field modeling approach because the green-field approach models an efficient deployment without presuming the existence of any facilities, meaning that it would be logically inconsistent to assume that some areas already have service. It may be more difficult under a brown-field model to implement an approach that supports areas with existing broadband deployment. Ongoing support may be required to ensure continued service—the areas may have been previously supported by legacy high-cost support mechanisms or deployment may have occurred despite high costs—but the incremental cost to deploy broadband to areas that already have service will likely be too small to generate support under the model.

57. *Exclude existing areas.* Under this approach, costs would be included and support provided only to areas that do not already have broadband that meets the broadband public interest obligations. This would allow targeting of support to completely unserved areas and would not support providers that may have deployed to certain high-cost areas for which unsubsidized business cases may exist. It would also exclude, however, areas to which broadband deployment was made possible only by legacy high-cost support. This approach may be more consistent with a brown-field modeling approach because of its focus on the additional costs associated with network upgrades. It is not completely inconsistent with a green-field approach but, as noted, presumably would not ensure sufficient ongoing support for service whose costs exceed end-user revenues.

58. The Bureau proposes to include areas that already are served by broadband in cost and support calculations. The Bureau seeks comment on its analysis on this issue.

5. What benchmarks should be used to identify areas with costs too low or high to receive support pursuant to CAF Phase II?

59. In the *USF/ICC Transformation Order,* the Commission established that the model would be used to determine what areas would be eligible to receive support based on the costs of serving them. Specifically, the Commission adopted a methodology ''that will target support to areas that exceed a specified cost benchmark, but not provide support for areas that exceed an 'extremely high cost' threshold.'' Support for each census block will be the amount the modeled cost exceeds the cost benchmark, provided that the census block's cost does not exceed the ''extremely high cost'' threshold. The Bureau seeks comment on how to establish both the cost benchmark above which a high-cost area will be eligible for support and the extremely high-cost threshold, above which an area will be ineligible for support through CAF Phase II and will instead be eligible for support through the Remote Areas Fund (RAF). Given the fixed $1.8 billion ceiling for CAF Phase II, it is necessary that these benchmarks be established at levels coordinated to provide no more than the available amount of support.

60. With regard to the cost benchmark, the Commission stated that it would use the model ''to identify those census blocks where the cost of service is likely to be higher than can be supported through reasonable end-user rates alone.'' The ABC plan proponents proposed a benchmark of $80 per loop per month.

61. With regard to the RAF threshold, the Commission also concluded that ''a small number of extremely high-cost census blocks that should receive funding specifically set aside for remote and extremely high-cost areas * * * rather than receiving CAF Phase II support.'' The Commission found that excluding these extremely high-cost areas was consistent with its ''recognition that the very small percentage of households that are most expensive to serve via terrestrial technology represent a disproportionate share of the cost of serving currently unserved areas.'' The Commission exempted those areas from the broadband service requirements associated with the CAF and set aside at least $100 million to serve those areas through alternative technologies subject

to modestly relaxed broadband requirements. The Commission delegated to the Bureau ''the responsibility for setting the extremely high-cost threshold in conjunction with the adoption of the final cost model.

62. The Bureau seeks comment on how best to determine the low-end threshold for determining which census blocks should receive support and the extremely high cost threshold to identify the areas eligible for the Remote Area Fund.

63. In setting these thresholds, the Bureau is mindful of certain principles established by the Commission in the *USF/ICC Transformation Order*. First, the Commission directed that ''[t]he threshold should be set to maintain total support in price cap areas within our up to $1.8 billion annual budget.'' Second, as noted above, the Commission set aside at least $100 million to serve the highest cost areas through the RAF. Third, the Commission ''anticipated that less—and possibly much less—than one percent of all U.S. residences are likely to fall above the 'extremely high-cost'' threshold in the final cost model.''

64. Given these principles, the Bureau could first establish the extremely high-cost threshold by taking into consideration the Commission's anticipation that fewer than one percent of American homes would be above the threshold and the size of the RAF. The Bureau could then calculate how far below the extremely high-cost benchmark the $1.8 billion CAF Phase II budget could extend, the result being the cost benchmark. Alternatively, the Bureau could first determine the cost benchmark using the principle that it should identify places where the cost of service exceed reasonable end user rates alone, and then calculate the extremely high-cost benchmark based on the $1.8 billion CAF Phase II budget. Under this alternative the Bureau would need to ensure that the resulting extremely high-cost benchmark did not cause more than one percent of American households to be covered by the RAF or unduly increase the size of the RAF.

65. As suggested by the State Members of the Joint Board, another possibility is to establish the extremely high-cost threshold at a level approximately the same as the price of satellite broadband service. Also, the ABC plan proposed to limit support to no more than $176 per line per month which, given the $80 cost benchmark it proposed, would effectively set the threshold for extremely high-cost areas at $256 per line per month.

66. The Bureau seeks comment on these alternative methods of calculating the CAF Phase II cost benchmark and the extremely high-cost threshold.

B. Data Inputs

67. In this section, the Bureau seeks comment on seven data source issues. Four relate to geographic information systems (GIS) data: wire center boundaries, boundaries of existing broadband footprints, business locations, and consumer locations. The other three issues relate to carrier plant: the outside plant mix for individual carriers, the age of the carriers' plant, and the gauge of the carriers' copper wire plant. The Bureau also seeks comment regarding methods of validating data inputs generally.

68. *Wire center boundaries.* Wire center boundaries represent the edges of the service territories served by each wire center. Typically, locations will be connected to the wire center in whose boundary they fall, even if, absent existing infrastructure, it might be more efficient to connect to a different wire center. In this section, the Bureau seeks comment on three sources of wire center boundary data.

69. *Use a commercial data set, such as TeleAtlas.* The TeleAtlas wirecenter boundary database is a readily available data set already in use by the Commission and in the National Broadband Plan modeling. The accuracy of the data has been questioned in other circumstances, however. For example, all areas of the country are assigned to a wire center, even if they lack roads, population, or buildings, which can lead to an overestimate of wire center area. Additionally, given commercial licensing agreements, the Commission is unlikely to have rights to freely distribute commercial data, meaning that commenters may have to rely on aggregated data that can be released consistent with license agreements, or purchase the data set themselves. There also may be areas for which commercial data are unavailable, and the Bureau would need to take one of the approaches described below for those areas.

70. *Develop a new data source.* The Bureau recently sought comment on a new data collection to obtain certain boundary data from all local exchange carriers, including the wire center boundaries of price cap carriers. However, the data collection may not be finalized, approved by the Office of Management and Budget (OMB), and implemented in the timeframe that would enable those boundaries to be used in the CAF Phase II model development process. Once the Bureau develops a new source of data, however, the Commission would own the data without being subject to license agreements or other commercial limitations, and could presumably tailor the data to make it more accurate for the intended modeling purposes.

71. *Use efficient routing regardless of wire center boundaries.* Allowing the model to disregard existing wire center boundaries would be consistent with the forward-looking costs of an efficient provider and would allow the same approach and data set in all areas, even those without available commercial data. In addition, the data would not be subject to propriety claims, which would allow free use by the Commission and all interested parties.

72. The commercial data approach should be more accurate than efficient routing. Efficient routing would underestimate costs in some areas because it would model network deployments that are significantly different from what providers would actually implement given the constraints of existing wire centers. Efficient routing would also be inconsistent with both a scorched node approach to a green-field model and a brown-field model.

73. Although commercial data may not achieve as high a degree of accuracy as a newly developed data set, developing a data source will likely require a significant amount of time. Also, the Bureau notes that the footprints of providers eligible for CAF Phase II support are quite large, so any small error is likely to average out. Moreover, any overstatement of footprint by including uninhabited areas will not affect costs for a model that relies on demographic information.

74. A hybrid approach involving a commercial data source supplemented by data collected from service providers or efficient routing may also make sense or prove necessary in some areas that are not covered by those sources.

75. The Bureau proposes to use wire center boundaries obtained through a new data collection as described above, or in the alternative, commercial datasets, such as TeleAtlas, if the data collection can not be completed in time for the model development process. The Bureau seeks comment on the relative merits of each alternative.

76. *Existing broadband footprints.* The footprints of unsubsidized competitors are ineligible for support, so a data source for their footprints is essential. In addition, a data source for the footprints of support recipients would be important if the model excludes areas they currently serve. The Bureau seeks comment regarding two possible sources of data regarding existing broadband footprints.

77. *Use State Broadband Initiative (SBI) data collected for the National Broadband Map.* The SBI represents a single, public data source of where broadband is available at the census block (or smaller) level, as a function of upload and download speeds. However, the National Broadband Map does not differentiate among providers who serve residential and business customers, and therefore may count census blocks as served when only a business-focused service provider is present. As discussed elsewhere, there are other limits to the data set.

78. *Augment SBI data with additional data source(s).* Augmenting the SBI data with other data sources that would improve its reliability by correcting the most significant errors in the SBI data. This is the approach taken by the ABC Coalition. It may require the use of commercial data sources, however, with all of the attendant licensing obligations and limitations, including the time required to acquire the necessary licenses. Moreover, it does not address other concerns about the SBI data, including specifically the problem of business-only service providers.

79. The Bureau does not propose a particular data source for existing broadband footprints at this time but seeks comment on each alternative and the Bureau's analysis of the relative attributes of each.

80. *Business locations (including community anchor institutions)* The model will need to include information about the location of business customers and community anchor institutions, both to ensure that it captures the appropriate number of end-user locations, and to ensure that the cost of shared resources are shared among all users appropriately. The Bureau seeks comment on two possible sources of business location data.

81. *Use government data.* Government data, such as the economic census, are publicly available and could be used in the model. This is the approach taken by the ABC Coalition. However, the data are available only at a larger geography, so the model would need to make assumptions about the specific location (distribution) of businesses and community anchor institutions. It also may be inconsistent with the approach taken for consumer locations, discussed below. This approach should provide a reasonable level of accuracy.

82. *Use a commercial data set.* Several vendors have business-location-count data sets available that could be used in the model. This is the approach taken by the National Broadband Plan. While each of these data sets has its limitations, each is regarded as an industry standard. Commercial data are, or can be, highly precise, providing actual customer locations at the address level. Some commercial data sources may even estimate the broadband demand at a given location, allowing for the appropriate scaling of any network infrastructure. Restrictions on the license rights may limit the ability to distribute data at the census block level, however, and the time required to acquire the necessary licenses may delay implementation.

83. The Bureau proposes to use government data for business locations and seeks comment on its analysis of the alternatives.

84. *Consumer locations.* The model will need information about the location of consumers, which make up the bulk of locations in most areas. The Bureau seeks comment on three sources of consumer location data.

85. *Use a commercial data set.* Commercial consumer location data are updated annually (or even more frequently) so that location counts are more likely to reflect growth since the last decennial census. Using such commercial data is consistent with the approaches taken in the National Broadband Plan modeling and by the ABC Coalition. However, using such commercial data would entail all of the difficulties of acquiring and using commercial data, including limited ability to distribute data at the census block level and the possible delay associated with acquiring the necessary licenses. In addition, because such commercial data are available at the census block level, the model would need to make assumptions to locate the consumers' specific locations within the census block.

86. *Use 2010 census data.* Official government census data is easily procured and the data could be used without restrictions. The disadvantage is that data are from 2010, and will not be updated until 2020. In addition, data are at the census block level and so the model will need to make assumptions in order to locate individual residences within the census block. Also, 2010 data are not yet available for all U.S. territories.

87. *Collect actual customer location data from providers.* Collecting actual customer location from carriers would eliminate the need to use assumptions to distribute locations within a geography and the data could be obtained without procurement. The data collection would, however, be subject to approval by OMB and could entail significant administrative burdens for carriers, especially because some carriers may not have geocoded data for all customers. In addition, it would be difficult for the Commission to verify the accuracy of provider-submitted data. For those reasons, it may be difficult for the Bureau to develop, obtain approval for, and implement the data collection in the timeframe anticipated by the Commission.

88. The Bureau proposes to use a commercial data set for customer locations and seeks comment on its analysis of the relative merits of each alternative.

89. *Plant mix (aerial, underground, and buried).* A network's outside plant may be hung from utility poles (aerial plant), housed in underground utility conduits (e.g., areas with utility access via manholes), or buried. The cost differences for these different approaches are likely very large. Therefore, the model will be more accurate if it has better information about what areas have what type of outside plant. The Bureau seeks comment on two sources of outside plant mix data.

90. *Use provider-submitted data.* The model could rely on carrier-provided data. Using carrier-provided data would permit the model to account for unique or uncommon circumstances in a carrier's outside plant. It would, however, be difficult for the Commission to verify the data submitted by the carriers. In addition, this approach may create administrative burdens on both the carriers and Commission, and would be subject to approval by OMB. This is the approach taken in the ABC Coalition's model.

91. *Use the approach from prior Commission modeling.* The high-cost proxy model estimates the mix of aerial, underground and buried plant for areas of different density. Using the high-cost proxy model's approach would be administratively feasible because the data are publicly available, and a limited number of inputs are required to estimate the mix. It is unclear, however, the extent to which nationwide average plant mixes reflect actual plant mixes in any given area. The variance from the average plant mix would have potentially significant impact on the support levels for smaller price cap carriers or for states that have large variances from the average. The National Broadband Plan modeling used this approach.

92. The Bureau proposes to use provider-submitted data for plant-mix data and seeks comment on its analysis. In particular, the Bureau seeks comment on how best to validate provider-submitted data.

93. *Existing plant.* If the Bureau adopts the brown-field approach to

modeling, the age of the existing plant could be an important driver of cost. Those areas where the outside plant, in particular the cabling of the feeder and distribution lines, are likely to reach the end of their useful lives before the end of the modeling period will require investments more like a green-field build. In addition, the location of fiber in the feeder and distribution plant is likely to be a major driver of costs since costs will depend, in part, on connecting fiber facilities to existing copper. Understanding where such areas are will be important to calculating geographic-specific costs. The Bureau seeks comment regarding two methods identifying the age of existing plant.

94. *Collect data from providers about location of fiber facilities and age of plant.* Collecting data directly from carriers would allow the model to account for the actual facts associated with a carrier's existing plant and unique circumstances. It would, however, be difficult for the Commission to verify the data submitted by the carriers. In addition, this approach may create administrative burdens on both the carriers and Commission, and the data collection would require OMB approval. Moreover, it is not clear whether providers have geocoded information on fiber facilities and age of plant.

95. *Infer location of fiber based on existing broadband footprint, and ignore any geographic variation in plant age.* The model could assume that fiber is used to provide broadband wherever it is offered currently (assuming efficient routing) and calculate costs so that, on average, the cost is representative of areas with a typical distribution of the outside plant age. This is a simple approach that would not require significant data collection. It would provide only carrier- or state-average assumptions, however, which may make it more difficult to justify particular inputs. This is the approach taken in the modeling for the National Broadband Plan.

96. The Bureau seeks comment on these alternatives and its analysis of the relative attributes of each.

97. *Gauge of existing twisted-pair copper plant.* If the Bureau selects the brown-field approach to modeling, areas with smaller diameter twisted-pair copper wires (higher gauge number) will need shorter loops to achieve the same speed as areas with larger diameter wires. Understanding where such areas are will be important to calculating geographic-specific costs. The Bureau seeks comment regarding two methods of determining the gauge of existing twisted-pair copper plant.

98. *Collect data from providers.* The model could use the carriers' actual gauge of copper wire, as provided by the carrier. This would permit the model to address the unique circumstances of each carrier's existing copper wire deployment. It would, however, be difficult for the Commission to verify the data submitted by the carriers. In addition, this approach may create administrative burdens on both the carriers and Commission, and the data collection would be subject to OMB approval. Moreover, it is not clear whether providers have geocoded information on the gauge of their copper plant.

99. *Use average cost.* The model could ignore any geographic variation in the gauge of copper plant and instead calculate costs so that, on average, the cost is representative of areas with all sizes of copper gauge. This is a simple approach that would not require significant data collection. It would provide only carrier- or state-average assumptions, however, which may make it more difficult to justify particular inputs. This is the approach taken in the modeling for the National Broadband Plan.

100. The Bureau seeks comment on these alternatives and its analysis of the relative attributes of each.

101. *Validation of Cost Inputs.* In order for the model to estimate the cost of providing service, it must include reliable inputs related to cost of the equipment and labor used to provide the service. The Bureau seeks comment on sources for such data and how the data should be validated. For example, the Bureau notes that the ABC Plan includes cost inputs, but that some parties have raised questions about how the inputs were developed. In addition, it is difficult to compare the ABC Plan's cost inputs to ones actually experienced by the carriers since the model will calculate the forward-looking costs of an efficient provider. Furthermore, even unit costs (*i.e.,* the cost per unit for equipment and supplies) can be hard to compare or even make public given restrictions in purchasing contracts. In light of this example, how should cost inputs be selected? Alternatively, what steps can the Commission take to validate input submitted by providers?

102. *Additional Comments Regarding Submitted Models.* In the *USF/ICC Transformation Order,* the Commission declined to immediately adopt the ABC Coalition's CQBAT model as presented because there had been insufficient opportunity to review and modify the model. Specifically, the Commission cited the established transparency standard that ''before any cost model may be 'used to calculate the forward-looking economic costs of providing universal service in rural, insular, and high cost areas,' the 'model and all underlying data, formulae, computations, and software associated with the model must be available to all interested parties for review and comment.'' In addition, the Commission reiterated that ''[a]ll underlying data should be verifiable, engineering assumptions reasonable, and outputs plausible.' ''

103. In addition to the comment sought above on particular design decisions and data sources used in the models in the record, the Bureau also seeks comment on the ABC Plan's CQBAT model and the ACS model in light of the established transparency standard. Specifically, the Bureau asks parties to identify any issues of availability that the Bureau should address. The Bureau notes that at least 15 parties have gained access to the models in the record through the protective order process. The Bureau asks parties to identify outstanding questions relating to the verifiability of the underlying data, the reasonableness of engineering or economic assumptions, the reasonableness of model design decisions and choices of data sources additional to those identified here, and the plausibility of outputs on which the Bureau should seek further information for the record, either from the parties that submitted the models or from other interested parties through additional comment, workshops, or other record development processes.

III. Procedural Matters

A. Paperwork Reduction Act

104. This document contains proposed new information collection requirements. The Bureau, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. 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 Bureau seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

B. Initial Regulatory Flexibility Act Analysis

105. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Bureau has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this Notice. Written 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 Notice. The Commission will send a copy of the FNPRM, 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**.

a. Need for, and Objectives of, the Proposed Rules

106. The Notice seeks comment on a variety of issues relating to the design of a model to estimate the forward-looking economic costs of providing broadband to high-cost areas. The model will be to calculate support levels to be provided to price cap carriers and their affiliates that accept their right of first refusal and deploy services consistent with the obligations set forth in the *USF/ICC Transformation Order.* The model will also be used to determine which areas are above the ''extremely high cost'' threshold and are therefore subject to the Remote Areas Fund.

b. Legal Basis

107. The legal basis for any action that may be taken pursuant to the Notice is contained in sections 1, 2, 4(i), 214, 254, 303(r), 403, and 706 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 214, 254, 303(r), 403, and 706, and §§ 1.1 and 1.1421 of the Commission's rules, 47 CFR 1.1, 1.421.

c. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

108. 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 generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. A small-business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

109. *Small Businesses.* Nationwide, there are a total of approximately 27.5 million small businesses, according to the SBA.

110. *Wired Telecommunications Carriers.* The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. According to Census Bureau data for 2007, there were 3,188 firms in this category, total, that operated for the entire year. Of this total, 3144 firms had employment of 999 or fewer employees, and 44 firms had employment of 1000 employees or more. Thus, under this size standard, the majority of firms can be considered small.

111. *Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,307 carriers reported that they were incumbent local exchange service providers. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most providers of local exchange service are small entities that may be affected by the rules and policies proposed in the FNPRM.

112. *Incumbent Local Exchange Carriers (incumbent LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to incumbent local exchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,307 carriers reported that they were incumbent local exchange service providers. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by rules adopted pursuant to the FNPRM.

113. We have included small incumbent LECs in this present RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (*e.g.,* a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent LECs in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

114. *Competitive Local Exchange Carriers (competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees and 186 have more than 1,500 employees. In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees. In addition, 72 carriers have reported that they are Other Local Service Providers. Of the 72, seventy have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities that may be affected by rules adopted pursuant to the FNPRM.

115. *Wireless Telecommunications Carriers (except Satellite).* Since 2007, the SBA has recognized wireless firms within this new, broad, economic census category. Prior to that time, such firms were within the now-superseded categories of Paging and Cellular and Other Wireless Telecommunications. Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. For this category, census data for 2007 show that there were 1,383 firms that operated for the entire year. Of this total, 1,368 firms had employment of 999 or fewer employees

and 15 had employment of 1000 employees or more. Similarly, according to Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service (PCS), and Specialized Mobile Radio (SMR) Telephony services. Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. Consequently, the Commission estimates that approximately half or more of these firms can be considered small. Thus, using available data, we estimate that the majority of wireless firms can be considered small.

116. *Local Multipoint Distribution Service.* Local Multipoint Distribution Service (LMDS) is a fixed broadband point-to-multipoint microwave service that provides for two-way video telecommunications. The auction of the 986 LMDS licenses began and closed in 1998. The Commission established a small business size standard for LMDS licenses as an entity that has average gross revenues of less than $40 million in the three previous calendar years. An additional small business size standard for ''very small business'' was added as an entity that, together with its affiliates, has average gross revenues of not more than $15 million for the preceding three calendar years. The SBA has approved these small business size standards in the context of LMDS auctions. There were 93 winning bidders that qualified as small entities in the LMDS auctions. A total of 93 small and very small business bidders won approximately 277 A Block licenses and 387 B Block licenses. In 1999, the Commission re-auctioned 161 licenses; there were 32 small and very small businesses winning that won 119 licenses.

117. *Satellite Telecommunications.* Since 2007, the SBA has recognized satellite firms within this revised category, with a small business size standard of $15 million. The most current Census Bureau data are from the economic census of 2007, and we will use those figures to gauge the prevalence of small businesses in this category. Those size standards are for the two census categories of ''Satellite Telecommunications'' and ''Other Telecommunications.'' Under the ''Satellite Telecommunications'' category, a business is considered small if it had $15 million or less in average annual receipts. Under the ''Other Telecommunications'' category, a business is considered small if it had $25 million or less in average annual receipts.

118. The first category of Satellite Telecommunications ''comprises establishments primarily engaged in providing point-to-point telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' For this category, Census Bureau data for 2007 show that there were a total of 512 firms that operated for the entire year. Of this total, 464 firms had annual receipts of under $10 million, and 18 firms had receipts of $10 million to $24,999,999. Consequently, we estimate that the majority of Satellite Telecommunications firms are small entities that might be affected by rules adopted pursuant to the FNPRM.

119. The second category of Other Telecommunications ''primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing Internet services or voice over Internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry.'' For this category, Census Bureau data for 2007 show that there were a total of 2,383 firms that operated for the entire year. Of this total, 2,346 firms had annual receipts of under $25 million. Consequently, we estimate that the majority of Other Telecommunications firms are small entities that might be affected by our action.

120. *Cable and Other Program Distribution.* Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers; that category is defined as follows: ''This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies.'' The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were a total of 955 firms in this previous category that operated for the entire year. Of this total, 939 firms had employment of 999 or fewer employees, and 16 firms had employment of 1,000 employees or more. Thus, under this size standard, the majority of firms can be considered small and may be affected by rules adopted pursuant to the FNPRM.

121. *Cable Companies and Systems.* The Commission has developed its own small business size standards, for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers, nationwide. Industry data indicate that, of 1,076 cable operators nationwide, all but eleven are small under this size standard. In addition, under the Commission's rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Industry data indicate that, of 7,208 systems nationwide, 6,139 systems have under 10,000 subscribers, and an additional 379 systems have 10,000–19,999 subscribers. Thus, under this second size standard, most cable systems are small and may be affected by rules adopted pursuant to the FNPRM.

122. *Cable System Operators.* The Act also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' The Commission has determined that an operator serving fewer than 677,000 subscribers shall be deemed a small operator, if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Industry data indicate that, of 1,076 cable operators nationwide, all but ten are small under this size standard. We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million, and therefore we are unable to estimate more accurately the number of cable system operators that would qualify as small under this size standard.

123. *Open Video Services.* The open video system (OVS) framework was established in 1996, and is one of four statutorily recognized options for the provision of video programming services by local exchange carriers. The OVS framework provides opportunities for the distribution of video

programming other than through cable systems. Because OVS operators provide subscription services, OVS falls within the SBA small business size standard covering cable services, which is ''Wired Telecommunications Carriers.'' The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were a total of 955 firms in this previous category that operated for the entire year. Of this total, 939 firms had employment of 999 or fewer employees, and 16 firms had employment of 1,000 employees or more. Thus, under this second size standard, most cable systems are small and may be affected by rules adopted pursuant to the Notice. In addition, we note that the Commission has certified some OVS operators, with some now providing service. Broadband service providers (BSPs) are currently the only significant holders of OVS certifications or local OVS franchises. The Commission does not have financial or employment information regarding the entities authorized to provide OVS, some of which may not yet be operational. Thus, again, at least some of the OVS operators may qualify as small entities.

124. *Internet Service Providers.* Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers; that category is defined as follows: ''This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies.'' The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were 3,188 firms in this category, total, that operated for the entire year. Of this total, 3,144 firms had employment of 999 or fewer employees, and 44 firms had employment of 1,000 employees or more. Thus, under this size standard, the majority of firms can be considered small. In addition, according to Census Bureau data for 2007, there were a total of 396 firms in the category Internet Service Providers (broadband) that operated for the entire year. Of this total, 394 firms had employment of 999 or fewer employees, and two firms had employment of 1,000 employees or more. Consequently, we estimate that the majority of these firms are small entities that may be affected by rules adopted pursuant to the FNPRM.

d. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

125. In this Notice, the Commission seeks public comment on model design and input issues associated with a forward-looking economic cost model to be used to determine support for price cap carriers and their affiliates pursuant to Phase II of the Connect America Fund. The Notice seeks comment on possible data inputs that would require reporting by small entities. Specifically, the Notice seeks comment on the use of wire center boundaries based on data collected from local exchange carriers, the use of residential location data collected from service providers, and the use of data from local exchange carriers regarding their mix of aerial, underground and buried plant, the age of existing plant, and the gauge of existing twisted-pair copper plant.

e. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

126. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which 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 rules for such 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 such small entities.''

127. The Notice seeks comment on a number of model design and inputs questions. The model design issues are not anticipated to have a significant economic impact on small entities insofar as the results produce high-cost support amounts for price cap carriers and their affiliates that accept the right of first refusal pursuant to CAF Phase II. This is primarily because most (and perhaps all) of the affected carriers are not small entities. Moreover, the choice of alternatives discussed is not anticipated to systematically increase or decrease support for any particular group of entities and therefore any significant economic impact cannot necessarily be minimized through alternatives.

128. In one respect, the model design may have a significant economic impact on small entities. The Notice seeks comment on using the model to set the ''extremely high-cost'' threshold, which would identify ''remote areas.'' Such areas will be included in the Remote Areas Fund if they are in a price cap service territory, and would thus be subject an alternative support mechanism that could include small entities. The definition of such areas could also affect the service obligations of rate-of-return carriers, many of which are small entities. The Bureau does not propose a specific methodology for establishing the extremely high-cost threshold, but seeks broad comment on how to do so. The Bureau anticipates that it will consider alternatives, including those that would minimize the significant economic impact on small entities.

f. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

129. None.

A. Filing Requirements

130. *Filing Requirements.* 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, May 1, 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 St. 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.

131. *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).

132. The proceeding this Notice 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) of the Commission's rules. In proceedings governed by Commission 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.

Federal Communications Commission.

Trent B. Harkrader,

Division Chief, Telecommunications Access Policy Division, Wireline Competition Bureau.

[FR Doc. 2012–15991 Filed 6–28–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, 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 the renewal of an existing information collection, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comment on renewal of the information collection described below.

DATES: Comments must be submitted on or before August 28, 2012.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@fdic.gov.* Include the name of the collection in the subject line of the message.
- *Mail:* Gary A. Kuiper (202.898.3877), Counsel, Room NYA–5046, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Gary A. Kuiper, at the FDIC address above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently-Approved Collection of Information

Title: Notices Required of Government Securities Dealers or Brokers (Insured State Nonmember Banks).

OMB Number: 3064–0093.

Form Number: G–FIN; G–FINW; G–FIN4 & G–FIN5.

Affected Public: Insured state nonmember banks acting as government securities brokers and dealers.

Estimated Number of Respondents: 17.

Frequency of Response: On occasion.

Estimated Annual Burden Hours per Response: 1 hour.

Estimated Total Annual Burden Hours: 17 hours.

General Description of Collection: The Government Securities Act of 1986 requires all financial institutions acting as government securities brokers and dealers to notify their Federal regulatory agencies of their broker-dealer activities, unless exempted from the notice requirements by Treasury Department regulation.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 25th day of June 2012.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2012–15926 Filed 6–28–12; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*)

(BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 26, 2012.

A. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *First PactTrust Bancorp, Inc.,* Irvine, California; to merge with Gateway Bancorp, Santa Ana, California, with First PacTrust Bancorp, Inc., and thereby indirectly acquire Gateway Business Bank, Cerritos, California.

Board of Governors of the Federal Reserve System, June 26, 2012.

Margaret McCloskey Shanks,

Associate Secretary of the Board.

[FR Doc. 2012–15982 Filed 6–28–12; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 26, 2012.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. *Financial Services Partners Fund I LLC, Hovde Acquisition I LLC, and Hovde Private Equity Advisors LLC,* all of Washington, DC (collectively the ''Hovde Group''), to acquire control of a savings and loan holding company, Carrollton Bancorp, Columbia, Maryland, upon Carrollton Bancorp's conversion to a savings and loan holding company through a merger with Jefferson Bancorp, Inc., Washington, DC, a subsidiary of the Hovde Group, and thereby control Carrollton Bank, Columbia, Maryland, and Bay Bank FSB, Lutherville, Maryland.

In addition, Carrollton Bank will merge with Bay Bank, FSB, Lutherville, Maryland, with Bay Bank, FSB, as the surviving entity.

Board of Governors of the Federal Reserve System, June 26, 2012.

Margaret McCloskey Shanks,

Associate Secretary of the Board.

[FR Doc. 2012–15981 Filed 6–28–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5644–N–02]

Credit Watch Termination Initiative; Termination of Direct Endorsement (DE) Approval

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice advises of the cause and effect of termination of Direct Endorsement (DE) Approval taken by HUD's Federal Housing Administration (FHA) against HUD-approved mortgagees through the FHA Credit Watch Termination Initiative. This notice includes a list of mortgagees which have had their DE Approval terminated.

FOR FURTHER INFORMATION CONTACT: The Quality Assurance Division, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room B133–P3214, Washington, DC 20410–8000; telephone 202–708–2830 (this is not a toll-free number). Persons with hearing or speech impairments may access that number through TTY by calling the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: HUD has the authority to address deficiencies in the performance of lenders' loans as provided in HUD's mortgagee approval regulations at 24 CFR 202.3. On May 17, 1999, HUD published a notice (64 FR 26769), on its procedures for terminating Origination Approval Agreements with FHA lenders and placement of FHA lenders on Credit Watch status (an evaluation period). In the May 17, 1999 notice, HUD advised that it would publish in the **Federal Register** a list of mortgagees, which have had their Approval Agreements terminated. On January 21, 2010 HUD issued Mortgagee Letter 2010–03 which advised the extended procedures for terminating Underwriting Authority of Direct Endorsement mortgagees.

Termination of Direct Endorsement Approval: Approval of a DE mortgagee by HUD/FHA authorizes the mortgagee to underwrite single family mortgage loans and submit them to FHA for insurance endorsement. The Approval may be terminated on the basis of poor performance of FHA-insured mortgage loans underwritten by the mortgagee. The termination of a mortgagee's DE Approval is separate and apart from any action taken by HUD's Mortgagee Review Board under HUD's regulations at 24 CFR part 25.

Cause: HUD's regulations permit HUD to terminate the DE Approval with any mortgagee having a default and claim rate for loans endorsed within the preceding 24 months that exceeds 200 percent of the default and claim rate within the geographic area served by a HUD field office, and also exceeds the national default and claim rate. For the quarterly review period ending December 31, 2011, HUD is terminating the DE Approval of mortgagees whose default and claim rate exceeds both the national rate and 200 percent of the field office rate.

Effect: Termination of the DE Approval precludes the mortgagee from underwriting FHA-insured single-family mortgages within the area of the HUD field office(s) listed in this notice. Mortgagees authorized to purchase, hold, or service FHA-insured mortgages may continue to do so.

Loans that closed or were approved before the Termination became effective may be submitted for insurance endorsement. Approved loans are those already underwritten and approved by a DE underwriter, and cases covered by a firm commitment issued by HUD. Cases at earlier stages of processing cannot be submitted for insurance by the terminated mortgagee; however, the cases may be transferred for completion of processing and underwriting to another mortgagee with DE Approval in that area. Mortgagees are obligated to continue to pay existing insurance premiums and meet all other obligations associated with insured mortgages.

A terminated mortgagee may apply for reinstatement of the DE Approval if the DE Approval for the affected area or areas has been terminated for at least six months and the mortgagee continues to be an approved mortgagee meeting the requirements of 24 CFR 202.5, 202.6, 202.7, 202.10 and 202.12. The mortgagee's application for reinstatement must be in a format prescribed by the Secretary and signed by the mortgagee. In addition, the application must be accompanied by an independent analysis of the terminated office's operations as well as its mortgage production, specifically including the FHA-insured mortgages cited in its termination notice. This independent analysis shall identify the underlying cause for the mortgagee's high default and claim rate. The analysis must be prepared by an independent Certified Public Accountant (CPA) qualified to perform audits under Government Auditing Standards as provided by the Government Accountability Office. The mortgagee must also submit a written corrective action plan to address each of the issues identified in the CPA's report, along with evidence that the plan has been implemented. The application for a new Agreement should be in the form of a letter, accompanied by the CPA's report and corrective action plan. The request should be sent to the Director, Office of Lender Activities and Program Compliance, 451 Seventh Street SW., Room B133–P3214, Washington, DC 20410–8000 or by courier to 490 L'Enfant Plaza, East SW., Suite 3214, Washington, DC 20024–8000.

Action: The following mortgagees have had their DE Approvals terminated by HUD:

Mortgagee name	Mortgagee home office address	HUD Office jurisdiction	Termination effective date	Homeownership center
Community Central Mortgage Co. LLC	120 N Main St., Mount Clemens, MI 48043.	Indianapolis	4/17/12	Atlanta.
Strategic Mortgage Company	40 W 3rd Ave., Columbus, OH 43201	Columbus	4/17/12	Philadelphia.

Dated: June 18, 2012.

Carol Galante,

Acting Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 2012–16036 Filed 6–28–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5644–N–01]

Credit Watch Termination Initiative; Termination of Origination Approval Agreements

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice advises of the cause and effect of termination of Origination Approval Agreements taken by HUD's Federal Housing Administration (FHA) against HUD-approved mortgagees through the FHA Credit Watch Termination Initiative. This notice includes a list of mortgagees which have had their Origination Approval Agreements terminated.

FOR FURTHER INFORMATION CONTACT: The Quality Assurance Division, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room B133–P3214, Washington, DC 20410–8000; telephone 202–708–2830 (this is not a toll-free number). Persons with hearing or speech impairments may access that number through TTY by calling the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: HUD has the authority to address deficiencies in the performance of lenders' loans as provided in HUD's mortgagee approval regulations at 24 CFR 202.3. On May 17, 1999 HUD published a notice (64 FR 26769), on its procedures for terminating Origination Approval Agreements with FHA lenders and placement of FHA lenders on Credit Watch status (an evaluation period). In the May 17, 1999 notice, HUD advised that it would publish in the **Federal Register** a list of mortgagees, which have had their Origination Approval Agreements terminated.

Termination of Origination Approval Agreement: Approval of a mortgagee by HUD/FHA to participate in FHA mortgage insurance programs includes an Origination Approval Agreement (Agreement) between HUD and the mortgagee. Under the Agreement, the mortgagee is authorized to originate single-family mortgage loans and submit them to FHA for insurance endorsement. The Agreement may be terminated on the basis of poor performance of FHA-insured mortgage loans originated by the mortgagee. The termination of a mortgagee's Agreement is separate and apart from any action taken by HUD's Mortgagee Review Board under HUD's regulations at 24 CFR part 25.

Cause: HUD's regulations permit HUD to terminate the Agreement with any mortgagee having a default and claim rate for loans endorsed within the preceding 24 months that exceeds 200 percent of the default and claim rate within the geographic area served by a HUD field office, and also exceeds the national default and claim rate. For the quarterly review period ending December 31, 2011, HUD is terminating

the Agreement of mortgagees whose default and claim rate exceeds both the national rate and 200 percent of the field office rate.

Effect: Termination of the Agreement precludes branch(es) of the mortgagee from originating FHA-insured single-family mortgages within the area of the HUD field office(s) listed in this notice. Mortgagees authorized to purchase, hold, or service FHA-insured mortgages may continue to do so.

Loans that closed or were approved before the termination became effective may be submitted for insurance endorsement. Approved loans are those already underwritten and approved by a DE underwriter, and cases covered by a firm commitment issued by HUD. Cases at earlier stages of processing cannot be submitted for insurance by the terminated branch; however, they may be transferred for completion of processing and underwriting to another FHA-insured mortgagee with direct endorsement approval for the area covered by the termination. Mortgagees are obligated to continue to pay existing insurance premiums and meet all other obligations associated with insured mortgages.

A terminated mortgagee may apply for reinstatement of the Origination Approval Agreement if the approval for the affected branch or branches has been terminated for at least six months and the mortgagee continues to be an approved mortgagee meeting the requirements of 24 CFR 202.5, 202.6, 202.7, 202.8 and 202.12. However, Mortgagee Letter 2010–20 and Final Rule 5356–F–02 at 24 CFR part 202 eliminates FHA approval for loan correspondents after December 31, 2010. Therefore, HUD will not accept requests for reinstatement from loan correspondents after that date. The mortgagee's application for reinstatement must be in a format prescribed by the Secretary and signed by the mortgagee. In addition, the application must be accompanied by an independent analysis of the terminated office's operations as well as its mortgage production, specifically including the FHA-insured mortgages cited in its termination notice. This independent analysis shall identify the underlying cause for the mortgagee's high default and claim rate. The analysis must be prepared by an independent Certified Public Accountant (CPA) qualified to perform audits under Government Auditing Standards as provided by the Government Accountability Office. The mortgagee must also submit a written corrective action plan to address each of the issues identified in the CPA's report, along with evidence that the plan has been implemented. The application for a new Agreement should be in the form of a letter, accompanied by the CPA's report and corrective action plan. The request should be sent to the Director, Office of Lender Activities and Program Compliance, 451 Seventh Street SW., Room B133–P3214, Washington, DC 20410–8000 or by courier to 490 L'Enfant Plaza, East SW., Suite 3214, Washington, DC 20024–8000.

Action: The following mortgagees have had their Origination Agreements terminated by HUD:

Mortgagee name	Mortgagee branch office address	HUD office jurisdiction	Termination effective date	Homeownership center
Strategic Mortgage Company	40 W 3rd Ave., Columbus, OH 43201	Columbus	4/17/12	Philadelphia.

Dated: June 18, 2012.

Carol Galante,

Acting Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2012–16041 Filed 6–28–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2012–0036; FXES11120300000F2–123–FF03E15000]

Availability of a Draft Environmental Impact Statement and Habitat Conservation Plan; Receipt of an Application for an Incidental Take Permit, Buckeye Wind Power Project, Champaign County, OH

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application from Buckeye Wind, LLC (applicant), for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA), for its Buckeye Wind Power Project (project). If approved, the ITP would be for a 30-year period and would authorize the incidental take of an endangered species, the Indiana bat. The applicant has prepared a habitat conservation plan (HCP) that describes the actions and measures the applicant would implement to avoid, minimize, and mitigate incidental take of the Indiana bat. The ITP application also includes a draft implementing agreement (IA). We also announce the availability of a draft Environmental Impact Statement (EIS) that has been prepared in response to the permit application in accordance with the requirements of the National Environmental Policy Act (NEPA). We request public comment on the application and associated documents.

DATES: *Public Meeting:* July 12, 2012, 4–8 p.m., Champaign County Community Center Auditorium, 1512 S. U.S. Highway 68, Urbana, OH 43078.

Comments: We will accept comments received or postmarked on or before September 27, 2012. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: *Document availability:*

- *Internet:* You may obtain copies of the documents on the Internet at *http://www.regulations.gov* (Docket Number FWS–R3–ES–2012–0036) or *http://www.fws.gov/midwest/endangered/permits/hcp/r3hcps.html.*
- *U.S. Mail:* You can obtain the documents by mail from the Ecological Services Office in the Midwest Regional Office (see **FOR FURTHER INFORMATION CONTACT**).
- *In-Person:* To view hard copies of the documents in person, go to one of the Ecological Services Offices (8 a.m. to 4 p.m.) listed under **FOR FURTHER INFORMATION CONTACT,** or to one of the following libraries during normal business hours: Champaign County Library, 1060 Scioto Street, Urbana, OH 43078–2228; or North Lewisburg Branch, 161 Winder Street, North Lewisburg, OH 43060.

Public Meeting: See **DATES**.

Comment submission: In your comment, please specify whether your comment addresses the HCP, the draft EIS, both the HCP and draft EIS, or other supporting documents. You may submit written comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R3–ES–2012–0036, which is the docket number for this notice. Then, on the left side of the screen, under the

Document Type heading, click on the Notices link to locate this document and submit a comment.

• *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R3–ES–2012–0036; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all information received on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Megan Seymour, Fish and Wildlife Biologist, Ohio Ecological Services Field Office, U.S. Fish and Wildlife Service, 4625 Morse Road, Suite 104, Columbus, OH 43230; 614–416–8993, extension 16; or Rick Amidon, Fish and Wildlife Biologist, Ecological Services, Midwest Regional Office, U.S. Fish and Wildlife Service, 5600 American Blvd., West, Suite 990, Bloomington, MN 55437–1458; 612–713–5164.

SUPPLEMENTARY INFORMATION: We have received an application from Buckeye Wind, LLC, for an incidental take permit (TE66315A) under the ESA (16 U.S.C. 1531 *et seq.*). If approved, the ITP would be for a 30-year period and would authorize incidental take of the Indiana bat (*Myotis sodalis*).

The applicant has prepared a draft HCP to cover the construction, operation, maintenance, and decommissioning of the project. The project consists of a wind-powered electric generation facility located in an approximately 80,051-acre area (the action area) located in portions of Union, Wayne, Urbana, Salem, Rush, and Goshen Townships, in Champaign County, Ohio. The draft HCP describes the following: (1) Biological goals and objectives of the HCP; (2) the covered activities; (3) permit duration; (4) permit area; (5) alternatives to the taking that were considered; (5) public participation; (6) life history of the Indiana bat; (6) a quantification of the take for which authorization is requested; (7) an assessment of direct and indirect effects of the taking on the Indiana bat within the action area and within the Midwest Recovery Unit (as delineated in the 2007 Indiana Bat Draft Recovery Plan, USFWS); (8) a conservation program consisting of avoidance and minimization measures, mitigation, monitoring, and adaptive management; (9) funding for the HCP; (10) procedures to deal with changed and unforeseen circumstances; and (11) methods for ITP amendments.

In addition to the draft HCP, the applicant has prepared an Implementing Agreement (IA) to document the responsibilities of the parties. The USFWS invites comment on the IA as well as the applicant's HCP.

Under the NEPA (43 U.S.C. 4321 *et seq.*) and the ESA, the Service announces that we have gathered the information necessary to:

1. Determine the impacts and formulate alternatives for an EIS related to:

a. Issuance of an ITP to the applicant for the take of the Indiana bat, and

b. Implementation of the associated HCP; and

2. Evaluate the application for ITP issuance, including the HCP, which provides measures to minimize and mitigate the effects of the proposed incidental take of Indiana bat.

Background

Buckeye Wind, LLC, is a wholly owned subsidiary of EverPower Wind Holdings, Inc. (EverPower).

The project has been in the planning and development phase since 2006. Indiana bats were discovered in and around the Buckeye Wind action area during pre-construction wildlife surveys in 2008 and 2009. Because wind power projects across the eastern United States have been documented to cause mortality of bats in general, and Indiana bats specifically, Buckeye Wind determined it was appropriate to develop an HCP and apply for an ITP to authorize the potential incidental take of Indiana bats from construction, operation, maintenance, and decommissioning of the project. The HCP was developed by Buckeye Wind and their consultants, in coordination with the Service.

The HCP provides a detailed conservation plan to ensure that the incidental take caused by the project will not appreciably reduce the likelihood of the survival and recovery of the covered species in the action area or in the recovery unit, and provides mitigation to fully offset the impact of the taking. Further, the HCP provides a long-term monitoring and adaptive management strategy to ensure that the ITP terms are satisfied, and to account for changed and unforeseen circumstances.

Purpose and Need for Action

In accordance with NEPA, the Service has prepared an EIS to analyze the impacts to the human environment that would occur if the requested ITP were issued and the associated HCP were implemented.

Proposed Action

Section 9 of the ESA prohibits the ''taking'' of threatened and endangered species. However, provided certain criteria are met, the Service is authorized to issue permits under section 10(a)(1)(B) of the ESA for take of federally listed species when, among other things, such a taking is incidental to, and not the purpose of, otherwise lawful activities. Under the ESA, the term ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect endangered and threatened species, or to attempt to engage in any such conduct. Our implementing regulations define ''harm'' as an act which actually kills or injures wildlife, and such act may include significant habitat modification or degradation that results in death or injury to listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). Harass, as defined, means ''an intentional or negligent act or omission which creates the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns which include, but are not limited to, breeding, feeding, or sheltering'' (50 CFR 17.3).

The HCP analyzes, and the ITP would cover, take from harassment, harm, and killing of bats due to the construction, operation, maintenance, and decommissioning associated with the project. If issued, the ITP would authorize incidental take consistent with the applicant's HCP and the permit. To issue the ITP, the Service must find that Buckeye Wind's application, including its HCP, satisfies the criteria of section 10(a)(1)(B) of the ESA and the Service's implementing regulations at 50 CFR parts 13 and 17.22. If the ITP is issued, the applicant would receive assurances under the Service's No Surprises policy, as codified at 50 CFR 17.22(b)(5).

Buckeye Wind proposes to construct and operate a maximum of 100 wind turbines and associated facilities (described below) for a period of 30 years in eastern Champaign County, Ohio. The project will consist of wind turbines, associated access roads, an underground and aboveground electrical collector system, a substation for connection of the wind turbines to the local transmission system, four permanent meteorological towers, and an operations and maintenance building. In addition, up to four temporary construction staging areas

will be created during development. Project facilities and infrastructure will be placed on private land via long-term easement agreements between Buckeye Wind and respective landowners.

While approximately 80,051 acres are located within the Buckeye Wind action area, a relatively small portion of that land, approximately 0.16 percent (129.8 acres), will be permanently occupied by the project facilities. Beyond the approximately 129 acres of occupied area, as described in Section 2.2 of the HCP, the project will not impact or change the existing land use.

The draft HCP describes the impacts of take associated with Buckeye Wind's activities and includes measures to avoid, minimize, mitigate, and monitor the impacts of incidental take on the Indiana bat. Buckeye Wind will be mitigating for take and associated impacts through permanent preservation, enhancement, and restoration of suitable Indiana bat habitat within 7 miles of a Priority 2 Indiana bat hibernaculum (USFWS, 2007, Draft Indiana Bat Recovery Plan) in Ohio. Mitigation will occur on private lands and will be permanently protected by a conservation easement held by a third-party conservation organization. Section 6.3 of the HCP describes the details of compensatory mitigation and its implementation. The HCP also includes numerous avoidance and minimization measures, as described in sections 6.1 through 6.2, as well as adaptive management, as described in section 6.5, which will limit the take of the Indiana bat.

The Service is soliciting information regarding the adequacy of the HCP to avoid, minimize, mitigate, and monitor the proposed incidental take of the covered species and to provide for adaptive management. In compliance with section 10(c) of the ESA (16 U.S.C. 1539(c)), the Service is making the ITP application materials available for public review and comment as described above.

We invite comments and suggestions from all interested parties on the draft documents associated with the ITP application (HCP, HCP Appendices, and IA), and request that comments be as specific as possible. In particular, we request information and comments on the following topics:

1. Whether adaptive management and monitoring provisions in the Proposed Action alternative are sufficient;

2. Any threats to the covered species that may influence its population over the life of the ITP that are not addressed in the HCP or EIS;

3. Any new information on white-nose syndrome effects on the covered species;

4. Whether the models and model inputs used to estimate risk to the covered species are appropriate; and

5. Any other information pertinent to evaluating the effects of the proposed action on the Indiana bat.

Alternatives in the Draft EIS

The draft EIS contains an analysis of four alternatives: (1) No Action (no permit issuance); (2) Proposed Action—Modified Operations Alternative, including implementation of the HCP and Issuance of a 30-year ITP; (3) Maximally Restricted Operations Alternative, without an HCP or ITP; and (4) Minimally Restricted Operations Alternative and Issuance of a 30-year ITP. The draft EIS considers the direct, indirect, and cumulative effects of the alternatives, including any measures under the Proposed Action alternative intended to minimize and mitigate such impacts. The draft EIS also identifies additional alternatives that were considered but were eliminated from consideration as detailed in Section 2.3 of the EIS.

The Service invites comments and suggestions from all interested parties on the content of the draft EIS. In particular, information and comments regarding the following topics are requested:

1. The direct, indirect, or cumulative effects that implementation of any alternative could have on the human environment;

2. Whether or not the significance of the impact on various aspects of the human environment has been adequately analyzed; and

3. Any other information pertinent to evaluating the effects of the proposed action on the human environment.

Public Comments

You may submit your comments and materials concerning the notice by one of the methods listed in **ADDRESSES**. We request that you send comments only by one of the methods described in **ADDRESSES**.

If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the Web site. We will post all hardcopy comments on *http://www.regulations.gov* as well. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as documents associated with the notice, will be available for public inspection on *http://www.regulations.gov* at Docket No. FWS–R3–ES–2012–0036, or by appointment, during normal business hours, at the Ohio Ecological Services Field Office in Columbus, Ohio (see **FOR FURTHER INFORMATION CONTACT**).

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22), and NEPA (42 U.S.C. 4371 *et seq.*) and its implementing regulations (40 CFR 1506.6; 43 CFR part 46).

Dated: June 21, 2012.

Lynn Lewis,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2012–15664 Filed 6–28–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Final Environmental Impact Statement for the Menominee Indian Tribe of Wisconsin's Proposed Fee-to-Trust Transfer and Casino-Hotel Project in the City of Kenosha, Kenosha County, WI

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Availability.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA) as the lead Federal agency, with the Menominee Indian Tribe of Wisconsin (Tribe), the National Indian Gaming Commission (NIGC), the City of Kenosha, and Kenosha County, as cooperating agencies, has prepared a Final Environmental Impact Statement (FEIS) for the proposed approval of a 223-acre fee-to-trust transfer and the construction of a casino-hotel complex. This notice also announces the FEIS is now available for public review. Hard copies are available upon request or may be found at the addresses indicted in the **SUPPLEMENTARY INFORMATION** section below.

DATES: The Record of Decision on the proposed action will be issued no sooner than 30 days after the release of the FEIS. Thus, any comments on the FEIS must arrive at the addresses indicated below by July 30, 2012.

ADDRESSES: You may request a copy of the FEIS, by contacting Scott Doig, Regional Environmental Protection Specialist, Midwest Region, Bureau of Indian Affairs, 5600 West American Boulevard, Suite 500, Bloomington, Minnesota 55437, telephone (612) 725–4514, fax (612) 713–4401.

FOR FURTHER INFORMATION CONTACT: Scott Doig, Regional Environmental Protection Specialist, Midwest Region, Bureau of Indian Affairs, 5600 West American Boulevard, Suite 500, Bloomington, Minnesota 55437, telephone (612) 725–4514, fax (612) 713–4401.

SUPPLEMENTARY INFORMATION: The Tribe has asked the BIA to take 223 acres of land into trust on behalf of the Tribe, on which the Tribe proposes to develop a casino-hotel complex. The proposed project is located at the site of the existing Dairyland Greyhound Park, at 5522–104th Ave., Kenosha, Wisconsin 53144. The property is approximately one half mile east of Interstate 94, and approximately 35 miles south of Milwaukee, Wisconsin. The BIA serves as lead agency for compliance with the National Environmental Policy Act. The Tribe, the NIGC, the City of Kenosha, and Kenosha County, as entities having jurisdiction and special expertise relevant to potentially affected resources, are acting as cooperating agencies.

The project design includes taking the 223-acre Dairyland Greyhound Park property into trust for the Tribe, and the development of a casino-hotel complex, while potentially retaining the current greyhound racetrack, structure, concourse and kennel facilities. Future development includes a water park, a second hotel, and a recreational vehicle park. Interim Class III gaming would be conducted inside the existing clubhouse until the new casino is built. The FEIS considers a range of project alternatives, including: (1) Preferred casino-hotel complex; (2) reduced intensity; (3) off-site expansion of existing Keshena facilities; (4) hotel-conference center/recreational development; and (5) no action. Environmental issues addressed in the FEIS include land and water resources, air quality, biological resources, cultural and paleontological resources, socioeconomic conditions, transportation and circulation, land use, public services, noise, hazardous materials, visual resources, environmental justice, cumulative effects, indirect effects and mitigation.

The BIA has afforded other government agencies and the public opportunity to participate in the preparation of this FEIS. The BIA published a Notice of Intent to prepare a Draft Environmental Impact Statement (DEIS) for the proposed action in the **Federal Register** on June 23, 2004 (69 FR 35058), with a correction published on July 7, 2004 (69 FR 40966). The BIA held a public scoping meeting on August 3, 2004, in Kenosha, WI. A Notice of Availability for the DEIS was published in the **Federal Register** on September 23, 2005 (70 FR 55835). The document was available for public comment from September 23, 2005, to November 21, 2005, and a public hearing was held on October 25, 2005, in Pleasant Prairie, WI. An extended comment period for the DEIS was announced in the **Federal Register** on February 3, 2006 (71 FR 5837). The document was available for public comment from February 3, 2006, to March 6, 2006. Applicable information including population and traffic densities were updated in the preliminary FEIS and completed in January 2012.

Locations where the FEIS is Available for Review: The FEIS will be available for review at the following branches of the Kenosha Public Library: Simmons, 711 59th Place, Kenosha, WI 53140; Southwest, 7979 38th Avenue, Kenosha, WI 53142; Northside, 1500 27th Avenue, Kenosha, WI 53140; Uptown, 2419 63rd Street, Kenosha, WI 53143. General information for the Kenosha Public Library system can be obtained by calling (262) 564–6100. The FEIS will also be available for review at the Waukegan Public Library, 128 North County Street, Waukegan, IL 60085. General information for the Waukegan Public Library can be obtained by calling (847) 623–2041. An electronic version of the FEIS can be viewed at the following Web site: *http://www.kenoshaeis.com*

Public Availability of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: This notice is published pursuant to Sec. 1503.1 of the Council of Environmental Quality Regulations (40 CFR part 1500 through 1508) and Sec. 46.305 of the Department of Interior Regulations (43 CFR part 46), implementing the procedural requirements of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4371 et seq.), and is in the exercise of authority delegated to the Assistant Secretary—Indian Affairs by 209 DM 8.

Dated: May 31, 2012.

Donald E. Laverdure,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2012–15878 Filed 6–28–12; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NVN–089176 & NVN–091072 LLNVS00560 L51010000.ER0000 LVRWF1103400]

Notice of Availability: Record of Decision for KRoad Moapa Solar Facility

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM) announces the Notice of Availability (NOA) of the Record of Decision (ROD) for the KRoad Moapa Solar Facility located in Clark County, Nevada. The Secretary of the Interior approved the ROD on June 21, 2012, which constitutes the final decision of the Department of the Interior.

ADDRESSES: Copies of the ROD are available upon request from the BLM Southern Nevada District Office, 4701 N. Torrey Pines Drive, Las Vegas, Nevada 89130, or via the Internet at the following Web site: *http://www.blm.govl/nv/st/en/fo/lvfo.html*.

FOR FURTHER INFORMATION CONTACT: Gregory Helseth, Renewable Energy Project Manager; telephone: (702) 515–5173; mailing address: BLM Southern Nevada District Office, 4701 N. Torrey Pines Drive, Las Vegas, Nevada 89130; or email: *Gregory_Helseth@blm.gov*.

SUPPLEMENTARY INFORMATION: The applicant, KRoad Moapa Solar, LLC, (KRoad) filed two right-of-way (ROW) applications to construct a 500 kV transmission line, NVN–89176, as well as an access road, NVN–91072, on BLM administered lands as ancillary facilities for a 350 megawatt (MW) solar generation facility on the Moapa River Indian Reservation (Reservation). The BLM was a cooperating agency with the Bureau of Indian Affairs (BIA) on the KRoad Moapa Solar Facility. The purpose of the project is to provide access to the transmission grid via the Crystal Substation; to supply power to the Moapa Travel Plaza and a water line to the solar energy facility.

The BLM's purpose and need for the proposed Federal action responds to KRoad's application for an up to 500 kV

transmission line and access road ROW's within an existing BLM administered utility corridor, of which five miles are located on the Reservation and 0.5 miles is located on BLM land just south of the Reservation boundary, pursuant to the Federal Land Policy and Management Act and BLM's ROW regulations. The transmission corridor and access road ROW will be approximately 150 feet wide by approximately 5.5 miles long, for approximately 100 acres. The transmission line and access road supports the KRoad solar project by providing access to the transmission grid.

The Final EIS analyzed three alternatives: The Proposed Action, Alternative I; Reduced Solar Facility Footprint and Alternative 500kV Transmission line; and the No Action Alternative. These alternatives were shaped in part by comments received from the public and internal BLM, BIA, and Tribal review.

The BLM Proposed Action (Selected Alternative) includes an up to 500kV transmission line ROW and parallel access road. The transmission line is approximately 5.5 miles long, with five miles being within the Moapa Band of Paiute Indians reservation (Pub. L. 96–491) in a BLM administered utility corridor, and the remaining half mile on BLM lands. The transmission line ROW would be approximately 5.5 miles long by 150 feet wide and encompass approximately 100 acres. The access road ROW will be within the transmission line ROW foot print and will be approximately 16–24 feet wide and approximately 5.5 miles long. The transmission line and access road provide access to the Crystal substation operated by NV Energy.

The No Action Alternative assumed the BLM ROW's would not be issued.

The NOA (77 FR 15750) for the Final EIS, was published in the **Federal Register** by the EPA on March 16, 2012. The publication of the NOA for the Final EIS initiated a 30-day review period on the Final EIS. The comment period ended on April 16, 2012.

The BLM and the BIA received two letters as a result of the NOA. The BLM and the BIA determined that there were no significant new information presented in the letters that would require reissuance of the Draft or Final EIS. A final response comment table is attached to the ROD as (Attachment B). Because the Record of Decision was approved by the Secretary of the Interior, it is not subject to administrative appeal (43 CFR 4.410(a)(3)).

Authority: 40 CFR 1506.6 and 1506.10.

Michael J. Pool,

Acting Director, Bureau of Land Management.

[FR Doc. 2012–16011 Filed 6–28–12; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CACA–052537, LLCAD05000, L51010000.FX0000, LVRWB11B4520]

Notice of Availability of the Alta East Wind Project Draft Environmental Impact Statement/Environmental Impact Report and Proposed California Desert Conservation Area Plan Amendment, Kern County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) and Kern County, California, have prepared a Draft Environmental Impact Statement (EIS)/Environmental Impact Report (EIR) and a Draft California Desert Conservation Area (CDCA) Plan Amendment (PA) for the Alta East Wind Project (AEWP), and by this notice the BLM is announcing the opening of the comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Draft EIS/EIR/PA within 90 days following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**. The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: You may submit comments related to the AEWP by any of the following methods:

- *Web site: http://www.blm.gov/ca/st/en/fo/ridgecrest/alta_east_wind_project.html.*
- *Email: altaeast@blm.gov.*
- *Fax:* 951 697–5299.
- *Mail:* ATTN: Jeffery Childers, Project Manager, BLM California Desert District Office, 22835 Calle San Juan de Los Lagos, Moreno Valley, California 92553–9046.

Copies of the Draft EIS/EIR/PA are available in the California Desert District Office at the above address, in the BLM Ridgecrest Field Office, 300 S. Richmond Road, Ridgecrest, California 93555, and on the BLM Web site: *http://www.blm.gov/ca/st/en/fo/cdd.html.*

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to our mailing list, contact Jeffery Childers, telephone 951 697–5308; address BLM California Desert District Office, 22835 Calle San Juan de Los Lagos, Moreno Valley, California 92553–9046; email *jchilders@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Alta Windpower Development, LLC (AWD) has requested a right-of-way (ROW) authorization to construct, operate, maintain, and decommission the AEWP. The Project would be located on about 3,200 acres on the north and south sides of State Route 58 in southeastern Kern County, California. The project area is approximately 3 miles northwest of the town of Mojave and approximately 11 miles east of the city of Tehachapi. The proposed project would include up to 106 wind turbines, access roads, energy collection lines, and ancillary facilities on 3,200 acres, of which 2,083 acres are on public land under the jurisdiction of the BLM and 1,117 acres are on private land under the jurisdiction of Kern County. The Project could produce up to 318 Megawatts (mW).

The BLM's purpose and need for the AEWP is to respond to AWD's application for a ROW grant to construct, operate, maintain, and decommission a wind energy facility on public lands in compliance with FLPMA, BLM ROW regulations, and other applicable Federal laws. The BLM will decide whether to grant, grant with modification, or deny a ROW to AWD for the proposed AEWP. The BLM is also proposing to amend the CDCA Plan by designating the project area as either available or unavailable for wind energy projects. The CDCA Plan (1980, as amended), while recognizing the potential compatibility of wind energy generation facilities with other uses on public lands, requires that all sites proposed for power generation or transmission not already identified in the Plan be considered through the plan amendment process. If the BLM decides to grant a ROW for this project, the CDCA Plan would be amended as required.

In addition to the proposed action and a no action alternative, the BLM is analyzing a reconfigured site layout alternative with up to 106 turbines, an alternative that would allow up to 97 turbines, and an alternative that would allow up to 87 turbines. The Draft EIS/EIR/PA also analyzes two no-project alternatives that would deny a ROW for the project but amend the CDCA Plan to find the project area either (1) available for future wind energy generation projects; or (2) unavailable for future wind energy generation projects.

The Draft EIS/EIR/PA evaluates the potential impacts of the proposed AEWP on air quality and greenhouse gas emissions, biological resources including Golden Eagles and California Condors, special status species, cultural resources, geology and soils, hazards and hazardous materials, hydrology and water quality, land use, noise, recreation, traffic, visual resources, wilderness characteristics, cumulative effects, and areas with high potential for renewable energy development.

A Notice of Intent to Prepare an EIS/EIR/PA for the AEWP was published in the **Federal Register** on July 15, 2011 (FR 41817–41819). The BLM held one joint public scoping meeting with Kern County in Mojave on August 4, 2011. The formal scoping period ended on August 16, 2011.

Please note that public comments and information submitted including names, street addresses, and email addresses of persons who submit comments will be available for public review at the above address during regular business hours (8:00 a.m. to 4:00 p.m.), Monday through Friday, except holidays.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2.

Thomas Pogacnik,

Deputy State Director, California.

[FR Doc. 2012–16005 Filed 6–28–12; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[COF000–LLCOF00000–L19900000–XZ0000]

Notice of Meeting, Front Range Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Front Range Resource Advisory Council (RAC), will meet as indicated below.

DATES: The meeting will be held on August 8, 2012, from 9:30 p.m. to 4:30 p.m.

ADDRESSES: Bank of the West, 146 G. Street, Salida, Colorado 81201.

FOR FURTHER INFORMATION CONTACT: Denise Adamic, Front Range RAC Coordinator, BLM Royal Gorge Field Office, 3028 E. Main St., Cañon City, CO 81212. Phone: (719) 269–8553. Email: *dadamic@blm.gov.*

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in the BLM Front Range District, which includes the Royal Gorge Field Office (RGFO) and the San Luis Valley Field Office. Planned topics of discussion items include: Field Manager updates as well as recreation and resource management issues at the Cache Creek Placer Mining Area. There will be an afternoon field trip to Cache Creek. The public is encouraged to make oral comments to the Council at 9:45 a.m. or written statements may be submitted for the Council's consideration. Summary minutes for the RAC meetings will be maintained in the RGFO and will be available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting. Previous meeting minutes and agendas are available at: *www.blm.gov/co/st/en/BLM_Resources/racs/frrac/co_rac_minutes_front.html.*

Helen M. Hankins,

State Director.

[FR Doc. 2012–15980 Filed 6–28–12; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2310–0070–422]

Winter Use Plan, Supplemental Draft Environmental Impact Statement, Yellowstone National Park

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability of the Draft Supplemental Environmental Impact Statement for the Winter Use Plan, Yellowstone National Park.

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 a Draft Supplemental Environmental Impact Statement (Draft SEIS) for a Winter Use Plan for Yellowstone National Park, located in Idaho, Montana and Wyoming.

DATES: The National Park Service will accept comments from the public for 45 days from the date the Environmental Protection Agency publishes its Notice of Availability. The NPS intends to hold public meetings in Jackson, WY on July 16, 2012; West Yellowstone, MT on July 17, 2012; Bozeman, MT on July 18, 2012; and Cody, WY on July 19, 2012. Additional details regarding the public meeting locations and times can be found at *http://parkplanning.nps.gov/YELL* (click on the link to the 2012 Supplemental Winter Use Plan EIS, and then on the Meeting Notices link).

More information regarding Yellowstone in the winter, including educational materials and a detailed history of winter use in Yellowstone, is available at *http://www.nps.gov/yell/planvisit/winteruse/index.htm.*

ADDRESSES: Information will be available for public review and comment online at *http://parkplanning.nps.gov/YELL* (click on the link to the 2012 Supplemental Winter Use Plan EIS), and at Yellowstone National Park headquarters, Mammoth Hot Springs, WY.

FOR FURTHER INFORMATION CONTACT: Wade Vagias, P.O. Box 168, Yellowstone National Park, WY 82190, (307) 344–2035.

SUPPLEMENTARY INFORMATION: Four alternatives are considered in the Draft SEIS. Alternative 1, the no-action alternative, would not permit public over-snow vehicle (OSV) use in Yellowstone but would allow for approved non-motorized use to continue. Alternative 1 has been identified as the environmentally preferable alternative. Alternative 2

would manage OSV use at the same levels as the 2011/2012 interim rule (318 best available technology (BAT) snowmobiles and 78 snowcoaches per day). Sylvan Pass would remain open. Alternative 3 would initially allow for the same level of use as alternative 2 (318 BAT snowmobiles and 78 snowcoaches per day), but would transition to snowcoaches only over a three year period beginning in the 2017/2018 winter season. Upon complete transition, there would be 0 snowmobiles and up to 120 snowcoaches per day in the park, and Sylvan Pass would be closed.

Alternative 4 is the NPS preferred alternative. This alternative would manage OSV use by transportation events. A total of 110 transportation events would be allowed in the park each day. A transportation event would initially equal one snowcoach or one group of snowmobiles (average of 7 snowmobiles per group, averaged over the winter use season; groups could not exceed a maximum of 10 snowmobiles). Operators would decide whether to use their daily allocation of transportation events for snowmobiles or snowcoaches, but no more than 50 daily transportation events could come from snowmobiles. OSV use would continue to be 100 percent guided, with four transportation events per day (one per gate) of up to 5 snowmobiles each allocated for non-commercially guided access. BAT requirements for snowmobiles would remain the same as the BAT requirements in the 2011/2012 interim regulation until the 2017/2018 winter season, at which time additional sound and air emission requirements would be implemented. BAT requirements for snowcoaches would also be implemented beginning in the 2017/2018 season. If OSVs meet additional established standards for air and sound emissions beyond those required for BAT, the group size of snowmobiles would be allowed to increase from an average of 7 to an average of 8 per transportation event, and snowcoaches would be allowed to increase from one to two snowcoaches per transportation event. These changes would allow for an increase in visitation while reducing transportation-generated noise and air impacts. Sylvan Pass would remain open.

If you wish to comment on the Draft Supplemental Environmental Impact Statement, you may submit your comments by any one of several methods. We encourage you to comment via the Internet at *http://parkplanning.nps.gov/YELL* (click on the link to the 2012 Supplemental Winter Use Plan EIS). You may also comment by mail to: Yellowstone National Park, Winter Use Draft SEIS, P.O. Box 168, Yellowstone NP, WY 82190. Finally, you may hand deliver your comments to: Management Assistant's Office, Headquarters Building, Mammoth Hot Springs, Yellowstone National Park, WY. Comments will not be accepted by fax, email, or in any other way than those specified above. Bulk comments in any format (hard copy or electronic) submitted on behalf of others will not be accepted.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 21, 2012.

Colin Campbell,

Deputy Regional Director, Intermountain Region, National Park Service.

[FR Doc. 2012–15678 Filed 6–28–12; 8:45 am]

BILLING CODE 4312–CT–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–739 (Third Review)]

Clad Steel Plate From Japan; Scheduling of a Full Five-Year Review Concerning the Antidumping Duty Order on Clad Steel Plate From Japan

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of a full review pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)) (the Act) to determine whether revocation of the antidumping duty order on clad steel plate from Japan would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

DATES: *Effective Date:* June 25, 2012.

FOR FURTHER INFORMATION CONTACT: Angela M.W. Newell (202–708–5409), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—On May 7, 2012, the Commission determined that responses to its notice of institution of the subject five-year review were such that a full review pursuant to section 751(c)(5) of the Act should proceed (77 FR 37439, June 21, 2012). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's Web site.

Participation in the review and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in this review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the review need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this review available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the review. A party

granted access to BPI following publication of the Commission's notice of institution of the review need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the review will be placed in the nonpublic record on November 13, 2012, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the review beginning at 9:30 a.m. on December 6, 2012, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before November 29, 2012. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on December 3, 2012, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the review may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is November 29, 2012. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is December 14, 2012; witness testimony must be filed no later than three days before the hearing. In addition, any person who has not entered an appearance as a party to the review may submit a written statement of information pertinent to the subject of the review on or before December 14, 2012. On January 7, 2013, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before January 9, 2013, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to electronic filing have been amended. The amendments took effect on November 7, 2011. See 76 Fed. Reg. 61937 (Oct. 6, 2011) and the newly revised Commission's Handbook on E-Filing, available on the Commission's Web site at *http://edis.usitc.gov.*

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: June 25, 2012.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–15917 Filed 6–28–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–745]

Certain Wireless Communication Devices, Portable Music and Data Processing Devices, Computers and Components Thereof, Commission Decision To Review in Part a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the presiding administrative law judge's (''ALJ'') final initial determination (''ID'') issued on April 24, 2012, finding a violation of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337 in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 8, 2010, based on a complaint filed by Motorola Mobility, Inc. of Libertyville, Illinois. 75 FR 68619–20 (Nov. 8, 2010). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain wireless communication devices, portable music and data processing devices, computers and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 6,272,333 (''the '333 patent''); 6,246,862 (''the '862 patent''); 6,246,697 (''the '697 patent''); 5,359,317 (''the '317 patent''); 5,636,223 (''the '223 patent''); and 7,751,826 (''the '826 patent''). The complaint further alleges the existence of a domestic industry. The Commission's notice of investigation named Apple Inc. of Cupertino, California as respondent. The Office of Unfair Import Investigation (''OUII'') was named as a participating party, however, on July 29, 2011, OUII withdrew from further participation in the investigation. *See* Commission Investigative Staff's Notice of Nonparticipation (July 29, 2011). The

Commission later partially terminated the investigation as to the '317 patent and the '826 patent. Notice (June 28, 2011); Notice (Jan 27, 2012).

On April 24, 2012, the ALJ issued his final ID, finding a violation of section 337 as to the '697 patent and finding no violation as to the '223, '333, and '697 patents. On May 9, 2012, the ALJ issued his recommended determination on remedy and bonding. In his final ID, the ALJ found that the products accused of infringing the '697 patent literally infringe claims 1–4 of that patent, and that Apple induces others to infringe the asserted claims of the '697 patent. The ALJ also found that the asserted claims of the '697 patent are not invalid as anticipated under 35 U.S.C. 102, as obvious under 35 U.S.C. 103, or for failure to satisfy the written description requirement or the best mode requirement of 35 U.S.C. 112. The ALJ also found that the '697 patent is not unenforceable for unclean hands. The ALJ further found that Motorola has satisfied the domestic industry requirement for the '697 patent. The ALJ also found that the products accused of infringing the '223 patent literally infringe the asserted claim of that patent and that Apple induces others to infringe the claim 1 of the '223 patent. The ALJ further found, however, that the asserted claim of the '223 patent is invalid as anticipated under 35 U.S.C. 102. The ALJ also found that Motorola has satisfied the domestic industry requirement for the '223 patent. The ALJ further found that the products accused of infringing the '333 patent do not literally infringe claim 12 of that patent. The ALJ also found that the asserted claim of the '333 patent is not invalid as anticipated under 35 U.S.C. 102 or for obviousness under 35 U.S.C. 103. The ALJ further found that Motorola has not satisfied the domestic industry requirement for the '333 patent. The ALJ also found that that claim 1 of the '862 patent is invalid as indefinite under 35 U.S.C. 112, ¶ 2 and, therefore, that the products accused of infringing the '862 patent do not literally infringe the asserted claim of that patent and that Motorola has not satisfied the domestic industry requirement for the '862 patent.

On May 7, 2012, Motorola filed a joint petition for review and contingent petition for review of certain aspects of the final ID's findings concerning claim construction, infringement, validity, and domestic industry. Also on May 7, 2012, Apple filed a joint petition for review and contingent petition for review of certain aspects of the final ID's findings concerning claim construction, infringement, validity, and patent unenforceability. On May 15, 2012, Motorola filed a response to Apple's petition. Also on May 15, 2012, Apple filed a response to Motorola's petition.

On June 6, 2012, Apple filed a post-RD statement on the public interest pursuant to Commission Rule 201.50(a)(4). Also on June 6, 2012, several non-parties filed public interest statements in response to the post-RD Commission Notice issued on May 15, 2012. *See* 77 FR. 28621–22 (May 15, 2012). The non-parties include: Federal Trade Commission; Business Software Alliance; Association for Competitive Technology; Retail Industry Leaders Association; Verizon; Nokia Corporation; Hewlett-Packard Company; and Microsoft Corporation.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. Specifically, with respect to the '223 patent the Commission has determined to review the ID's claim construction of the claim limitation ''access priority value'' in claim 1. The Commission has also determined to review the ID with respect to the validity of claim 1 of the '223 patent under 35 U.S.C. 102 in light of U.S. Patent No. 5,453,987 to Tran (''Tran '987) and U.S. Patent No. 5,657,317 to Mahany et al (''Mahany '317'') and under 35 U.S.C. 103 in light of Tran '987 in combination with Mahany '317. The Commission has further determined to review the ID's finding that the 802.11 standard necessarily practices claim 1 of the '223 patent, and thus, the ID's findings concerning infringement and whether Motorola has satisfied the technical prong of the domestic industry requirement with respect to the '223 patent.

With respect to the '697 patent, the Commission has determined to review the ID's construction of the limitation ''selecting a chip time in a complex PN [pseudonoise] sequence generator'' in claim 1. The Commission has also determined to review the ID's construction of the claim limitation ''restricting a phase difference between a previous complex PN chip and a next complex PN chip to a preselected phase angle.'' The Commission has further determined to review the ID's findings with respect to the validity of claims 1–4 the '697 patent under 35 U.S.C. 102 in light of prior art π/2-shift BPSK modulation and under 35 U.S.C. 103 in light of the combination of prior art QPSK and π/2-shift BPSK modulation schemes. The Commission has also determined to review the ID's finding of direct and induced infringement with respect to the '697 patent. The Commission has further determined to review the ID's finding that Motorola has satisfied the technical prong of the domestic industry requirement for the '697 patent.

With respect to the '862 patent, the Commission has determined to review the ID's construction of the limitation ''close proximity to a user'' in claim 1 and his finding that claim 1 is indefinite.

With respect to the '333 patent, the Commission has determined to review the ID's construction of the limitation ''a list of all software applications that are currently accessible to the subscriber unit'' in claim 12. The Commission has further determined to review the ALJ's finding that claim 12 is not invalid under 35 U.S.C. 102 in light of U.S. Patent Nos. 5,502,831 to Grube et al. (''Grube '831''), 6,008,737 to DeLuca et al. (''DeLuca '797''), or 5,612,682 to DeLuca et al. (''DeLuca '682''), or under 35 U.S.C. 103 in view of Grube '831 combined with DeLuca '682 and DeLuca '737. The Commission has also determined to review the ALJ's finding of non-infringement of claim 12. The Commission has further determined to review the ID's finding that Motorola's domestic industry product does not practice claim 12 of the '333 patent.

With respect to whether Motorola has satisfied the economic prong of the domestic industry requirement, the Commission has determined to review the ID's finding that Motorola has not satisfied the economic prong as to the '333 patent under section 337(a)(3)(C) for its investments in licensing. The Commission has also determined to review in part the ID's finding that Motorola has satisfied the economic prong with respect to the '223 and '697 patents under section 337(a)(3)(A) and (B).

The Commission has determined not to review the remaining issues decided in the ID.

The parties are requested to brief their positions on the issues under review with reference to the applicable law and the evidentiary record. In connection with its review, the Commission is particularly interested in responses to the following questions:

1. Does the description of the present invention in the specification of the '697 patent (*e.g.,* at col. 4, lns. 54–64) limit the scope of claim 1 to a π/2 BPSK modulation scheme at ''selected chip times?'' If so, does this restriction in the scope of claim 1 affect the validity of claim 4 under 35 U.S.C. 112, ¶ 4, where claim 4 is also limited to a π/2 BPSK modulation scheme at ''selected chip times?''

2. If claim 4 of the '697 patent is not invalid under 35 U.S.C. 112, ¶ 4, can a claim differentiation argument be made with respect to claims 1 and 4 that would resolve the appropriate scope of claim 1, considering the description of the present invention in the specification of the '697 patent?

3. With respect to the '333 patent, does the limitation ''currently available'' in claim 12 require that a non-web based software application need only be installed on a subscriber unit or does the software application have to be both installed and enabled for use? In discussing this issue, please refer to the ALJ's finding that the '333 Accused Products do not communicate with Apple's servers regarding changes in user credentials (*see* Final ID at 254). Also, please provide citations to the record in support of any arguments.

4. With regard to the '697 and '223 patents, are there substantial costs and delays associated with switching away from the standardized technology in question?

5. With regard to the '697 and '223 patents, do the patents in question cover relatively minor components of the accused products?

6. Has Apple waived its right to assert that Motorola failed to offer a license on reasonable and non-discriminatory (''RAND'') terms? In discussing this issue, please refer to Commission Investigative Staff Motion in Limine to Exclude The Expert Opinion of Jerry Hausman filed July 14, 2011, and to Respondent Apple Inc.'s Opposition to Commission Investigative Staff's Motion In Limine to Exclude the Expert Opinion of Robert O'Hara at page 1, n. 1 filed July 22, 2011.

7. If the record of an investigation lacks evidence sufficient to support a RAND-based affirmative defense (*e.g.,* equitable estoppel, implied license, waiver, etc.), under what circumstances (if any) should a RAND obligation nonetheless preclude issuance of an exclusion order? Please discuss theories in law, equity, and the public interest, and identify which (if any) of the 337(d)(1) public interest factors allegedly precludes issuance of such an order.

8. Does the mere existence of a RAND obligation preclude issuance of an exclusion order? Please discuss theories in law, equity, and the public interest, and identify which (if any) of the 337(d)(1) public interest factors allegedly precludes issuance of such an order.

9. Should a patent owner that has refused to offer a license to a named respondent in a Commission investigation on a RAND obligated patent be able to obtain an exclusion order? Please discuss theories in law, equity, and the public interest, and identify which (if any) of the 337(d)(1) public interest factors allegedly precludes issuance of such an order.

10. Should a patent owner that has refused to offer a license on a RAND obligated patent to some entity (regardless of whether that entity is a named respondent in a Commission investigation) be able to obtain an exclusion order? Please discuss theories in law, equity, and the public interest, and identify which (if any) of the 337(d)(1) public interest factors allegedly precludes issuance of such an order.

11. Should a patent owner that has refused to negotiate a license on RAND terms with a named respondent in a Commission investigation be precluded from obtaining an exclusion order? Please discuss theories in law, equity, and the public interest, and identify which (if any) of the 337(d)(1) public interest factors allegedly precludes issuance of such an order.

12. Should a patent owner that has refused to negotiate a license on RAND terms with some entity (regardless of whether that entity is a named respondent in a Commission investigation) be precluded from obtaining an exclusion order? Please discuss theories in law, equity, and the public interest, and identify which (if any) of the 337(d)(1) public interest factors allegedly precludes issuance of such an order.

13. Should a patent owner who has offered a RAND license that the named respondent in a Commission investigation has rejected be precluded from obtaining an exclusion order? Please discuss theories in law, equity, and the public interest, and identify which (if any) of the 337(d)(1) public interest factors allegedly precludes issuance of such an order.

The parties have been invited to brief only these discrete issues, as enumerated above, with reference to the applicable law and evidentiary record. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent(s) being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see In the Matter of Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, the Office of Unfair Import Investigations, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainant is also requested to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the dates that the patents expire and the HTSUS numbers under which the accused products are

imported. The written submissions and proposed remedial orders must be filed no later than close of business on July 9, 2012. Initial submissions are limited to 70 pages, not including any attachments or exhibits related to discussion of the public interest. Reply submissions must be filed no later than the close of business on July 16, 2012. Reply submissions are limited to 25 pages, not including any attachments or exhibits related to discussion of the public interest. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–754'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.42–46 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 210.42–46 and 210.50).

Issued: June 25, 2012.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–15916 Filed 6–28–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–850]

Certain Electronic Imaging Devices; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on May 23, 2012, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of FlashPoint Technology, Inc. of Peterborough, New Hampshire. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electronic imaging devices by reason of infringement of certain claims of U.S. Patent No. 6,400,471 (''the '471 patent''); U.S. Patent No. 6,222,538 (''the '538 patent''); U.S. Patent No. 6,504,575 (''the '575 patent''); and U.S. Patent No. 6,223,190 (''the '190 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of the Secretary, Docket Services Division, U.S. International Trade Commission, telephone (202) 205–1802.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2012).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on June 22, 2012, *ordered that—*

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain electronic imaging devices that infringe one or more of claims 1–5, 7, 8, 10, 22, 24, 26, 28, 31, 34–43, 60, and 62–69 of the '471 patent; claims 1, 17, 19, and 21–23 of the '538 patent; claims 1, 8, 17, 18, 20–22, 26, and 28 of the '575 patent, and claims 13, 14, 16, 20–29, 31–33, 36–39, 42, 43, 46–49, and 52–56 of the '190 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: FlashPoint Technology, Inc., 20 Depot Street, Suite 2A, Peterborough, NH 03458.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

HTC Corporation, 23 Xinghua Road, Taoyuan, 330, Taiwan.

HTC America, Inc., 13920 SE Eastgate Way, Suite 400, Bellevue, WA 98005.

Pantech Co., Ltd., Pantech Building I–2, DMC, Sangam-dong, Mapo-gu, Seoul 121–792, Republic of Korea.

Pantech Wireless, Inc., 5607 Glenridge Dr. NE Ste 500, Atlanta, GA 30342–7200.

Huawei Technologies Co., Ltd., Bantian, Longgang District, Shenzhen, Guangdong Province 51 g 1–29, China.

FutureWei Technologies, Inc. d/b/a Huawei Technologies (USA), 5700 Tennyson Parkway, Suite 500, Plano, TX 75021–4234.

ZTE Corporation, ZTE Plaza, No. 55 Hi-Tech Road South, Shenzhen, Guangdong Province 518057, China.

ZTE (USA) Inc., 2425 N. Central Expy., Ste. 600, Richardson, TX 75080.

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission,

shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

Issued: June 25, 2012.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–15975 Filed 6–28–12; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of an Amendment to Consent Decree Under the Clean Air Act

Notice is hereby given that on June 25, 2012, a proposed Second Amendment to the consent decree in *United States et al.* v. *Lafarge North America, et al.,* Civil Action No. 3:10-cv-44–JPG was lodged with the United States District Court for the Southern District of Illinois.

On March 18, 2010, the United States District Court for the Southern District of Illinois entered a consent decree (''decree'') resolving claims of the United States and twelve states or state agencies against Lafarge North America, Inc., Lafarge Midwest, Inc., and Lafarge Building Materials, Inc. (''Lafarge'') for alleged violations of the Clean Air Act (''CAA'' or ''Act'') at its thirteen portland cement production facilities in the United States. Specifically, the consent decree resolved alleged violations of the Act's Prevention of Significant Deterioration (''PSD'') provisions, 42 U.S.C. 7470–92; Nonattainment New Source Review (''NNSR'') provisions, 42 U.S.C. 7501–15; the federally approved and enforceable state implementation plans (''SIPs'') which incorporate and/or implement the above-listed federal PSD and/or NNSR requirements; and the CAA Title V operating permit requirements, 42 U.S.C. 7661–61f, including Title V's implementing federal and state regulations.

The proposed Second Amendment affects only three of the thirteen cement plants addressed in the Consent Decree: the Roberta, Alabama; Harleyville, South Carolina; and Atlanta, Georgia cement plants. The Amendment substitutes Argos USA Corp. and Argos Cement LLC (collectively, ''Argos'') for Lafarge with respect to those facilities following their sale by Lafarge to Argos on October 3, 2011. Argos has agreed to undertake the Consent Decree obligations applicable to those facilities, to be substituted for Lafarge with respect to those facilities and has demonstrated that it has the financial and technical ability to assume the Decree's obligations at those facilities. The proposed Second Amendment also amends the Consent Decree to terminate Consent Decree requirements applicable to the Atlanta facility because all Decree obligations at that plant have been met and no further obligations apply to that facility under the Decree.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Second Amendment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either emailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States et al.* v. *Lafarge North America, et al.,* Civil Action No. 3:10-cv-44–JPG, DJ# 90–5–2–1–08221.

During the public comment period, the proposed Second Amendment to the consent decree may be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed consent decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or emailing a request to ''Consent Decree Copy'' (*EESCDCopy.ENRD@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–5271. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $ 11.50 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by email or fax, forward a check in that amount to the Consent Decree Library at the given address above.

Maureen M. Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2012–15994 Filed 6–28–12; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—DVD Copy Control Association

Notice is hereby given that, on May 24, 2012, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), DVD Copy Control Association (''DVD CCA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Audio + Video Labs Inc., Pennsauken, NJ, has been added as a party to this venture.

Also, East European Authoring and Encoding Centre Ltd., Sofia, Bulgaria; Hansong (Nanjing) Electronics Ltd., Nanjing, People's Republic of China; Primare Systems, Växjö, Sweden; Rohm Co., Ltd., Ukyo-ku, Kyoto, Japan; and Seripress SAS, Bulgnevile, France, have withdrawn as parties to this venture.

In addition, SM Summit Holdings Limited has changed its name to Centurion Corporation Limited, Singapore, Singapore; and Ultra Source Technology Corp. has changed its name to Ultra Source Trading Hong Kong Limited, Shatin N.T., Hong Kong-China.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and DVD CCA intends to file additional written

notifications disclosing all changes in membership.

On April 11, 2001, DVD CCA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on August 3, 2001 (66 FR 40727).

The last notification was filed with the Department on February 24, 2012. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 15, 2012 (77 FR 15395).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2012–15935 Filed 6–28–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Tizen Association (Formerly LiMo Foundation)

Notice is hereby given that, on June 4, 2012, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Tizen Association (''Tizen'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. LiMo Foundation has changed its name to Tizen Association (''Tizen''). In addition, Huawei Device Co., Ltd., Shenzhen, PEOPLE'S REPUBLIC OF CHINA; Intel Corporation, Chandler, AZ; and France Telecom S.A. (Orange Personal Communications Services Limited, Moulineaux, FRANCE, have been added as parties to the Association.

The following parties have withdrawn from the venture: Access Co. Ltd., Tokyo, JAPAN; France Telecom S.A. (Orange Personal Communications Services Limited, Moulineaux, FRANCE; Adobe, San Jose, CA; ARM Holdings, PLC, Cambridge, UNITED KINGDOM; ETRI Embedded SW Division, Daejon, REPUBLIC OF KOREA; Gemalto, N.V., Amsterdam, NETHERLANDS; Huawei Communication Technologies Co. Ltd., Shenzhen, PEOPLE'S REPUBLIC OF CHINA; Incross Co. Ltd., Seoul, REPUBLIC OF KOREA; Marvell International Ltd., Hamilton, BERMUDA; McAfee Inc., Santa Clara, CA; NTT DATA MSE, Yokohama, JAPAN; Renesas Mobile Corporation, Tokyo, JAPAN; Verizon Communications, Inc., Basking Ridge, NJ, and Wind River Systems, Alameda, CA.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Tizen intends to file additional written notifications disclosing all changes in membership.

On March 1, 2007, Tizen (Formerly LiMo Foundation) filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 9, 2007 (72 FR 17583).

The last notification was filed with the Department on July 19, 2011. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on September 23, 2011 (76 FR 59161).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2012–15936 Filed 6–28–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—3D PDF Consortium, Inc.

Notice is hereby given that, on June 4, 2012, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), 3D PDF Consortium, Inc. (''3D PDF'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ITI TranscenData Business, Milford, OH; Actify, Inc., San Francisco, CA; and SpaceClaim, Concord, MA, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and 3D PDF intends to file additional written notifications disclosing all changes in membership.

On March 27, 2012, 3D PDF filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 20, 2012 (77 FR 23754).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2012–15933 Filed 6–28–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Bluetooth Sig, Inc.

Notice is hereby given that, on May 30, 2012, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Bluetooth SIG, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the name and principal place of business of the Delaware non-stock, non-profit standards development organization is Bluetooth SIG, Inc., Kirkland, WA. The nature and scope of Bluetooth SIG, Inc.'s standards development activities are to develop Bluetooth® wireless specifications and profiles. Additional information concerning Bluetooth SIG, Inc. may be obtained from Christine Scott, Bluetooth SIG, Inc.'s Director of Operations.

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2012–15932 Filed 6–28–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Regulations Governing Longshore and Harbor Workers' Compensation Act Administration

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, ''Regulations Governing Longshore and Harbor Workers' Compensation Act Administration,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before July 30, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the *RegInfo.gov* Web site, *http://www.reginfo.gov/public/do/PRAMain*, on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov*.

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov*.

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: The OWCP administers the Longshore and Harbor Workers' Compensation Act (LHWCA). The LHWCA provides benefits to workers injured in maritime employment on the navigable waters of the U.S. or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend Longshore Act coverage to certain other employees. Regulations sections 20 CFR 702.111, –.162, –.174, –.175, –.201, –.202, –.242, –.285, –.285, –.310, and –.321 and Forms LS–200, LS–201, LS–203, LS–204, LS–262, LS–267, LS–271, LS–274, and LS–513 cover the submission of information relating to the processing of claims for benefits under the Longshore Act and extensions. This ICR has been characterized as a revision under the PRA for technical reasons. The agency has reformatted elements of the forms (e.g., replaced an obsolete logo with the DOL Seal and removed references to the no longer existent Employment Standards Administration). Those changes should not affect respondent information collection burden.

These information collections are subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1240–0014. The current approval is scheduled to expire on June 30, 2012; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on April 17, 2012 (77 FR 22806).

Interested parties are encouraged to send timely comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section of this notice. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240–0014. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Regulations Governing Longshore and Harbor Workers' Compensation Act Administration.

Affected Public: Individuals or Households and Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 130,036.

Total Estimated Number of Responses: 130,036.

Total Estimated Annual Burden Hours: 44,950.

Total Estimated Annual Other Costs Burden: $727,417.

Dated: June 25, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–15934 Filed 6–28–12; 8:45 a.m.]

BILLING CODE 4510–CF–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Marine Terminals and Longshoring Standards

ACTION: Notice.

SUMMARY: On June 29, 2012, the Department of Labor (DOL) will submit the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Marine Terminals and Longshoring Standards'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before July 30, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the *RegInfo.gov* Web site, *http://www.reginfo.gov/public/do/PRAMain,* on or after June 30, 2012, or by contacting Michel Smyth by

telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov*.

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov*.

Authority: 44 U.S.C. 3507(a)(1)(D).

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov*.

SUPPLEMENTARY INFORMATION: The Marine Terminals and Longshoring Standards information collection requirements are related to the testing, certification, and marking of specific types of cargo lifting appliances and associated cargo handling gear and other cargo handling equipment such as conveyors and industrial trucks. The information the OSHA requires from employers are necessary to reduce worker injuries and fatalities associated with cargo lifting gear, transfer of vehicular cargo, manual cargo handling, and exposure to hazardous atmospheres.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0196. The current OMB approval is scheduled to expire on June 30, 2012; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on April 26, 2012 (77 FR 24990).

Interested parties are encouraged to send timely comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section of this notice. In order to help ensure appropriate consideration, comments should reference OMB Control Number 1218–0196. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–OSHA.

Title of Collection: Marine Terminals and Longshoring Standards.

OMB Control Number: 1218–0196.

Affected Public: Private Sector—businesses or other for-profits and not-for-profit institutions; Federal Government; State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 1,020.

Total Estimated Number of Responses: 205,624.

Total Estimated Annual Burden Hours: 47,398.

Total Estimated Annual Other Costs Burden: $0.

Dated: June 25, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–15948 Filed 6–28–12; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Job Accommodation Network

AGENCY: Office of Disability Employment Policy, Department of Labor.

Announcement Type: New Notice of Availability of Funds and Solicitation for Grant Applications (SGA) for Cooperative Agreements. The full announcement is posted on *http://www.grants.gov.*

Funding Opportunity Number: SGA–12–03.

Key Dates: The closing date for receipt of applications is July 18, 2012.

Funding Opportunity Description

The U.S. Department of Labor (DOL or Department), Office of Disability Employment Policy (ODEP) announces the availability of approximately $2.5 million to fund a cooperative agreement to manage and operate its Job Accommodation Network (JAN), a national technical assistance center that facilitates the employment and retention of workers with disabilities. Created in 1983, JAN is the most comprehensive job accommodation resource available. It is the leading source of free, expert, and confidential one-on-one guidance on workplace accommodations, the Americans with Disabilities Amendment Act of 2008 (ADAA) and related legislation, and self-employment and entrepreneurship options for people with disabilities. JAN provides technical assistance via phone, email and chat, and maintains a Web site containing online resources and publications. Technical assistance regarding individualized job accommodations and workplace strategies for job applicants and employees with disabilities is provided to private and federal sector employers, people with disabilities including disabled veterans, employment service providers, educational institutions and others. JAN develops and conducts trainings both in person and electronically (web-based and telephonic); works in collaboration with businesses, professional organizations, federal agencies and others on effective practices and other issues related to accommodations in the workplace; and engages in outreach to the public about its services. JAN establishes and maintains effective working relationships and collaborations with outside entities with the goal of sharing knowledge and promoting the adoption and implementation of ODEP policies and effective practices. JAN also conducts research and collects and analyzes data related to the cost and effectiveness of workplace accommodations and provides data that contribute to ODEP's annual performance measures and the development of its policies.

Funding of $2.5 million will be awarded through a competitive process for a 12-month period of performance, with the possibility of up to four option years of funding depending on the availability of funds and satisfactory performance.

This solicitation provides background information, describes the application submission requirements, outlines the process that eligible entities must use to apply for funds covered by this solicitation, and outlines the evaluation

criteria used as a basis for selecting the grantee.

The full Solicitation for Grant Applications is posted on *www.grants.gov* under U.S. Department of Labor/ODEP. Applications submitted through *www.grants.gov* or hard copy will be accepted. If you need to speak to a person concerning these grants, you may telephone Cassandra Mitchell, Grant Officer, at 202–693–4570 (not a toll-free number). If you have issues regarding access to the *www.grants.gov* Web site, you may telephone the Contact Center Phone at 1–800–518–4726.

Signed in Washington, DC, this 14th day of June 2012.

Cassandra R. Mitchell,

Grant Officer.

[FR Doc. 2012–15952 Filed 6–28–12; 8:45 am]

BILLING CODE 4510–FT–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received under the Antarctic Conservation Act of 1978.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by July 30, 2012. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Polly A. Penhale at the above address or (703) 292–7420.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

The applications received are as follows:

Permit Application: 2013–010

1. *Applicant:* Diane H. Tuft, 101 Central Park West, New York, NY 10023.

Activity for Which Permit Is Requested

Enter Antarctic Specially Protected Areas. The applicant is a member of the Artists and Writers Program and plans to enter Caughley Beach, Cape Bird (ASPA 116), Cape Royds (ASPA 121), and Cape Crozier (ASPA 124) to photograph and record sounds of wildlife in Antarctica including Adelie and Emperor penguins. The recordings along with that of the wind and other aspects of the environment will allow the applicant to capture the essence of Antarctica through light, sound and movement. The resulting images and sounds will be included in the installation that will be created about Antarctica.

Location

Caughley Beach, Cape Bird (ASPA 116), Cape Royds (ASPA 121), Cape Crozier (ASPA 124), and Cape Bird, Ross Island.

Dates

October 1, 2012 to January 31, 2013.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. 2012–15885 Filed 6–28–12; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Innovation Corps; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Innovation Corps for Advisory Committee, #80463.

Dates/Time: July 18, 2012, 12:00 p.m.–5:00 p.m.

Places: National Science Foundation, 4201 Wilson Boulevard, Room 1295, Arlington, VA 22230.

Type of Meeting: Open.

Contact Person: Dr. Dedric A. Carter, Senior Advisor for Strategic Initiatives, Office of the Director, Suite 1205, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone Number: (703) 292–8002, email: *dacarter@nsf.gov.*

Purpose of Meeting: To provide advice and recommendations concerning Innovation Corps.

Agenda

July 18, 2012

12:00–3:00 p.m. Opening Statements by Dr. Subra Suresh, Director, NSF I–Corps Showcase

3:00 p.m.–5:00 p.m. Review and discussion of the current I–Corps projects and future directions.

Dated: June 26, 2012.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 2012–16047 Filed 6–28–12; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

SUPPLEMENTARY INFORMATION: On May 24, 2012, the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on June 25, 2012 to:

Permit No. 2013–005

Jean Pennycook.

Nadene G. Kennedy,

Permit Officer.

[FR Doc. 2012–15891 Filed 6–28–12; 8:45 am]

BILLING CODE 7555–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from Clinton Engineer Works in Oak Ridge, Tennessee, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On May 11, 2012, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Tennessee Eastman Corporation (1943–1947) and the Carbide and Carbon Chemicals Corporation (1947–1949) who were employed at the Clinton Engineer Works in Oak Ridge, Tennessee, from January 1, 1943 through December 31, 1949 for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more classes of employees included in the Special Exposure Cohort.

This designation became effective on June 10, 2012, as provided for under 42 U.S.C. 7384*l*(14)(C). Hence, beginning on June 10, 2012, members of this class of employees, defined as reported in this notice, became members of the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012–15964 Filed 6–28–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the Sandia National Laboratories in Albuquerque, New Mexico, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On May 11, 2012, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked in any area at Sandia National Laboratories in Albuquerque, New Mexico, from January 1, 1963 through December 31, 1994, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation became effective on June 10, 2012, as provided for under 42 U.S.C. 7384*l*(14)(C). Hence, beginning on June 10, 2012, members of this class of employees, defined as reported in this notice, became members of the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012–15966 Filed 6–28–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the Electro Metallurgical site in Niagara Falls, New York, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On May 11, 2012, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Electro Metallurgical site in Niagara Falls, New York, from August 13, 1942 through December 31, 1947, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation became effective on June 10, 2012, as provided for under 42 U.S.C. 7384*l*(14)(C). Hence, beginning on June 10, 2012, members of this class of employees, defined as reported in this notice, became members of the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012–15968 Filed 6–28–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the Brookhaven National Laboratory in Upton, New York, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On May 11, 2012, as provided for under 42 U.S.C. § 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Brookhaven National Laboratory in Upton, New York, from January 1, 1980 through December 31, 1993, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for

one or more other classes of employees included in the Special Exposure Cohort.

This designation became effective on June 10, 2012, as provided for under 42 U.S.C. 7384*l*(14)(C). Hence, beginning on June 10, 2012, members of this class of employees, defined as reported in this notice, became members of the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012–15977 Filed 6–28–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–437A and 437B and CMS–10406]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (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.

1. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations in 42 CFR 412.20–412.29. *Use:* For first time verification requests for exclusion from the Inpatient Prospective Payment System (IPPS), a hospital/unit must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion from the IPPS. Currently, all new inpatient rehabilitation facilities (IRFs) must provide written certification that the inpatient population it intends to serve will meet the requirements of the IPPS exclusion criteria for IRFs. They must also complete the Form CMS–437A if they are a rehabilitation unit or complete Form CMS–437B if they are a rehabilitation hospital. This information is submitted to the State Agency (SA) no later than 5 months before the date the hospital/unit would become subject to IRF–PPS.

CMS proposes to continue to use the Criteria Worksheets (Forms CMS–437A and CMS–437B) for verifying first-time exclusions from the IPPS, for complaint surveys, for its annual 5 percent validation sample, and for facility self-attestation. These forms are related to the survey and certification and Medicare approval of the IPPS-excluded rehabilitation units and rehabilitation hospitals.

For rehabilitation hospitals and rehabilitation units already excluded from the IPPS, annual onsite re-verification surveys by the SA are not required. These hospitals and units will be provided with a copy of the appropriate CMS–437 Worksheet at least 5-months prior to the beginning of its cost reporting period, so that the hospital/unit official may complete and sign an attestation statement and complete and return the appropriate CMS–437A or CMS–437B at least 5 months prior to the beginning of its cost reporting period. Fiscal Intermediaries will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for rehabilitation hospitals and rehabilitation units through a sample of medical records and the SA will verify the medical director requirement.

The SA will maintain the documents unless instructed otherwise by the RO. The SA will notify the RO at least 60 days prior to the end of the rehabilitation hospital's/unit's cost reporting period of the IRF's compliance or non-compliance with the payment requirements. The information collected on these forms, along with other information submitted by the IRF is necessary for determining exclusion from the IPPS. Hospitals and units that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria.

Both forms have been revised since the publication of the 60-day **Federal Register** notice on April 4, 2012 (77 FR 20404). Burden estimates have not changed.

Form Number: CMS–437A and CMS–437B (OCN 0938–0986). *Frequency:* Yearly. *Affected Public:* Private Sector (Business or other for-profits). *Number of Respondents:* 1,164. *Total Annual Responses:* 1,164. *Total Annual Hours:* 291. (For policy questions regarding this collection contact Georgia Johnson at 410–786–6859. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* New collection. *Title of Information Collection:* Probable Fraud Measurement Pilot; *Use:* The Centers for Medicare & Medicaid Services (CMS) is seeking Office of Management and Budget (OMB) approval of the collections required for a probable fraud measurement pilot. The probable fraud measurement pilot would establish a baseline estimate of probable fraud in payments for home health care services in the fee-for-service Medicare program. CMS and its agents will collect information from home health agencies, the referring physicians and Medicare beneficiaries selected in a national random sample of home health claims. The pilot will rely on the information collected along with a summary of the service history of the HHA, the referring provider, and the beneficiary to estimate the percentage of total payments that are associated with probable fraud and the percentage of all claims that are associated with probable fraud for Medicare fee-for-service home health. CMS is requesting an exemption from the Paperwork Reduction Act under 5 CFR 1320.14A. However, CMS is providing information related to the purpose and need for this data collection in Supporting Statement Part A.

Form Number: CMS–10406 (OCN: 0938—New). *Frequency:* Yearly; *Affected Public:* Individual and Private Sector—Business or other for-profits; *Number of Respondents:* 6,000; *Total Annual Responses:* 6,000; *Total Annual Hours:* 10,500. (For policy questions regarding this collection contact Kelly Gent at 410–786–0918. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or email

your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 30, 2012.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: June 26, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–16002 Filed 6–28–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8052–N]

Medicare Program; Meeting of the Medicare Economic Index Technical Advisory Panel

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Economic Index Technical Advisory Panel (''the Panel''). The purpose of the Panel is to review all aspects of the Medicare Economic Index (MEI). During this third and final meeting the Panel will discuss their findings and recommendations regarding the MEI's inputs, input weights, price-measurement proxies, and productivity adjustment. This meeting is open to the public in accordance with the Federal Advisory Committee Act.

DATES: *Meeting date:* The public meeting will be held on Wednesday, July 11, 2012 from 8:30 a.m. until 5 p.m., Eastern Daylight Time (EDT).

Deadline for submission of written comments: Written comments must be received at the mailing or email address specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m. EDT, Thursday, July 5, 2012.

Deadlines for speaker registration and presentation materials: The deadline to register to be a speaker and to submit PowerPoint presentation materials and any other written materials that will be used in support of an oral presentation is 5 p.m. EDT, Thursday, July 5, 2012. Speakers may register by contacting Toya Via, HCD International, by phone at (301) 552–8803 or via email at *MEITAP@hcdi.com.* Materials that will be used in support of an oral presentation must be received at the mailing or email address specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice, by 5 p.m. EDT, Thursday, July 5, 2012.

Registration deadline for all other attendees: Individuals may register online at *http://www.hcdi.com/mei/or* by phone by contacting Toya Via, HCD International, at (301) 552–8803 by 5 p.m. EDT, Thursday, July 5, 2012.

Deadline for submission of a request for special accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Designated Federal Officer as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m. EDT, Thursday, July 5, 2012.

ADDRESSES: *Meeting location:* We will be broadcasting the meeting live via webinar and conference call (for audio purposes). Webinar details will be sent to registered attendees. At the close of the second meeting on June 25, 2012 (77 FR 34050), the Designated Federal Officer will decide if the third and final meeting, in addition to the webinar, will also be held in the Auditorium of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, MD 21244. The decision will be available online at *http://www.hcdi.com/mei/after* 5 p.m. EDT, Monday, June 25, 2012.

FOR FURTHER INFORMATION CONTACT: John Poisal, Designated Federal Officer, Centers for Medicare & Medicaid Services, Office of the Actuary, Mail stop N3–02–02, 7500 Security Boulevard, Baltimore, MD 21244 or contact Mr. Poisal by phone at (410) 786–6397 or via email at *John.Poisal@cms.hhs.gov.* Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare Economic Index Technical Advisory Panel (''the Panel'') was established by the Secretary to conduct a technical review of the Medicare Economic Index (MEI). The review will include the inputs, input weights, price-measurement proxies, and productivity adjustment. For more information on the Panel, see the October 7, 2011 **Federal Register** (76 FR 62415). You may view and obtain a copy of the Secretary's charter for the Panel at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP.html.* The members of the Panel are: Dr. Ernst Berndt, Dr. Robert Berenson, Dr. Zachary Dyckman, Dr. Kurt Gillis, and Ms. Kathryn Kobe.

This notice announces the Wednesday, July 11, 2012 public meeting of the Panel. This meeting will focus on the Panel's findings and recommendations regarding the MEI's inputs, input weights, price-measurement proxies, and the productivity adjustment.

II. Meeting Format

This meeting is open to the public. There will be up to 45 minutes allotted at this meeting for the Panel to hear oral presentations from the public. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, we will conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by 5 p.m. EDT, Friday, July 6, 2012. Any presentations that are not selected based on the lottery will be forwarded to the panel for consideration. For this meeting, public comments should focus on the MEI's inputs, input weights, price-measurement proxies, and productivity adjustment. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Panel will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Panel will not hear further comments during this time except at the request of the chairperson. The Panel will also allow up to 15 minutes for an unscheduled open public session for any attendee to address issues specific to the topics under consideration.

III. Registration Instructions

HCD International is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at *http://www.hcdi.com/mei/* or by phone by contacting Toya Via, HCD International, at (301) 552–8803, by the

deadline specified in the **DATES** section of this notice. Please provide your full name (as it appears on your government-issued photographic identification), address, organization, telephone, and email address. At the time of registration, you will be asked to designate if you plan to attend in person or via webinar. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified that the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 5 U.S.C. App. 2, section 10(a).

Dated: June 26, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–15997 Filed 6–26–12; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0558]

Compliance Policy Guide Sec. 230.110—Registration of Blood Banks, Other Firms Collecting, Manufacturing, Preparing, or Processing Human Blood or Blood Products; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the compliance policy guide (CPG) entitled ''Sec. 230.110 Registration of Blood Banks, Other Firms Collecting, Manufacturing, Preparing, or Processing Human Blood or Blood Products (CPG 7134.01),'' dated June 17, 1974.

DATES: The withdrawal is effective June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Robert L. Hummel, Division of Compliance Policy (HFC–230), Food and Drug Administration, 12420 Parklawn Dr., ELEM–4152, Rockville, MD 20857, 301–796–4510.

SUPPLEMENTARY INFORMATION: FDA issued the CPG entitled ''Sec. 230.110 Registration of Blood Banks, Other Firms Collecting, Manufacturing, Preparing, or Processing Human Blood or Blood Products (CPG 7134.01)'' on June 17, 1974. We originally issued CPG 7134.01 entitled ''Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products,'' to provide FDA's current thinking regarding the registration required by 21 CFR part 607 of blood banks and other establishments collecting, manufacturing, preparing, or processing human blood or blood products. Since the last update to CPG 7134.01 in 2000, the regulations for blood establishment registration under part 607 have been amended several times. FDA is withdrawing CPG 7134.01 because it is obsolete.

Dated: June 13, 2012.

Dara Corrigan,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 2012–15907 Filed 6–26–12; 4:15 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

AGENCY: Health Resources and Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice advises the public of the published lists of all geographic areas, population groups, and facilities designated as primary medical care, mental health, and dental health professional shortage areas (HPSAs) as of April 1, 2012, available on the Health Resources and Services Administration (HRSA) Web site at *http://bhpr.hrsa.gov/shortage/index.html.* HPSAs are designated or withdrawn by the Secretary of Health and Human Services (HHS) under the authority of section 332 of the Public Health Service (PHS) Act and 42 CFR part 5.

FOR FURTHER INFORMATION CONTACT: Requests for further information on the HPSA designations listed on the HRSA Web site below and requests for additional designations, withdrawals, or reapplication for designation should be submitted to Andy Jordan, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; (301) 594–0816.

SUPPLEMENTARY INFORMATION:

Background: Section 332 of the PHS Act, 42 U.S.C. 254e, provides that the Secretary of HHS shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. Section 332 further requires that the Secretary annually publish a list of the designated geographic areas, population groups, and facilities. The lists of HPSAs are to be reviewed at least annually and revised as necessary. HRSA's Bureau of Health Professions (BHPr) has the responsibility for designating and updating HPSAs.

Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps (NHSC) personnel to provide primary care, dental, or mental health services in these HPSAs. NHSC health

professionals with a service obligation may enter into service agreements to serve only in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain residency training program grants administered by BHPr. Many other Federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare and Medicaid Services, certain qualified providers in HPSAs are eligible for increased levels of Medicare reimbursement.

Development of the Designation and Withdrawal Lists: Criteria for designating HPSAs were published as final regulations (42 CFR part 5) in 1980. Criteria then were defined for each of seven health professional types (primary medical care, dental, psychiatric, vision care, podiatric, pharmacy, and veterinary care). The criteria for correctional facility HPSAs were revised and published on March 2, 1989, in **Federal Register** (54 FR 8735). The criteria for psychiatric HPSAs were expanded to mental health HPSAs on January 22, 1992 (57 FR 2473). Currently-funded PHS Act programs use only the primary medical care, mental health, or dental HPSA designations.

Individual requests for designation or withdrawal of a particular geographic area, population group, or a facility as a HPSA are received and reviewed continuously by BHPr. The majority of the requests come from the Primary Care Office (PCO) in the State Health Departments, who have access to the on-line application and review system. Requests that come from other sources are referred to the PCOs for their review and concurrence. In addition, applicants are expected to share copies of the requests with other interested parties, including the Governor, the State Primary Care Association and State professional associations for their comments and recommendations.

Annually, lists of designated HPSAs are made available to all PCOs, state medical and dental societies and others, with a request to review and update the data on which the designations are based. Emphasis is placed on updating those designations that are more than three years old or where significant changes relevant to the designation criteria have occurred.

Recommendations for possible additions, continuations, revisions or withdrawals from a HPSA list are reviewed by BHPr, and the review findings are provided by letter to the agency or individual requesting action or providing data, with copies to other interested organizations and individuals. These letters constitute the official notice of designation as a HPSA, rejection of recommendations for HPSA designation, revision of a HPSA designation, and/or advance notice of pending withdrawals from the HPSA list. Designations (or revisions of designations) are effective as of the date of the notification letter from BHPr. Proposed withdrawals become effective only after interested parties in the area affected have been afforded the opportunity to submit additional information to BHPr in support of its continued or revised designation. If no new data are submitted, or if BHPr review confirms the proposed withdrawal, the withdrawal becomes effective upon publication of the lists of designated HPSAs in the **Federal Register**. In addition, lists of HPSAs are continuously available on the HRSA Web site, *http://bhpr.hrsa.gov/shortage/index.html,* so that interested parties can access the most accurate and timely information.

Publication and Format of Lists: Due to the large volume of designations, this notice serves to inform the public of the availability of the complete listings of the designated HPSAs on the HRSA Web site. The three lists of designated HPSAs are available at a link on the Office of Shortage Designation Web site at *http://bhpr.hrsa.gov/shortage/index.html.* Each list (primary medical care, mental health, and dental) includes all those geographic areas, population groups, and facilities that were designated HPSAs as of April 1, 2012. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the **Federal Register** on November 3, 2011 (76 FR 68198). The lists include those automatic facility HPSAs that have been entered into the HPSA data base. Automatic facility HPSAs, designated as a result of the Health Care Safety Net Amendments of 2002 (Pub. L. 107–251), are not subject to the updating requirements. The lists are constantly changing based on the identification of new sites that meet the eligibility criteria or current sites that lose their eligibility and need to be removed. Each list of designated HPSAs (primary medical care, mental health, and dental) is arranged by state. Within each state, the list is presented by county. If only a portion (or portions) of a county is (are) designated, or if the county is part of a larger designated service area, or if a population group residing in the county or a facility located in the county has been designated, the name of the service area, population group, or facility involved is listed under the county name. Counties that have a whole county geographic HPSA are indicated by the ''Entire county HPSA'' notation following the county name. Further details for the HPSAs listed can be found on the HRSA Web site: *http://bhpr.hrsa.gov/shortage/index.html.*

In addition to the specific listings included in this notice, all Indian Tribes that meet the definition of such Tribes in the Indian Health Care Improvement Act of 1976, 25 U.S.C. 1603(d), are automatically designated as population groups with primary medical care and dental health professional shortages. The Health Care Safety Net Amendments of 2002 also made the following entities eligible for automatic facility HPSA designations: all federally qualified health centers (FQHCs) and rural health clinics that offer services regardless of ability to pay. These entities include: FQHCs funded under section 330 of the PHS Act, FQHC Look-Alikes, and Tribal and Urban Indian clinics operating under the Indian Self-Determination and Education Act of 1975 (25 U.S.C. 450) or the Indian Health Care Improvement Act. Many, but not all, of these entities are included on this listing. Exclusion from this list does not exclude them from the list of HPSAs; all will be included in the data base as they are identified.

Future Updates of Lists of Designated HPSAs: The lists of HPSAs on the HRSA Web site below consist of all those that were designated as of April 1, 2012. It should be noted that additional HPSAs may have been designated by letter since that date. The appropriate agencies and individuals have been or will be notified of these actions by letter. These newly designated HPSAs will be included in the next publication of the HPSA list and are currently included on the HRSA Web site at *http://hpsafind.hrsa.gov/.*

Any designated HPSA listed on the HRSA Web site below is subject to withdrawal from designation if new information received and confirmed by HRSA indicates that the relevant data for the area involved have significantly changed since its designation. The effective date of such a withdrawal will be the next publication of a notice regarding this list in the **Federal Register**.

All requests for new designations, updates, or withdrawals should be based on the relevant criteria in regulations published at 42 CFR part 5.

Electronic Access Address: The complete list of HPSAs designated as of April 1, 2012, are available on the HRSA Web site at *http://bhpr.hrsa.gov/shortage/index.html.* Frequently updated information on HPSAs is also

available at *http://datawarehouse.hrsa.gov.*

Dated: June 19, 2012.

Mary K. Wakefield,

Administrator.

[FR Doc. 2012–15819 Filed 6–28–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Institute of Nursing Research (NINR) Summer Genetics Institute Alumni Survey

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Nursing Research (NINR), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB).

Prosposed Collection: Title: NIH/National Institute of Nursing Research (NINR) Summer Genetics Institute Alumni Survey. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The NINR Summer Genetics Institute Alumni Survey will obtain information on the long-term outcomes of this training program for nurse scientists and faculty. Target participants are alumni of this training institute which began in 2000. The survey inquires about career activities, including research, clinical, teaching and educational activities, since completion of the NINR Summer Genetics Institute. This is a 39-item survey that takes an average of 30 minutes to complete. The findings will provide valuable information on the influence of the Institute in developing genetics research capability among Institute alumni, and development and expansion of clinical practice in genetics among alumni who are nurse clinicians. *Frequency of Response:* Annual for three (3) years. *Affected Public:* Individual alumni of the NINR Summer Genetics Institute. *Type of Respondents:* Nurse scientists, clinicians, and faculty. The annual reporting burden is as follows: *Estimated Number of Respondents:* 150; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* .5; and *Estimated Total Annual Burden Hours Requested:* 75. There are no Capital Costs, Operating or Maintenance Costs to report.

Type of respondents	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Researchers	150	1	0.5	75

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Amanda Greene, Science Evaluation Officer, Office of Science Policy and Public Liaison, NINR, Democracy One, 6701 Democracy Blvd., Suite 700, Bethesda, MD 20892, or call non-toll-free number 301–496–9601, or email your request to *amanda.greene@nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: June 22, 2012.

Amanda Greene,

NINR Project Clearance Officer, Science Evaluation Officer, NINR, National Institutes of Health.

[FR Doc. 2012–16022 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Child Health Disparities Substudy for the National Children's Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 16, 2012, pages 15780–15782 (Volume 77, Number 52) of the **Federal Register** and allowed 60 days for public comment. No written comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Child Health Disparities Substudy for the National Children's Study (NCS). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The Children's Health Act of 2000 (Pub. L. 106–310) states:

(a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) Plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) Investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that

influence health and developmental processes.

(c) REQUIREMENT.—The study under subsection (b) shall—

(1) Incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) Consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the Child Health Disparities Substudy will validate measures needed for studying health disparities and selected biomarkers. Utilizing cognitive interview techniques and components of standardized questionnaires, responses will be used to assess and validate measures of health literacy, discrimination, parenting self-efficacy, and health care accessibility. Acceptability and feasibility of saliva collection from a subsample of women and young children will also be evaluated. The incorporation of saliva measurements will increase understanding of biological responses to environmental factors and how these may be correlated with health disparities within this population.

Background: The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines ''environment'' broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. By studying children through their different phases of growth and development, researchers will be better able to understand the role these factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible. The National Children's Study is led by a consortium of federal partners: The U.S. Department of Health and Human Services (including the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences of the National Institutes of Health and the Centers for Disease Control and Prevention), and The U.S. Environmental Protection Agency.

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

In this information collection request, the NCS requests approval from OMB to perform a multi-center substudy called the Child Health Disparity Substudy. This substudy aims to validate measures needed for studying health disparities and selected biomarkers. Developing optimum measures for studying health disparities is of particular interest to the NCS because studies have shown that health literacy, discrimination, parenting self-efficacy, health care (access, utilization, and quality) contribute to health disparities. Additionally, aspects of the social environment such as social isolation, lack of control and contingency and social support, violence, discrimination, challenging and changing social relationships, and restricted access to health care are thought to interact with biological processes. Variation in these processes has been associated with negative emotional states, cognitive deficits, problem behavior, and a variety of metabolic and immune-related processes. Alone, or particularly in combination with other commonly collected measures of social forces and family relationships, salivary analytes have the potential to advance our understanding of maternal and child health and development. This project will make its contribution to the NCS Main Study and to the health disparities field as a whole by constructing a validated set of questionnaire measures and biomarker analyses that can be used among pregnant women and mothers of young children for the purpose of investigating disparities.

Frequency of Response: One-time data collection conducted in multiple phases.

Affected Public: Pregnant women, mothers with young children, and their children.

Type of Respondents: Pregnant women, mothers with young children, and their children who are not geographically eligible to enroll in the NCS Vanguard Study.

Annual reporting burden: See Table 1. The annualized cost to respondents is estimated at $25,000 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN AND COST SUMMARY, CHILD HEALTH DISPARITIES SUBSTUDY

Data collection activity		Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden hours	Estimated total annual respondent cost
Screening for Cognitive Interview.	Mothers of children ages 0–5.	Members of NCS target population (not NCS participants).	100	1	5/60	8	$83
Screening for Primary Data Collection.	Women	Members of NCS target population (not NCS participants).	2,000	1	5/60	167	1,667
Screening for Saliva Collection.	Women	Members of NCS target population (not NCS participants).	600	1	5/60	50	500
Cognitive Interview	Mothers of children ages 0–5.	Members of NCS target population (not NCS participants).	60	1	75/60	75	750

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN AND COST SUMMARY, CHILD HEALTH DISPARITIES SUBSTUDY—Continued

Primary Data Collection.	Pregnant Women/ Mothers of children ages 0–5.	Members of NCS target population (not NCS participants).	600	2	65/60	1,300	13,000
	Mothers of children ages 0–5.		600	1	65/60	650	6,500
Saliva Collection ..	Pregnant Women/ Mothers of children ages 0–5.	Members of NCS target population (not NCS participants).	200	2	15/60	100	1,000
	Additional mothers of children ages 0–5.		200	1	15/60	50	500
	Children ages 0–5		400	1	15/60	100	*1,000
Total	.....	.....	4,760	.....	.....	2,500	25,000

*The allotted hourly wage rate accounts for the mother's time associated with the data collection activity.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: NIH Desk Officer, by Email to *OIRA_submission@omb.eop.gov,* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Jamelle E. Banks, Public Health Analyst, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496–1877 or Email your request, including your address, to *banksj@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: June 19, 2012.

Jamelle E. Banks,

Project Clearance Liaison, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

[FR Doc. 2012–16028 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: PHS Applications and Pre-Award Reporting Requirements; Revision

SUMMARY: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act (PRA) of 1995, the Office of the Director (OD), Office of Extramural Research (OER), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 5, 2012, Volume 77, No. 43, page 13132–13133, and allowed 60 days for public comment. One public comment was received, which asked for clarification about new reporting burdens. It was noted in follow-up that NIH has seen a 21-percent increase in competing applications since the last clearance which has resulted in an increase in the burden hours. We are also transitioning to the Research Performance Progress Report as mandated by OMB.

The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection: Title: Public Health Service (PHS) Applications and Pre-award Reporting Requirements. *Type of Information Collection Request:* Revision, OMB 0925–0001, Expiration Date 6/30/2012. Form numbers: PHS 398, PHS 416–1, 416–5, and PHS 6031. This collection represents a consolidation of PHS applications and pre-award reporting requirements into a revised data collection under the PRA. *Need and Use of Information Collection:* This collection includes PHS applications and pre-award reporting requirements: PHS 398 [paper] Public Health Service Grant Application forms and instructions; PHS 398 [electronic] PHS Grant Application component forms and agency-specific instructions used in combination with the SF424 (R&R); PHS Fellowship Supplemental Form and agency-specific instructions used in combination with the SF424 (R&R) forms/instructions for Fellowships [electronic]; PHS 416–1 Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Application Instructions and Forms used only for a change of sponsoring institution application [paper]; Instructions for a Change of Sponsoring Institution for NRSA Fellowships (F30, F31, F32 and F33) and non-NRSA Fellowships; PHS 416–5 Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Activation Notice; and PHS 6031 Payback Agreement. The PHS 398 (paper and electronic) is currently approved under 0925–0001; PHS 416–1, 416–5, and PHS 6031 are currently approved under 0925–0002. All forms expire 6/30/2012. Post-award reporting requirements are simultaneously consolidated under 0925–0002, and include the new Research Performance Progress Report (RPPR).

The PHS 398 application is used by applicants to request federal assistance funds for traditional investigator-initiated research projects and to request access to databases and other PHS resources. The PHS 416–1 is used only for a change of sponsoring institution application. PHS Fellowship

Supplemental Form and agency-specific instructions is used in combination with the SF424 (R&R) forms/instructions for Fellowships and is used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The PHS 416–5 is used by individuals to indicate the start of their NRSA awards. The PHS 6031 Payback Agreement is used by individuals at the time of activation to certify agreement to fulfill the payback provisions. *Frequency of response:* Applicants may submit applications for published receipt dates. For NRSA awards, Fellowships are activated and trainees appointed. *Affected Public:* Universities and other research institutions; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. *Type of Respondents:* University administrators and principal investigators. The annual reporting burden is as follows: *Total Estimated Number of Respondents:* 94,326; Estimated Number of Responses per Respondent: 1; Average Burden Hours Per Response: 21.75; *Estimated Total Annual Burden Hours Requested:* 2,051,794. The estimated annualized cost to respondents is $71,812,769.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be sent via email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Seleda M. Perryman, Chief, Project Clearance Officer, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3509, 6705 Rockledge Drive, Bethesda, MD 20892–7974; or call non-toll-free number 301–594–7949; or email your request, including your address, to *perrymansm@od.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: June 25, 2012.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2012–15930 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Post-Award Reporting Requirements Including New Research Performance Progress Report Collection; Revision

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 5, 2012, page 13131 (corrected on March 26, 2012, page 17488), and allowed 60 days for public comment. One public comment was received, which asked for clarification about new reporting burdens. It was noted in follow-up that NIH has seen a 21-percent increase in competing applications since the last clearance, which has resulted in an increase in the burden hours. We are also transitioning to the Research Performance Progress Report as mandated by OMB. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection: Title: Public Health Service (PHS) Post-award Reporting Requirements. *Type of Information Collection Request:* Revision, OMB 0925–0002, Expiration Date 06/30/2012. This collection represents a consolidation of post-award reporting requirements under the Paperwork Reduction Act and includes the new Research Performance Progress Report (RPPR). It also includes continued use of the PHS Non-competing Continuation Progress Report (PHS 2590, currently approved under 0925–0001, expiration 06/30/2012), and the NIH AHRQ Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Progress Report for Continuation Support (PHS 416–9). Only one interim progress report (RPPR or PHS2590/416–9) will be utilized for any given award until the RPPR is fully implemented for all awards. This collection also includes other PHS post-award reporting requirements: PHS 416–7 NRSA Termination Notice and PHS 6031–1 NRSA Annual Payback Activities Certification. Post-award reporting requirements previously cleared under OMB 0925–0001 now included under 0925–0002 are: PHS 2271 Statement of Appointment, HHS 568 Final Invention Statement and Certification, Final Progress Report instructions, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. Pre-award reporting requirements are simultaneously consolidated under 0925–0001.

Need and Use of Information Collection: The RPPR will replace existing interim performance reports used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR requires the maintenance of dual reporting processes for a period of time. Thus this information collection is for the new use of the RPPR, the continued use of the PHS Non-competing Continuation Progress Report (PHS 2590), and the use of the NIH AHRQ Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Progress Report for Continuation Support (PHS 416–9). Only one interim progress report (RPPR or PHS2590/416–9) will be utilized for any given award. The PHS 416–7, 2271, and 6031–1 are used by NRSA recipients to activate, terminate, and provide for payback of an NRSA. Closeout of an award requires a Final Invention Statement (HHS 568) and Final Progress Report. iEdison allows grantees and federal agencies to meet statutory requirements for reporting inventions and patents. The PHS 3734 serves as the official record of grantee relinquishment of a PHS award when an award is transferred from one grantee institution to another.

Frequency of response: Grantees are required to report annually. *Affected Public:* Universities and other research

institutions; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. *Type of Respondents:* University administrators and principal investigators. The annual reporting burden is as follows: *Total Estimated Number of Respondents:* 112,986. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours per Response:* 5.6. *Estimated Total Annual Burden Hours Requested:* 640,677. The annualized cost to respondents is estimated to be $22,423,709.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov;* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Seleda M. Perryman, Chief, Project Clearance Officer, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3509, 6705 Rockledge Drive, Bethesda, MD 20892–7974; or call non-toll-free number 301–594–7949; or email your request, including your address to: *perrymansm@od.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Date: June 25, 2012.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2012–15929 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of NIH Consensus Development Conference: Diagnosing Gestational Diabetes Mellitus

SUMMARY: The National Institutes of Health (NIH) is holding a conference titled ''Consensus Development Conference: Diagnosing Gestational Diabetes Mellitus.'' The conference will be open to the public.

DATES: The conference will be held October 29–31, 2012, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892.

FOR FURTHER INFORMATION CONTACT: Advance information about the conference and conference registration materials may be obtained from the NIH Consensus Development Program Information Center by calling 888–644–2667 or by sending an email to *Prevention@mail.nih.gov.* The Information Center's mailing address is P.O. Box 2577, Kensington, Maryland, 20891. Registration and conference information are also available on the NIH Consensus Development Program Web site at *http://prevention.nih.gov/cdp.*

SUPPLEMENTARY INFORMATION: Gestational diabetes mellitus (GDM) is a condition in which women without previously diagnosed diabetes exhibit high blood glucose levels during pregnancy (especially during the third trimester of pregnancy). It is defined as carbohydrate intolerance, which is the inability of the body to adequately process carbohydrates (sugars and starches) into energy for the body that develops or is first recognized during pregnancy. GDM is estimated to occur in 1–14 percent of U.S. pregnancies, affecting more than 200,000 women annually. It is one of the most common disorders in pregnancy and is associated with an increased risk of complications for the mother and child. Potential complications during pregnancy and delivery include preeclampsia (high blood pressure and excess protein in the urine), caesarean delivery, macrosomia (large birth weight), shoulder dystocia (when a baby's shoulders become lodged during delivery), and birth injuries. For the neonate, complications include difficulty breathing at birth, hypoglycemia (low blood sugar), and jaundice. Up to one-half of women who have GDM during pregnancy will develop type 2 diabetes later in life.

Although the U.S. Preventive Services Task Force found in 2008 that the evidence was insufficient to assess the balance between the benefits and harms of screening women for GDM, the American College of Obstetricians and Gynecologists recommends universal screening for gestational diabetes using patient history, risk factors, or laboratory testing, such as with a glucose challenge test (GCT). Different approaches are used internationally for screening and diagnosis of GDM. The standard method in the United States begins with a GCT, which involves drinking a sweetened liquid containing 50 grams of sugar (glucose). A blood sample is taken after 1 hour, which measures the glucose level. If high, a diagnostic test is administered using a larger dose of glucose, and several blood tests are performed over 3 hours. Depending on the test used, and the chosen blood glucose levels that are used to diagnose GDM, the number of women who will receive the diagnosis will vary. Debate continues regarding the choice of tests and the effectiveness of treatment, especially in women with mild to moderate glucose intolerance. Potential harms of screening for GDM include anxiety for patients and the potentially adverse effects of a ''high-risk'' label in pregnancy. In addition, women diagnosed with GDM face stressors including dietary constraints, a need to add or increase exercise, frequent self-monitoring of blood glucose levels, and for some, self-administration of insulin which will require adjustments of insulin doses.

To better understand the benefits and risks of various GDM screening and diagnostic approaches, the NIH has engaged in a rigorous assessment of the available scientific evidence. This process is sponsored by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the Office of Disease Prevention. A multidisciplinary planning committee developed the following key questions:

1. What are the current screening and diagnostic approaches for gestational diabetes mellitus, what are the glycemic thresholds for each approach, and how were these thresholds chosen?

2. What are the effects of various gestational diabetes mellitus screening/diagnostic approaches for patients, providers, and U.S. health care systems?

3. In the absence of treatment, how do health outcomes of mothers who meet various criteria for gestational diabetes

mellitus and their offspring compare with those who do not?

4. Does treatment modify the health outcomes of mothers who meet various criteria for gestational diabetes mellitus and their offspring?

5. What are the harms of treating gestational diabetes mellitus, and do they vary by diagnostic approach?

6. Given all of the above, what diagnostic approach(es) for gestational diabetes mellitus should be recommended, if any?

7. What are the key research gaps in the diagnostic approach of gestational diabetes mellitus?

An evidence report on GDM will be prepared through the Agency for Healthcare Research and Quality's Evidence-based Practice Centers program, and a Consensus Development Conference will be held on October 29–31, 2012.

During the conference, invited experts, including the authors of the evidence report, will present scientific data. Attendees will have opportunities to ask questions and provide comments during open discussion periods. After weighing the evidence, an unbiased, independent panel will prepare and present a consensus statement addressing the key questions. The statement will be widely disseminated to practitioners, policymakers, patients, researchers, the general public, and the media.

Please Note: As part of measures to ensure the safety of NIH employees and property, all visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the security measures at NIH, please visit the Web site at *http://www.nih.gov/about/visitorsecurity.htm.*

Dated: June 21, 2012.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2012–15992 Filed 6–28–12; 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, 2013–01 SBIR Review.

Date: September 24, 2012.

Time: 10:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, 301–496–4773, *zhour@mail.nih.gov.*

Dated: June 22, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16075 Filed 6–28–12; 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 Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Scientific Management Review Board.

The NIH Reform Act of 2006 (Public Law 109–482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the Scientific Management Review Board (also referred to as SMRB or Board) is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Scientific Management Review Board.

Date: July 11, 2012.

Time: 08:00 a.m. to 4:30 p.m.

Agenda: The focus of this meeting will be on the deliberations of the SMRB's NIH Small Business Innovation Research/Small Business Technology Transfer Program Working Group and its first stakeholder consultation. Presentation and discussion will include, but is not limited to, representatives from NIH Institutes and Centers and other government agencies with Small Business Innovation Research and Small Business Technology Transfer Programs. The Board will also discuss next steps regarding future SMRB activities. Time will be allotted on the agenda for public comment. Sign up for public comments will begin approximately at 7:30 a.m. on July 11, 2012 and will be restricted to one sign-in per person. In the event that time does not allow for all those interested to present oral comments, any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Lyric Jorgenson, Ph.D., Office of Science Policy, Office of the Director, NIH, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, *smrb@mail.nih.gov,* (301) 496–6837.

This meeting is being published less than 15 days prior to the meeting due to scheduling conflicts of the Members.

The meeting will also be webcast. The draft meeting agenda and other information about SMRB, including information about access to the webcast, will be available at *http://smrb.od.nih.gov.*

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(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: June 22, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16074 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed 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 General Medical Sciences Special Emphasis Panel NIGMS Postdoctoral T32 Training Grant Review.

Date: July 20, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An18, Bethesda, MD 20892, 301–594–2769, *pikbr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 22, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16073 Filed 6–28–12; 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; Small Business: Basic and Integrative Bioengineering.

Date: July 24, 2012.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: General Services Administration Building, 301 7th Street SW., Washington, DC 20407.

Contact Person: Paul Sammak, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, MSC 7892, Bethesda, MD 20892, 301–435–0601, *sammakpj@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Respiratory Sciences.

Date: July 26–27, 2012.

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: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240–498–7546, *diramig@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Tumor Progression.

Date: July 27, 2012.

Time: 3:00 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: Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@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: June 22, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16072 Filed 6–28–12; 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: AIDS and Related Research Integrated Review Group, AIDS Immunology and Pathogenesis Study Section.

Date: July 20, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington, DC, 923 16th Street NW., Washington, DC 20006.

Contact Person: Shiv A Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: HIV/AIDS Innovative Research Applications.

Date: July 24–25, 2012.

Time: 10:00 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: Kenneth A Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, RFA Panel: Economic Studies in Health Care Delivery.

Date: July 24, 2012.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Melinda Jenkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892, 301–437–7872, *jenkinsml2@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Program Project: National Center for Functional Glycomics.

Date: July 25–27, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Emory Inn, 1615 Clifton Road Northeast, Atlanta, GA 30322.

Contact Person: Arnold Revzin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7806, Bethesda, MD 20892, (301) 435–1153, *revzina@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: June 22, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16071 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases, Special Emphasis Panel, Small Grant Research Review (R03).

Date: July 18, 2012.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Eric H. Brown, MS, Ph.D., Scientific Review Officer, National Institute of Arthritis,Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Blvd., Room 824, MSC 4872, Bethesda, MD 20892–4872, (301) 594–4955, *browneri@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: June 22, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16068 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of 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 Mental Health Special Emphasis Panel; Fellowships and Dissertation Grants.

Date: July 17, 2012.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Interventions Conflicts and Eating Disorders 1.

Date: July 24, 2012.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health,Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marina Broitman, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, 301–402–8152, *mbroitma@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: June 21, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16067 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; State

Health Policy Database for Research (SHPDR).

Date: July 17, 2012.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: June 21, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16066 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, July 24, 2012, 11:00 a.m. to July 24, 2012, 4:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD, 20852 which was published in the **Federal Register** on June 13, 2012, 77 FR 35411.

The start time for this meeting has been changed to 1:00 p.m. The meeting is closed to the public.

Dated: June 21, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16065 Filed 6–28–12; 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, Member Conflict: Child Psychopathology and Developmental Disabilities.

Date: July 23, 2012.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301–500–5829, *sechu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Molecular Genetics.

Date: July 26, 2012.

Time: 12:00 p.m. to 2:00 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: Barbara J. Thomas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2218, MSC 7890, Bethesda, MD 20892, 301–435–0603, *bthomas@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: June 25, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16077 Filed 6–28–12; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Peer Review Meeting.

Date: July 19, 2012.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Jane K. Battles, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Room 3128, Bethesda, MD 20892–7616, 301–451–2744, *battlesja@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 22, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16076 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Library of Medicine Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the Literature Selection Technical Review Committee.

The meeting will be open to the public as indicated below, with attendance limited to space available.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The portions of the meeting devoted to the review and evaluation of journals for potential indexing by the National Library of Medicine will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. Premature disclosure of the titles of the journals as potential titles to be indexed by the National Library of Medicine, the discussions, and the presence of individuals associated with these publications could significantly frustrate the review and evaluation of individual journals.

Name of Committee: Literature Selection Technical Review Committee.

Date: October 25–26, 2012.

Open: October 25, 2012, 9:00 a.m. to 11:00 a.m.

Agenda: Administrative.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: October 25, 2012, 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: October 26, 2012, 8:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Joyce Backus, M.S.L.S., Deputy Associate Director, Division of Library Operations, National Library of Medicine, 8600 Rockville Pike, Building 38, Room 2W04, Bethesda, MD 20892, 301–496–6921, *backusj@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: June 25, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16025 Filed 6–28–12; 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; Program Project: Pharmacogenetics and Animal Models.

Date: July 16, 2012.

Time: 3:00 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: David J Remondini, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2210, MSC 7890, Bethesda, MD 20892, 301–435–1038, *remondid@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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: AIDS and AIDS Related Applications.

Date: July 17, 2012.

Time: 10:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurobiology/Neurochemistry in Psychiatric Disorders.

Date: July 17, 2012.

Time: 3:00 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: Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435–1252, *cinquej@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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Disease and Function: cullin-RING Pathways.

Date: July 20, 2012.

Time: 3:00 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: David J Remondini, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2210, MSC 7890, Bethesda, MD 20892, 301–435–1038, *remondid@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: June 22, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16026 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Long Term Outcomes in Acute Respiratory Failure (R24).

Date: July 18, 2012.

Time: 10 a.m. to 1 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: Keary A Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892–7924, 301–435–2222, *copeka@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Molecular Imaging of the Lung.

Date: July 19, 2012.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn—Washington, DC/Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, *sunnarborgsw@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 25, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–16019 Filed 6–28–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5601–N–25]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AIR FORCE: Mr. Robert Moore, Air Force Real Property Agency, 143 Billy Mitchell Blvd., San Antonio, TX 78226, (210) 395–9512; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084;

NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426; (These are not toll-free numbers).

Dated: June 21, 2012.

Ann Marie Oliva,

Deputy Assistant Secretary for Special Needs (Acting).

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 06/29/2012

Suitable/Available Properties

Building

Missouri

Nat'l Personnel Records Center
111 Winnebago
St. Louis MO 63118
Landholding Agency: GSA
Property Number: 54201220009
Status: Excess
GSA Number: 7–G–MO–0684
Comments: 440,000 +/- sf.; two floors; storage; asbestos, lead, & high level of radon; needs remediation

Virginia

Building 2113
Marine Corps Base
Quantico VA 22134
Landholding Agency: Navy
Property Number: 77201220016
Status: Excess
Comments: off-site removal only; 4,905 sf.; extensive repairs needed; potential ground water contamination; secured area; need approval to access and remove property off installation

Suitable/Available Properties

Land

Missouri

Whiteman ILS Outer Marker Anne
Hwy 23 North, 9 miles S. of Knob Noster
Knob Noster MO 65336
Landholding Agency: GSA
Property Number: 54201220010
Status: Unutilized
GSA Number: 7–D–MO–0428–2
Directions: previously reported by Air Force under property # 18200940001
Comments: .75 acres +/-; fenced grassy area

Unsuitable Properties

Building

New Jersey

Building 2602
Joint Base McGuire-Dix Lakehurst
Trenton NJ 08641
Landholding Agency: Air Force
Property Number: 18201220044
Status: Unutilized
Comments: nat'l security concerns; approval for the public to gain access w/out comprising nat'l security is not feasible; will promote a breach of security
Reasons: Secured Area

[FR Doc. 2012–15610 Filed 6–28–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5642–D–04]

Redelegation of Authority to Directors and Deputy Directors of Community Planning and Development in Field Offices

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of redelegation of authority to field offices.

SUMMARY: On May 30, 2012, a new Consolidated Delegation of Authority was published in the **Federal Register**, at 77 FR 31972, giving concurrent authority for Community Planning and Development (CPD) programs from the Secretary of HUD to the Assistant Secretary for Community Planning and Development, the General Deputy Assistant Secretary for Community Planning and Development and the Deputy Assistant Secretary for Special Needs Programs. In this notice, the Assistant Secretary of Community Planning and Development redelegates to the Directors and Deputy Directors of Community Planning and Development in HUD Field Offices all powers and authorities necessary to carry out Office of Community Planning and Development programs, except those powers and authorities specifically excluded.

DATES: *Effective Date:* June 20, 2012.

FOR FURTHER INFORMATION CONTACT: David H. Enzel, Director of Technical Assistance and Management, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7228, Washington, DC 20410–7000; telephone number 202–402–5557. This is not a toll-free number. For those needing assistance, this number may be accessed via TTY by calling the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: Published in the **Federal Register** on May 30, 2012, at 77 FR 31972, is a revised consolidated delegation of authority from the Secretary of HUD to the Assistant Secretary, the General Deputy Assistant Secretary for CPD, and the Deputy Assistant Secretary for Special Needs Programs. This notice updates and revises redelegations of authority from the Assistant Secretary for Community Planning and Development to CPD Directors and Deputy Directors in HUD Field Offices. This notice supersedes all previous redelegations of authority to CPD Directors and Deputy Directors in HUD Field Offices, including a redelegation published on October 18, 2011 at 76 FR 64364. Also published elsewhere in today's **Federal Register** is a redelegation of authority from the Assistant Secretary for CPD to the Deputy Assistant Secretaries and other specified HUD officials.

Section A. General Redelegation of Authority

Except those authorities specifically excluded, the Assistant Secretary redelegates to the Directors and Deputy Directors of Community Planning and Development in HUD Field Offices all powers and authorities of the Assistant Secretary necessary to carry out the following Community Planning and Development programs and matters:

1. Community Development Block Grants (CDBG), Section 108 Loan Guarantees, Neighborhood Stabilization Programs (NSP), CDBG Disaster Recovery Grants, and other programs covered by Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5301 *et seq.*); 24 CFR part 570.

Authority not redelegated:

a. Terminate, reduce, or limit the availability of grant payments pursuant to section 111(a), 42 U.S.C. 5311.

b. Adjust entitlement and state grants pursuant to section 104(e), 42 U.S.C. 5304.

c. Determine basic grant amounts for metropolitan cities, urban counties, and States pursuant to section 106, 42 U.S.C. 5306.

d. Reallocate funds pursuant to section 106(c) or (d), 42 U.S.C. 5306.

e. Determine the qualifications of localities for special consideration. This includes, but is not limited to, the determination of qualifications of counties as urban counties pursuant to section 102(a)(6), 42 U.S.C. 5302, the determination of what constitutes a city pursuant to section 102(a)(5), 42 U.S.C. 5302, and the determination of levels of physical and economic distress of cities and urban counties for eligibility for urban development action grants pursuant to section 119(b), 42 U.S.C. 5318.

f. Approve and disapprove applications, or amendments to applications, filed for loan guarantee or grant assistance, issue commitments or grant awards, execute grant agreements, or issue guarantees pursuant to section 108, 42 U.S.C. 5308.

2. Comprehensive Housing Affordability Strategies (CHAS), Title I of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12701 et seq.); consolidated plans, 24 CFR part 91.

3. Emergency Shelter Grants/ Emergency Solutions Grants program, Title IV, Subtitle B of the McKinney-Vento Homeless Assistance Act, Public Law 100–77, 101 Stat. 482 (1987) (codified as amended at 42 U.S.C. 11371 *et seq.*), renamed by Act of Oct. 30, 2000, Public Law 106–400, 114 Stat. 1675 (2000); 24 CFR part 576.

Authority not redelegated:

a. Determine allocation amounts.

b. Approve built-in waivers or exceptions authorized under Title IV of the McKinney-Vento Homeless Assistance Act and applicable implementing regulations (such as section 414(b), 42 U.S.C. 11374(b); 24 CFR 576.21(b)(2) and section 415(d), 42 U.S.C. 11375(d); 24 CFR 576.56(b); 24 CFR 576.57(d).

4. The HOME Investment Partnerships Act, Title II of the Cranston-Gonzalez National Affordable Housing Act (NAHA), Public Law 101–625, 104 Stat. 4094 (1990) (codified as amended at 42 U.S.C. 12721 *et seq.*); 24 CFR part 92.

Authority not redelegated:

a. Determine allocation and reallocation amounts pursuant to section 217 of NAHA.

b. Revoke a jurisdiction's designation as a participating jurisdiction pursuant to section 216 of NAHA.

c. Effect remedies for noncompliance pursuant to section 223 of NAHA.

d. Approve a change in the number of units designated as HOME-assisted units during the period of affordability pursuant to 24 CFR 92.205(d).

e. Make a determination that a consortium does not have sufficient authority and administrative capability to administer the HOME Program pursuant to 24 CFR 92.101(a)(3).

5. Housing Trust Fund (HTF), Section 1338 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, added by Section 1131 of Public Law 110–289, 122 Stat. 2654 (codified at 12 U.S.C. 4568).

Authority not redelegated:

a. Determine allocations, adjustments, and reallocation amounts.

6. Homelessness Prevention and Rapid Re-Housing Program (HPRP) as authorized under the Homelessness Prevention Fund heading of Division A, Title XII of the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115.

7. AIDS Housing Opportunity Act, Title VIII, Subtitle D of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12901–12912); 24 CFR part 574.

Authority not redelegated:

a. Determine allocations, adjustments, and reallocation amounts.

b. Revoke a jurisdiction's designation as an eligible state or eligible metropolitan statistical area for a formula allocation or as an eligible applicant for a nonformula allocation.

c. Suspend or terminate current awards in whole or in part, withhold further awards, and effect other legally available remedies pursuant to 24 CFR 85.43(a)(3), (4) and (5).

d. Approve built-in waivers pursuant to section 858, 42 U.S.C. 12907(b)(1)(B); 24 CFR 574.310(c)(2).

8. Title IV Subtitles C–F of the McKinney-Vento Homeless Assistance Act, Public Law 100–77, 101 Stat. 482 (1987) (codified as amended at 42 U.S.C. 11381 et seq.), renamed by Act of Oct. 30, 2000, Public Law 106–400, 114 Stat. 1675 (2000) including the following: Supportive Housing Program, 24 CFR part 583, Shelter Plus Care program, 24 CFR part 582, Moderate Rehabilitation for Single Room Occupancy program, 24 CFR part 882, Subpart H, Continuum of Care program, and Rural Housing Stability Assistance program.

Authority not redelegated:

a. Make funding decisions.

b. Approve built-in waivers or exceptions authorized under Title IV of the McKinney-Vento Homeless Assistance Act and applicable implementing regulations (such as section 426(g), 42 U.S.C. 11386(g); 24 CFR 583.300(f); section 455(c), 42 U.S.C. 11403d(c); 24 CFR 582.300(a); section 441(h), 42 U.S.C. 11401(h); 24 CFR 882.808(q); 24 CFR 582.340(b); 24 CFR 583.330(e)).

9. Economic Development Initiative grants, as provided for in annual HUD appropriations acts (e.g., Consolidated Appropriations Resolution, Fiscal Year 2003, Public Law 108–7, 117 Stat. 11 (2003)).

10. Neighborhood Initiatives grants specifically designated in annual HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Public Law 111–117, 123 Stat. 3034 (2009)).

11. Rural Innovation Fund grants as provided for in annual HUD appropriations act(s) (e.g., Consolidated Appropriations Act 2010, Public Law 111–117, 123 Stat. 3084 (2009)).

12. The urban Empowerment Zones (EZ), as authorized under title 26, subtitle A, chapter 1, subchapter U of the Internal Revenue Code (codified as amended at 26 U.S.C. 1391 *et seq.*); 24 CFR parts 597 and 598.

Authority not redelegated:

a. Approve or amend strategic plans or other state and local commitments, including boundary changes.

b. Revoke a designation, including issuing a warning letter pursuant to 24 CFR parts 597 and 598.

13. Overall Departmental responsibility for compliance with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Public Law 91–646, 84 Stat. 1894 (1971) (codified as amended at 42 U.S.C. 4601 et seq.); 49 CFR part 24.

Authority not redelegated:

a. Exercise the Federal Agency waiver authority provided under 49 CFR 24.7.

14. Technical Assistance and Capacity Building awards authorized under any program or matter delegated under Section A (e.g., section 107 of the Housing and Community Development Act of 1987, Pub. L. No 100–242, 101 Stat. 1815 (1988)) and as provided for in annual and supplemental HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3093 (2009)).

15. Certain Community Planning and Development programs that are no longer authorized for funding (or future funding is not anticipated) but administration of the programs must continue until all Department responsibilities are discharged and finally terminated. These programs, as of June 2011, include the following:

a. Any program superseded by, or inactive by reason of, Title I of the Housing and Community Development Act of 1974, Pub.L. No. 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5316).

b. Grants for urban Empowerment Zones (EZ) as provided for in annual HUD appropriations acts (e.g., Consolidated Appropriations Resolution, Fiscal Year 2003, Pub. L. 108–7, 117 Stat. 11 (2003)).

c. HOPE for Homeownership of Single-family Housing Program (HOPE 3), Title IV, Subtitle C of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified at 42 U.S.C. 12891).

d. New Communities Program, Section 413 of the Housing and Urban Development Act of 1968, Public Law 90–448, 82 Stat. 476 (repealed 1983), Section 726 of the Housing and Urban Development Act of 1970, Public Law 91–609 (repealed 1983), 84 Stat. 1784, Section 474 of the Housing and Urban-Rural Recovery Act of 1983, Public Law 98–181, 97 Stat. 1237 (codified at 12 U.S.C. 1701g–5b), and any other functions, powers and duties which may affect the liquidation of the New Communities program.

e. Rural Housing and Economic Development grants specifically designated originally in the Fiscal Year 1998 HUD Appropriations Act, Public Law 105–65, 111 Stat. 1344 (1997), and subsequent annual HUD appropriations acts.

f. Renewal Communities (RC), as authorized under Title 26, Subtitle A, Chapter 1, Subchapter X of the Internal Revenue Code (codified as amended at 26 U.S.C. 1400E *et seq.*); 24 CFR part 599.

g. All programs consolidated in the Revolving Fund (Liquidating Programs) established pursuant to Title II of the Independent Offices Appropriations Act, Public Law 98–45, 97 Stat. 223 (1983) (codified as amended at 12 U.S.C. 1701g–5)) including all authority of the Assistant Secretary with respect to the functions, administration and management of the Revolving Fund (Liquidating Programs). Only the Assistant Secretary is the responsible official for allotments in the Revolving Fund (Liquidating Programs).

h. Youthbuild Program, Title IV, Subtitle D of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (repealed 2006); 24 CFR part 585; and Youthbuild TA as authorized under Title IV of the Cranston-Gonzalez National Affordable Housing Act, as amended by the Housing and Community Development Act of 1992, Public Law 102–550, 106 Stat. 3723 (1992) (repealed 2006).

Section B. Limited Denial of Participation

Subject to the excepted authority in Section C, the Assistant Secretary redelegates to Directors and Deputy Directors of CPD in HUD Field Offices the authority to order a limited denial of participation sanction pursuant to HUD regulations at 2 CFR part 2424, with respect to the programs and matters listed in Section A; provided that the General Counsel, or such other official as may be designated by the General Counsel, must: (1) Concur in any proposed sanction under 2 CFR part 2424 before it is issued, and (2) concur in any proposed settlement of a sanction under 2 CFR part 2424.

Section C. General Authority Excepted

The authority redelegated under Section A does not include:

1. The authority to issue or waive regulations covered by section 7(q) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(q));

2. The authority to sue and be sued;

3. The authority to effect remedies for noncompliance requiring notice and an opportunity for an administrative hearing;

4. The authority for allotments in the Revolving Fund (Liquidating Programs) under paragraph g of Section A; or

5. Any authority not delegated to the Assistant Secretary for CPD under the Consolidated Delegation of Authority for Community Planning and Development.

The Assistant Secretary may revoke at any time this redelegation with respect to the programs and matters listed in Section A and orders of limited denial of participation issued in accordance with Section B.

Section D. Authority To Further Redelegate

The authority redelegated in Sections A and B may not be further redelegated.

Section E. Redelegations Superseded

This notice supersedes all prior redelegations of authority from the Assistant Secretary of CPD to Directors and Deputy Directors of Community Planning and Development in HUD Field Offices, including the redelegation of authority published on October 18, 2011 at 76 FR 64364.

Section F. Actions Ratified

The Assistant Secretary hereby ratifies all actions previously taken by the Directors and Deputy Directors of CPD in HUD Field Offices with respect to the programs and matters listed in Section A and orders of limited denial of participation issued in accordance with Section B.

Authority: Section 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: June 20, 2012.

Mark Johnston,

Acting Assistant Secretary for Community Planning and Development.

[FR Doc. 2012–16043 Filed 6–28–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5642–D–03]

Redelegation of Authority to the Deputy Assistant Secretaries in the Office of Community Planning and Development

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of redelegation of authority to Deputy Assistant Secretaries in Community Planning and Development.

SUMMARY: On May 30, 2012, a new Consolidated Delegation of Authority was published in the **Federal Register,** at 77 FR 31972, giving concurrent authority for Community Planning and Development (CPD) programs from the Secretary of HUD to the Assistant Secretary for Community Planning and Development, the General Deputy Assistant Secretary for Community Planning and Development and the Deputy Assistant Secretary for Special Needs Programs. In this notice, the Assistant Secretary of Community Planning and Development redelegates to the Deputy Assistant Secretaries and other specified HUD officials all powers and authorities necessary to carry out Office of Community Planning and Development programs, except those powers and authorities specifically excluded.

DATES: *Effective Date:* June 20, 2012.

FOR FURTHER INFORMATION CONTACT: David H. Enzel, Director of Technical Assistance and Management, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7228, Washington, DC 20410–7000; telephone number 202 402–5557. This is not a toll-free number. For those needing assistance, this number may be accessed via TTY by calling the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: Published in the **Federal Register** on May 30, 2012, at 77 FR 31972, is a revised consolidated delegation of authority from the Secretary to the Assistant Secretary for Community Planning and Development, the General Deputy Assistant Secretary for Community Planning and Development and the Deputy Assistant Secretary for Special Needs Programs. This notice updates and revises redelegations of authority to Deputy Assistant Secretaries and other specified HUD officials within the Office of Community Planning and Development. This notice supersedes all previous redelegations of authority to CPD Deputy Assistant Secretaries and other specified HUD officials in CPD, including a redelegation published on October 18, 2011 at 76 FR 64369. Also published elsewhere in today's **Federal Register** is a redelegation of authority from the Assistant Secretary for Community Planning and Development to Directors and Deputy Directors of CPD in HUD Field Offices.

Section A. General Redelegation of Authority

1. Deputy Assistant Secretary for Grant Programs

Except those authorities specifically excluded, the Assistant Secretary redelegates to the Deputy Assistant Secretary for Grant Programs all powers and authorities of the Assistant Secretary necessary to carry out the following Community Planning and Development programs and matters:

a. Comprehensive Housing Affordability Strategies (CHAS), Title I of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12701 *et seq.*); consolidated plans, 24 CFR part 91.

b. The HOME Investment Partnerships Act, Title II of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12721 *et seq.*); 24 CFR part 92.

c. Housing Trust Fund (HTF), Section 1338 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, added by Section 1131 of Public Law 110–289, 122 Stat. 2654 (codified at 12 U.S.C. 4568).

d. Tax Credit Assistance Program (TCAP) as authorized under the HOME Investments Partnership Program heading of Division A, Title XII of American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115, 220–21.

e. Self-Help Housing Opportunity Program (SHOP) under section 11 of the Housing Opportunity Program Extension Act of 1996, Public Law 104–120, 110 Stat. 834 (codified as amended at 42 U.S.C. 12805 note).

f. Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5301 *et seq.*); 24 CFR part 570 including:

(1) Community Development Block Grant (CDBG) program;

(2) Section 108 loan guarantee program;

(3) Economic development grants pursuant to Section 108(q);

(4) Neighborhood Stabilization Programs Under Housing and Economic Recovery Act of 2008, Public Law 110–289, 122 Stat. 2850; Title XII of Division A of the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115; and Section 1497 of the Wall Street Reform and Consumer Protection Act of 2010, Public Law 111–203, 124 Stat. 1376 (codified as amended at 42 U.S.C. 5301 note);

(5) CDBG Disaster Recovery Grants as provided for in annual and supplemental HUD appropriations acts; and

(6) Appalachian Regional Commission grants pursuant to section 214 of the Appalachian Regional Development Act of 1965, Public Law 89–4, 79 Stat. 5 (codified as amended at 40 U.S.C. 14507) and consistent with the CDBG program authorized under Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5301 *et seq.*).

g. Overall Departmental responsibility for compliance with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Public Law 91–646, 84 Stat. 1894 (1971) (codified as amended at 42 U.S.C. 4601 *et seq.*); 49 CFR part 24 (except for the authority to exercise the Federal Agency waiver authority provided under 49 CFR 24.7).

h. Environment, overall Departmental responsibility for compliance with the National Environmental Policy Act of 1969, Public Law 91–190, 83 Stat. 852 (1970) (codified as amended at 42 U.S.C. 4321–4347), and the related laws and authorities cited in 24 CFR 50.4.

i. Slum Clearance and Urban Renewal Program Under Title I of the Housing Act of 1949, Public Law 81–171, 63 Stat. 413 and any program that is superseded or inactive by, or inactive by reason of, Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5316).

j. Rental Rehabilitation Program, United States Housing Act of 1937 § 17, Public Law 98–181, 97 Stat. 1196 (repealed 1990); 24 CFR part 511.

k. Section 312 Rehabilitation Loan Program, Housing Act of 1964 § 312, Public Law 88–560, 78 Stat. 769; 24 CFR part 510.

l. HUD's Homeownership Zone Initiative (HOZ) grants as provided for in section 205 of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1997, Public Law 104–204, 110 Stat. 2874 (1996) and funded with recaptured Nehemiah grants authorized under Title VI of the Housing and Community Development Act of 1987, Pub. L. 100–242, 101 Stat. 1815 (1988) (codified at 12 U.S.C. 17151 note).

m. HOPE for Homeownership of Single-family Housing Program (HOPE 3), Title IV, Subtitle C of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified at 42 U.S.C. 12891).

n. New Communities Program, Section 413 of the Housing and Urban Development Act of 1968, Public Law 90–448, 82 Stat. 476 (repealed 1983), Section 726 of the Housing and Urban Development Act of 1970, Public Law 91–609 (repealed 1983), 84 Stat. 1784, Section 474 of the Housing and Urban-Rural Recovery Act of 1983, Public Law 98–181, 97 Stat. 1237 (codified at 12 U.S.C. 1701g–5b), and any other functions, powers and duties which may affect the liquidation of the New Communities program.

o. Technical assistance and capacity building awards authorized under any program or matter listed in Section A.1 and as provided for in annual and supplemental HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3093 (2009)).

Further, in the absence of the Deputy Assistant Secretary for Grant Programs, the Assistant Secretary redelegates to the Director of the Office of Block Grant Assistance all powers and authorities of the Assistant Secretary necessary to carry out programs and matters listed in paragraphs f and i of Section A.1.

Further, in the absence of the Deputy Assistant Secretary for Grant Programs, the Assistant Secretary redelegates to the Director of the Office of Affordable Housing Programs all powers and authorities of the Assistant Secretary necessary to carry out programs and matters listed in paragraphs b, c, d, e, g, and l of Section A.1.

2. Deputy Assistant Secretary for Special Needs

Except those authorities specifically excluded, the Assistant Secretary redelegates to the Deputy Assistant Secretary for Special Needs all powers and authorities of the Assistant Secretary necessary to carry out the following Community Planning and Development programs and matters:

a. Title IV of the McKinney-Vento Homeless Assistance Act, Public Law 100–77, 101 Stat. 482 (1987) (codified as amended at 42 U.S.C. 11301 *et seq.*), renamed by Act of Oct. 30, 2000, Public Law 106–400, 114 Stat. 1675 (2000), including the following: Emergency Shelter Grants/Emergency Solutions Grants Program, 24 CFR part 576; Supportive Housing program, 24 CFR part 583; Shelter Plus Care program, 24 CFR part 582; Moderate Rehabilitation for Single Room Occupancy program, 24 CFR part 882, Subpart H; Continuum of Care program; Rural Housing Stability Assistance program.

b. Base Closure, Base Closure Community Redevelopment and Homeless Assistance Act of 1994, Public

Law 103–421, 108 Stat. 4352 (codified as amended at 10 U.S.C. 2687 note); 24 CFR part 586.

c. Homelessness Prevention and Rapid Re-Housing Program (HPRP), as authorized under the Homelessness Prevention Fund heading of Division A, Title XII of the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115.

d. Title V of the McKinney-Vento Homeless Assistance Act, Public Law 100–77, 101 Stat. 482 (1987) (codified as amended 42 U.S.C. 11411 *et seq.*), renamed by Act of Oct. 30, 2000, Public Law 106–400, 114 Stat. 1675 (2000), 24 CFR part 581.

e. Veterans Homelessness Prevention Demonstration Program, as provided for in annual HUD appropriations act(s) (e.g., Omnibus Appropriations Act, 2009, Public Law 111–8, 123 Stat. 524 (2009)).

f. AIDS Housing Opportunity Act, Title VIII, Subtitle D of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12901–12912); 24 CFR part 574.

Further, in the absence of the Deputy Assistant Secretary for Special Needs, the Assistant Secretary redelegates to the Director of the Office of Special Needs Programs all powers and authorities of the Assistant Secretary necessary to carry out programs and matters listed in paragraphs a, b, c, d, and e of Section A.2. Further, the Assistant Secretary redelegates to the Director of the Community Assistance Division the authority to sign notices of available properties and subsequent letters regarding the properties under Title V of the McKinney-Vento Homeless Assistance Act (codified as amended 42 U.S.C. 11411 *et seq.*).

Further, in the absence of the Deputy Assistant Secretary for Special Needs, the Assistant Secretary redelegates to the Director of the Office of HIV/AIDS Housing all powers and authorities of the Assistant Secretary necessary to carry out programs and matters listed in paragraph f of Section A.2.

3. Deputy Assistant Secretary for Economic Development

Except those authorities specifically excluded, the Assistant Secretary redelegates to the Deputy Assistant Secretary for Economic Development all powers and authorities of the Assistant Secretary necessary to carry out the following Community Planning and Development programs and matters:

a. Economic Development Initiative grants, as provided for in annual HUD appropriations acts (e.g., Consolidated Appropriations Resolution, Fiscal Year 2003, Pub. L. 108–7, 117 Stat. 11 (2003)).

b. Grants for urban Empowerment Zones (EZ) as provided for in annual HUD appropriations acts (e.g., Consolidated Appropriations Resolution, Fiscal Year 2003, Pub. L. 108–7, 117 Stat. 11 (2003)).

c. The Loan Guarantee Recovery Program under Section 4 of the Church Arson Prevention Act of 1996, Public Law 104–155, 110 Stat. 1392 (codified at 18 U.S.C. 241 note); 24 CFR part 573.

d. Neighborhood Initiatives grants specifically designated in annual HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3034 (2009)).

e. Rural Innovation Fund grants as provided for in annual HUD appropriations act(s) (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3084 (2009)).

f. Rural Housing and Economic Development grants specifically designated originally in the Fiscal Year 1998 HUD Appropriations Act, Public Law 105–65, 111 Stat. 1344 1997, and subsequent annual HUD appropriations acts.

g. The Renewal Communities (RC) Initiative as authorized under title 26, subtitle A, chapter 1, subchapter X of the Internal Revenue Code, as amended, 26 U.S.C. 1400E *et seq.;* 24 CFR part 599.

h. Urban Development Action Grants under Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5318).

i. The urban Empowerment Zones (EZ), as authorized under title 26, subtitle A, chapter 1, subchapter U of the Internal Revenue Code (codified as amended at 26 U.S.C. 1391 *et seq.*); 24 CFR parts 597 and 598.

j. Youthbuild Program, Title IV, Subtitle D of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified at 42 U.S.C. 12899 *et seq.*) (repealed 2006); 24 CFR part 585.

Further, in the absence of the Deputy Assistant Secretary for Economic Development, the Assistant Secretary redelegates to the Director of the Congressional Grants Division all powers and authorities of the Assistant Secretary necessary to carry out programs and matters listed in Section A.3.

4. Deputy Assistant Secretary for Operations

Except those authorities specifically excluded, the Assistant Secretary redelegates to the Deputy Assistant Secretary for Operations and the Director of Technical Assistance and Management all powers and authorities of the Assistant Secretary necessary to carry out the following Community Planning and Development programs and matters:

a. Technical Assistance and Capacity Building awards authorized under any program or matter delegated to the Assistant Secretary for Community Planning and Development (e.g., section 107 of the Housing and Community Development Act of 1987, as amended and Section 4 Capacity Building for Community Development and Affordable Housing Grants program as authorized by Section 4 of the HUD Demonstration Act of 1993 (Pub. L. 103–120, 107 Stat. 1148, 42 U.S.C. 9816 note), as amended, and as provided for in annual and supplemental HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3093 (2009)).

b. All programs consolidated in the Revolving Fund (Liquidating Programs) established pursuant to Title II of the Independent Offices Appropriations Act, Public Law 98–45, 97 Stat. 223 (1983) (codified at 12 U.S.C. 1701g–5), including all authority of the Assistant Secretary with respect to functions, administration and management of the Revolving Fund (Liquidating Programs). Only the Assistant Secretary is the responsible official for allotments in the Revolving Fund (Liquidating Programs).

Section B. General Authority Excepted

The authority redelegated under Section A does not include:

1. The authority to issue or waive regulations covered by section 7(q) of the Department of Housing and Urban Development Act;

2. The authority to exercise the Federal Agency waiver authority provided under 49 CFR 24.7;

3. The authority to enter regulations or directives into Departmental clearance; or

4. Any authority not delegated to the Assistant Secretary for Community Planning and Development under the Consolidated Delegation of Authority for Community Planning and Development.

The Assistant Secretary may revoke at any time this redelegation with respect to the programs and matters listed in Section A.

Section C. Authority to Further Redelegate

The authority redelegated in Section A may be further redelegated to employees of the Department.

Section D. Redelegations Superseded

This notice supersedes all prior redelegations of authority from the Assistant Secretary of Community Planning and Development to Deputy Assistant Secretaries and other specified HUD officials, including the redelegation of authority published on October 18, 2011 at 76 FR 64369.

Section E. Actions Ratified

The Assistant Secretary hereby ratifies all actions previously taken by the Deputy Assistant Secretaries of Community Planning Development and other specified HUD officials, with respect to the programs and matters listed in Section A.

Authority: Section 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: June 20, 2012.

Mark Johnston,

Acting Assistant Secretary for Community Planning and Development.

[FR Doc. 2012–16042 Filed 6–28–12; 8:45 am]

BILLING CODE 4210–67–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0110]

An Approach for Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guides; extension of comment period.

SUMMARY: On May 17, 2012 (77 FR 29391), the U.S. Nuclear Regulatory Commission (NRC or the Commission) issued for public comment four (4) draft regulatory guides (DGs), DG–1285, ''An Approach for Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,'' (proposed Revision 3 of Regulatory Guide [RG] 1.174); DG–1286, ''An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing,'' (proposed Revision 1 of RG 1.175); DG 1287, ''An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications'' (proposed Revision 2 of RG 1.177); and DG–1288, ''An Approach for Plant-Specific Risk-Informed Decisionmaking for Inservice Inspection of Piping'' (proposed Revision 2 of RG 1.178) in the **Federal Register** for a 30 day public comment period. The NRC is extending the public comment period for these DGs from June 29, 2012 to August 13, 2012. These guides describe methods the NRC staff considers acceptable for plant-specific, risk-informed decisionmaking on specific licensee activities.

DATES: Submit comments by August 13, 2012. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and are publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2012–0110. You may submit comments by any of the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0110. 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 directions on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Carol Moyer, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–251–7641 or email: *Carol.Moyer@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2012–0110 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, by any of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0110.
- *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 DGs and their corresponding regulatory analysis are available electronically under the following ADAMS Accession Numbers: DG–1285 (ML12012A006 and ML12013A089), DG–1286 (ML12017A053 and ML12017A052), DG–1287 (ML12017A054 and ML12017A059), and DG1288 (ML12017A076 and ML12017A077).
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

B. Submitting Comments

Please include Docket ID NRC–2012–0110 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* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publically 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. Further Information

The NRC is issuing for public comment 4 draft regulatory guides in the NRC's ''Regulatory Guide'' series. This series was developed to describe

and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

These 4 draft regulatory guides are temporarily identified by their task numbers, DG–1285, DG–1286, DG–1287, and DG–1288. The focus of the revisions to these RGs addresses the Commission's Staff Requirements Memorandum (SRM) (SECY–11–0014, issued 3–15–2011), titled ''Use of Containment Accident Pressure in Analyzing Emergency Core Cooling System and Containment Heat Removal System Pump Performance in Postulated Accidents'' directing the staff to revise the discussion on defense-in-depth. Specifically, the SRM stated,

> Because the statements in Regulatory Guide 1.174 are subject to different interpretations, the staff should revise this guide using precise language to assure that the defense-in-depth philosophy is interpreted and implemented consistently. To the extent that other regulatory guidance refers to defense in depth, the relevant documents should be updated also, as appropriate.

In reviewing these RGs, it was observed that clarification could be added in several other places; for example:

- The use of the terms ''PRA technical acceptability,'' ''PRA technical adequacy,'' and ''PRA quality'' were not clear.
- References in the RGs, in places, have been either updated or are no longer in use.

Although the focus of this proposed revision is to revise the discussion on defense-in-depth, the NRC staff believes that the identified clarifications should be addressed. In DG–1285 (proposed Rev. 3 of RG 1.174) the terms on PRA technical acceptability, PRA technical adequacy, and PRA quality are revised to be consistent with RG 1.200, ''An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities'' and the references were updated. It is the intent of the staff, following the public review and comment period, to review all four RGs and identify administrative changes that will improve the consistency, quality, and usability of each guide. Stakeholders and the public are requested to provide any input regarding areas in these DGs where clarification and improvements may be needed.

DG–1285, is proposed revision 3 of Regulatory Guide 1.174 dated May 2011, it provides guidance on an approach the NRC finds acceptable for analyzing issues associated with proposed changes to a plant's licensing basis and for assessing the impact of these changes on the risk associated with plant design and operation. One key element to this type of decisionmaking is an engineering analysis of the proposed change. As part of the engineering analysis, licensees evaluate the impact of the change on maintaining adequate defense-in-depth. This proposed revision incorporates additional language and specific examples of how maintaining defense-in-depth is achieved when licensees use risk-informed analysis of proposed changes to the plant's licensing basis.

DG–1286, is proposed revision 1 of Regulatory Guide 1.175 dated August 1998, it provides an approach to using risk-informed decisionmaking in developing inservice testing programs for nuclear power plants. This revision updates the defense-in-depth evaluation to be consistent with the proposed changes to Regulatory Position 2.1.1 in draft Regulatory Guide DG–1285, (above) which provides guidance on evaluating proposed changes to a plant's licensing basis, including changes to the inservice testing program.

DG–1287, is proposed revision 2 of Regulatory Guide 1.177 dated May 2011, it describes a method acceptable to the NRC for using probabilistic risk analysis to evaluate proposed changes to a plant's technical specifications. As in evaluating changes to a plant's licensing basis, a key element in evaluating changes to technical specifications is an engineering analysis of the proposed change. As part of the engineering analysis, licensees evaluate the impact of the change on maintaining adequate defense-in-depth. This revision updates the defense-in-depth evaluation to be consistent with the proposed changes to Regulatory Position 2.1.1 in draft Regulatory Guide DG–1285, (above) which provides guidance on evaluating proposed changes to the plant's technical specifications.

DG–1288, is proposed revision 2 of Regulatory Guide 1.178 dated September 2003, it provides an approach to using risk-informed decisionmaking in developing inservice inspection programs for piping in nuclear power plants. This revision updates the defense-in-depth evaluation to be consistent with the proposed changes to Regulatory Position 2.1.1 in draft Regulatory Guide DG–1285, which provides guidance on evaluating proposed changes to a plant's licensing basis, including changes to the inservice inspection program for piping systems.

On May 17, 2012 (77 FR 29391), the U.S. Nuclear Regulatory Commission (NRC or the Commission) issued for public comment four (4) DGs (DG–1285, DG–1286, DG–1287 and DG–1288). By letter dated June 4, 2012, the Nuclear Energy Institute (ADAMS Accession No. ML12174A174) requested an extension of the stated comment period for the purpose of providing sufficient review of the changes involving defense-in-depth evaluations. It is the desire of the NRC to receive comments of high quality from all stakeholders. Several factors have been considered in granting an extension. The requested comment period extension is reasonable and does not affect NRC deadlines. The additional time will allow for stakeholders to discuss the proposed guide during related meetings. Therefore, the comment submittal period is extended from the original date of June 29, 2012 to August 13, 2012.

Dated at Rockville, Maryland, this 22nd day of June, 2012.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2012–15962 Filed 6–28–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0152]

Design, Inspection, and Testing Criteria for Air Filtration and Adsorption Units of Normal Atmosphere Cleanup Systems in Light-Water-Cooled Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is issuing for public comment draft regulatory guide (DG), DG–1280, ''Design, Inspection, and Testing Criteria for Air Filtration and Adsorption Units of Normal Atmosphere Cleanup Systems in Light-Water-Cooled Nuclear Power Plants.'' This guide describes a method for design, inspection, and testing of normal atmosphere cleanup systems for controlling releases of airborne radioactive materials to the environment during normal operations, including

anticipated operational occurrences. This guide applies to all types of nuclear power plants that use water as the primary means of cooling.

DATES: Submit comments by August 27, 2012. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and are publically available, by searching on *http://www.regulations.gov* under Docket ID NRC–2012–0152. You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0152. 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.

FOR FURTHER INFORMATION CONTACT: Mekonen Bayssie, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–251–7489 or email: *Mekonen.Bayssie@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2012–0152 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 the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0152.
- *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 draft regulatory guide is available electronically under ADAMS Accession Number ML11273A057. The regulatory analysis may be found in ADAMS under Accession No. ML11273A060.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

- *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–2012–0152 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 in comment submissions that you do not want to be publicly disclosed. The NRC posts all comment submissions at *http://www.regulations.gov* as well as enters the comment submissions into ADAMS. The NRC does not 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 in their comment submissions that they do not want to be publicly disclosed. Your request should state that the NRC will not edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Further Information

The NRC is issuing for public comment a draft guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

The draft regulatory guide, entitled, ''Design, Inspection, and Testing Criteria for Air Filtration and Adsorption Units of Normal Atmosphere Cleanup Systems in Light-Water-Cooled Nuclear Power Plants,'' is temporarily identified by its task number, DG–1280. The DG–1280 is proposed revision 3 of Regulatory Guide 1.140, dated June 2001. Since the last revision of RG 1.140, The American Society of Mechanical Engineers (ASME) Committee on Nuclear Air and Gas Treatment (CONAGT) has revised and expanded the scope of equipment covered by ASME–AG–1, ''Code on Nuclear Air and Gas Treatment,'' which the staff previously endorsed RG 1.140. The revision to ASME–AG–1b consolidated some requirements from ASME–N509, ''Nuclear Power Plant Air Cleaning Units and Components''; ASME–N510, ''Testing of Nuclear Air-Treatment Systems''; and other documents previously endorsed by the staff in RG 1.140. In addition, CONAGT has developed and published a new standard, ASME N511–2007, ''Inservice Testing of Nuclear Air Treatment, Heating Ventilation and Air Conditioning Systems.'' This new standard provides comprehensive test and inspection requirements and is written to complement the expanded ASME–AG–1b. This revision of the regulatory guide reflects the referenced industry standards.

III. Backfitting and Issue Finality

Because this regulatory guide reflects current regulatory practice, it does not require a backfit analysis as described in 10 CFR 50.109(c).

Dated at Rockville, Maryland, this 21st day of June, 2012.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2012–15960 Filed 6–28–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0153]

Governors' Designees Receiving Advance Notification of Transportation of Certain Shipments of Nuclear Waste and Spent Fuel

On January 6, 1982 (47 FR 596 and 47 FR 600), the U.S. Nuclear Regulatory Commission (NRC) published in the **Federal Register** final amendments to Title 10 of the Code of Federal Regulations (10 CFR) parts 71 and 73 (effective July 6, 1982), that require advance notification to Governors or their designees by NRC licensees prior to transportation of certain shipments of nuclear waste and spent fuel. The advance notification covered in Part 73 is for spent nuclear reactor fuel shipments and the notification for Part 71 is for large quantity shipments of radioactive waste (and of spent nuclear reactor fuel not covered under the final amendment to 10 CFR part 73).

The following list updates the names, addresses, and telephone numbers of those individuals in each State who are responsible for receiving information on these shipments. The list is published annually in the **Federal Register** to reflect any changes in information. Current State contact information can also be accessed throughout the year at *http://nrc-stp.ornl.gov/special/designee.pdf.*

Questions regarding this matter should be directed to Stephen N. Salomon, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, by email at *Stephen.Salomon@nrc.gov* or by telephone at 301–415–2368.

Dated at Rockville, Maryland, this 22nd day of June 2012.

For the U.S. Nuclear Regulatory Commission.

Josephine M. Piccone,

Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs.

INDIVIDUALS TO RECEIVE ADVANCE NOTIFICATION OF NUCLEAR WASTE SHIPMENTS

State	Part 71	Part 73
ALABAMA	Colonel Hugh McCall, Director, Alabama Department of Public Safety, P.O. Box 1511, Montgomery, AL 36102–1511, (334) 242–4394, 24 hours: (334) 242–4128, Fax: (334) 242–0512.	SAME.
ALASKA	Marlena Brewer, Department of Environmental Conservation, State of Alaska, 555 Cordova Street, Anchorage, AK 99501, (907) 269–1099, 24 hours: (907) 457–1421, Fax: (907) 269–7600.	SAME.
ARIZONA	Aubrey V. Godwin, Director, Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, AZ 85040, (602) 255–4845, ext. 222, Cell: (408) 861–9609, 24 hours: (602) 223–2212, Fax: (602) 437–0705.	SAME.
ARKANSAS	Bernard Bevill, Radiation Control Section, Arkansas Department of Health, 4815 West Markham Street, Mail Slot # 30, Little Rock, AR 72205–3867, (501) 661–2301, 24 hours: (501) 661–2136, Fax: (501) 661–2236.	SAME.
CALIFORNIA	Captain Steve Dowling, California Highway Patrol, Commercial Vehicle Section, 601 North 7th Street, Sacramento, CA 95811, (916) 843–3400, 24 hours: (916) 843–4199, Fax: (916) 322–3154.	SAME.
COLORADO	Captain Matthew Packard, Colorado State Patrol, Hazardous Materials Unit, Troop 8–C, 15065 South Golden Road, Golden CO 80401, (303) 273–1910, Cell: (303) 524–5618, 24 hours: (303) 329–4501, Fax: (303) 273–1911.	SAME.
CONNECTICUT	Edward L. Wilds, Jr., Ph.D., Director, Radiation Division, Department of Energy and Environmental Protection, 79 Elm Street, Hartford, CT 06106–5127, (860) 424–3029, Cell: (860) 490–3211, 24 hours: (860) 424–3333, Fax: (860) 424–4065.	SAME.
DELAWARE	Lewis D. Schiliro, Secretary, Department of Safety & Homeland Security, P.O. Box 818, Dover, DE 19903–0818, (302) 744–2665, 24 hours: (302) 698–7744, Fax: (302) 739–4874.	SAME.
FLORIDA	John A. Williamson, Environmental Administrator, Bureau of Radiation Control, Environmental Radiation Program, Department of Health, P.O. Box 680069, Orlando, FL 32868–0069, (407) 297–2096 x212, Cell: (850) 528–4151, 24 hours: (407) 297–2095, Fax: (407) 297–2085.	SAME.

INDIVIDUALS TO RECEIVE ADVANCE NOTIFICATION OF NUCLEAR WASTE SHIPMENTS—Continued

State	Part 71	Part 73
GEORGIA	Captain Bruce Bugg, Region 3 Commander, Georgia Department of Public Safety, Motor Carrier Compliance Division, 320 Chester Avenue, Atlanta, GA 30316, (404) 463–3899, 24 hours: (404) 463–3800, Fax: (770) 357–8867. Alternate: Sergeant First Class Brent Moore, 24 hour: (404) 357–8880, Fax: (404) 624–7295.	SAME.
HAWAII	Gary Gil, Deputy Director for Environmental Health, State of Hawaii, Department of Health, 1250 Punchbowl Street, Honolulu, HI 96813, (808) 586–4424, 24 hours: (808) 366–8950, Fax: (808) 586–4368.	SAME.
	Lynn Nakosone, Division Administrator, Environmental Health Services Division, State of Hawaii, Department of Health, 591 Ala Moana Boulevard, #125, Honolulu, HI 96813, (808) 586–4576, 24 hours: (808) 348–6418, Fax: (808) 586–1522.	SAME.
IDAHO	Captain William L. (Bill) Reese, Idaho State Police, Commercial Vehicle Safety, 700 South Stratford Drive, Meridian, ID 83642, (208) 884–7220, 24 hours: (208) 846–7550, Fax: (208) 884–7192.	SAME.
ILLINOIS	Joseph G. Klinger, Assistant Director, Illinois Emergency Management Agency, Division of Nuclear Safety, 2200 S. Dirksen Parkway, Springfield, IL 62703, (217) 785–9868, Mobile: (217) 720–4634, 24 hours: (217) 782–7860, Fax: (217) 558–7398.	SAME.
INDIANA	Major Jeffrey L. Walker, Commander, Commercial Vehicle Enforcement Division, Indiana State Police, 5252 Decatur Boulevard, Indianapolis, IN 46241, (317) 615–7431, Mobile: (317) 432–4929, 24 hours: (317) 232–8248, Fax: (317) 821–2350 or 821–2353.	SAME.
IOWA	Mark Shouten, Administrator, Iowa Homeland Security and Emergency Management Division, 7105 NW 70th Avenue, Camp Dodge, Building W–4, Johnston, IA 50131–1824, (515) 725–3231, Mobile: (515) 473–8944, 24 hours: (515) 725–3231, Fax: (515) 725–3260.	SAME.
KANSAS	Jennifer Clark, Technological Hazards Section Chief, Department of the Adjutant General, Division of Emergency Management, 2800 SW Topeka Boulevard, Topeka, KS 66611–1287, (785) 274–1394, Mobile: (785) 207–1540, 24 hours: (785) 296–3176, Fax: (785) 274–1426.	SAME.
KENTUCKY	Matthew W. McKinley, Administrator, Radiation Control Program, Cabinet for Health and Family Services, 275 East Main Street, Mail Stop HS–1C–A, Frankfort, KY 40621, (502) 564–3700, ext 3701, 24 hours: (502) 229–6254, Fax: (502) 564–1492.	SAME.
LOUISIANA	Captain Allen T. Moss, Louisiana State Police, 7919 Independence Boulevard, P.O. Box 66168, #A–26, Baton Rouge, LA 70896–6614, (225) 925–6113, ext. 241, Cell: (225) 485–9240, 24 hours: (877) 925–6595, Fax: (225) 925–3559.	SAME.
MAINE	Lieutenant Shawn Currie, State Police, Maine Dept. of Public Safety, 36 Hospital St., 20SHS, Augusta, ME 04333–0020, (207) 624–8932 or (207) 624–8939, Mobile: (207) 441–6212, 24 hours: (207) 624–7076, Fax: (207) 287–5247.	SAME.

INDIVIDUALS TO RECEIVE ADVANCE NOTIFICATION OF NUCLEAR WASTE SHIPMENTS—Continued

State	Part 71	Part 73
MARYLAND	Major A. J. McAndrew, Field Operations Bureau, Special Operations and Transportation Safety Command, Maryland State Police, 901 Elkridge Landing Road, Suite 300, Linthicum Heights, MD 21090, (410) 694–6100, Cell: (301) 573–3915, 24 hours: (410) 653–4200, Fax: (410) 694–6135.	SAME.
MASSACHUSETTS	Robert L. Gallaghar, Deputy Director, Radiation Control Program, Massachusetts Department of Public Health, Shraffts Center, Suite 1M2A, 529 Main Street, Charlestown, MA 02129, (617) 242–3035 x2001, 24 hours: (617) 242–3453, Fax: (617) 242–3457.	SAME.
MICHIGAN	Captain W. Thomas Sands, Michigan State Police, Emergency Management & Homeland, Security Division, 4000 Collins Rd., Lansing, MI 48910, (517) 333–5042, 24 hours: (517) 241–8000, Fax: (517) 333–4987.	SAME.
MINNESOTA	Kevin C. Leuer, Director, Preparedness Branch, Minnesota Division of Homeland Security & Emergency Management, 444 Cedar Street, Suite 223, St. Paul, MN 55101–6223, (651) 201–7406, 24 hours: 1–800–422–0798, Fax: (651) 296–0459.	SAME.
MISSISSIPPI	Brian E. Maske, HAZMAT/WIPP, Program Manager, Planner—Districts 2 & 4, LEPC Coordinator, Mississippi Emergency Management Agency, Office of Preparedness-Plans Bureau, P.O. Box 5644, #1 MEMA Drive 39208, Pearl, MS 39288, (601) 933–6369, 24 hours: (601) 933–6362, Fax: (601) 933–6815.	SAME.
MISSOURI	Paul D. Parmenter, Director, Emergency Management Agency, P.O. Box 116, 2302 Militia Drive, Jefferson City, MO 65102, (573) 526–9100, 24 hours: (573) 751–2748, Fax: (573) 634–7966.	SAME.
MONTANA	Ed Tinsley, Administrator, Homeland Security Advisor, Montana Disaster & Emergency Services, 1956 MT Majo Street, P.O. Box 4789, Fort Harrison, MT 59636–4789, (406) 841–3911, Mobile: (406) 461–1674, 24 hours: (406) 841–3911, Fax: (406) 841–3965.	SAME.
NEBRASKA	Sergeant Glenn Elwell, Nebraska State Patrol/NIAC, Nebraska Information Analysis Center, 3800 NW 12th Street, Lincoln, NE 68521, (402) 479–4076, Cell: (402) 540–0036, NIAC: (402) 479–4049, Fax: (402) 479–4950.	SAME.
NEVADA	Karen K. Beckley, Radiation Control, Program Manager, Nevada State Health Division, 727 Fairview Drive, Suite E, Carson City, NV 89701, (775) 687–7540, Cell: (775)-720–8530, 24 hours: 1 (877) 438–7231, Fax: (775) 687–7552.	SAME.
NEW HAMPSHIRE	Sergeant Christopher Scott, Department of Safety, Division of Motor Vehicles, Intelligence Unit/Information and Analysis Unit, 33 Hazen Drive, Concord, NH 03305, (603) 223–8757, Cell: (603) 717–5546, 24 hours: (603) 271–3636 × 0, Fax: (603) 271–1760.	SAME.
NEW JERSEY	Paul Baldauf, Director, Radiation Protection Programs, Division of Environmental Safety & Health, Department of Environmental Protection, P.O. Box 420 Mailcode: 401–03E, Trenton, NJ 08625–0420, (609) 633–7964, 24 hours: 1–800–927–6337, Fax: (609) 777–1330.	SAME.

INDIVIDUALS TO RECEIVE ADVANCE NOTIFICATION OF NUCLEAR WASTE SHIPMENTS—Continued

State	Part 71	Part 73
NEW MEXICO	Don Shainin, Technical Hazards Unit Leader, WIPP Program Manager, New Mexico Department of Homeland Security and Emergency Management (DHSEM), P.O. Box 27111, Santa Fe, NM 87502, (505) 476–9628, 24 hours: (505) 476–9635, Fax: (505) 476–9695.	SAME.
NEW YORK	Steven Kuhr, Director, New York State Office of Emergency Management, 1220 Washington Avenue, Building 22, Albany, NY 12226–2251, (518) 292–2301, 24 hours: (518) 292–2200, Fax: (518) 322–4978.	SAME.
NORTH CAROLINA	Sergeant Herbert Tucker, Jr., North Carolina State Highway Patrol, 1142 SE Maynard Rd., Cary, NC 27511, (919) 319–1523, Mobile: (919) 218–1271, 24 hours: (919) 319–1523, Fax: (919) 319–1534.	SAME.
NORTH DAKOTA	Terry L. O'Clair, Director, Division of Air Quality, North Dakota Department of Health, 918 East Divide Avenue—2nd Floor, Bismarck, ND 58501–1947, (701) 328–5188, 24 hours: (701) 328–9921, Fax: (701) 328–5185.	SAME.
OHIO	Michael Bear, Branch Chief, Radiological Branch, Ohio Emergency Management Agency, 2855 West Dublin Granville Road, Columbus, OH 43235–2206, (614) 799–3687, 24 hours: (614) 889–7150, Fax: (614) 799–5950.	SAME.
OKLAHOMA	Lt. Colonel Gregory Allen, Deputy Chief, Oklahoma Dept. of Public Safety, Oklahoma Highway Patrol, P.O. Box 11415, Oklahoma City, OK 73136–0145, (405) 425–7044, 24 hours: (405) 833–1428, Fax: (405) 425–2254.	SAME.
OREGON	Ken Niles, Administrator, Nuclear Safety and Energy Emergency, Preparedness Division, Oregon Department of Energy, 625 Marion Street, NE, Salem, OR 97301, (503) 378–4906; Cell: (503) 884–3905, 24 hours: (503) 884–3905, Fax: (503) 373–7806.	SAME.
PENNSYLVANIA	Timothy Baughman, Deputy Director for Operations, Pennsylvania Emergency Management Agency, 2605 Interstate Drive, Harrisburg, PA 17110, (717) 651–2001, 24 hours: (717) 651–2001, Fax: (717) 651–2021.	SAME.
RHODE ISLAND	Terrence Mercer, Associate Administrator, Motor Carriers Section, Division of Public Utilities and Carriers, 89 Jefferson Boulevard, Warwick, RI 02888, (401) 941–4500, Ext. 150, 24 hours: (401) 444–1183 (State Police).	SAME.
SOUTH CAROLINA	Susan Jenkins, Bureau of Land and Waste Management, Department of Health & Environmental Control, 2600 Bull Street, Columbia, SC 29201, (803) 896–4271, 24 hours: (803) 667–0019 or, (803) 408–2816, Fax: (803) 896–4242.	SAME.
SOUTH DAKOTA	Kristi Turman, Director, South Dakota Department of Public Safety, Office of Emergency Management, 118 W. Capitol Avenue, Pierre, SD 57501–2000, (605) 773–3231, 24 hours: (605) 773–3231, Fax: (605) 773–3580.	SAME.
TENNESSEE	Sean Kice, Radiological Protection Officer, Tennessee Emergency Management Agency, 3041 Sidco Drive, Nashville, TN 37204, (615) 253–3811, Mobile: (615) 428–8923, 24 hours: (615) 741–0001, Fax: (615) 741–8238.	SAME.

INDIVIDUALS TO RECEIVE ADVANCE NOTIFICATION OF NUCLEAR WASTE SHIPMENTS—Continued

State	Part 71	Part 73
TEXAS	Richard A. Ratliff, P.E. L.M.P., Radiation Safety Licensing Branch Mgr., Division for Regulatory Services, Texas Dept. of State Health Services, Mail Code 2835, P.O. Box 149347, Austin, TX 78714–9347, (512) 834–6679, 24 hours: (512) 458–7460, Fax: (512) 834–6716.	Steven C. McCraw, Director, Texas Dept of Public Safety, Office of Homeland Security, P.O. Box 4087, Austin, TX 78773, Mobile: (512) 563–3898, 24 hours: (512) 424–2208, Fax: (512) 424–5708
UTAH	Rusty Lundberg, Director, Division of Radiation Control, Department of Environmental Quality, 195 North 1950 West, P.O. Box 144850, Salt Lake City, UT 84114–4850, (801) 536–4257, 24 hours: (801) 536–4123, Mobile: (801) 867–1769, Fax: (801) 553–4097.	SAME.
VERMONT	Keith W. Flynn, Commissioner, Department of Public Safety, Division of Vermont State Police, 103 South Main Street, Waterbury, VT 05671–2101, (802) 244–8718, Cell: (802) 371–9147, 24 hours: (802) 244–8727, Fax: (802) 241–5610.	SAME.
VIRGINIA	Gregory F. Britt, Director, Technological Hazards Division, Virginia Department of Emergency Management, 10501 Trade Court, Richmond, VA 23236, (804) 897–9950, 24 hours: (804) 674–2400 or 1–800–468–8892, Fax: (804) 897–6576.	SAME.
WASHINGTON	Mr. Kevin Zeller, Commercial Vehicle Division, Washington State Patrol, P.O. Box 42600, Olympia, WA 98504–2600, (360) 596–3816; Cell: (360) 239–0467, 24 hours: (253) 536–6210, Fax: (360) 596–3828. Alternate: Captain Darrin Grondel, Commercial Vehicle Division, Washington State Patrol, P.O. Box 42600, Olympia, WA 98504–2600, (360) 596–3801.	SAME.
WEST VIRGINIA	Lieutenant Colonel J.C. Chambers, Deputy Superintendent, West Virginia State Police, 725 Jefferson Road, South Charleston, WV 25309, (304) 746–2100, 24 hours: (304) 746–2158, Fax: (304) 746–2111.	SAME.
WISCONSIN	Brian Satula, Administrator, Wisconsin Emergency Management, Department of Military Affairs, P.O. Box 7865, Madison, WI 53707–7865, (608) 242–3210, Cell: (608) 514–3461, 24 hour: 1–800–943–0003, Fax: (608) 242–3313.	SAME.
WYOMING	Captain Scot Montgomery, Support Services Officer, Commercial Carrier, Wyoming Highway Patrol, 5300 Bishop Boulevard, Cheyenne, WY 82009–3340, (307) 777–3915, Cell: (307) 630–3736, 24 hours: (307) 777–4321, Fax: (307) 777–4282.	SAME.
DISTRICT OF COLUMBIA	Frederick Goldsmith, Critical Infrastructure Mgr., Homeland Security & Emergency Management Agency, 2720 Martin Luther King, Jr. Avenue, SE, 2nd Floor, Room 247, Washington, DC 20032, (202) 481–3169, Mobile: (202) 375–9506.	SAME.
PUERTO RICO	Dr. Pedro Nieves, Chairman, Puerto Rico Quality Board, P.O. Box 11488, San Juan, PR 00917, (787) 767–8056 or (787) 767–8057, Mobile: (787) 447–9222, 24 hours: (787) 447–9222, Fax: (787) 767–4861.	SAME.
GUAM	Governor Eddie Baza Calvo, Officer of the Governor, Ricardo J. Bordullo Governor's Complex, Adelup, GU 96910, (671) 472–8931, Fax: (671) 477–4826.	SAME.

INDIVIDUALS TO RECEIVE ADVANCE NOTIFICATION OF NUCLEAR WASTE SHIPMENTS—Continued

State	Part 71	Part 73
VIRGIN ISLANDS	Alicia Barnes, Commissioner, Department of Planning and Natural Resources, 45 Estate Mars Hill, Frederiksted, St. Croix, U.S. Virgin Islands 00840, (340) 713–2401, (340) 774–3320, 24 hours: (340) 774–5138, Fax: (340) 773–1716, (340) 775–5706.	SAME.
AMERICAN SAMOA	Dr. Toafa Vaiagae, Director, American Samoa Environmental Protection Agency, P.O. Box PPA, Pago Pago, AS 96799, (684) 633–2304, 24 hours: (684) 633–2304, Fax: (684) 633–5801.	SAME.
COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS.	Marvin K. Seman, Special Assistant for Homeland Security, Commonwealth of Northern Mariana Islands, 1326 Guguan Street, Caller Box 10007, Saipan, MP 96950, (670) 664–2216, Mobile: (670) 287–7154, Fax: (670) 664–2218.	SAME.

[FR Doc. 2012–15963 Filed 6–28–12; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on June 21, 2012, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add First-Class Package Service Contract 8 to Competitive Product List.* Documents are available at www.prc.gov, Docket Nos. MC2012–27, CP2012–36.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2012–15924 Filed 6–28–12; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on June 21, 2012, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add First-Class Package Service Contract 9 to Competitive Product List.* Documents are available at www.prc.gov, Docket Nos. MC2012–28, CP2012–37.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2012–15928 Filed 6–28–12; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 17a–11, SEC File No. 270–94, OMB Control No. 3235–0085.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for approval of extension of the previously approved collection of information provided for in Rule 17a-11 (17 CFR 240.17a-11) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'').

In response to an operational crisis in the securities industry between 1967 and 1970, the Commission adopted Rule 17a–11 under the Exchange Act on July 11, 1971. Rule 17a–11 requires broker-dealers that are experiencing financial or operational difficulties to provide notice to the Commission, the broker-dealer's designated examining authority (''DEA''), and the Commodity Futures Trading Commission (''CFTC'') if the broker-dealer is registered with the CFTC as a futures commission merchant. Rule 17a–11 is an integral part of the Commission's financial responsibility program which enables the Commission, a broker-dealer's DEA, and the CFTC to increase surveillance of a broker-dealer experiencing difficulties and to obtain any additional information necessary to gauge the broker-dealer's financial or operational condition.

Rule 17a–11 also requires over-the-counter (''OTC'') derivatives dealers and broker-dealers that are permitted to compute net capital pursuant to Appendix E to Exchange Act Rule 15c3–1 to notify the Commission when their tentative net capital drops below certain levels. OTC derivatives dealers must also provide notice to the Commission of backtesting exceptions identified pursuant to Appendix F of Rule 15c3–1 (17 CFR 240.15c3–1f).

Compliance with the Rule is mandatory. The Commission will generally not publish or make available to any person notices or reports received pursuant to Rule 17a–11. The

Commission believes that information obtained under Rule 17a–11 relates to a condition report prepared for the use of the Commission, other federal governmental authorities, and securities industry self-regulatory organizations responsible for the regulation or supervision of financial institutions.

Only broker-dealers whose capital declines below certain specified levels or who are otherwise experiencing financial or operational problems have a reporting burden under Rule 17a–11. In 2011, the Commission received 465 notices under this Rule, including one notice from an OTC derivatives dealer permitted to compute net capital pursuant to Appendix E to Exchange Act Rule 15c3–1.

Each broker-dealer reporting pursuant to Rule 17a–11 will spend approximately one hour preparing and transmitting the notice required by the Rule. Accordingly, the total estimated annualized burden under Rule 17a–11 is 465 hours.

The Commission 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.

The public may view background documentation for this information collection at the following Web site, *www.reginfo.gov*. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an email to: *Shagufta_Ahmed@omb.eop.gov*; and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to *PRA_Mailbox@sec.gov*. Comments must be submitted within 30 days of this notice.

Dated: June 25, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–15942 Filed 6–28–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 17Ad–4(b) & (c), OMB Control No. 3235–0341, SEC File No. 270–264.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in the following rule: Rule 17Ad–4(b) & (c) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17Ad–4(b) & (c) (17 CFR 240.17Ad–4) is used to document when transfer agents are exempt, or no longer exempt, from the minimum performance standards and certain recordkeeping provisions of the Commission's transfer agent rules. Rule 17Ad–4(c) sets forth the conditions under which a registered transfer agent loses its exempt status. Once the conditions for exemption no longer exist, the transfer agent, to keep the appropriate regulatory authority (''ARA'') apprised of its current status, must prepare, and file if the ARA for the transfer agent is the Board of Governors of the Federal Reserve System (''BGFRS'') or the Federal Deposit Insurance Corporation (''FDIC''), a notice of loss of exempt status under paragraph (c). The transfer agent then cannot claim exempt status under Rule 17Ad–4(b) again until it remains subject to the minimum performance standards for non-exempt transfer agents for six consecutive months. The ARAs use the information contained in the notice to determine whether a registered transfer agent qualifies for the exemption, to determine when a registered transfer agent no longer qualifies for the exemption, and to determine the extent to which that transfer agent is subject to regulation.

The BGFRS receives approximately two notices of exempt status and two notices of loss of exempt status annually. The FDIC also receives approximately two notices of exempt status and two notices of loss of exempt status annually. The Commission and the Office of the Comptroller of the Currency (''OCC'') do not require transfer agents to file a notice of exempt status or loss of exempt status. Instead, transfer agents whose ARA is the Commission or OCC need only to prepare and maintain these notices. The Commission estimates that approximately ten notices of exempt status and ten notices of loss of exempt status are prepared annually by transfer agents whose ARA is the Commission. We estimate that the transfer agents for whom the OCC is their ARA prepare and maintain approximately five notices of exempt status and five notices of loss of exempt status annually. Thus, a total of approximately thirty-eight notices of exempt status and loss of exempt status are prepared and maintained by transfer agents annually. Of these thirty-eight notices, approximately eight are filed with an ARA. Any additional costs associated with filing such notices would be limited primarily to postage, which would be minimal. Since the Commission estimates that no more than one-half hour is required to prepare each notice, the total annual burden to transfer agents is approximately nineteen hours.

Written comments are invited on: (a) 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; (b) the accuracy of the Commission's estimates 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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

The Commission 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.

Please direct your written comments to: Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov*.

Dated: June 25, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–15943 Filed 6–28–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:
Rule 17a–6, OMB Control No. 3235–0489, SEC File No. 270–433.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 17a–6 (17 CFR 240.17a–6) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) permits national securities exchanges, national securities associations, registered clearing agencies, and the Municipal Securities Rulemaking Board (''MSRB'') (collectively, ''SROs'') to destroy or convert to microfilm or other recording media records maintained under Rule 17a–1, if they have filed a record destruction plan with the Commission and the Commission has declared such plan effective.

There are currently 26 SROs: 15 national securities exchanges, 1 national securities association, the MSRB, and 9 registered clearing agencies. Of the 26 SROs, 2 SRO respondents have filed a record destruction plan with the Commission. The staff calculates that the preparation and filing of a new record destruction plan should take 160 hours. Further, any existing SRO record destruction plans may require revision, over time, in response to, for example, changes in document retention technology, which the Commission estimates will take much less than the 160 hours estimated for a new plan. Thus, the total annual compliance burden is estimated to be 60 hours per year. The approximate cost per hour is $305, resulting in a total cost of compliance for these respondents of $18,300 per year (30 hours @ $305 per hour).

The Commission 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.

Background documentation for this information collection may be viewed at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an email to *Shagufta_Ahmed@omb.eop.gov* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or by sending an email to *PRA_Mailbox@sec.gov.* Comments must be submitted within 30 days of this notice.

Dated: June 25, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–15941 Filed 6–28–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67247; File No. SR–FINRA–2012–030]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Sections 4 and 6 of Schedule A to the FINRA By-Laws Regarding Fees Relating to the Central Registration Depository

June 25, 2012.

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 June 11, 2012, Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 FINRA. FINRA has designated the proposed rule change as ''establishing or changing a due, fee or other charge'' under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend Sections 4 and 6 of Schedule A to the FINRA By-Laws to implement changes to certain fees relating to the Central Registration Depository (''CRD®'' or ''CRD system'').

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA 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, FINRA 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. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

As described in further detail below, FINRA is proposing to amend Schedule A to the FINRA By-Laws (''Schedule A'') to implement changes to certain fees relating to the CRD system.[5]

Initial/Transfer Registration Fee

Under Section 4(b)(1) of Schedule A, FINRA charges an $85 fee for each initial or transfer Uniform Application for Securities Industry Registration or Transfer (''Form U4'') filed by a member in the CRD system to register an

[5] The CRD system is the central licensing and registration system for the U.S. securities industry. The CRD system enables individuals and firms seeking registration with multiple states and self-regulatory organizations (''SROs'') to do so by submitting a single form, fingerprint card and a combined payment of fees to FINRA. Through the CRD system, FINRA maintains the qualification, employment and disciplinary histories of registered associated persons of broker-dealers. Certain information reported to the CRD system is displayed in BrokerCheck®, an electronic system that provides the public with information on the professional background, business practices, and conduct of FINRA members and their associated persons. Investors use BrokerCheck to help make informed choices about the individuals and firms with which they currently conduct or are considering conducting business.

individual. In those cases where a member is transferring the registrations of individuals in connection with the acquisition of all or part of another member's business, FINRA provides a discount to the fee, ranging from 10 to 50 percent, based on the number of registered personnel being transferred. FINRA is proposing to increase the registration fee to $100; it is not proposing to make any changes to the current discount schedule.

This fee has been static since 1995.[6] Since 1995, FINRA has regularly enhanced the CRD system by adding features and functionality (*e.g.,* work queues, standard reports, email notifications) designed to make form filing more efficient for members, and to otherwise help members meet their reporting and related regulatory obligations. FINRA also has consistently made usability and navigational enhancements since deploying the web-based CRD system in 1999. Finally, FINRA has increased the number of registration categories available to individuals, as well as the number of SROs and jurisdictions with which individuals and firms may register.

Disclosure Filing Fees

As part of the securities industry's licensing and registration process, individuals and members are required to report certain disclosure events or proceedings to the CRD system. These disclosure matters include, for example, certain criminal charges and convictions, regulatory actions, investment-related civil judgments and injunctions, and financial events such as bankruptcies and unsatisfied liens. Individuals report these disclosure events or proceedings through Form U4 or Uniform Termination Notice for Securities Industry Registration (''Form U5''), while members report disclosure matters in which they or a control affiliate have been involved via the Uniform Application for Broker-Dealer Registration (''Form BD'').

When a disclosure filing is made for either an individual or member, FINRA must, among other things, confirm that the matter is properly reported; review any documentation submitted and/or determine whether additional documentation is required; conduct any necessary independent research; and, depending on the matter reported, analyze whether the event or proceeding subjects the individual or member to a statutory disqualification pursuant to Section 3(a)(39) of the Act.[7]

Under Section 4(b)(3) of Schedule A, FINRA assesses a $95 fee to process an initial or amended Form U4 or Form U5 that includes the initial reporting, amendment or certification of one or more disclosure events or proceedings. FINRA currently does not charge a fee to process a Form BD that contains a disclosure event or proceeding. FINRA is proposing to increase the disclosure filing fee for Forms U4 and U5 to $110 and to establish a disclosure filing fee for Form BD of $110.

Reviewing disclosure information has become more complex, in part because Forms U4 and U5 have added further disclosure questions [8] and FINRA's By-Laws have been revised to expand the categories under which an individual or member can be subject to a statutory disqualification.[9] As a result, while costs to administer the CRD program have increased, those costs have not been offset by a commensurate increase in the current disclosure filing fee, which has remained static since 1995,[10] or the establishment of a fee to cover the costs associated with review of disclosure matters submitted on Form BD.

System Processing Fee

Under Section 4(b)(6) of Schedule A, FINRA currently charges an annual $30 system processing fee for each member's registered individuals. FINRA is proposing to increase the system processing fee to $45. This fee has not been increased since January 2000.[11] Since 2000, FINRA's costs to operate, develop, and maintain the CRD system (*e.g.,* investments in system infrastructure and data security) have increased.

Fingerprint Fees

FINRA processes fingerprints submitted by members on behalf of their associated persons who are required to be fingerprinted pursuant to Section 17(f)(2) of the Act [12] and Rule 17f–2 thereunder.[13] Under Section 4(b)(4) of Schedule A, FINRA currently charges a fee of $13 to process each set of fingerprints submitted by a member, plus an additional fee that FINRA collects on behalf of the Federal Bureau of Investigation (''FBI''), consistent with FBI guidelines.[14]

Members submit fingerprints to FINRA either electronically or via a hard copy fingerprint card. FINRA is proposing to increase the processing fee for fingerprints submitted electronically to $15 and to increase the fee for fingerprints submitted by a hard copy fingerprint card to $30.

The fingerprint fee has not increased since 2003.[15] FINRA is proposing a two-tiered fingerprint processing fee structure in part to reflect that the costs associated with processing fingerprints submitted via a hard copy fingerprint card are much higher than those that are submitted electronically. Specifically, fingerprints submitted by a hard copy card require additional processing by FINRA, including adding a barcode, if necessary, to the card for tracking purposes; scanning the fingerprints and converting them to a digital image for submission to the FBI; and, for first-time registrants, entering the individual's personal and demographic information into the CRD system. FINRA also believes that the two-tiered fingerprint fee structure will incentivize firms to submit fingerprints electronically, making processing less time-intensive for FINRA staff. FINRA notes that members will be able to choose how they submit their associated persons' fingerprints and therefore will have some control over the fees they incur for fingerprint processing.

In addition to processing fingerprints submitted by members, FINRA also processes and posts fingerprint results and identifying information submitted by a member that have been processed through another SRO. Pursuant to Section 4(b)(5) of Schedule A, FINRA charges a fee of $13 for processing and posting these submissions. FINRA is proposing to increase this fee to $30.

This fee has been static since 2003.[16] FINRA notes there are higher costs associated with the processing and posting of fingerprint results and identifying information from other SROs. In this regard, upon receipt of the fingerprint results and identifying information, FINRA images and stores the documents received, verifies and matches the fingerprint processing results to an existing record in the CRD

[6] *See* Securities Exchange Act Release No. 36025 (July 26, 1995), 60 FR 39200 (August 1, 1995) (Notice of Filing and Immediate Effectiveness of File No. SR–NASD–95–32).

[7] 15 U.S.C. 78c(a)(39).

[8] *See* Securities Exchange Act Release No. 59916 (May 13, 2009), 74 FR 23750 (May 20, 2009) (Order Approving File No. SR–FINRA–2009–008).

[9] *See* Securities Exchange Act Release No. 56145 (July 26, 2007), 72 FR 42169 (August 1, 2007) (Order Approving File No. SR–NASD–2007–023).

[10] *See supra* note 6.

[11] *See* Securities Exchange Act Release No. 41937 (September 28, 1999), 64 FR 53762 (October 4, 1999) (Notice of Filing and Immediate Effectiveness of File No. SR–NASD–99–43).

[12] 15 U.S.C. 78q(f)(2).

[13] 17 CFR 240.17f–2.

[14] The current FBI fee is $14.50. *See* Revised User Fee Schedule, 76 FR 78950 (December 20, 2011).

[15] *See* Securities Exchange Act Release No. 48379 (August 20, 2003), 68 FR 51622 (August 27, 2003) (Notice of Filing and Immediate Effectiveness of File No. SR–NASD–2003–109).

[16] *See supra* note 15.

system, if available, and manually posts the results to the CRD system.

Mass Transfer Registration Fees

FINRA's Mass Transfer Program allows for the bulk transfer of registration and fingerprint information within the CRD system when a member is involved in a business combination such as a merger, consolidation or reorganization with another member. Under Section 6(b) of Schedule A, a member that FINRA determines to be a successor organization to a predecessor member is not required to pay the fees for the re-registration of branch offices and personnel of the predecessor as part of the mass transfer. A non-successor member, however, is required to pay these re-registration fees.

FINRA is proposing to eliminate the exception to the payment of re-registration fees for successor members involved in a mass transfer. FINRA notes that a mass transfer, which is an optional service that FINRA makes available to member firms that engage in a business combination, involves significant work on FINRA's part, including reviewing transaction details; entering the mass transfer into the CRD system; addressing questions from firm personnel or, in certain circumstances, providing them with training; and post-mass transfer troubleshooting. The elimination of the exception will result in all members that participate in FINRA's Mass Transfer Program to be [sic] assessed fees for the re-registration of branch offices and personnel of the predecessor member.

Late Disclosure Fee

Under Section 4(h) of Schedule A, FINRA charges a fee of $10 per day, up to a maximum of $300, for each day that a new disclosure event or a change in the status of a previously reported disclosure event is not timely filed on an initial or amended Form U5 or an amended Form U4. This fee is assessed starting on the day following the last date on which the event or change in status was required to be reported.

FINRA is proposing to increase the late disclosure fee to $100 for the first day that an applicable disclosure event is not timely filed and $25 for each subsequent day, up to a maximum of 60 days. Under the proposal, the maximum amount of the late disclosure fee will increase from $300 to $1,575.

The current late disclosure filing fee has been in effect and remained static since 2004.[17] Notwithstanding this fact, some members and individuals still fail to timely report initial or updated disclosure events.[18] While FINRA continues to address the issue of late disclosure filings through other avenues, including disciplinary actions, FINRA believes that it is appropriate to increase the late disclosure filing fee in part to help ensure that disclosure events are reported and updated in a timely manner.

Implementation

FINRA has filed the proposed rule change for immediate effectiveness. FINRA is proposing that the implementation date of the proposed rule change will be January 2, 2013. Specifically, the proposed initial/transfer registration fee, disclosure filing, fingerprint, and late disclosure fees would become effective for filings or fingerprints submitted on or after January 2, 2013. The proposed changes to the mass transfer registration fees would become effective for mass transfers executed on or after January 2, 2013. Lastly, the proposed system processing fee would become effective for the 2013 Renewal Program.[19]

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[20] which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls.

FINRA believes that the proposed fees are reasonable based on the increased costs associated with operating and maintaining its registration and disclosure programs, specifically the CRD system and BrokerCheck. The proposed fees also contribute to the general funding of FINRA's overall regulatory program and serve to ensure that FINRA is sufficiently capitalized to meet its regulatory responsibilities. The current fees have remained static for at least seven years and some of the fees have not been increased in over 16 years. During this time, several enhancements have been made to the CRD system, including: (1) Incorporation of various uniform registration form changes; (2) electronic fingerprint processing; (3) Web EFT™, which allows subscribing firms to submit batch filings to the CRD system; (4) increases in the number and types of reports available through the CRD system; and (5) significant changes to BrokerCheck, including making BrokerCheck easier to use and expanding the amount of information made available through the system.

FINRA further believes that the proposed fees are reasonable because they help to ensure the integrity of the information in the CRD system. The integrity of the information in the CRD system is very important because the Commission, FINRA, other SROs and state securities regulators use the CRD system to make licensing and registration decisions, among other things. Furthermore, the information displayed in BrokerCheck, which investors use to help make informed choices about the individuals and firms with which they currently conduct or are considering conducting business, is derived from the CRD system.

FINRA also believes that the proposed fees are equitably allocated in that they will apply equally to all individuals and members required to report information to the CRD system. Thus, those members that register more individuals or submit more filings through the CRD system will generally pay more in fees than those members that use the CRD system to a lesser extent.

B.Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[21] and paragraph (f)(2) of Rule 19b-4 thereunder.[22] 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

[17] *See* Securities Exchange Act Release No. 49224 (February 11, 2004), 69 FR 7833 (February 19, 2004) (Notice of Filing and Immediate Effectiveness of File No. SR–NASD–2003–192).

[18] *See, e.g.,* MML Investors Services, LLC, FINRA AWC No. 2010020873501 (November 16, 2011); Goldman, Sachs & Co., FINRA AWC No. 2010022473801 (November 9, 2010), available at *http://www.finra.org/Industry/Enforcement/DisciplinaryActions/FDAS/.*

[19] As part of the 2013 Renewal Program, Preliminary Renewal Statements reflecting the proposed $45 system processing fee will be made available to members in the fourth quarter of 2012.

[20] 15 U.S.C. 78*o*–3(b)(5).

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(2).

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–FINRA–2012–030 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–FINRA–2012–030. 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 FINRA. 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–FINRA–2012–030 and should be submitted on or before July 20, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Kevin M. O'Neill,

Deputy Secretary .

[FR Doc. 2012–15937 Filed 6–28–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67251; File No. SR–ISE–2012–56]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Obvious Error Rule

June 25, 2012.

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 June 14, 2012, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend ISE Rule 720 regarding Obvious Errors. The text of the proposed rule change is available on the Exchange's Web site *www.ise.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 self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend ISE Rule 720 regarding Obvious Errors.[3] Under the current rule, buyers of options with a zero bid may request that their execution be busted if at least the two strikes below (for calls) or above (for puts) in the same options class were quoted with a zero bid at the time of the execution.[4] A zero bid option refers to an option where the bid price is $0.00. Series of options quoted zero bid are usually deep out-of-the-money series that are perceived as having little if any chance of expiring in-the-money. For this reason, relatively few transactions occur in these series and those that do are usually the result of a momentary pricing error.

This proposed rule change will add additional criteria and clarifying language to the current rule. Specifically, under the revised rule, trades in series quoted no bid on the Exchange would be subject to nullification provided: (i) The bid in that series immediately preceding the execution was, and for five (5) seconds prior to the execution remained, zero and (ii) at least one strike below (for calls) or above (for puts) in the same option class was quoted no bid at the time of execution. Thus, for example, if a trade occurs in the ABC 45 call option series when the series was quoted $0.00–$0.10, the trade may be nullified if (i) the bid was $0.00 for at least five (5) seconds prior to the execution and (ii) at least one call option series in ABC with a strike below 45 (e.g., the ABC 30, 35 or 40 call option series) had a bid of $0.00 at the time of execution.

The revised no bid provision would also provide that each group of series in an options class with a non-standard deliverable will be treated as a separate options class. Thus, for example, if due to a reorganization certain of the series in the ABC option class have a deliverable of 150 shares per options contract (as compared to the standard 100 shares per option contract), all ABC option series that are subject to the 150 contract delivery requirements would be considered separately from the ABC

[23] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The changes proposed to ISE Rule 720 are based on Chicago Board Option Exchange (''CBOE'') Rule 6.25.

[4] *See* ISE Rule 720, Supplementary Material .05.

option series that are subject to the 100 contract delivery requirements for purposes of applying the no bid provision. The revised rule would also provide that, when determining the Exchange's quotes in the relevant series, bids and offers of the parties to the subject trade that are in any of the series in the same options class and are believed to be erroneous shall not be considered. Thus, for example, if a member had a system error that caused it to quote a $0.05 bid in all the series of an options class and a trade(s) resulted in some of those series, the erroneous $0.05 bids would not be considered when determining the quoted market in the strike prices below (for calls) or above (for puts) each of the series for the subject trade(s). Finally, the revised rule would clarify that the no bid provision is intended to apply to series quoted no bid on the Exchange (as opposed to series for which the national best bid is quoted no bid). As is currently required, buyers must notify ISE's market operations group within the designated timeframe to seek relief.

The Exchange believes that the proposed rule change is reasonable and objective, and would serve to better identify instances where the no bid provision in intended to apply. The purpose of this proposed rule change is to align the Exchange's rule with rules currently in place at other exchanges.[5] The proposed rule change will provide members with similar opportunities for trade nullification that are available on CBOE which has an identical rule in place to address obvious errors.

2. Basis

The basis under the Securities Exchange Act of 1934 (''Exchange Act'') for this proposed rule change is the requirement under Section 6(b)(5) that an exchange have rules that are designed to promote just and equitable principles of trade, and to remove impediments to and perfect the mechanism for a free and open market and a national market system, and in general, to protect investors and the public interest.

The Exchange understands that, in approving proposals of other exchanges related to adjusting and nullifying option trades involving obvious errors, the Commission has focused on the need for specificity and objectivity with respect to exchange determinations and processes for reviewing such determinations.[6] In this regard, the Exchange believes that the proposed rule change would clarify the application of the Exchange's obvious error rule, while also simplifying the administration of the rule in order to more efficiently render such determinations. The Exchange further believes that the proposed rule change would benefit investors and be in the public's interest because it would provide increased clarity and specificity concerning the objective standards used by the Exchange when making trade nullification determinations.

The Exchange also believes that the proposed rule change would benefit investors and market participants that are members of multiple exchanges by more closely aligning the Exchange's rules with respect to obvious errors with those of other exchanges. In this respect, the proposed rule change helps foster certainty for market participants trading on multiple exchanges. Accordingly, the Exchange believes that the increased specificity resulting from the proposed rule change, combined with the continued objective nature of the Exchange's process for rendering and reviewing trade nullification determinations, is consistent with prior guidance from the Commission, is consistent with the Exchange Act and is consistent with the maintenance of a fair and orderly market and the protection of investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes 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 not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)[7] of the Act and Rule 19b–4(f)(6)[8] thereunder. The Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing the proposed rule change.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2012–56 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–ISE–2012–56. 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

[5] *See,* for example, CBOE Rule 6.25(a)(2).

[6] *See supra* note 1. [sic] *See also* Securities Exchange Act Release No. 63692 (January 11, 2011), 76 FR 2940 (January 18, 2011) (SR–Phlx–2010–163).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of 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–ISE–2012–56, and should be submitted on or before July 20, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–15939 Filed 6–28–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67253; File No. SR–NASDAQ–2012–069]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify an Optional Depth Data Enterprise License Fee for Broker-Dealer Distribution of Depth-of-Book Data

June 25, 2012.

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 June 12, 2012, The NASDAQ Stock Market LLC (''NASDAQ'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

NASDAQ proposes to modify the optional Enterprise License fee for Non-Professional Subscribers of certain NASDAQ Depth-of-Book market data. NASDAQ will implement the proposed revised fee on July 1, 2012.

* * * * *

7023. NASDAQ Depth-of-Book Data

(a)–(b) No change.

(c) Enterprise License Fees

(1)–(2) No Change.

(3) As an alternative to subsections (1) and (2) above, a Distributor that is also a broker-dealer may pay a monthly fee of $*500,000* [325,000] to provide NASDAQ Level 2, NASDAQ TotalView, or NASDAQ OpenView for Display Usage by Non-Professional Subscribers with whom the firm has a brokerage relationship. This Enterprise License shall not apply to relevant Level 1 or Depth Distributor fees.

(d)–(e) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASDAQ has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ is proposing a change to the Enterprise License Fee for Non-Professional Usage of certain NASDAQ Depth-of-Book market data. NASDAQ Rule 7023(c)(3) offers an optional Enterprise License for unlimited Non-Professional Subscribers of NASDAQ Level 2, NASDAQ TotalView, or NASDAQ OpenView for broker-dealers registered under the Act. Specifically, NASDAQ proposes to increase the optional fee for Distributors from $325,000 to $500,000 per month that covers all Non-Professional Subscribers with whom the firm has a brokerage relationship. This Depth-of-Book Enterprise License Fee includes Non-Professional Subscriber fees, but does not include Distributor fees. Non-broker-dealer vendors and application service providers are not eligible for the Enterprise License; such firms typically pass through the cost of market data Subscriber fees to their customers.[3]

NASDAQ continues to seek broader distribution of Depth-of-Book data and to reduce the cost of providing Depth-of-Book data to larger numbers of investors. In the past, NASDAQ has accomplished this goal in part by offering similar enterprise licenses for Professional and Non-Professional Usage of TotalView which contains the full Depth-of-Book data for the NASDAQ Market Center Execution System. NASDAQ believes that the adoption of enterprise licenses has led to greater distribution of market data, particularly among Non-Professional Subscribers.

In addition to increased administrative flexibility, enterprise licenses also encourage broader distribution by firms that are currently over the fee cap as well as those that are approaching the cap and wish to take advantage of the benefits of the program. Further, NASDAQ believes that capping fees in this manner creates goodwill with broker-dealers and increases transparency for retail investors.

The Depth-of-Book Enterprise License Fee is completely optional and does not replace existing enterprise license fee alternatives set forth in Rule 7023. Additionally, the proposal does not impact individual Subscriber fees for any product or raise the costs to any Subscriber of any NASDAQ data product. The market for this Depth-of-Book information is highly competitive and continually evolves as products develop and change. As a result, it is proposed that the current fee be increased, in part, due to a change in market data distribution and growing economies of scale in the industry. Subsequent to the introduction of the Depth-of-Book Enterprise License, there has been a substantial change in the adoption rate and distribution of Depth-of-Book data. Additionally, as broker/dealers consolidate and continue to grow organically, NASDAQ needs to adjust its enterprise license pricing model to better reflect current market conditions. The adjustment of this fee reflects these and other market forces.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[4] in general, and with Section 6(b)(4) of the

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] NASDAQ relies on Distributor self-reporting of usage rather than on individual contact with each end-user Subscriber. For this Enterprise License, NASDAQ permits Distributors to designate an entire Subscriber population as Non-Professional provided that the number of Professional Subscribers within that Subscriber population does not exceed ten percent (10%) of the total population.

[4] 15 U.S.C. 78f.

Act,[5] in particular, in that it provides an equitable allocation of reasonable fees among Subscribers and recipients of NASDAQ data. In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data.

The Commission concluded that Regulation NMS—by deregulating the market in proprietary data—would itself further the Act's goals of facilitating efficiency and competition:

> [E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.[6]

By removing ''unnecessary regulatory restrictions'' on the ability of exchanges to sell their own data, Regulation NMS advanced the goals of the Act and the principles reflected in its legislative history. If the free market should determine whether proprietary data is sold to broker-dealers at all, it follows that the price at which such data is sold should be set by the market as well. Level 2, TotalView and OpenView are precisely the sort of market data products that the Commission envisioned when it adopted Regulation NMS.

On July 21, 2010, President Barack Obama signed into law H.R. 4173, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (''Dodd-Frank Act''), which amended Section 19 of the Act. Among other things, Section 916 of the Dodd-Frank Act amended paragraph (A) of Section 19(b)(3) of the Act by inserting the phrase ''on any person, whether or not the person is a member of the self-regulatory organization'' after ''due, fee or other charge imposed by the self-regulatory organization.'' As a result, all SRO rule proposals establishing or changing dues, fees, or other charges are immediately effective upon filing regardless of whether such dues, fees, or other charges are imposed on members of the SRO, non-members, or both.

Section 916 further amended paragraph (C) of Section 19(b)(3) of the Act to read, in pertinent part, ''At any time within the 60-day period beginning on the date of filing of such a proposed rule change in accordance with the provisions of paragraph (1) [of Section 19(b)], the Commission summarily may temporarily suspend the change in the rules of the self-regulatory organization made thereby, if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of this title. If the Commission takes such action, the Commission shall institute proceedings under paragraph (2)(B) [of Section 19(b)] to determine whether the proposed rule should be approved or disapproved.''

The decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC,* No. 09–1042 (D.C. Cir. 2010), although reviewing a Commission decision made prior to the effective date of the Dodd-Frank Act, upheld the Commission's reliance upon competitive markets to set reasonable and equitably allocated fees for market data. ''In fact, the legislative history indicates that the Congress intended that the market system 'evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed' and that the SEC wield its regulatory power 'in those situations where competition may not be sufficient,' such as in the creation of a 'consolidated transactional reporting system.' '' *NetCoalition,* at 15 (quoting H.R. Rep. No. 94–229, at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 321, 323). The court's conclusions about Congressional intent are therefore reinforced by the Dodd-Frank Act amendments, which create a presumption that exchange fees, including market data fees, may take effect immediately, without prior Commission approval, and that the Commission should take action to suspend a fee change and institute a proceeding to determine whether the fee change should be approved or disapproved only where the Commission has concerns that the change may not be consistent with the Act.

For the reasons stated above, NASDAQ believes that the proposed fees are fair and equitable, and not unreasonably discriminatory. As described above, the proposed fees are based on pricing conventions and distinctions that exist in NASDAQ's current fee schedule, and the fee schedules of other exchanges. These distinctions (top-of-book versus Depth-of-Book, Professional versus non-Professional Subscribers, Direct versus Indirect Access, Internal versus External Distribution) are each based on principles of fairness and equity that have helped for many years to maintain fair, equitable, and not unreasonably discriminatory fees, and that apply with equal or greater force to the current proposal.

As described in greater detail below, if NASDAQ has calculated improperly and the market deems the proposed fees to be unfair, inequitable, or unreasonably discriminatory, firms can diminish or discontinue the use of their data because the proposed fee is entirely optional to all parties. Firms are not required to purchase Depth-of-Book data or to utilize any specific pricing alternative if they do choose to purchase Depth-of-Book data. NASDAQ is not required to make Depth-of-Book data available or to offer specific pricing alternatives for potential purchases. NASDAQ can discontinue offering a pricing alternative (as it has in the past) and firms can discontinue their use at any time and for any reason (as they often do), including due to their assessment of the reasonableness of fees charged. NASDAQ continues to establish and revise pricing policies aimed at increasing fairness and equitable allocation of fees among Subscribers.

NASDAQ believes that the Depth-of-Book Enterprise License promotes increased transparency by offering a pricing option resulting in lower fees for heavy users of Depth-of-Book data. While NASDAQ may need to periodically adjust the Depth-of-Book Enterprise License to reflect market forces, it continues to view the fee cap as a way for firms to make additional information available to the firms' clients, thereby increasing transparency of the market.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Notwithstanding its determination that the Commission may rely upon competition to establish fair and equitably allocated fees for market data, the *NetCoalition* court found that the Commission had not, in that case, compiled a record that adequately supported its conclusion that the market for the data at issue in the case was competitive. NASDAQ believes that a record may readily be established to

[5] 15 U.S.C. 78f(b)(4).

[6] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

demonstrate the competitive nature of the market in question.

There is intense competition between trading platforms that provide transaction execution and routing services and proprietary data products. Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. The decision whether and on which platform to post an order will depend on the attributes of the platform where the order can be posted, including the execution fees, data quality and price and distribution of its data products. Without the prospect of a taking order seeing and reacting to a posted order on a particular platform, the posting of the order would accomplish little. Without trade executions, exchange data products cannot exist. Data products are valuable to many end Subscribers only insofar as they provide information that end Subscribers expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that a trading platform earns reflects the revenues it receives from both products and the joint costs it incurs. Moreover, an exchange's customers view the costs of transaction executions and of data as a unified cost of doing business with the exchange. A broker-dealer will direct orders to a particular exchange only if the expected revenues from executing trades on the exchange exceed net transaction execution costs and the cost of data that the broker-dealer chooses to buy to support its trading decisions (or those of its customers). The choice of data products is, in turn, a product of the value of the products in making profitable trading decisions. If the cost of the product exceeds its expected value, the broker-dealer will choose not to buy it. Moreover, as a broker-dealer chooses to direct fewer orders to a particular exchange, the value of the product to that broker-dealer decreases, for two reasons. First, the product will contain less information, because executions of the broker-dealer's orders will not be reflected in it. Second, and perhaps more important, the product will be less valuable to that broker-dealer because it does not provide information about the venue to which it is directing its orders. Data from the competing venue to which the broker-dealer is directing orders will become correspondingly more valuable.

Thus, a super-competitive increase in the fees charged for either transactions or data has the potential to impair revenues from both products. ''No one disputes that competition for order flow is 'fierce'.'' *NetCoalition* at 24. However, the existence of fierce competition for order flow implies a high degree of price sensitivity on the part of broker-dealers with order flow, since they may readily reduce costs by directing orders toward the lowest-cost trading venues. A broker-dealer that shifted its order flow from one platform to another in response to order execution price differentials would both reduce the value of that platform's market data and reduce its own need to consume data from the disfavored platform. Similarly, if a platform increases its market data fees, the change will affect the overall cost of doing business with the platform, and affected broker-dealers will assess whether they can lower their trading costs by directing orders elsewhere and thereby lessening the need for the more expensive data.

Analyzing the cost of market data distribution in isolation from the cost of all of the inputs supporting the creation of market data will inevitably underestimate the cost of the data. Thus, because it is impossible to create data without a fast, technologically robust, and well-regulated execution system, system costs and regulatory costs affect the price of market data. It would be equally misleading, however, to attribute all of the exchange's costs to the market data portion of an exchange's joint product. Rather, all of the exchange's costs are incurred for the unified purposes of attracting order flow, executing and/or routing orders, and generating and selling data about market activity. The total return that an exchange earns reflects the revenues it receives from the joint products and the total costs of the joint products.

Competition among trading platforms can be expected to constrain the aggregate return each platform earns from the sale of its joint products, but different platforms may choose from a range of possible, and equally reasonable, pricing strategies as the means of recovering total costs. For example, some platform may choose to pay rebates to attract orders, charge relatively low prices for market information (or provide information free of charge) and charge relatively high prices for accessing posted liquidity. Other platforms may choose a strategy of paying lower rebates (or no rebates) to attract orders, setting relatively high prices for market information, and setting relatively low prices for accessing posted liquidity. In this environment, there is no economic basis for regulating maximum prices for one of the joint products in an industry in which suppliers face competitive constraints with regard to the joint offering. This would be akin to strictly regulating the price that an automobile manufacturer can charge for car sound systems despite the existence of a highly competitive market for cars and the availability of after-market alternatives to the manufacturer-supplied system.

The market for market data products is competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange, as well as other entities, in a vigorously competitive market.

Broker-dealers currently have numerous alternative venues for their order flow, including ten SRO markets, as well as internalizing BDs and various forms of alternative trading systems (''ATSs''), including dark pools and electronic communication networks (''ECNs''). Each SRO market competes to produce transaction reports via trade executions, and two FINRA-regulated Trade Reporting Facilities (''TRFs'') compete to attract internalized transaction reports. Competitive markets for order flow, executions, and transaction reports provide pricing discipline for the inputs of proprietary data products.

The large number of SROs, TRFs, BDs, and ATSs that currently produce proprietary data or are currently capable of producing it provides further pricing discipline for proprietary data products. Each SRO, TRF, ATS, and BD is currently permitted to produce proprietary data products, and many currently do or have announced plans to do so, including NASDAQ, NYSE, NYSE Amex, NYSEArca, and BATS.

Any ATS or BD can combine with any other ATS, BD, or multiple ATSs or BDs to produce joint proprietary data products. Additionally, order routers and market data vendors can facilitate single or multiple broker-dealers' production of proprietary data products.

The potential sources of proprietary products are virtually limitless.

The fact that proprietary data from ATSs, BDs, and vendors can by-pass SROs is significant in two respects. First, non-SROs can compete directly with SROs for the production and sale of proprietary data products, as BATS and Arca did before registering as exchanges by publishing Depth-of-Book data on the Internet. Second, because a single order or transaction report can appear in an SRO proprietary product, a non-SRO proprietary product, or both, the data available in proprietary products is exponentially greater than the actual number of orders and transaction reports that exist in the marketplace.

Market data vendors provide another form of price discipline for proprietary data products because they control the primary means of access to end Subscribers. Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Thomson Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end Subscribers will not purchase in sufficient numbers. Internet portals, such as Google, impose a discipline by providing only data that will enable them to attract ''eyeballs'' that contribute to their advertising revenue. Retail broker-dealers, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue. Although the business models may differ, these vendors' pricing discipline is the same: they can simply refuse to purchase any proprietary data product that fails to provide sufficient value. NASDAQ and other producers of proprietary data products must understand and respond to these varying business models and pricing disciplines in order to market proprietary data products successfully.

In addition to the competition and price discipline described above, the market for proprietary data products is also highly contestable because market entry is rapid, inexpensive, and profitable. The history of electronic trading is replete with examples of entrants that swiftly grew into some of the largest electronic trading platforms and proprietary data producers: Archipelago, Bloomberg Tradebook, Island, RediBook, Attain, TracECN, BATS Trading and Direct Edge. A proliferation of dark pools and other ATSs operate profitably with fragmentary shares of consolidated market volume.

Regulation NMS, by deregulating the market for proprietary data, has increased the contestability of that market. While broker-dealers have previously published their proprietary data individually, Regulation NMS encourages market data vendors and broker-dealers to produce proprietary products cooperatively in a manner never before possible. Multiple market data vendors already have the capability to aggregate data and disseminate it on a profitable scale, including Bloomberg, and Thomson Reuters.

The court in *NetCoalition* concluded that the Commission had failed to demonstrate that the market for market data was competitive based on the reasoning of the Commission's *NetCoalition* order because, in the court's view, the Commission had not adequately demonstrated that the Depth-of-Book data at issue in the case is used to attract order flow. NASDAQ believes, however, that evidence not before the court clearly demonstrates that availability of data attracts order flow. For example, as of July 2010, 92 of the top 100 broker-dealers by shares executed on NASDAQ consumed NQDS and 80 of the top 100 broker-dealers consumed TotalView. During that month, the NQDS-Subscribers were responsible for 94.44% of the orders entered into NASDAQ and TotalView Subscribers were responsible for 92.98%.

Competition among platforms has driven NASDAQ continually to improve its platform data offerings and to cater to customers' data needs. For example, NASDAQ has developed and maintained multiple delivery mechanisms (IP, multi-cast, and compression) that enable customers to receive data in the form and manner they prefer and at the lowest cost to them. NASDAQ offers front end applications such as its ''Bookviewer'' to help customers utilize data. NASDAQ has created new products like TotalView Aggregate to complement TotalView ITCH and/NQDS, because offering data in multiple formatting allows NASDAQ to better fit customer needs. NASDAQ offers data via multiple extranet providers, thereby helping to reduce network and total cost for its data products. NASDAQ has developed an online administrative system to provide customers transparency into their data feed requests and streamline data usage reporting. NASDAQ has also expanded its Enterprise License options that reduce the administrative burden and costs to firms that purchase market data.

Despite these enhancements and a dramatic increase in message traffic, NASDAQ's fees for market data have remained flat. In fact, as a percent of total Subscriber costs, NASDAQ data fees have fallen relative to other data usage costs—including bandwidth, programming, and infrastructure—that have risen. The same holds true for execution services; despite numerous enhancements to NASDAQ's trading platform, absolute and relative trading costs have declined. Platform competition has intensified as new entrants have emerged, constraining prices for both executions and for data.

The vigor of competition for Depth-of-Book information is significant and the Exchange believes that this proposal itself clearly evidences such competition. NASDAQ is offering a new pricing model in order to keep pace with changes in the industry and evolving customer needs. It is entirely optional and is geared towards attracting new customers, as well as retaining existing customers.

The Exchange has witnessed competitors creating new products and innovative pricing in this space over the course of the past year. NASDAQ continues to see firms challenge its pricing on the basis of the Exchange's explicit fees being higher than the zero-priced fees from other competitors such as BATS. In all cases, firms make decisions on how much and what types of data to consume on the basis of the total cost of interacting with NASDAQ or other exchanges. Of course, the explicit data fees are but one factor in a total platform analysis. Some competitors have lower transactions fees and higher data fees, and others are vice versa. The market for this Depth-of-Book information is highly competitive and continually evolves as products develop and change.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[7] 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

[7] 15 U.S.C. 78s(b)(3)(a)(ii). [sic]

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–2012–069 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–2012–069. 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 NASDAQ. 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–2012–069, and should be submitted on or before July 20, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–15956 Filed 6–28–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67246; File No. SR–NASDAQ–2012–071]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change To Amend Rule 4758(a)(1)(A) To Reflect a Change in NASDAQ's Routing Functionality

June 25, 2012.

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 June 14, 2012, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 4758(a)(1)(A) to reflect a change in NASDAQ's routing functionality.

The text of the proposed rule change is below. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

4758. Order Routing

(a) Order Routing Process

(1) The Order Routing Process shall be available to Participants from 7:00 a.m. until 8:00 p.m. Eastern Time, and shall route orders as described below. All routing of orders shall comply with Rule 611 of Regulation NMS under the Exchange Act.

(A) The System provides a variety of routing options. Routing options may be combined with all available order types and times-in-force, with the exception of order types and times-in-force whose terms are inconsistent with the terms of a particular routing option. The System will consider the quotations only of accessible markets. The term ''System routing table'' refers to the proprietary process for determining the specific trading venues to which the System routes orders and the order in which it routes them. Nasdaq reserves the right to maintain a different System routing table for different routing options and to modify the System routing table at any time without notice. The System routing options are:

(i) DOT is a routing option for orders that the entering firm wishes to designate for participation in the NYSE or NYSE Amex opening or closing processes. DOT orders are routed directly to NYSE or NYSE Amex, as appropriate. After attempting to execute in the opening or closing process, DOT orders thereafter check the System for available shares and are converted into SCAN or STGY orders, depending on the designation of the entering firm. DOT orders that are designated to participate in the NYSE or NYSE Amex opening process but that are entered after 9:30 a.m. will also be converted into SCAN or STGY orders, depending on the designation of the entering firm.

(ii) a. DOTI is a routing option for orders that the entering firm wishes to direct to the NYSE or NYSE Amex without returning to the Nasdaq Market Center. DOTI orders check the System for available shares and then are sent to destinations on the System routing table before being sent to NYSE or NYSE Amex, as appropriate. DOTI orders do not return to the Nasdaq Market Center book after routing.

b. The entering firm may alternatively elect to have DOTI orders check the System for available shares and thereafter be directly sent to NYSE or NYSE Amex as appropriate.

(iii) STGY is a routing option under which orders check the System for available shares and *simultaneously route the remaining shares*[then are sent] to destinations on the System routing table. If shares remain un-executed after routing, they are posted on the book. Once on the book, should the order subsequently be locked or crossed by another accessible market center, the System shall route the order to the locking or crossing market center. SKNY is a form of STGY in which the entering firm instructs the System to bypass any market centers included in the STGY System routing table that are not posting Protected Quotations within the meaning of Regulation NMS.

(iv) SCAN is a routing option under which orders check the System for available shares and *simultaneously route the remaining shares*[then are sent] to destinations on the System routing table. If shares remain un-executed after routing, they are posted on the book. Once on the book, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center. SKIP is a form of SCAN in which the entering firm instructs the System to bypass any market centers included in the SCAN System routing table that are not posting Protected Quotations within the meaning of Regulation NMS.

(v) TFTY is a routing option under which orders check the System for available shares only if so instructed by the entering firm and are thereafter routed to destinations on the System routing table. If shares remain un-

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

executed after routing, they are posted to the book. Once on the book, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center.

(vi) MOPP is a routing option under which orders route only to Protected Quotations and only for displayed size. If shares remain unexecuted after routing, they are posted to the book. Once on the book, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center.

(vii) SAVE is a routing option under which orders may either (i) route to the NASDAQ OMX BX Equities Market and NASDAQ OMX PSX, check the System, and then route to other destinations on the System routing table, or (ii) may check the System first and then route to destinations on the System routing table. If shares remain un-executed after routing, they are posted to the book. Once on the book, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center.

(viii) SOLV is a routing option under which orders may either (i) route to the NASDAQ OMX BX Equities Market and NASDAQ OMX PSX, check the System, and then route to other destinations on the System routing table, or (ii) may check the System first and then route to destinations on the System routing table. If shares remain un-executed after routing, they are posted to the book. Once on the book, should the order subsequently be locked or crossed by another accessible market center, the System shall route the order to the locking or crossing market center.

(ix) ''Directed Orders'' are routed orders described in Rule 4751.

(x) LIST is a routing option under which an order, if received before the security has opened on its primary listing market, will be routed to the primary listing market for participation in that market's opening process. After the security has opened on its primary listing market, unexecuted shares will be returned to the NASDAQ system. Thereafter, the order will check the System for available shares *and simultaneously route the remaining shares*[before being sent] to destinations on the System routing table. Any remaining shares will be posted on the book. In addition, LIST orders entered after the security has opened on the primary listing market (but before 3:58 p.m.) will check the System for available shares *and simultaneously route the remaining shares*[before being sent] to destinations on the System routing table, with remaining shares posted on the book. Once on the book, if the order is subsequently locked or crossed by another market center, the System will not route the order to the locking or crossing market center. At 3:58pm, all LIST orders will be cancelled on the System and any remaining shares will route to the security's primary listing market for participation in its closing process. LIST orders received at or after 3:58 p.m. but before 4:00 p.m. will check the System for available shares *and simultaneously route the remaining shares*[before being sent] to destinations on the System routing table, and remaining shares will be routed to the security's primary listing market to participate in its closing process. Shares unexecuted in the closing process will be posted to the NASDAQ book. LIST orders received after 4:00 p.m. will be posted to the NASDAQ book. If trading in the security is stopped across all markets, LIST orders will be sent to the primary listing market to participate in the re-opening process. When normal trading resumes, unexecuted shares will be cancelled off of the primary and posted on the NASDAQ book. LIST orders may not be designated as MGTC or SGTC.

(xi) CART is a routing option under which orders route to the NASDAQ OMX BX Equities Market and NASDAQ OMX PSX and then check the System. If shares remain un-executed, they are posted to the book or cancelled. Once on the book, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center.

Orders that do not check the System for available shares prior to routing may not be sent to a facility of an exchange that is an affiliate of Nasdaq, except for orders that are sent to the NASDAQ OMX BX Equities Market or to the NASDAQ OMX PSX facility of NASDAQ OMX PHLX.

(B) No change.

(b)–(c) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ is proposing to amend Rule 4758(a)(1)(A) to reflect a change in NASDAQ's order routing functionality, which will allow routable orders [3] to simultaneously execute against NASDAQ available shares and route to other markets for execution of the remainder of the order. Currently, when a routable order is entered into the NASDAQ system, the NASDAQ book is first checked for available shares. If such an order is not filled or filled only partially, then the order is routed to away markets with the best bid or best offer pursuant to NASDAQ's System routing table.[4] For example, if a NASDAQ member submitted an order to buy 5,000 shares of a security, and NASDAQ had 500 shares displayed with another 500 shares undisplayed, under the current routing process 1,000 shares would be executed on NASDAQ. Thereafter, NASDAQ would route the remaining 4,000 shares of the order to other markets for execution.

NASDAQ has observed that upon partial execution of a routable order at NASDAQ, as in the example above, market participants often react to the order by cancelling their orders on other markets and entering new orders at inferior prices. This occurs because the current process directs the order to NASDAQ before attempting to access available liquidity at other markets and thereby allows market participants to react to the execution (an effect known as ''market impact'' or ''information leakage''). As a consequence, the available shares at the away market are no longer available, resulting in a lower likelihood of successfully accessing liquidity on away markets (*i.e.,* the ''fill rate'') and an increased likelihood of ultimately receiving an execution at an inferior price. As such, NASDAQ is addressing this problem by changing how the routing process will operate.

NASDAQ is proposing to execute routable orders against the NASDAQ book for available shares and to simultaneously route any remaining shares to additional markets. Specifically, under the proposed change a routable order would attempt to execute against the available shares at NASDAQ and, to the extent the order would not be filled by such available shares, NASDAQ would simultaneously route the remainder of the order to other venues, according to NASDAQ's System routing table, in a manner consistent with Regulation NMS (*i.e.,* satisfying all displayed protected quotes). For example, using the scenario above, if a member enters a routable order to buy 5,000 shares of a security and NASDAQ is displaying 500 shares of that security, with 500 undisplayed, NASDAQ would execute against the 500 displayed shares and 500 undisplayed shares, while

[3] For purposes of this filing, a ''routable order'' is an order entered into the NASDAQ System, which is not of an Order Type precluded from routing to other markets.

[4] The ''System routing table'' is the proprietary process for determining the specific trading venues to which the System routes orders and the order in which it routes them. *See* Rule 4758(a)(1)(A).

simultaneously routing the remaining 4,000 shares to other venues for execution. In the event that the amount of shares on other markets is insufficient to completely fill the order, or the order fails to completely execute, NASDAQ would then post the remaining shares on the NASDAQ book or cancel the remaining shares per the routed order's instructions. NASDAQ believes that this simultaneous execution against NASDAQ available shares and routing to other venues' shares will avoid the deleterious effect of market impact discussed above and result in overall faster and better executions of its members' routable orders.

NASDAQ notes that it is not changing the execution and routing sequence of all routable orders. The TFTY, SAVE, SOLV, and CART orders are designed to execute serially as part of their strategies, which is generally to reduce the blended fees associated with transacting on multiple markets. As such, simultaneous routing of such orders would not result in a better execution in terms of the goals of these routable order types.

2. Statutory Basis

The statutory basis for the proposed rule change is Section 6(b)(5) of the Securities Exchange Act of 1934 (the ''Act''),[5] which requires the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the proposed rule meets these requirements in that it promotes efficiency in the market, and increases the speed of execution and likelihood that a routable order will be filled at the best price possible. In this regard, NASDAQ notes that simultaneous execution minimizes the market impact a routable order has on the markets under the current multi-step execution and routing process, thus improving fill rates. Accordingly, the proposed rule change will serve to improve execution quality for investors sending their routable orders to NASDAQ.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

[5] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2012–071 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–2012–071. 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. The text of the proposed rule change is available on the Commission's Web site at *http://www.sec.gov.* 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–2012–071, and should be submitted on or before July 20, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–15955 Filed 6–28–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67248; File No. SR–NYSEArca–2012–19]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Amend Commentary .01 to NYSE Arca Rule 6.35

June 25, 2012.

I. Introduction

On March 9, 2012, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to allow certain cross trades effected on the trading floor to count toward a market maker's in-appointment trading requirement and to make certain non-substantive changes to its rules. The proposed rule change was published for comment in the **Federal Register** on March 28, 2012.[3] The Commission received no comment letters on the proposed rule change. On

[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 66642 (March 22, 2012), 77 FR 18875 (''Notice'').

May 8, 2012, the Commission extended the time period for Commission action to June 26, 2012.[4] On June 13, 2012, the Exchange filed Amendment No. 1 to the proposed rule change.[5] This order approves the proposed rule change, as modified by Amendment No. 1 thereto.

II. Description of the Proposal

Under NYSE Arca Rule 6.35, a market maker is required to effect at least 75% of its trading activity (measured in terms of contract volume per quarter) in classes within its appointment. Commentary .01 to NYSE Arca Rule 6.35 clarifies that a market maker's trades effected on the trading floor to accommodate cross trades executed pursuant to NYSE Arca Rule 6.47 do not count for or against the market maker's 75% requirement, regardless of whether the trades are in issues within or without the market maker's appointment. The Exchange proposes to amend Commentary .01 to NYSE Arca Rule 6.35 to allow a market maker's trades effected on the trading floor to accommodate cross trades executed pursuant to NYSE Arca Rule 6.47 to count toward the market maker's 75% requirement, regardless of whether the trades are in issues within or without the market maker's appointment.

Specifically, the Exchange asserts that the proposed rule change would not diminish a market maker's obligation when trading in open outcry or when trading electronically. The Exchange states that whenever market makers trade in classes of options outside of their appointment, they must fulfill the same obligations as they do in their appointed classes. The Exchange also states that, when trading in open outcry in option classes outside of their appointment, market makers may not engage in transactions that are disproportionate in relation to or in derogation of the performance of their obligations in their appointed classes. In addition, while all option classes listed on the Exchange have appointed market makers, not all of those appointed market makers are located on the trading floor, and therefore market makers may be called upon to provide liquidity via open outcry in issues outside of their appointment. According to the Exchange, the proposed rule change will thus help to encourage market maker participation in open outcry, which will promote liquidity and price improvement on the Exchange. The Exchange also notes that the proposed rule change is only applicable to trades where a market maker is trading with a floor broker representing agency orders, and not when a market maker is trading with another market maker. Finally, the Exchange states its belief that the proposed rule change could lead to a decrease in internalization of orders because of the potential for greater participation by competing market makers on open outcry trades.

In addition, the Exchange proposes to make non-substantive changes to NYSE Arca Rules 6.35, 6.37, 6.84, and 10.12. Specifically, the Exchange proposes to replace the term ''Primary Appointment,'' which is not a defined term, with the word ''appointment'' as it is used elsewhere in NYSE Arca Rule 6.35.

III. Discussion and Commission Findings

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[6] Specifically, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[7] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange proposes to allow a market maker's trades effected on the trading floor to accommodate cross trades executed pursuant to NYSE Arca Rule 6.47 to count toward the 75% in-appointment requirement, regardless of whether the trades are in issues within or without the market maker's appointment. The Commission believes that the proposal is consistent with the Act. According to the Exchange, while all option classes listed on the Exchange have appointed market makers, not all of those market makers are located on the trading floor. Thus, at times the Exchange may need to call upon a market maker to provide liquidity via open outcry in issues outside of the market maker's appointment. The Commission notes that the proposed rule change may provide an incentive for market makers to provide liquidity to the trading floor. Market makers may be encouraged to increase participation in open outcry trading, because the trades effected on the trading floor to accommodate cross trades executed pursuant to NYSE Arca Rule 6.47 will be counted towards a market maker's 75% in-appointment requirement. Greater market maker participation in cross trades executed pursuant to NYSE Arca Rule 6.47 may also present opportunities for price improvement on the trading floor.[8]

The Commission notes that whenever market makers enter the trading crowd for a class of options in which they do not hold an appointment in other than a floor brokerage capacity, they must fulfill the market maker obligations established by Exchange rules.[9] In addition, when present anywhere on the options trading floor, with regard to all securities traded on the trading floor and not just those to which they are appointed, market makers are expected to undertake the obligations of a market maker in response to a demand from a trading official.[10] Also, with respect to classes of option contracts outside of their appointment, market makers should not engage in transactions for an account in which they have an interest that are disproportionate in relation to, or in derogation of, the performance of their obligations with respect to those classes within their appointment.[11]

Further, the Commission believes that the proposal to replace the undefined term ''Primary Appointment'' with the term ''appointment'' is consistent with the Act because using consistent terminology should provide clarity and reduce confusion with respect to the application of Exchange rules regarding market makers.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[12] that the proposed rule change (SR–NYSEArca–2012–19), as modified by Amendment No. 1 thereto, be, and hereby is, approved.

[4] *See* Securities Exchange Act Release No. 66945 (May 8, 2012), 77 FR 28413 (May 14, 2012).

[5] In Amendment No. 1, the Exchange made a technical change to Exhibit 5 and provided additional justifications for the proposed rule change. Because Amendment No. 1 does not materially alter the substance of the proposed rule change, Amendment No. 1 is not subject to notice and comment.

[6] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[7] 15 U.S.C. 78f(b)(5).

[8] In this regard, the Exchange notes that the proposal is applicable to trades where a market maker is trading with a floor broker representing agency orders, and not when a market maker is trading with another market maker.

[9] *See* NYSE Arca Rules 6.37(c) and 6.37A(d).

[10] *See id.*

[11] *See id.*

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–15938 Filed 6–28–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67252; File No. SR–NYSEArca–2012–05]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Change Adding New Paragraph (cc) to NYSE Arca Options Rule 6.62 To Provide for a Post No Preference Light Only Quotation

June 25, 2012.

I. Introduction

On May 3, 2012, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to add new paragraph (cc) to NYSE Arca Options Rule 6.62 to provide for a Post No Preference Light Only Quotation (''PNPLO Quotation''). The proposed rule change was published for comment in the **Federal Register** on May 11, 2012.[3] The Commission received no comments on the proposal. This order approves the proposed rule change.

II. Description of the Proposal

The Exchange has proposed to provide a new quotation type—the PNPLO Quotation. The PNPLO Quotation would be an electronic Market Maker [4] quotation that, upon initial entry into the Exchange's trading system, would only be eligible to execute against displayed liquidity on Arca's Consolidated Book.[5] If a PNPLO Quotation, upon entry, would: (1) Execute exclusively against non-displayed liquidity on the Consolidated Book, it would be rejected; (2) execute against both displayed and non-displayed liquidity on the Consolidated Book, it would immediately execute against such displayed liquidity, but not against the non-displayed liquidity, and any remaining size would be rejected; (3) execute exclusively against displayed liquidity on the Consolidated Book, it would immediately execute and any remaining size would be placed on the Consolidated Book and treated as a standard Market Maker quotation; and (4) not execute against either displayed or non-displayed liquidity, it would be placed on the Consolidated Book and treated as a standard Market Maker quotation.[6] The entry of a PNPLO Quotation would cause the automatic removal of the pre-existing quotation(s) of a Market Maker, regardless of whether the PNPLO Quotation is accepted or rejected by the NYSE Arca System.[7] Accordingly, in instances where the PNPLO Quotation is rejected by the system because of the presence of otherwise marketable non-displayed interest, the Market Maker would be required to re-enter a quotation for purposes of satisfying any applicable quoting obligations under NYSE Arca Options Rule 6.37B.[8]

The PNPLO Quotation may only be submitted for options in penny pilot issues.[9] On the Exchange, penny pilot issues are subject to a make/take fee structure, under which Market Makers receive credits for posting liquidity and incur fees for taking liquidity.[10] By preventing interactions with resting, non-displayed liquidity through use of the PNPLO Quotation, Market Makers in penny pilot issues would be able to avoid incurring unexpectedly the fees associated with such interactions. The Exchange notes that this is desirable for Market Makers because it is difficult for them to account for this risk of interacting with non-displayed liquidity in their quoting models.[11]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[12] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[13] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and not be designed to permit unfair discrimination between customers, issuers, brokers or dealers.

The Exchange noted that the quoting algorithms of Market Makers may not be able to account accurately for the risk of interacting with resting, non-displayed liquidity in penny pilot issues and the related take fees. The Exchange represents that this challenge may result in Market Makers widening their quotes in penny pilot classes.[14] The Exchange further represents that use of the PNPLO Quotation should allow Market Makers to better control their execution costs by avoiding unexpected take fees related to executions with resting, non-displayed liquidity in penny pilot issues. This cost certainty, according to the Exchange, could lead to narrower quote widths in penny pilot issues, thereby improving the Exchange's market and benefiting investors. Additionally, if the PNPLO Quotation is rejected by the NYSE Arca system because of the presence of otherwise marketable non-displayed interest, the Market Maker would be required to re-enter a quotation for purposes of satisfying any applicable quoting obligations under NYSE Arca Options Rule 6.37B. For these reasons, the Commission believes that the proposed PNPLO Quotation is consistent with Section 6(b)(5) of the Exchange Act as it is designed to remove impediments to and perfect the mechanisms of a free and open market

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 66937 (May 7, 2012), 77 FR 27820 (May 11, 2012) (''Notice'').

[4] *See* NYSE Arca Options Rule 6.32 (defining ''Market Maker'').

[5] *See* new NYSE Arca Options Rule 6.62(cc); *see also* NYSE Arca Options Rule 6.1(b)(37) (defining ''Consolidated Book'').

[6] *See* new NYSE Arca Options Rule 6.62(cc).

[7] *See supra* note 3, at 27821.

[8] *See id.*

[9] *See* new NYSE Arca Options Rule 6.62(cc); *see also* Securities Exchange Act Release Nos. 55156 (January 23, 2007), 72 FR 4759 (February 21, 2007) (order approving penny pilot program); 56568 (September 27, 2007), 72 FR 56422 (October 3, 2007) (order approving expansion and extension of penny pilot); 59628 (March 26, 2009), 74 FR 15025 (April 2, 2009) (notice of extension of penny pilot); 60224 (July 1, 2009), 74 FR 32991 (July 9, 2009) (notice of extension of penny pilot); 60711 (September 23, 2009), 74 FR 49419 (September 28, 2009) (order partially approving expansion of penny pilot); 61061 (November 24, 2009), 74 FR 62857 (December 1, 2009) (order partially approving expansion of penny pilot); 63376 (November 24, 2010), 75 FR 75527 (December 3, 2010) (notice of extension of penny pilot); 65977 (December 15, 2011), 76 FR 79234 (December 21, 2011) (notice of extension of penny pilot).

[10] *See supra* note 3, at 27821.

[11] *See id.*

[12] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 15 U.S.C. 78f(b)(5).

[14] *See supra* note 3, at 27821.

and a national market system, and in general to protect investors and the public interest.

The Commission also believes that the proposed rule change is not unfairly discriminatory. Currently, market participants including Market Makers can achieve functionality similar to the PNPLO Quotation through use of the PNP-Light Order, which is a non-routable order type that is only eligible to execute against displayed liquidity.[15] The Exchange is proposing a similar functionality for use by Market Makers when quoting. The PNPLO Quotation would be available for use by all Market Makers quoting in the penny pilot classes on the Exchange.[16]

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[17] that the proposed rule change (SR–NYSEArca–2012–05) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–15940 Filed 6–28–12; 8:45 am]

BILLING CODE 8011–01–P

[15] *See* NYSE Arca Options Rule 6.62(v).

[16] *See supra* note 3, at 27821.

[17] 15 U.S.C. 78s(b)(2).

[18] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA 2012–0002]

Privacy Act of 1974, as Amended; Computer Matching Program (SSA/Railroad Retirement Board (SSA/RRB))—Match Number 1308

AGENCY: Social Security Administration (SSA).

ACTION: Notice of a renewal of an existing computer matching program that will expire on September 30, 2012.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces a renewal of an existing computer matching program that we are currently conducting with RRB.

DATES: We will file a report of the subject matching program with the Committee on Homeland Security and Governmental Affairs of the Senate; the Committee on Oversight and Government Reform of the House of Representatives; and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

ADDRESSES: Interested parties may comment on this notice by either telefaxing to (410) 966–0869 or writing to the Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, 617 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: The Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, as shown above.

SUPPLEMENTARY INFORMATION:

A. General

The Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the conditions under which computer matching involving the Federal government could be performed and adding certain protections for persons applying for, and receiving, Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such persons.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain approval of the matching agreement by the Data Integrity Boards of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating, or denying a person's benefits or payments.

B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of our computer matching programs comply with the requirements of the Privacy Act, as amended.

Mary A. Zimmerman,

Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

Notice of Computer Matching Program, SSA With the Railroad Retirement Board (RRB)

A. Participating Agencies

SSA and RRB.

B. Purpose of the Matching Program

This computer matching agreement sets forth the terms, conditions, and safeguards under which RRB will disclose to us information necessary to verify an individual's self-certification of eligibility for Extra Help with Medicare Prescription Drug Plan Costs program (Extra Help). It will also enable us to identify individuals who may qualify for Extra Help as part of our Medicare outreach efforts.

C. Authority for Conducting the Matching Program

The legal authority for us to conduct this matching activity is contained in section 1860D–14 (42 U.S.C. 1395w–114) and section 1144 (42 U.S.C. 1320b–14) of the Act.

D. Categories of Records and Persons Covered by the Matching Program

1. Systems of Records

RRB will provide us with data from its RRB–22 and RRB–20 systems of records.

We will match RRB's data with our Medicare Database (MDB) File, system of records No. 60–0321

2. Number of Records and Frequency of Matching

RRB will transmit its annuity payment data monthly. The file will consist of approximately 560,000 electronic records.

RRB will transmit its Post Entitlement System file daily. The number of records will differ each day, but consist of approximately 3,000 to 4,000 records each month.

RRB will transmit files on all Medicare eligible Qualified Railroad Retirement Beneficiaries from its RRB–20 and RRB–22 systems of records to report address changes and subsidy changing event information monthly. The file will consist of approximately 520,000 electronic records. The number of people who apply for Extra Help determines in part the number of records matched.

Our comparison file will consist of approximately 47.5 million records obtained from MDB.

3. Specified Data Elements

We will conduct the computer match using each individual's Social Security Number, name, date of birth, RRB claim number, and RRB annuity payment amount in both RRB and MDB files.

E. Inclusive Dates of the Matching Program

The effective date of this matching program is October 1, 2012; if the following notice periods have lapsed: 30 days after publication of this notice in the **Federal Register** and 40 days after notice of the matching program is sent to Congress and OMB. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 2012–15959 Filed 6–28–12; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 7937]

Culturally Significant Objects Imported for Exhibition Determinations: ''Regarding Warhol: Sixty Artists, Fifty Years''

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, and 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 ''Regarding Warhol: Sixty Artists, Fifty Years,'' 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 Metropolitan Museum of Art, New York, New York from on or about September 11, 2012, until on or about December 31, 2012; then at the Andy Warhol Museum in Pittsburgh, Pennsylvania from on or about February 2, 2013 to on or about April 28, 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 Ona M. Hahs, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6473). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: June 25, 2012.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2012–16010 Filed 6–28–12; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Two New Ohio River Bridge Crossings in Kentucky and Indiana

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FWHA that are final within the meaning of 23 U.S.C. 139(*l*)(1). The actions relate to a proposed highway project, the Louisville-Southern Indiana Ohio River Bridges Project, which would provide a new Ohio River Bridge carrying Interstate 65 (I–65) between Louisville, Kentucky and Jeffersonville, Indiana immediately upstream and adjacent to the existing I–65 bridge, and a second new Ohio River Bridge located approximately eight miles upstream of the existing I–65 crossing, providing a connection between KY 841 (Gene Snyder Freeway) in eastern Jefferson County, Kentucky and SR 265 in eastern Clark County, Indiana. Both Bridges are located in Jefferson County, Kentucky and Clark County, Indiana.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 26, 2012. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA: Mr. Duane Thomas, Project Manager, Federal Highway Administration—Kentucky Division, John C. Watts Federal Building, 330 W. Broadway, Frankfort, KY 40601; telephone—502–223–6720; email—*Duane.Thomas@dot.gov*. For Kentucky: Mr. Gary Valentine, Project Manager, Kentucky Transportation Cabinet, 8310 Westport Road, Louisville, KY 40242; telephone—502–210–5453; email—*Gary.Valentine@ky.gov*. For Indiana: Mr. Ron Heustis, Project Manager, Indiana Department of Transportation, 100 N. Senate Avenue, IGCN925, Indianapolis, Indiana 46204.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA has taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing approvals for the following highway project in the Commonwealth of Kentucky and the State of Indiana: The Louisville-Southern Indiana Ohio River Bridges Project. The proposed action will improve cross-river mobility between Jefferson County, Kentucky and Clark County, Indiana, by constructing a new Ohio River Bridge carrying I–65 between Louisville, Kentucky and Jeffersonville, Indiana immediately upstream and adjacent to the existing I–65 bridge (the ''Downtown Crossing''), and a second new Ohio River Bridge located approximately eight miles upstream of the existing I–65 crossing, providing a connection between KY 841 (Gene Snyder Freeway) in eastern Jefferson County, Kentucky and SR 265 in eastern Clark County, Indiana (the ''East End Crossing''), and reconstructing the highway approaches to both the Downtown Crossing and the East End Crossing in Kentucky and Indiana. The Downtown Crossing will provide for a new Ohio River Bridge to carry northbound I–65 traffic and the reconstruction of the existing I–65 Kennedy Bridge to carry southbound traffic. The Downtown Crossing also will include the reconstruction of the Kennedy Interchange (where I–65, I–64, and I–71 converge in Kentucky just south of the Kennedy Bridge) in its existing location, and the reconstruction of the I–65 approach in Indiana. In total, reconstruction of approximately 2.8 miles of I–65 is involved. The East End Crossing will provide for a new Ohio River Bridge and approach roadways connecting the Gene Snyder Freeway (KY 841) in Kentucky to the Lee Hamilton Highway (IN–265) in Indiana. The East End Crossing will extend from the I–71/Gene Snyder Freeway interchange in Kentucky to the Lee Hamilton Highway north of S.R. 62 in Indiana for a total length of approximately 8.1 miles. The East End Crossing also will include new

interchanges at S.R. 62/Port Road and Utica-Old Salem Road.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Supplemental Final Environmental Impact Statement (SFEIS) for the project, approved on April 20, 2012, in the FHWA Revised Record of Decision (Revised ROD) issued on June 20, 2012, and in other documents in the FHWA administrative record. A Final Environmental Impact Statement (FEIS) and Section 4(f) Evaluation were previously issued for the Project on April 8, 2003 and were followed by the issuance of a Record of Decision on September 6, 2003. The SFEIS, Revised ROD, and other project records are available by contacting FHWA, the Kentucky Transportation Cabinet, or the Indiana Department of Transportation at the addresses provided above. The SFEIS and Revised ROD can be viewed and downloaded from the project Web site at *www.kyinbridges.com,* or viewed at public libraries in the project area.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Farmland Protection Policy ACT (FPPA) [7 U.S.C. 4201–4209].

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) et seq.]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–470(ll)]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c).

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; Uniform Relocation Assistance and Real Property Act of 1970 (42 U.S.C. 4601 *et seq.,* Pub. L. 91–646) as amended by the Uniform Relocation Act of 1987 (Pub. L. 100–17); Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations, February 11, 1994..

7. *Wetlands and Water Resources:* Clean Water Act (Section 404, Section 401, Section 319) [33 U.S.C. 1251–1377]; Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(6)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Emergency Wetlands Resources Act, [16 U.S.C. 3921, 3931]; Wetlands Mitigation [23 U.S.C. 103(b)(6)(M) and 133(b)(11)]; Flood Disaster Protection Act, 42 U.S.C. 4001–4128.

8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Issued on: June 20, 2012.

Jose Sepulveda,

FHWA Division Administrator, Frankfort, KY 40601.

[FR Doc. 2012–15931 Filed 6–28–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Availability of a Draft Environmental Impact Statement, for the Chicago, IL to St. Louis, MO High Speed Rail Corridor Program

AGENCY: Federal Railroad Administration (FRA) United State Department of Transportation (DOT).

ACTION: Notice of availability of draft environmental impact statement.

SUMMARY: FRA is issuing this notice to advise the public that a Draft Environmental Impact Statement (Draft EIS) has been prepared for the Chicago, Illinois to St. Louis, Missouri High Speed Rail Corridor Program. The Draft EIS includes a Tier 1 corridor-level evaluation and a Tier 2 project-level evaluation for the Springfield Rail Improvements Project. FRA is the lead federal agency and the Illinois Department of Transportation (IDOT) is the lead state agency for the environmental review process.

IDOT proposes to improve high speed passenger rail service between Chicago, Illinois and St. Louis, Missouri, including the rail lines through Springfield, Illinois. The proposed including the development of double tracking along the existing Amtrak railroad corridor to improve high-speed passenger service reliability and safety, and to increase the number of trips between Chicago and St. Louis, as well as including improvements to railroad crossings, signals, and stations.

The Draft EIS presents the Program's purpose and need, identifies all reasonable alternatives, describes the affected environment, analyzes the potential environmental impacts of all the reasonable alternatives and the no action alternative, and identifies appropriate mitigation measures to minimize the potential environmental impacts.

DATES: Written comments on the 45-day Draft EIS should be provided to IDOT on or before Monday, August 20th, 2012. Public hearings are scheduled to occur in August, 2012 in Chicago, IL, Springfield, IL, Alton, IL, Joliet, IL, and Bloomington, IL at times and dates to be announced on the High Speed Rail Program's Web site at *http://www.idothsr.org/*.

ADDRESSES: Written comments on the Draft EIS should be sent directly to Joseph Shacter, Illinois Department of Transportation, 100 West Randolph Street, Suite 6–600, Chicago, Illinois 60601, or submitted through the High Speed Rail Program's Web site at *http://www.idothsr.org/*, or via email with the subject line ''Draft EIS'' to *Joseph.Shacter@Illinois.gov*. Comments may also be provided orally or in writing at the public hearings.

FOR FURTHER INFORMATION CONTACT: Andrea E. Martin, Environmental Protection Specialist, Office of Railroad Policy and Development, Federal Railroad Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., MS–20, Washington, DC 20590; email: *andrea.martin@dot.gov*; telephone: 202–493–6201 or Joseph Shacter, Illinois Department of Transportation, 100 West Randolph Street, Suite 6–600, Chicago, Illinois 60601; email: *Joseph.Shacter@Illinois.gov*; telephone: 312–793–2116.

SUPPLEMENTARY INFORMATION: The proposed High Speed Rail Program would include the development of double track along the existing Amtrak railroad corridor between Chicago, Illinois and St. Louis, Missouri to improve high-speed passenger service reliability and safety, and to increase the number of trips, as well as include improvements to railroad crossings, signals, and stations. These proposed improvements are in addition to those improvements associated with the

January 8, 2004 Record of Decision (ROD) for the Chicago-St. Louis High-Speed Rail Program and the 2011 Environmental Assessment (EA)/ Finding of No Significant Impacts (FONSI) concerning improvements to the existing track and the construction of additional side tracks. Implementation of those improvements is currently underway.

The current Chicago to St. Louis Corridor operates on a single track that is shared by both traditional freight and Amtrak passenger rail service. The EIS identifies and evaluates the environmental and transportation impacts associated with route alternatives and corridor-wide capacity enhancements, including double-track.

IDOT and FRA are using a tiered environmental process to evaluate the proposed Program. A tiered environmental process is a phased environmental review used in the development of complex projects. Under this process, the Draft EIS addresses broad, corridor-level issues and alternatives. Tier 2 environmental documents address individual component projects of the Selected Alternative carried forward from the Tier 1 environmental process. Concurrently with this Tier 1 study of the full Chicago to St. Louis Corridor, IDOT and FRA are conducting a Tier 2 analysis for the portion of the High Speed Rail corridor in Springfield, IL.

The corridor alternatives retained in the Draft EIS are the result of a screening process that used several evaluation criteria developed specifically for the Program. The screening criteria determined the route options that should be eliminated from further consideration. The four alternatives and no-build retained utilize combinations of the existing Amtrak passenger rail routes between Chicago and Joliet, Illinois, the City of Springfield, Illinois, and approaching St. Louis, Missouri and allow for eight daily round trips at 110 miles per hour (mph) on two tracks.

Other improvements identified in the Draft EIS include sidings, pedestrian grade separations at the stations, and grade separations along major roadways. After the public comment period for the Draft EIS and following completion of the Final EIS, individual component projects along the corridor would be advanced and studied in greater detail as Tier 2 project-level evaluations in the tiered environmental review process.

A Tier 2 project-level evaluation for improvements in Springfield is also included within the Draft EIS. The Springfield Rail Improvements Project has been advanced concurrently as a component of the overall corridor program. The Tier 2 evaluation considers the environmental and transportation impacts of rail routes through the City of Springfield, Illinois; addressing safety, noise, and traffic delays that would result from increased volumes of both passenger and freight rail traffic on the three north-south rail corridors that pass through the City of Springfield.

This Draft EIS has been prepared by FRA and IDOT consistent with the provisions of Section 102(2)(c) of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.), the Council on Environmental Quality (CEQ) regulations implementing NEPA (40 CFR part 1500 et seq.), and FRA's Procedures for Considering Environmental Impacts (64 FR 28545; May 26, 1999).

Copies of the Draft EIS are available online at FRA's Web site: *http://www.fra.dot.gov* and IDOT's Web site: *http://www.idothsr.org/*; the document is also available for viewing at the following locations along the Corridor:

- Hayner Library, 326 Belle Street, Alton, IL 62002
- Atlanta Public Library District, 100 Race Street, Atlanta, IL 61723
- Auburn Public Library, 338 West Jefferson Street, Auburn, IL 62615
- Bloomington Public Library, 205 East Olive Street, Bloomington, IL 61701
- Blue Island Library, 2433 York Street, Blue Island, IL 60406
- Fossil Ridge Public Library, 386 West Kennedy Road, Braidwood, IL 60408
- Brighton Memorial Public Library, 110 North Main Street, Brighton, IL 62012
- Carlinville Public Library, 510 North Broad Street, Carlinville, IL 62626
- Chatham Area Public Library, 600 East Spruce Street, Chatham, IL 62629
- Chenoa Public Library District, 211 South Division Street, Chenoa, IL 61726
- Chicago Public Library-Harold Washington, 400 South State Street, Chicago, IL 60605
- Prairie Creek Public Library, 501 Carriage House Lane, Dwight, IL 60420
- East Alton Public Library, 250 Washington Avenue, East Alton, IL 62024
- East St. Louis Public Library, 5300 State Street, East St. Louis, IL 62203
- Elkhart Public Library District, 121 East Bohan Street, Elkhart, IL 62634
- Manhattan-Elwood Public Library District, 240 Whitson Street, Manhattan, IL 60442
- Frankfort Public Library District, 21119 South Pfeiffer Road, Frankfort, IL 60423
- Girard Township Library, 201 West Madison Street, Girard, IL 62640
- Six Mile Regional Library District, 2001 Delmar Avenue, Granite City, IL 62040
- Hartford Public Library District, 143 West Hawthorne Street, Hartford, IL 62048
- Joliet Public Library, 150 North Ottawa Street, Joliet, IL 60432
- Lemont Public Library, 50 East Wend Street, Lemont, IL 60439
- Lexington Public Library District, 207 South Cedar Street, Lexington, IL 61753
- Lincoln Public Library, 725 Peking Street, Lincoln, IL 62656
- Lockport Public Library, 121 East 8th Street, Lockport, IL 60441
- Madison Public Library, 1700 Fifth Street, Madison, IL 62060
- Mount Hope-Funks Grove Public Library, 111 South Hamilton Street, McLean, IL 61754
- Midlothian Public Library, 14701 South Kenton Avenue, Midlothian, IL 60445
- Mokena Community Public Library, 11327 West 195th Street, Mokena, IL 60448
- New Lenox Public Library, 120 Veterans Parkway, New Lenox, IL 60451
- Normal Public Library, 206 West College Avenue, Normal, IL 61761
- Acorn Public Library District, 15624 South Central Avenue, Oak Forest, IL 60452
- Odell Public Library District, 301 East Richard Street, Odell, IL 60460
- Orland Park Public Library, 14921 South Ravinia Avenue, Orland Park, IL 60462
- Pontiac Public Library, 211 East Madison Street, Pontiac, IL 61764
- William Leonard Public Library District, 13820 Central Park Avenue, Robbins, IL 60472
- Sherman Public Library District, 2100 East Andrew Road, Sherman, IL 62684
- Springfield Lincoln Library, 326 South Seventh Street, Springfield, IL 62701
- St. Louis Central Library, 1310 Olive Street, St. Louis, MO 63103
- Summit Public Library District, 6233 South Archer Road, Summit, IL 60501
- Tinley Park Public Library, 7851 Timber Drive, Tinley Park, IL 60477
- Towanda District Library, 301 South Taylor Street, Towanda, IL 61776
- Venice Public Library, 325 Broadway Avenue, Venice, IL 62090
- Grand Prairie of the West Public Library District, 142 West Jackson Street, Virden, IL 62690
- Williamsville Public Library, 141 West Main Street, Williamsville, IL 62693

- Wilmington Public Library District, 201 South Kankakee Street, Wilmington, IL 60481
- Wood River Public Library, 326 East Ferguson Avenue, Wood River, IL 62095

Issued in Washington, DC on June 25, 2012.

Corey W. Hill,

Director, Rail Project Development and Delivery.

[FR Doc. 2012–15993 Filed 6–28–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35640]

Wyoming Connect Railroad LLC—Acquisition and Operation Exemption—Union Pacific Railroad Company

Wyoming Connect Railroad LLC (WCR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire by lease from Union Pacific Railroad Company and to operate approximately 18.5 miles of rail line between milepost 0.0 at or near Yoder and milepost 18.5 at or near South Torrington, in Goshen County, Wyo.

The transaction is scheduled to be consummated on or after July 15, 2012 (30 days after the notice of exemption was filed).

WCR certifies that its projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class III rail carrier and will not exceed $5 million.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than July 6, 2012 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35640, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Thomas F. McFarland, 208 South LaSalle St., Suite 1890, Chicago, IL 60604.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: June 21, 2012.

By the Board.

Richard Armstrong,

Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Unit.

[FR Doc. 2012–15798 Filed 6–28–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35641]

Sisseton Milbank Railroad Company—Acquisition and Operation Exemption—SLA Property Management Limited Partnership and Sisseton Milbank Railroad, Inc.

Sisseton Milbank Railroad Company (SMRC), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire from SLA Property Management Limited Partnership and Sisseton Milbank Railroad, Inc., their interests in, and to operate, an approximately 37.1-mile rail line between approximate railroad milepost 0.9 in or near Milbank and approximate railroad milepost 38.0 in or near Sisseton, in Grant and Roberts Counties, S.D.

This transaction is related to a concurrently filed petition for exemption in Docket No. FD 35642, *Twin Cities & Western Railroad Company, the Estate of Douglas M. Head and the DMH Trust fbo Martha M. Head—Continuance in Control Exemption—Sisseton Milbank Railroad Company,* in which Twin Cities & Western Railroad Company (TCW), the Estate of Douglas M. Head (Estate), and the DMH Trust fbo Martha M. Head (Trust) seek Board approval to continue in control of SMRC upon SMRC's becoming a Class III rail carrier.[1]

The parties expect to consummate the transaction on or after July 16, 2012.[2]

SMRC certifies that its projected annual revenues as a result of this transaction do not exceed those that would qualify it as a Class III rail carrier and will not exceed $5 million.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than July 6, 2012 (at least seven days before the exemption becomes effective).

An original and ten copies of all pleadings, referring to Docket No. FD 35641, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Rose-Michele Nardi, Weiner Brodsky Sidman Kider, PC, 1300 Nineteenth Street NW., Fifth Floor, Washington, DC 20036–1609.

Board decisions and notices are available on our Web site at ''*www.stb.dot.gov.*''

Decided: June 26, 2012.

By the Board.

Rachel D. Campbell,

Director, Office of Proceedings.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2012–15957 Filed 6–28–12; 8:45 am]

BILLING CODE 4915–01–P

[1] SMRC states that it is a wholly owned subsidiary of TCW, which is currently controlled by the Estate, and that it is anticipated that the TCW stock held by the Estate will be distributed to the Trust in the near future.

[2] SMRC indicates that, because it is likely that the acquisition transaction will close prior to the Board's issuance of a decision on TCW's continuance-in-control petition, TCW has entered into a Voting Trust Agreement pursuant to 49 CFR part 1013, under which the shares of SMRC will be deposited in a voting trust.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. MCF 21046]

Professional Transportation, Inc.—Asset Acquisition—CUSA ES, LLC and CUSA CSS, LLC

AGENCY: Surface Transportation Board.

ACTION: Notice of Finance Application.

SUMMARY: Professional Transportation, Inc. (PTI or Applicant), an interstate passenger motor carrier (MC–217444), has filed an application under 49 U.S.C. 14303 to acquire the assets of two interstate motor passenger common carrier subsidiaries of noncarrier Coach America Holdings, Inc.—CUSA ES, LLC (MC–463168) and CUSA CSS, LLC (MC–522544) (collectively, Coach America Subsidiaries). On June 5, 2012, Michael Yusim, an individual, filed a letter in opposition, asserting that the public interest would not be served by allowing the transaction to proceed without certain Department of Labor proceedings first being completed. A copy of this notice will be served on Mr. Yusim. Persons wishing to oppose the application must follow the rules set forth at 49 CFR 1182.5 and 1182.8.

DATES: Comments must be filed by August 13, 2012. Applicant may file a reply to any comments by August 28, 2012.

ADDRESSES: Send an original and 10 copies of any comments referring to Docket No. MCF 21046 to: Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, send one copy of comments to Applicant's representative: Andrew K. Light, Scopelitis, Garvin, Light, Hanson & Feary, P.C., 10 W. Market Street, Suite 1500, Indianapolis, IN 46204.

FOR FURTHER INFORMATION CONTACT: Marc Lerner, (202) 245–0390. Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Coach America Subsidiaries are currently involved in proceedings instituted under Chapter 11 of the Bankruptcy Code, having filed a voluntary petition for relief with the U.S. Bankruptcy Court for the District of Delaware on January 3, 2012, and a motion to sell substantially all of their assets and effectively to liquidate on January 13, 2012. According to Applicant, the proposed transaction will be completed pursuant to 11 U.S.C. 105(a), 363 and 365 and Fed. R. Bankr. P. 2002, 6004, 6006, and 9014, and the bankruptcy court's order entered on May 25, 2012, authorizing and approving (1) the sale of substantially all of the assets of debtors CUSA ES, LLC and CUSA CSS, LLC free and clear of liens, claims, and encumbrances, and (2) the assumption and assignment of certain executory contracts and unexpired leases.

As indicated, Michael Yusim has filed a letter in opposition to the application by PTI to acquire the assets of the two Coach America Subsidiaries. The basis for his opposition relates to two cases alleging that his employer, an entity named Midnight Sun Tours, Inc. (Midnight Sun), a wholly owned subsidiary of the Coach America bus companies in bankruptcy, discriminated against drivers who accurately reported their hours on duty. According to Mr. Yusim, the two cases are pending before the Secretary of Labor (Secretary), but have been stayed by the bankruptcy court. Mr. Yusim requests that the Board disallow the sale of any subsidiaries of Coach America until the Secretary is allowed to hear the two cases.

Because we have received a timely comment in opposition to the application, we will not grant tentative authority under 49 CFR 1182.4(b). *See* 49 CFR 1182.6(a). Instead, we will institute a proceeding to address this matter, as well as to determine the merits of the application pursuant to 49 U.S.C. 14303. Comments and responses are to be submitted as ordered below. *See* 49 CFR 1182.5 and 1182.6.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

This decision will not significantly affect either the quality of the human environment or the conservation of energy resources.

It is ordered:

1. Comments must be filed by August 13, 2012. Applicant may file a reply to any comments by August 28, 2012.

2. This notice will be effective on its date of service.

3. A copy of this notice will be served on: (1) The U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 950 Pennsylvania Avenue NW., Washington, DC 20530; (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590; (4) the Federal Trade Commission, Bureau of Competition, Premerger Notification Office, 600 Pennsylvania Avenue NW., Washington, DC 20580; and (5) Michael Yusim, 7499 Eagle Point Drive, Delray Beach, FL 33446.

Decided: June 25, 2012.

By the Board, Chairman Elliott, Vice Chairman Mulvey, and Commissioner Begeman.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2012–16046 Filed 6–28–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35634]

Midwest Rail, LLC d/b/a Toledo, Lake Erie and Western Railway—Lease and Operation Exemption—Norfolk Southern Railway Company

Under 49 CFR 1011.7(a)(2)(x)(A), the Director of the Office of Proceedings (Director) is delegated the authority to determine whether to issue notices of exemption under 49 U.S.C. 10502 for lease and operation transactions under 49 U.S.C. 10902. However, the Board reserves to itself the consideration and disposition of all matters involving issues of general transportation importance. 49 CFR 1011.2(a)(6). Accordingly, the Board revokes the delegation to the Director with respect to issuance of the notice of exemption for lease and operation of the rail line at issue in this case. The Board determines that this notice of exemption should be issued, and does so here.

Midwest Rail, LLC d/b/a Toledo, Lake Erie and Western Railway (Toledo), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease from Norfolk Southern Railway Company (NSR) and operate a 1.8-mile line of railroad between milepost TS 13.2 near Maumee, Ohio and milepost TS 15.0 in Waterville, Ohio, (the Line). According to Toledo, Toledo and NSR have entered into a Lease Agreement (Agreement) whereby Toledo will lease the Line from NSR. The term of the lease is 10 years.

Pursuant to 49 CFR 1150.43(h), Toledo has disclosed that the Agreement contains an interchange commitment in the form of lease credits, depending on the number of carloads interchanged with NSR at milepost TS 13.2 in a given year.[1] According to Matthew Shawver, owner of Toledo, the interchange commitment will allow Toledo to ''invest in improvements on the leased line to increase traffic levels.'' [2] The Line connects only with NSR at Maumee and at Waterville with a 10-mile, stub-ended line leased and operated by Toledo.[3]

Toledo certifies that its projected annual revenues as a result of this transaction will not result in Toledo becoming a Class I or Class II rail carrier. Toledo further certifies that its projected annual revenues will not exceed $5 million.

The earliest the transaction can be consummated is July 15, 2012, the effective date of the exemption (30 days after the exemption was filed).

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Stay petitions must be filed no later than July 6, 2012 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35634, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on John D. Heffner,

[1] Concurrently with its verified notice of exemption, Toledo has filed under seal, pursuant to 49 CFR 1150.43(h)(1)(ii), a confidential, complete version of the Agreement. Toledo also filed a motion for protective order. The merits of Toledo's motion will be addressed in a separate decision.

[2] Pet. 6.

[3] *Midwest Rail d/b/a Toledo, Lake Erie and W. Ry.—Lease and Operation Exemption—Toledo, Lake Erie and W. Ry. and Museum, Inc.,* FD 35555 (STB served Oct. 14, 2011).

Strasburger & Price, LLP, 1700 K Street NW., Suite 640, Washington, DC 20006.

Board decisions and notices are available on our Web site at *www.stb.dot.gov*.

It is ordered:

1. The delegation of authority to the Director of the Office of Proceedings under 49 CFR 1011.7(a)(2)(x)(A) to determine whether to issue a notice of exemption in this proceeding is revoked.

2. This decision is effective on the date of service.

Decided: June 26, 2012.

By the Board, Chairman Elliott, Vice Chairman Mulvey, and Commissioner Begeman. Vice Chairman Mulvey approved with a separate expression.

Vice Chairman Mulvey, commenting:

Interchange commitments have the potential to limit or, in some cases, to effectively eliminate, competition between rail carriers. Because this can result in long-term harm to shippers, I believe that the Board should be carefully scrutinizing transactions that include interchange commitments. Typically, such scrutiny is not possible within the Notice of Exemption process due to its short time-frames. I have long urged the Board to require that such transactions be analyzed using more detailed processes that allow the Board to consider (1) the nature of the interchange commitment, (2) how many shippers and carloads will be impacted by the interchange commitment, and (3) what competitive routing options are being foreclosed during the term of the lease.

In this case, however, there appears to be no need for concern regarding competitive harm. Toledo has confirmed that it will not connect physically to any carrier other than NSR, the carrier from whom it is leasing the line. Although the lease contains a rental credit based on the number of cars Toledo interchanges with NSR, because Toledo physically cannot interchange cars with a third-party carrier in any event, there will be no adverse competitive impact from the interchange commitment. Accordingly, I vote to approve the Notice of Exemption process for this transaction.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2012–16003 Filed 6–28–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

Proposed Information Collections; Comment Request

AGENCY: Alcohol and Tobacco Tax and Trade Bureau; Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, we invite comments on the proposed or continuing information collections listed below in this notice.

DATES: We must receive your written comments on or before August 28, 2012.

ADDRESSES: You may send comments to Mary A. Wood, Alcohol and Tobacco Tax and Trade Bureau, at any of these addresses:

- P.O. Box 14412, Washington, DC 20044–4412;
- 202–453–2686 (facsimile); or
- *formcomments@ttb.gov* (email).

Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form or recordkeeping requirement number, and OMB number (if any) in your comment. If you submit your comment via facsimile, send no more than five 8.5 x 11 inch pages in order to ensure electronic access to our equipment.

FOR FURTHER INFORMATION CONTACT: To obtain additional information, copies of the information collection and its instructions, or copies of any comments received, contact Mary A. Wood, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044–4412; or telephone 202–453–2265.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau (TTB), as part of their continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to comment on the proposed or continuing information collections listed below in this notice, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this notice will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether this information collection is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the information collection's burden; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the information collection's burden on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide the requested information.

Information Collections Open for Comment

Currently, we are seeking comments on the following forms and recordkeeping requirements:

Title: Authorization to Furnish Financial Information and Certificate of Compliance.

OMB Control Number: 1513–0004.

TTB Form Number: 5030.6.

Abstract: The Right to Financial Privacy Act of 1978 limits access to records held by financial institutions and provides for certain procedures to gain access to the information. TTB F 5030.6 serves as both a customer authorization for TTB to receive such information and as the required certification to the financial institution.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 2,000.

Estimated Total Annual Burden Hours: 500.

Title: Formula and Process for Wine.

OMB Control Number: 1513–0010.

TTB Form Number: 5120.29.

Abstract: TTB F 5120.29 is used to determine the classification of wines for labeling and consumer protection purposes. The form describes the person filing, the type of product to be made, and any restrictions to labeling and manufacture. The form is also used to audit a product's compliance with the relevant regulations.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 600.

Estimated Total Annual Burden Hours: 1,200.

Title: Application for an Industrial Alcohol User Permit.

OMB Number: 1513–0028.

TTB Form Number: 5150.22.

Abstract: TTB F 5150.22 is used to determine the eligibility of the applicant to engage in certain operations and the extent of the operations for the production and distribution of specially denatured spirits (alcohol/rum). This form identifies the location of the premises and establishes whether the premises will be in conformity with Federal laws and regulations.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 738.

Estimated Total Annual Burden Hours: 738.

Title: Distilled Spirits Records and Monthly Report of Production Operations.

OMB Number: 1513–0047.

TTB Form Number: 5110.40.

TTB Recordkeeping Number: 5110/01.

Abstract: This information collected is used to account for a proprietor's excise tax liability, adequacy of bond coverage, and protection of the revenue. The information also provides TTB with data to analyze trends in the industry, plan efficient allocation of field resources, audit plant operations, and compile statistics for government economic analysis.

Current Actions: We are submitting this information collection as a revision. Changes in the supporting statement and form reflects changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants. The estimated number of respondents and estimated total annual burden hours remain unchanged.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1,800.

Estimated Total Annual Burden Hours: 3,600.

Title: Registration of Distilled Spirits Plants and Miscellaneous Requests and Notices for Distilled Spirits Plants.

OMB Control Number: 1513–0048.

TTB Form Number: 5110.41.

Abstract: The information provided by the applicants assists TTB in determining eligibility and providing for registration. These eligibility requirements are for persons who wish to establish distilled spirits plant operations. However, both statutes and regulations allow variances from regulations, and this information provides data to permit a variance.

Current Actions: We are submitting this information collection as a revision. Changes in the supporting statement and form reflects changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1,109.

Estimated Total Annual Burden Hours: 1,265.

Title: Letterhead Applications and Notices Relating to Wine.

OMB Control Number: 1513–0057.

TTB Recordkeeping Number: 5120/2.

Abstract: Letterhead applications and notices relating to wine are required to ensure that the intended activity will not jeopardize the revenue or defraud consumers.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1,650.

Estimated Total Annual Burden Hours: 826.

Title: Airlines Withdrawing Stock from Customs Custody.

OMB Control Number: 1513–0074.

TTB Recordkeeping Number: 5620/2.

Abstract: Airlines may withdraw tax-exempt distilled spirits, wine, and beer from Customs custody for foreign flights. The required record shows the amount of spirits and wine withdrawn, flight identification, and Customs certification. The records enable TTB to verify that tax is not due, allows spirits and wines to be traced, maintains accountability, and protects tax revenue. This collection of information is contained in 27 CFR 28.280 and 28.281.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 25.

Estimated Total Annual Burden Hours: 2,500.

Title: Alcohol, Tobacco, and Firearms Tax Returns, Claims, and Related Documents.

OMB Control Number: 1513–0088.

TTB Recordkeeping Number: 5000/24.

Abstract: TTB is responsible for the collection of the Federal excise taxes on firearms, ammunition, distilled spirits, wine, beer, various tobacco products, and cigarette papers and tubes. Alcohol, tobacco, firearms, and ammunition excise taxes, and tobacco special (occupational) taxes are required to be collected on the basis of a return. Section 5555 of title 26 of the United States Code (26 U.S.C. 5555) authorizes the Secretary of the Treasury to prescribe regulations requiring all persons liable for these taxes to prepare records, statements, or returns as necessary to protect the revenue.

Current Actions: We are submitting this information collection as a revision. Change in the supporting statement reflect changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants. The estimated number of respondents and estimated total annual burden hours remain unchanged.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for profit; Not-for-profit institutions; Individuals or households.

Estimated Number of Respondents: 503,921.

Estimated Total Annual Burden Hours: 503,921.

Title: Liquors and Articles from Puerto Rico or the Virgin Islands.

OMB Control Number: 1513–0089.

TTB Recordkeeping Number: 5530/3.

Abstract: This information collection applies to persons bringing nonbeverage

products into the United States from Puerto Rico and the Virgin Islands. These recordkeeping requirements are for the verification of claims for drawback of distilled spirits excise tax paid on nonbeverage products.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 20.

Estimated Total Annual Burden Hours: 160.

Title: Certificate of Taxpaid Alcohol.

OMB Control Number: 1513–0131.

TTB Form Number: 5100.4.

Abstract: This form is required by a Port Director of Customs and Border Patrol (Customs) to support refunding taxes paid on nonbeverage products that are exported. When the nonbeverage product is exported, the industry member submits TTB F 5100.4 and supporting documentation to TTB. TTB certifies the form and then submits it to Customs.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 10.

Estimated Total Annual Burden Hours: 1,000.

Dated: June 26, 2012.

Amy Greenberg,

Assistant Director, Regulations and Rulings Division.

[FR Doc. 2012–16008 Filed 6–28–12; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Prompt Payment Interest Rate; Contract Disputes Act

AGENCY: Bureau of the Public Debt, Fiscal Service, Treasury.

ACTION: Notice.

SUMMARY: For the period beginning July 1, 2012, and ending on December 31, 2012, the prompt payment interest rate is 1¾ per centum per annum.

ADDRESSES: Comments or inquiries may be mailed to Dorothy Dicks, Reporting Team Leader, Federal Borrowings Branch, Division of Accounting Operations, Office of Public Debt Accounting, Bureau of the Public Debt, Parkersburg, West Virginia 26106–1328. A copy of this Notice is available at *http://www.treasurydirect.gov.*

DATES: Effective July 1, 2012, to December 31, 2012.

FOR FURTHER INFORMATION CONTACT: Brant McDaniel, Manager, Federal Borrowings Branch, Office of Public Debt Accounting, Bureau of the Public Debt, Parkersburg, West Virginia 26106–1328, (304) 480–5114; Dorothy Dicks, Reporting Team Leader, Federal Borrowings Branch, Division of Accounting Operations, Office of Public Debt Accounting, Bureau of the Public Debt, Parkersburg, West Virginia 26106–1328, (304) 480–5115; Paul Wolfteich, Chief Counsel, Office of the Chief Counsel, Bureau of the Public Debt, (202) 504–3705; or Brenda L. Hoffman, Attorney-Advisor, Office of the Chief Counsel, Bureau of the Public Debt, (202) 504–3706.

SUPPLEMENTARY INFORMATION: An agency that has acquired property or service from a business concern and has failed to pay for the complete delivery of property or service by the required payment date shall pay the business concern an interest penalty. 31 U.S.C. 3902(a). The Contract Disputes Act of 1978, Sec. 12, Public Law 95–563, 92 Stat. 2389, and the Prompt Payment Act, 31 U.S.C. 3902(a), provide for the calculation of interest due on claims at the rate established by the Secretary of the Treasury.

The Secretary of the Treasury has the authority to specify the rate by which the interest shall be computed for interest payments under section 12 of the Contract Disputes Act of 1978 and under the Prompt Payment Act. Under the Prompt Payment Act, if an interest penalty is owed to a business concern, the penalty shall be paid regardless of whether the business concern requested payment of such penalty. 31 U.S.C. 3902(c)(1). Agencies must pay the interest penalty calculated with the interest rate, which is in effect at the time the agency accrues the obligation to pay a late payment interest penalty. 31 U.S.C. 3902(a). ''The interest penalty shall be paid for the period beginning on the day after the required payment date and ending on the date on which payment is made.'' 31 U.S.C. 3902(b).

Therefore, notice is given that the Secretary of the Treasury has determined that the rate of interest applicable for the period beginning July 1, 2012, and ending on December 31, 2012, is 1¾ per centum per annum.

Richard L. Gregg,

Fiscal Assistant Secretary.

[FR Doc. 2012–16040 Filed 6–28–12; 8:45 am]

BILLING CODE 4810–39–P

FEDERAL REGISTER

Vol. 77 Friday,
No. 126 June 29, 2012

Part II

Environmental Protection Agency

40 CFR Parts 50, 51, 52, *et al.*
National Ambient Air Quality Standards for Particulate Matter; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50, 51, 52, 53, and 58

[EPA–HQ–OAR–2007–0492; FRL–9682–9]

RIN 2060–AO47

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed 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 proposes to make revisions to the primary and secondary NAAQS for PM to provide requisite protection of public health and welfare, respectively, and to make corresponding revisions to the data handling conventions for PM and ambient air monitoring, reporting, and network design requirements. The EPA also proposes revisions to the prevention of significant deterioration (PSD) permitting program with respect to the proposed NAAQS revisions. With regard to primary standards for fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), the EPA proposes to revise the annual $PM_{2.5}$ standard by lowering the level to within a range of 12.0 to 13.0 micrograms per cubic meter ($\mu g/m^3$), 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. The EPA proposes changes to the Air Quality Index (AQI) for $PM_{2.5}$ to be consistent with the proposed 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 proposes 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., $PM_{10-2.5}$). With regard to the secondary PM standards, the EPA proposes to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment and to retain the current standards generally to address non-visibility welfare effects. The proposed distinct secondary standard would 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 dv or 28 dv.

DATES: Comments must be received on or before August 31, 2012.

Public Hearings: The EPA intends to hold public hearings on this proposed rule in July 2012. These will be announced in a separate **Federal Register** notice that provides details, including specific dates, times, addresses, and contact information for these hearings.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2007–0492 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.*

Docket: 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 FURTHER INFORMATION CONTACT: Ms. Beth M. Hassett-Sipple, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C504–06, Research Triangle Park, NC 27711; telephone: (919) 541–4605; fax: (919) 541–0237; email: *hassett-sipple.beth@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to the EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—the agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

Availability of Related Information

A number of the documents that are relevant to this rulemaking are available through 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.

Table of Contents

The following topics are discussed in this preamble:

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 proposed rulemaking is being done pursuant to these statutory requirements. The schedule for this proposed rule is set out in a court order.

In 2006, the EPA completed the 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. (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 EPA because EPA 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 is responding to the court's remands as part of the current review of the PM NAAQS.

This review was initiated in June 2007. Between 2007 and 2011, 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 peer reviewed by EPA's Clean Air Scientific Advisory Committee (CASAC). This proposed rulemaking is the next step in the review process.

In this rulemaking, the EPA proposes to make revisions to the suite of primary and secondary standards for PM to provide increased protection of public health and welfare. We also discuss EPA's current perspectives on implementation issues related to the proposed revisions to the PM NAAQS. The EPA proposes revisions to the Prevention of Significant Deterioration (PSD) permitting regulations to address the proposed changes in the primary and secondary PM NAAQS. The EPA also proposes an approach for implementing the PSD program specifically for the proposed secondary standard. The EPA is also proposing to update the Air Quality Index (AQI) for $PM_{2.5}$ and to make changes in the data handling conventions for PM and ambient air monitoring, reporting, and network design requirements to correspond with the proposed changes to the standards.

B. Summary of Major Provisions

With regard to the primary standards for fine particles, EPA proposes to revise the annual $PM_{2.5}$ standard by lowering the level from 15.0 to within a range of 12.0 to 13.0 μg/m³ so as to provide increased protection against health effects associated with long- and short-term exposures. The EPA proposes to retain the level (35 μg/m³) and the form (98th percentile) of the 24-hour $PM_{2.5}$ standard to provide supplemental protection against health effects associated with short-term exposures. This proposed action would provide 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 proposes to eliminate spatial averaging provisions as part of the form of the annual standard to avoid potential disproportionate impacts on at-risk populations.

The proposed changes to the primary annual $PM_{2.5}$ standard are within the range that CASAC advised the Agency to consider. These changes 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 proposed changes also reflect 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 proposes to conclude 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 the proposed revisions are warranted to provide the appropriate degree of increased public health protection. The EPA solicits comment on all aspects of the proposed primary $PM_{2.5}$ standards.

With regard to the primary standard for coarse particles, EPA proposes to retain the current 24-hour PM_{10} standard, with a level of 150 μg/m³ 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 proposes to conclude 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 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. The Administrator welcomes the public's views on these approaches to considering and accounting for the evidence and its limitations and uncertainties.

With regard to the secondary PM standards, the EPA proposes to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment. More specifically, the EPA proposes to establish a secondary standard 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, 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 deciviews (dv) or 28 dv. The EPA also proposes to rely upon the existing Chemical Speciation Network (CSN) to provide appropriate monitoring data for calculating $PM_{2.5}$ visibility index values.

The proposed secondary standard is based on the long-standing science characterizing the contribution of PM, especially fine particles, to visibility impairment and on air quality analyses, with consideration also given to a reanalysis of public perception surveys regarding people's stated preferences regarding acceptable and unacceptable visual air quality. Based on this information, the Administrator proposes to conclude that the current secondary $PM_{2.5}$ standards are not sufficiently protective of the public welfare with respect to visual air quality. The EPA solicits comment on all aspects of the proposed secondary standard.

To address other non-visibility welfare effects including ecological effects, effects on materials, and climate impacts, the EPA proposes to retain the current suite of secondary PM standards generally, while proposing to revise 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.

The proposed revisions to the PM NAAQS would 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 proposed new or revised NAAQS for $PM_{2.5}$. States will also review, modify and supplement their existing state implementation plans. The proposed NAAQS revisions would affect the applicable air permitting requirements and the transportation conformity and general conformity processes. This notice provides background information for understanding the implications of the proposed NAAQS revisions for these implementation processes and describes and requests comment on EPA's current perspectives on implementation issues. In addition, the EPA proposes to revise its PSD regulations to provide limited grandfathering from the requirements that result from the revised PM NAAQS for permit applications for which the public comment period has begun when the revised PM NAAQS take effect. The EPA also proposes to implement a surrogate approach that would provide a mechanism for permit applicants to demonstrate that they will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index NAAQS. It is the EPA's intention to finalize any time-sensitive revisions to its PSD regulations at the same time as any new or revised NAAQS are finalized.

With regard to implementation-related activities, the EPA intends to promulgate rules or develop guidance related to NAAQS implementation on a schedule that provides timely clarity to the states, tribes, and other parties responsible for NAAQS implementation. The EPA solicits comment on all implementation aspects during the public comment period for this notice and will consider these comments as it develops future rulemaking or guidance, as appropriate.

On other topics, the EPA proposes changes to the Air Quality Index (AQI) for $PM_{2.5}$ to be consistent with the proposed primary $PM_{2.5}$ standards. The EPA also proposes revisions to the data handling procedures consistent with the proposed 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 proposes updates to several aspects of the monitoring regulations and specifically proposes 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.

C. Costs and Benefits

In setting the NAAQS, the EPA may not consider the costs of implementing the standards. This was confirmed by the Supreme Court in *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001), as discussed in section II.A of this notice. 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 proposed 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 $88 million to $220 million (for 13.0 $\mu g/m^3$) and from $2.3 billion to $5.9 billion per year (for 12.0 $\mu g/m^3$) in 2020 and costs ranging from $2.9 million (for 13.0 $\mu g/m^3$) to $69 million (for 12.0 $\mu g/m^3$) per year.

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

[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.''

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 sensitive population(s) at risk, 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), 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 Clean Air Scientific Advisory Committee (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.

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/m^3, 24-hour average, not to be exceeded more than once per year, and 75 μg/m^3, annual geometric mean. The secondary standard was 150 μg/m^3, 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/m^3 with no more than one expected exceedance per year; and (2) replacing the annual TSP standard with a PM_{10} standard of 50 μg/m^3, 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).

TABLE 1—SUMMARY OF NATIONAL AMBIENT AIR QUALITY STANDARDS PROMULGATED FOR PM 1971–2006[5]

Final rule	Indicator	Averaging time	Level	Form
1971—36 FR 8186 April 30, 1971.	TSP	24-hour	260 μg/m^3 (primary), 150 μg/m^3 (secondary).	Not to be exceeded more than once per year.
		Annual	75 μg/m^3 (primary)	Annual average.
1987—52 FR 24634, July 1, 1987.	PM_{10}	24-hour	150 μg/m^3	Not to be exceeded more than once per year on average over a 3-year period.
		Annual	50 μg/m^3	Annual arithmetic mean, averaged over 3 years.
1997—62 FR 38652, July 18, 1997.	$PM_{2.5}$	24-hour	65 μg/m^3	98th percentile, averaged over 3 years.[6]
		Annual	15.0 μg/m^3	Annual arithmetic mean, averaged over 3 years.[7][8]
	PM_{10}	24-hour	150 μg/m^3	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/m^3	Annual arithmetic mean, averaged over 3 years.
2006—71 FR 61144, October 17, 2006.	$PM_{2.5}$	24-hour	35 μg/m^3	98th percentile, averaged over 3 years.[6]
		Annual	15.0 μg/m^3	Annual arithmetic mean, averaged over 3 years.[7][9]

[3] Lists of CASAC members and of members of the CASAC PM Review Panel are available at: *http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CommitteesandMembership?OpenDocument.*

[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 [5]—Continued

Final rule	Indicator	Averaging time	Level	Form
	PM_{10}	24-hour	150 μg/m³	Not to be exceeded more than once per year on average over a 3-year period.

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 $PM_{10-2.5}$).[10] The EPA established two new $PM_{2.5}$ standards: an annual standard of 15 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 [11]; 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 [12] 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 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 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 (DC Cir. 1999), rehearing granted in part and denied in part, 195 F. 3d 4 (DC 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 EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{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 PM_{10} standards from the CFR (69 FR 45592, July 30, 2004) and deleted the regulatory provision [at 40 CFR section 50.6(d)] that controlled the transition from the pre-existing 1987 PM_{10} standards to the 1997 PM_{10} standards. The pre-existing 1987 PM_{10} standards remained in place (65 FR 80776, December 22, 2000). The court also upheld 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 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 EPA's long-standing interpretation and DC 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 (DC Cir. 1999). The full Court of Appeals denied 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 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 EPA's discretion, affirming 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

[5] When not specified, primary and secondary standards are identical.

[6] 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).

[7] 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).

[8] 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'').

[9] 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).

[10] See 40 CFR parts 50, 53, and 58 for more information on reference and equivalent methods for measuring PM in ambient air.

[11] 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)].

[12] *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).

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 EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not ''arbitrary and capricious.'' *American Trucking Associations* v. *EPA,* 283 F. 3d 355, 369–72 (DC 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, 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 their 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 in the range of 35 to 30 $\mu g/m^3$ with a 98th percentile form, in concert with revising the level of the primary annual $PM_{2.5}$ standard in the range of 14 to 13 $\mu g/m^3$ (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 $\mu g/m^3$; (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, $PM_{10\text{-}2.5}$, this proposed indicator 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 $\mu g/m^3$ 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.[13] 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 promulgated 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 $\mu g/m^3$, retained the level of the primary annual $PM_{2.5}$ standard at 15 $\mu g/m^3$, and 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 $\mu g/m^3$ with a one-expected exceedance form), and revoked the annual PM_{10} standard. The EPA also established a new Federal Reference Method (FRM) for the measurement of $PM_{10\text{-}2.5}$ in the ambient air (71 FR 61212–13). Although the standards for thoracic coarse particles were not defined in terms of a $PM_{10\text{-}2.5}$ indicator, the EPA adopted a new FRM for $PM_{10\text{-}2.5}$ to facilitate consistent research on $PM_{10\text{-}2.5}$ 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 ''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 $\mu g/m^3$. 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).[14] 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 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 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).

[13] 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 $\mu g/m^3$ in conjunction with a form within a range of the 92nd to 98th percentile (71 FR 2685, January 17, 2006).

[14] 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).

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 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. 3d 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. 3d 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).[15] 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.[16] [17]

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 with 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). The first external review draft Integrated Science Assessment (U.S. EPA, 2008b; 73 FR 77686, December 19, 2008) was reviewed by CASAC and the public 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. 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) were 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 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,

[15] 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.

[16] 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, EPA 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, EPA will no longer issue a policy assessment in the form of an advance notice of proposed rulemaking (ANPR) as 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).

[17] 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.

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, 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 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. CASAC's comments on this preliminary draft were considered in developing a first draft PA (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. The second draft document was reviewed by CASAC at a meeting on July 26 and 27, 2010 (75 FR 32763, June 9, 2010). CASAC (Samet, 2010d) and public comments on the second draft Policy Assessment were considered by EPA staff 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 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. The court order, entered on June 2, 2012 and amended on June 6, 2012, provides that EPA will sign, for publication, a notice of proposed rulemaking concerning its review of the PM NAAQS no later than June 14, 2012.

The EPA is aware that a number of new scientific studies on the health effects of PM have been published since the mid-2009 cutoff date for inclusion in the Integrated Science Assessment. As in the last PM NAAQS review, the EPA intends to conduct a provisional review and assessment of any significant new studies published since the close of the Integrated Science Assessment, including studies that may be submitted during the public comment period on this proposed rule in order to ensure that, before making a final decision, the Administrator is fully aware of the new science that has developed since 2009. In this provisional assessment, the EPA will examine these new studies in light of the literature evaluated in the Integrated Science Assessment. This provisional assessment and a summary of the key conclusions will be placed in the rulemaking docket.

Today's action presents the Administrator's proposed decisions on the current PM standards. Throughout this preamble there are a number of conclusions, findings, and determinations that are part of the rationales for the decisions proposed by the Administrator. They are referred to throughout as ''provisional'' conclusions, findings, and determinations to reflect that they are not intended to be final or conclusive but rather proposals for public comment. The EPA invites general, specific, and technical comments on all issues involved with this proposal, including all such proposed decisions and provisional conclusions, findings, and determinations.

C. Related Control Programs To Implement PM Standards

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110 of the CAA, and related provisions, states are to submit, for EPA's approval, state implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the PSD program (CAA sections 160 to 169). In addition, Federal programs provide for nationwide reductions in emissions of 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 for stationary sources under section 111 of the CAA.

Currently, there are 55 areas in the U.S. (with a population of more than 100 million) that are designated as nonattainment for either the annual or 24-hour $PM_{2.5}$ standards. Regarding the 1997 $PM_{2.5}$ standards, the EPA designated 39 nonattainment areas in 2005. Regarding the 2006 24-hour $PM_{2.5}$ standard, the EPA designated 31 areas in 2009 and added one area in 2010. Sixteen areas are currently designated as nonattainment for both the 1997 and 2006 $PM_{2.5}$ standards. With regard to the PM_{10} NAAQS, 45 areas (with a population of more than 25 million) are currently designated as nonattainment. Upon any revisions to the PM NAAQS, the EPA would work with the states to conduct a new area designation process. Upon designation of new nonattainment areas, certain states would then be required to develop SIPs to attain the standards. In developing their attainment plans, states would first take into account projected emission reductions from federal and state rules that have been already adopted at the time of plan submittal. A number of significant emission reduction programs that will lead to reductions of 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 the Transport Rule for electric generating units, 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 would 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 any revised PM NAAQS.

III. Rationale for Proposed Decisions on the Primary $PM_{2.5}$ Standards

This section presents the rationale for the Administrator's proposed decision to revise the level and form of the existing primary annual $PM_{2.5}$ standard and to retain the existing primary 24-hour $PM_{2.5}$ standard. As discussed more fully below, this rationale 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. This proposal also takes 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; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately.

In developing this proposal, the Administrator recognizes that the CAA requires her to reach a public health policy judgment as to what standards would be requisite 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 standards to propose, and subsequently 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, 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 well reflect different demographic and air pollution characteristics.[18]

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 proposed rule, the EPA has drawn upon an integrative synthesis of the entire body of evidence between 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 in taking into account potential impacts on at-risk populations[19] and in considering alternative standard levels that provide protection with an appropriate margin of safety.

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 opportunities for public review and comment.

Although important uncertainties remain in the qualitative and quantitative characterizations of health effects attributable to ambient fine particles, the review of this information has been extensive and deliberate. This intensive evaluation of the scientific evidence and quantitative assessments has provided an 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 potential 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 will draw 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 this proposal.

In presenting the rationale for the proposed revisions of 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 those standards in 2006 (section III.A.1). The D.C. 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 history, section II.A.3 describes EPA's general approach used in the current review for considering the need to retain or revise the current suite of fine particle standards. Section III.B summarizes the body of scientific evidence supporting the rationale for the proposed decisions, including key health endpoints associated with long- and short-term exposures to ambient fine particles. This overview includes a discussion of at-risk populations and potential $PM_{2.5}$-related impacts on public health. Section III.C outlines the approach taken by the EPA to assess health risks associated with exposure to ambient $PM_{2.5}$, including a discussion of key uncertainties and limitations associated with these analyses. Section III.D discusses the scientific evidence, air quality, risk-based information; CASAC advice; and the Administrator's proposed decisions related to the adequacy of the current standards. Section III.E discusses the scientific evidence, air quality, and risk-based information; CASAC advice; and the

[18] 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.

[19] In this proposal, the term ''at-risk'' is the broadly encompassing term used for groups with specific factors that increase the risk of PM-related health effects in a population. In the Integrated Science Assessment, as discussed in section III.B.3 below, the term ''susceptibility'' was used broadly to recognize populations at greater risk.

Administrator's proposed decisions related to alternative standards. Section III.F summarizes the Administrator's proposed decisions with regard to the primary $PM_{2.5}$ NAAQS.

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/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. The 24-hour standard is set at a level of 35 μg/m³, 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 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, 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. 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. 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 used in the previous reviews focused on consideration of alternative standard levels that were somewhat below the long-term mean $PM_{2.5}$ concentrations reported in epidemiological studies (U.S. EPA, 2011a, section 2.1.1). This approach recognized that the strongest evidence of $PM_{2.5}$-related associations occurs at concentrations near 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 $PM_{2.5}$.[20] 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 a national 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 both short- and long-term exposure studies, 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/m³ to protect against effects associated with short-term exposures. The EPA relied upon evidence from long-term exposure 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

[20] 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).

any of the litigants and, thus, 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 PM NAAQS decisions, as summarized in section III.A.1. 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 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 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, 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 is broader and more integrative than in past reviews. Our general approach also reflects consideration of the issues raised by the court in its remand of the primary annual $PM_{2.5}$ standard, 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 takes 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, EPA staff developed a final Policy Assessment (U.S. EPA, 2011a) which provides as broad an array of policy options as is supportable 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 presented in this document.

The Policy Assessment concludes it is 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).[21] As the EPA recognized in 1997, 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 recognizes 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 recognizes 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

[21] By utilizing this approach, the Agency would also be responsive to the remand of the 2006 standard. As noted in section III.A.2, the DC Circuit, in remanding the 2006 primary annual $PM_{2.5}$ standard, concluded that the Administrator had failed to 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.

recognizes that the short-term exposure studies are 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 is 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 demonstrate 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 is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations.[22] For these reasons, strategies that focus primarily on reducing peak days are less likely to achieve reductions in the $PM_{2.5}$ concentrations that are most strongly associated with the observed health effects.

Furthermore, a policy approach that focuses 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, 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 discussed above.

The Policy Assessment concludes 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, is 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 concludes, however, 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 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 concludes it is 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 focuses 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 is 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 considers effects and estimated risks associated with short-term exposures. In both cases, the Policy Assessment places greatest weight on health effects that have 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 focuses on specific at-risk populations. The Policy Assessment places relatively greater weight on statistically significant associations that yield relatively more precise effect estimates and that are judged to be robust to confounding by other air pollutants. In the case of short-term exposure studies, the Policy Assessment places 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 considers a number of factors (U.S. EPA, 2011a, section 2.2). As an initial matter, the Policy Assessment considers 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 considers evidence on at-risk populations and potential impacts on such populations. Further, the Policy Assessment explores the extent to which $PM_{2.5}$-related health effects have been observed in areas where air quality distributions extend to lower levels 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 alternative standard levels for consideration (U.S. EPA, 2011a, sections 2.1.3 and 2.3.4), the Policy Assessment first recognizes 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).[23] In the absence of any discernible thresholds, the Agency's general approach for identifying appropriate standard levels for consideration involves 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 recognizes 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 decisions to either retain or revise the standards. Final decisions will necessarily also take into account

[22] In confirmation, a number of studies that have presented analyses excluding higher PM concentration days 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).

[23] 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 concludes that the studies evaluated support the use of a no-threshold, log-linear model but recognizes 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).

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 is appropriate to consider, the Policy Assessment focuses on identifying an annual standard that provides requisite protection from effects associated with both long- and short-term exposures. In so doing, the Policy Assessment explores 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.

The approach that most directly addresses this issue considers studies that present confidence intervals around concentration-response relationships, and in particular, analyses that average across multiple concentration-response models rather than considering a single concentration-response model.[24] The Policy Assessment explores the extent to which such analyses have 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 concludes 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 explores other approaches that consider different statistical metrics from epidemiological studies. The Policy Assessment first takes 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.[25] This approach recognizes that the strongest evidence of $PM_{2.5}$-related associations occurs at concentrations near the long-term (i.e., annual) mean. In using this approach, the Policy Assessment places 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 considers information beyond a single statistical metric of $PM_{2.5}$ concentrations (i.e., the mean) to the extent such information is available. In so doing, the Policy Assessment employs 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 epidemiological studies. Thus, the Policy Assessment considers the range of $PM_{2.5}$ concentrations where the data analyzed in the study (i.e., air quality and population-level data, as discussed below) are most concentrated, specifically, the range of $PM_{2.5}$ concentrations around the long-term mean over which our confidence in the associations observed in the epidemiological studies is greatest. The Policy Assessment then focuses on the lower part of this range to characterize where in the distributions the data become appreciably more sparse and, thus, where our understanding of the associations correspondingly becomes more uncertain. The Policy Assessment recognizes there is no one percentile value within a given distribution that is the most appropriate or ''correct'' way to characterize where our confidence in the associations becomes appreciably lower. The Policy Assessment concludes that the range from the 25th to 10th percentiles is a reasonable range to consider as a region where we have appreciably less confidence in the associations observed in epidemiological studies.[26]

In considering distributional statistics from epidemiological studies, the final Policy Assessment focused on two types of population-level metrics that CASAC advices are most useful to consider in identifying the $PM_{2.5}$ concentrations most influential in generating the health effect estimates reported in the epidemiological studies.[27] Consistent with CASAC advice, the most relevant information is 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, as discussed in section III.E.4.b below, the Policy Assessment also considers the number of study participants within each study area as an appropriate surrogate for health event data.

The Policy Assessment recognizes that an approach considering analyses of confidence intervals around concentration-response functions is intrinsically related to an approach that considers different distributional statistics. Both of these approaches could be employed to identify the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in epidemiological studies.

In applying these approaches, the Policy Assessment considers $PM_{2.5}$ concentrations from long- and short-term $PM_{2.5}$ exposure studies using composite monitor distributions.[28] For multi-city studies, this distribution reflects concentrations averaged across one or more ambient monitors within

[24] 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.

[25] Epidemiological studies typically report $PM_{2.5}$ concentrations averaged across the available ambient monitors. For multi-city studies, this metric reflects concentrations averaged across one or more ambient monitors within each area included in a given study 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.

[26] In the PM NAAQS review completed in 2006, the Staff Paper 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.

[27] The second draft Policy Assessment focused on the distributions of $PM_{2.5}$ concentrations 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, EPA considered area-specific health event and area-specific population data along with corresponding $PM_{2.5}$ concentrations to generate a cumulative distribution of the population data relative to long-term mean $PM_{2.5}$ concentrations to determine the most influential range (U.S. EPA, 2011a, Figure 2–7 and associated text).

[28] 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, as noted above, the composite monitor concentration represents the average concentration across one or more monitors within each area included in a given study and then averaged across study areas for an overall study mean $PM_{2.5}$ concentration.

each area included in a given study and then averaged across study areas for an overall study mean $PM_{2.5}$ concentration. Beyond considering air quality concentrations based on composite monitor distributions, the second draft Policy Assessment also considered $PM_{2.5}$ concentrations based on measurements at the monitor within each area that records the highest concentration (i.e., maximum monitor) (U.S. EPA, 2010f, sections 2.1.3 and 2.3.4.1).[29] Although the second draft Policy Assessment discussed whether consideration of alternative annual standard levels should be based on composite or maximum monitor distributions, the final Policy Assessment, consistent with CASAC advice (Samet, 2010d, p. 3), concluded that it is most reasonable to place more weight on an approach based on composite monitor distributions, which represent the $PM_{2.5}$ concentrations typically presented and used in epidemiological analyses and which provide a direct link between $PM_{2.5}$ concentrations and the observed health effects reported in both long- and short-term exposure studies (U.S. EPA, 2011a, p. 2–13).

In reaching staff conclusions on alternative standard levels that are appropriate to consider, the Policy Assessment also includes a broader consideration of the uncertainties related to the concentration-response relationships from multi-city, long- and short-term exposure studies. Most notably, these uncertainties relate to our currently limited understanding of the heterogeneity of relative risk estimates in areas across the country. This heterogeneity may be attributed, in part, to the potential for different components within the mix of ambient fine particles to differentially contribute to health effects observed in the studies and to exposure-related factors (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 further discussed in section III.B.2 below.

The Policy Assessment recognizes that the level of protection afforded by the NAAQS relies both on the level and the form of the standard. The Policy Assessment concludes that a policy approach that uses data based on composite monitor distributions to identify alternative standard levels, and then compares those levels to concentrations at maximum monitors to determine if an area meets a given standard, inherently has the potential to build in some margin of safety (U.S. EPA, 2011a, p. 2–14).[30] This conclusion is 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 informs 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 evaluates both the distributions of 24-hour $PM_{2.5}$ concentrations, with a focus on the 98th percentile concentrations to match the form of the current 24-hour $PM_{2.5}$ standard, to the extent such data were available, 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 considers air quality information based on county-level 24-hour and annual design values[31] to understand the policy implications of the alternative standard levels supported by the underlying science. In particular, the Policy Assessment considers 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. Based on the evidence-based considerations outlined above, the Policy Assessment develops integrated conclusions with regard to alternative suites of standards, including both annual and 24-hour standards that are appropriate to consider in this review based on the currently available evidence and air quality information. In so doing, the Policy Assessment discusses 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 considers the quantitative risk estimates and the key observations presented in the Risk Assessment. This assessment includes 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 considers 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 characterizes 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 recognizes the uncertainties inherent in such risk estimates, and takes 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 considers 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

[29] The maximum monitor distribution is relevant because it is generally used to determine whether a given standard is met in an area and the extent to which ambient $PM_{2.5}$ concentrations need to be reduced in order to bring an area into attainment with the standard. However, maximum monitor distributions represent a far less robust metric than composite monitor distributions for consideration of alternative annual standard levels in part because they are available for only a few epidemiological studies.

[30] 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. 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 and the composite monitor distributions may be well below the maximum monitor distributions (U.S. EPA, 2011a, p. 2–14).

[31] Design values are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance.

related to both long- and short-term $PM_{2.5}$ exposures.

The Policy Assessment conclusions related to the primary $PM_{2.5}$ standards reflect an 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) potential alternative standards, if any, that are appropriate to consider in this review to protect against effects associated with both long- and short-term exposures to fine particles. In addressing these broad questions, the discussions included in the Policy Assessment were organized around a series of more specific questions reflecting different aspects of each overarching question (U.S. EPA, 2011a, chapter 2, Figure 2–1). When evaluating the health protection afforded by the current or any alternative suites of standards considered, the Policy Assessment takes 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 provides a comprehensive basis to help inform the judgments required of the Administrator in reaching decisions about the current and potential alternative primary fine particle standards and in responding to the remand of the 2006 primary annual $PM_{2.5}$ standard.

B. Health Effects Related to Exposure to Fine Particles

This section outlines key information contained 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. As was true in the last review, evidence from epidemiologic studies plays a key role in the Integrated Science Assessment's evaluation of the scientific evidence. The following sections discuss 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).

1. Nature of Effects

In considering the strength of the associations between long- and short-term exposures to $PM_{2.5}$ and health effects, the Policy Assessment notes that in the PM NAAQS review completed in 2006 the Agency 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 epidemiological evidence 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).[32]

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 (U.S. EPA, 2009a, sections 2.3.1 and 2.3.2). The currently available evidence is stronger in comparison to evidence available in the last review because of its breadth and the substantiation of previously observed health effects. A number of large multi-city epidemiological studies have been conducted throughout the U.S., including extended analyses of studies that were important to inform decision-making in the last review. These studies have reported consistent increases in morbidity and/or mortality related to ambient $PM_{2.5}$ concentrations, with the strongest evidence reported for cardiovascular-related effects. In addition, the findings of new toxicological and controlled human exposure studies greatly expand and provide stronger support for a number of potential biologic mechanisms or pathways for cardiovascular and respiratory effects associated with long- and short-term PM exposures (U.S. EPA, 2009a, p. 2–17; chapter 5; Figures 5–4 and 5–5).

With regard to causal inferences described in the Integrated Science Assessment, the Policy Assessment notes that since the last review, the Agency has developed a more formal framework for reaching causal determinations that 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 (U.S. EPA, 2011a, p. 2–18; U.S. EPA, 2009a, section 1.5). 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 a causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (U.S. EPA, 2009a, Table 1–3).[33]

Using this causal framework, the Integrated Science Assessment concludes that the collective evidence is largely consistent with past studies and substantially strengthens what was known about fine particles in the last review to reach the conclusion that a causal relationship exists between both long- and short-term exposures to $PM_{2.5}$ and mortality and cardiovascular effects including cardiovascular-related mortality. The Integrated Science Assessment also concludes that the collective evidence continues to support a likely causal relationship between long- and short-term $PM_{2.5}$ exposures and respiratory effects, including respiratory-related mortality. Further, the Integrated Science Assessment concludes that the currently available evidence is 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) (U.S. EPA, 2009a, sections 2.3.1 and 2.6; Table 2–6; U.S. EPA, 2011a, Table 2–1).

a. Health Effects Associated With Long-Term $PM_{2.5}$ Exposures

With regard to mortality, the Integrated Science Assessment concludes that newly available evidence significantly strengthens the link between long-term exposure to $PM_{2.5}$ and mortality, while providing indications that the magnitude of the $PM_{2.5}$-mortality association may be larger than previously estimated (U.S. EPA, 2009a, sections 7.2.10, 7.2.11, and 7.6.1; Figures 7–6 and 7–7). A number of large U.S. cohort studies have been published since the last review, including extended analyses of the

[32] The term ''likely causal association'' was used in the 2004 Criteria Document to summarize the strength of the available epidemiological 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).

[33] Causal inferences, as discussed in the Integrated Science Assessment, 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).

American Cancer Society (ACS) and Harvard Six Cities studies (U.S. EPA, 2009a, pp. 7–84 to 7–85; Figure 7–6; Krewski et al., 2009; Pope et al., 2004; Jerrett et al., 2005; Laden et al., 2006). In addition, new long-term $PM_{2.5}$ exposure studies evaluating mortality impacts in additional cohorts are now available (U.S. EPA, 2009a, section 7.6). For example, the Women's Health Initiative (WHI) Observational Study reported effects of $PM_{2.5}$ on cardiovascular-related mortality in post-menopausal women with no previous history of cardiac disease (Miller et al., 2007). The $PM_{2.5}$ effect estimate in this study remained positive and statistically significant in a multi-pollutant model that included gaseous co-pollutants as well as coarse particles. In addition, multiple studies observed $PM_{2.5}$-associated mortality among older adults using Medicare data (Eftim et al., 2008; Zeger et al., 2007, 2008). Collectively, these new studies, along with evidence available in the last review, provide consistent and stronger evidence of associations between long-term exposure to $PM_{2.5}$ and mortality (U.S. EPA, 2009a, sections 2.3.1 and 7.6).

The strength of the causal relationship between long-term $PM_{2.5}$ exposure and mortality also builds upon new studies providing evidence of improvement in community health following reductions in ambient fine particles. Pope et al. (2009) documented the population health benefits of reducing ambient air pollution by correlating past reductions in ambient $PM_{2.5}$ concentrations with increased life expectancy. These investigators reported that reductions in ambient fine particles during the 1980s and 1990s account for as much as 15 percent of the overall improvement in life expectancy in 51 U.S. metropolitan areas, with the fine particle reductions reported to be associated with an estimated increase in mean life expectancy of approximately 5 to 9 months (U.S. EPA, 2009a, p. 7–95; Pope et al., 2009). An extended analysis of the Harvard Six Cities study found that as cities cleaned up their air, locations with the largest reductions in $PM_{2.5}$ saw the largest improvements in reduced mortality rates, while those with the smallest decreases in $PM_{2.5}$ concentrations saw the smallest improvements (Laden et al., 2006). Another extended follow-up to the Harvard Six Cities study investigated the delay between changes in ambient $PM_{2.5}$ concentrations and changes in mortality (Schwartz et al., 2008) and reported that the effects of changes in $PM_{2.5}$ were seen within the 2 years prior to death (U.S. EPA, 2009a, p. 7–92; Figure 7–9).

With regard to cardiovascular effects, 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. The Integrated Science Assessment concludes that the strongest evidence comes from recent studies investigating cardiovascular-related mortality. This includes evidence from a number of large, multi-city U.S. long-term cohort studies including extended follow-up analyses of the ACS and Harvard Six Cities studies, as well as the WHI study (U.S. EPA, 2009a, sections 7.2.10 and 7.6.1; Krewski et al., 2009; Pope et al., 2004; Laden et al., 2006; Miller et al., 2007). Pope et al. (2004) reported a positive association between mortality and long-term $PM_{2.5}$ exposure for a number of specific cardiovascular diseases, including ischemic heart disease, dysrhythmia, heart failure, and cardiac arrest (U.S. EPA, 2009a, p. 7–84; Figure 7–7). Krewski et al. (2009) provides further evidence for mortality related to ischemic heart disease associated with long-term $PM_{2.5}$ exposure (U.S. EPA, 2009a, p. 7–84, Figure 7–7).

With regard to cardiovascular-related morbidity associated with long-term $PM_{2.5}$ exposures, studies were not available in the last review. Recent studies, however, have provided new evidence linking long-term exposure to $PM_{2.5}$ with cardiovascular outcomes that has ''expanded upon the continuum of effects ranging from the more subtle subclinical measures to cardiopulmonary mortality'' (U.S. EPA, 2009a, p. 2–17). In the current review, studies are now available that evaluated a number of endpoints ranging from subtle indicators of cardiovascular health to serious clinical events associated with coronary heart disease and cardiovascular and cerebrovascular disease.[34] The most important new evidence comes from the WHI study which provides evidence of nonfatal cardiovascular events including both coronary and cerebrovascular events (Miller et al., 2007; U.S. EPA, 2009a, sections 7.2.9 and 7.6.1). Toxicological studies provide supportive evidence that the cardiovascular morbidity effects observed in long-term exposure epidemiological studies are biologically plausible and coherent with studies of cardiovascular-related mortality as well as with studies of cardiovascular-related effects associated with short-term exposures to $PM_{2.5}$, as described below (U.S. EPA, 2009a, p. 7–19).

With regard to respiratory effects, the Integrated Science Assessment concludes that 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 associated with long-term $PM_{2.5}$ exposure. The strongest evidence for respiratory-related effects available in this review is from studies that evaluated decrements in lung function growth, increased respiratory symptoms, and asthma development (U.S. EPA, 2009a, sections 2.3.1.2, 7.3.1.1, and 7.3.2.1).[35] Specifically, extended analyses of the Southern California Children's Health Study provide evidence that clinically important deficits in lung function [36] associated with long-term exposure to $PM_{2.5}$ persist into early adulthood (U.S. EPA, 2009a, p. 7–27; Gauderman et al., 2004). Additional analyses of the 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 24; McConnell et al., 2003) 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, 2009, 7–24; Islam et al., 2007). The outcomes observed in these 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 previously reported. Supporting these results are new longitudinal cohort studies conducted by other researchers in varying locations using different methods (U.S. EPA, 2009a, section 7.3.9.1). New evidence from a U.S. cohort of cystic fibrosis patients provided evidence of association between long-term $PM_{2.5}$ exposures and exacerbations of respiratory symptoms

[34] Coronary and cerebrovascular events include myocardial infarction, coronary artery revascularization (e.g., bypass graft, angioplasty, stent, atherectomy), congestive heart failure and stroke.

[35] Supporting evidence comes from studies ''that observed associations between long-term exposure to PM_{10} and an increase in respiratory symptoms and reductions in lung function growth in areas where PM_{10} is dominated by $PM_{2.5}$'' (U.S. EPA, 2009a, p. 2–12).

[36] 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 includes this interpretation for FEV_1 (75 FR 35525, June 22, 2010).

resulting in hospital admissions or use of home intravenous antibiotics (U.S. EPA, 2009a, p. 7–25; Goss et al., 2004).

Toxicological studies provide coherence and biological plausibility for the respiratory effects observed in epidemiological studies (U.S. EPA, 2009a, p. 7–42). For example, pre- and postnatal exposure to ambient levels of urban particles has been found to affect lung development in an animal model (U.S. EPA, 2009a, section 7.3.2.2; p. 7–43). This finding is important because impaired lung development is one mechanism by which PM exposure may decrease lung function growth in children (U.S. EPA, 2009a, p. 2–12; section 7.3).

With regard to respiratory-related mortality associated with long-term $PM_{2.5}$ exposure, the Integrated Science Assessment concludes that ''when deaths due to respiratory causes are separated from all-cause (nonaccidental) and cardiopulmonary deaths, there is limited and inconclusive evidence for an effect of $PM_{2.5}$ on respiratory mortality, with one large cohort study finding a reduction in deaths due to respiratory causes associated with reduced $PM_{2.5}$ concentrations, and another large cohort study finding no $PM_{2.5}$ associations with respiratory mortality'' (U.S. EPA, 2009a, p. 7–41). The extended follow-up of the Harvard Six Cities study reported a positive but statistically non-significant association between long-term $PM_{2.5}$ exposure and respiratory-related mortality (Laden et al., 2006), whereas Pope et al. (2004) found no association in the ACS cohort (U.S. EPA, 2009a, p. 7–84). There is emerging but limited evidence for an association between long-term $PM_{2.5}$ exposure and respiratory mortality in post-neonatal infants where long-term exposure was considered as approximately one month to one year (U.S. EPA, 2009a, pp. 7–54 to 7–55). Emerging evidence of short- and long-term exposure to $PM_{2.5}$ and respiratory morbidity and infant mortality provide some support for the weak respiratory-related mortality effects observed.

Beyond effects considered to have causal or likely causal relationships with long-term $PM_{2.5}$ exposure as discussed above, the following health outcomes are classified in the Integrated Science Assessment as having evidence suggestive of a causal relationship with long-term $PM_{2.5}$ exposure: (1) Reproductive and developmental effects and (2) cancer, mutagenicity, and genotoxicity effects (U.S. EPA, 2009a, Table 2–6). With regard to reproductive and developmental effects, the Integrated Science Assessment notes, ''[e]vidence is accumulating for $PM_{2.5}$-related effects on low birth weight and infant mortality, especially due to respiratory causes during the post-neonatal period'' (U.S. EPA, 2009a, p. 2–13). New evidence available in this review reports significant associations between exposure to $PM_{2.5}$ during pregnancy and lower birth weight and infant mortality, with less consistent evidence for pre-term birth and intrauterine growth restriction. (U.S. EPA, 2009a, section 7.4). The Integrated Science Assessment further notes that ''[i]nfants and fetal development processes may be particularly vulnerable to PM exposure, and although the physical mechanisms are not fully understood, several hypotheses have been proposed involving direct effects on fetal health, altered placenta function, or indirect effects on the mother's health'' (U.S. EPA, 2009a, section 7.4.1). Although toxicological studies provide some evidence that supports an association between long-term $PM_{2.5}$ exposure and adverse reproductive and developmental outcomes, there is ''little mechanistic information or biological plausibility for an association between long-term PM exposure and adverse birth outcomes (e.g., low birth weight, infant mortality)'' (U.S. EPA, 2009a, p. 2–13).

With regard to cancer, mutagenic and genotoxic 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 and sections 2.3.1.2 and 7.5; Table 7–7; Figures 7–6 and 7–7). The extended follow-up to the ACS study reported an association between long-term $PM_{2.5}$ exposure and lung cancer mortality (U.S. EPA, 2009a, p. 7–71; Krewski et al., 2009) as did the extended follow-up to the Harvard Six Cities study when considering the entire 25-year follow-up period (Laden et al., 2006). There is some evidence, primarily from *in vitro* studies, providing biological plausibility for the PM-lung cancer relationships observed in epidemiological studies (U.S. EPA, 2009a, p. 7–80), although *in vivo* toxicological studies of carcinogenicity generally reported mixed results (U.S. EPA, 2009a, section 7.5).

b. Health Effects Associated With Short-Term $PM_{2.5}$ Exposures

In considering effects associated with short-term $PM_{2.5}$ exposure, the body of currently available scientific evidence has 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 fine particle 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 climate and 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 (U.S. EPA 2009a, chapter 6).

With regard to mortality, new U.S. and Canadian multi-city and single-city $PM_{2.5}$ exposure studies have found generally consistent positive associations between short-term $PM_{2.5}$ exposures and cardiovascular- and respiratory-related mortality as well as all-cause (non-accidental) mortality (U.S. EPA, 2009a, sections 2.3.1.1, 6.2.11 and 6.5.2.2; Figures 6–26, 6–27, and 6–28). In an analysis of the National Morbidity, Mortality, and Air Pollution Study (NMMAPS) data, Dominici et al. (2007) reported associations between fine particle exposures and all-cause and cardiopulmonary-related mortality (U.S. EPA, 2009a, p. 6–175, Figure 6–26). In a study of 112 U.S. cities, Zanobetti and Schwartz (2009) reported positive associations (in 99 percent of the cities) and frequently statistically significant associations (in 55 percent of the cities) between short-term $PM_{2.5}$ exposure and total (non-accidental) mortality (U.S. EPA, 2009a, pp. 6–176 to 6–179; Figures 6–23 and 6–24).[37] A Canadian 12-city study (Burnett et al., 2004) is generally consistent with an earlier Canadian 8-city study (Burnett and Goldberg, 2003). Both studies reported a positive and statistically significant association between short-term $PM_{2.5}$ exposure and mortality (U.S. EPA, 2009a, p. 6–182, Figure 2–1), although the influence of nitrogen dioxide (NO_2) and limited $PM_{2.5}$ data for several years during the study period somewhat diminished the findings reported in the 12-city study. In addition to these multi-city studies, evidence from available single-city studies suggests that gaseous copollutants do not confound the $PM_{2.5}$-mortality association (U.S. EPA, 2009a, section 2.3.1.1). Collectively, these studies provide generally consistent and much stronger evidence for $PM_{2.5}$-

[37] Single-city Bayes-adjusted effect estimates for the 112 cities analyzed in Zanobetti and Schwartz (2009) were provided by the study author (personal communication with Dr. Antonella Zanobetti, 2009; see also U.S. EPA, 2009a, Figure 6–24).

associated mortality than the evidence available in the last review (U.S. EPA, 2011a, p. 2–24).

With regard to cardiovascular effects, new multi-city as well as single-city short-term $PM_{2.5}$ exposure studies conducted since the last review support a largely positive and frequently statistically significant association between short-term exposure to $PM_{2.5}$ and cardiovascular-related morbidity and mortality, substantiating prior findings. For example, among a multi-city cohort of older adults participating in the Medicare Air Pollution Study (MCAPS), investigators reported evidence of a positive association between short-term $PM_{2.5}$ exposures and hospital admissions related to cardiovascular outcomes (U.S. EPA, 2009a, pp. 6–57 to 58; Dominici et al, 2006a; Bell et al, 2008). The strongest evidence for cardiovascular effects has been observed predominantly for hospital admissions and emergency department visits for ischemic heart disease and congestive heart failure, and cardiovascular-related mortality (U.S. EPA, 2009a, Figure 2–1, p. 6–79, sections 6.2.10.3, 6.2.10.5, and 6.2.11; Bell et al., 2008; Dominici et al., 2006a; Tolbert et al., 2007; Zanobetti and Schwartz, 2009). In studies that evaluated the potential for confounding using co-pollutant models, $PM_{2.5}$ effect estimates for cardiovascular-related hospital admissions and emergency department visits generally remained positive, with the magnitude of $PM_{2.5}$ effect estimates increasing in some models and decreasing in others (U.S. EPA, 2009a, Figure 6–5). Furthermore, these findings are supported by a recent study of a multi-city cohort of women participating in the WHI study that reported a positive but statistically nonsignificant association between short-term exposure to $PM_{2.5}$ and electrocardiogram measures of myocardial ischemia (Zhang et al., 2009).

In focusing on respiratory effects, the strongest evidence from short-term $PM_{2.5}$ exposure studies has been observed for respiratory-related emergency department visits and hospital admissions for chronic obstructive pulmonary disease (COPD) and respiratory infections (U.S. EPA, 2009a, sections 2.3.1.1 and 6.3.8.3; Figures 2–1 and 6–13; Dominici et al., 2006a). In studies that employed co-pollutant models to evaluate the potential for confounding, $PM_{2.5}$ effect estimates for respiratory-related hospital admissions and emergency department visits generally remained positive, with the magnitude of $PM_{2.5}$ effect estimates increasing in some models and decreasing in others (U.S. EPA, 2009a, Figure 6–15). Evidence for $PM_{2.5}$-related respiratory effects has also been observed in panel studies, which indicate associations with respiratory symptoms, pulmonary function, and pulmonary inflammation among asthmatic children (U.S. EPA, 2009a, p. 2–10). Although not consistently observed, some controlled human exposure studies have reported small decrements in various measures of pulmonary function following controlled exposures to $PM_{2.5}$ (U.S. EPA, 2009a, p. 2–10). Furthermore, the comparatively larger body of toxicological evidence since the last review is coherent with the evidence from epidemiological and controlled human exposure studies that examined short-term exposures to $PM_{2.5}$ and respiratory effects (U.S. EPA, 2009a, section 6.3.10.1).

c. Summary

In considering the extent to which newly available scientific evidence strengthens or calls into question evidence of associations identified in the last review between ambient fine particle exposures and health effects, the Policy Assessment recognizes that much progress has been made in assessing some key uncertainties related to our understanding of health effects associated with long- and short-term exposure to $PM_{2.5}$. As briefly discussed above as well as in the more complete discussion of the evidence as presented and assessed in the Integrated Science Assessment, the Policy Assessment notes that the newly available information combined with information available in the last review provides substantially stronger confidence in a causal relationship between long- and short-term exposures to $PM_{2.5}$ and mortality and cardiovascular effects. In addition, the newly available evidence reinforces and expands the evidence supporting a likely causal relationship between long- and short-term exposure to $PM_{2.5}$ and respiratory effects. The body of scientific evidence is somewhat expanded 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 Integrated Science Assessment concludes that these data provide evidence that is suggestive of a causal relationship for these effects. Thus, the Policy Assessment concludes there is 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.

2. Limitations and Uncertainties Associated With the Currently Available Evidence

With respect to understanding the nature and magnitude of $PM_{2.5}$-related risks, the Policy Assessment recognizes that important uncertainties remain in the current review (U.S. EPA, 2011a, p. 2–25). Epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in responses both within and between cities and geographic regions within the U.S. In particular, the Policy Assessment notes that there are challenges with interpreting differences in health effects observed in the eastern versus western parts of the U.S., including evaluating effects stratified by seasons.[38] This heterogeneity may be attributed, in part, to differences in the fine particle composition or related to exposure measurement error.

In considering the relationships between PM composition and health effects, the ISA notes that the scientific evidence continues to evolve and concludes that, while many constituents of PM 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 (U.S. EPA, 2009a, p. 2–17). In particular, based on assessing the body of available evidence, the ISA notes that (1) cardiovascular effects have been linked with elemental carbon as well as with $PM_{2.5}$ from crustal sources, traffic, and wood smoke/vegetative burning; (2) respiratory effects have been linked with secondary sulfate $PM_{2.5}$ as well as with $PM_{2.5}$ from crustal/soil/road dust and traffic sources; and (3) a few studies have reported associations between total mortality and secondary sulfate/long-range transport, traffic, and salt. While specific $PM_{2.5}$ constituents have been linked with various $PM_{2.5}$-related health effects in a small number of studies, research continues to focus on the identification of specific constituents or sources that may be most closely related to specific $PM_{2.5}$-related health outcomes.

[38] Seasonal differences in effects may be related to $PM_{2.5}$ composition as well as regional differences in climate and infrastructure that may affect time spent outdoors or indoors, housing characteristics including air conditioning usage, and differences in baseline incidence rates (U.S. EPA, 2009a, p. 3–182).

Exposure measurement error is also an important source of uncertainty (U.S. EPA, 2009a, section 3.8.6). 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, climate, source characteristics, ventilation usage, personal activity patterns, photochemistry). As noted in the Integrated Science Assessment, exposure measurement error can introduce bias and increased uncertainty in associated health effect estimates (U.S. EPA, 2009a, p. 2–17).

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).[39] As noted above, although short-term studies of cardiovascular and respiratory hospital admissions and emergency department visits generally reported that $PM_{2.5}$ effect estimates remained positive, the magnitude of those effect estimates increased in some models and decreased in others. In addition, although evidence from single-city studies available in the last review suggests that gaseous copollutants do not confound the $PM_{2.5}$-related mortality association (U.S. EPA, 2004, section 8.4.3.3), a conclusion that is supported by studies that examined the PM_{10}-mortality relationship (U.S. EPA, 2009a, p. 6–182 and 6–201), many recent U.S. multi-city studies have not analyzed multipollutant models. 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.

3. At-Risk Populations

In identifying population groups or lifestages at greatest risk for health risk from a specific pollutant, the terms susceptibility, vulnerability, sensitivity, and at-risk are commonly employed. The definition for these terms sometimes varies, but in most instances ''susceptibility'' refers to biological or intrinsic factors (e.g., lifestage, gender, preexisting disease/conditions) while ''vulnerability'' refers to nonbiological or extrinsic factors (e.g., socioeconomic factors). However, factors included in the terms ''susceptibility'' and ''vulnerability'' are intertwined and are difficult to distinguish. In the Integrated Science Assessment, the term ''susceptibility'' has been used broadly to recognize populations that have a greater likelihood of experiencing effects related to ambient PM exposure[40], such that use of the term ''susceptible populations'' in the Integrated Science Assessment is used as a term that encompasses factors related both to susceptibility and vulnerability.[41] In the development of a more recent Integrated Science Assessment, the Agency is using the term ''at-risk'' groups to more broadly define the populations with characteristics that increase the risk of pollutant-related health effects (U.S. EPA, 2011d, p. 8–1). Therefore, in this proposal, the term ''at-risk'' is the broadly encompassing term used for groups with specific factors that increase the risk of PM-related health effects in a population. At-risk populations could exhibit a greater risk of PM-related health effects than the general population for a number of reasons including: being affected by lower concentrations of PM, experiencing a larger health impact at a given PM concentration or being exposed to higher PM concentrations than the general population. Given the heterogeneity of individual responses to PM exposures, the severity of the health effects experienced by an at-risk population may be much greater than that experienced by the population at large.

As summarized below and presented in more detail in chapter 8 of the Integrated Science Assessment and section 2.2.1 of the Policy Assessment, the currently available epidemiological and controlled human exposure 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) (U.S. EPA, 2009a, section 2.4.1, Table 8–2). In addition, toxicological studies provide underlying support for the biological mechanisms that potentially lead to increased susceptibility to PM-related health effects (U.S. EPA, 2009a, sections 2.4.1 and 8.1.8).

Two different lifestages have been associated with increased risk to PM-related health effects: childhood (i.e., less than 18 years of age) and older adulthood (i.e., 65 years of age and older). Childhood represents a lifestage where susceptibility to PM exposures may be related to the following observations: children spend more time outdoors; children have greater activity levels than adults; children have exposures resulting in higher doses per body weight and lung surface area; and the developing lung is prone to damage, including irreversible effects, from environmental pollutants as it continues to develop through adolescence (U.S. EPA, 2009a, section 8.1.1.2). Older adults represent a lifestage where susceptibility to PM-associated health effects may be related to the higher prevalence of pre-existing cardiovascular and respiratory diseases found in this age group compared to younger age groups as well as the gradual decline in physiological processes that occur as part of the aging process (U.S. EPA, 2009a, section 8.1.1.1). In addition, accumulating evidence suggests that the developing fetus may also represent an additional lifestage that is at greater risk to PM exposures (U.S. EPA, 2009a, sections 2.3.1.2 and 7.4).

With regard to mortality, recent epidemiological studies have continued to find that older adults are at greater risk of all-cause (non-accidental) mortality associated with short-term exposure to both $PM_{2.5}$ and PM_{10}, providing consistent and stronger evidence of effects in this at-risk population compared to the last review (U.S. EPA, 2009a, Figure 7–7, section 8.1.1.1, Zeger et al., 2008). Evidence is accumulating for $PM_{2.5}$-related infant mortality, especially due to respiratory causes during the post-neonatal period (U.S. EPA, 2009a, sections 2.3.1.2 and 7.4).

[39] 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).

[40] Although studies have primarily used exposures to PM_{10} or $PM_{2.5}$, the available evidence suggests that the identified factors also increase risk from $PM_{10-2.5}$ (U.S. EPA, 2009a, section 8.1.8).

[41] The term ''susceptible population'' is defined in the Integrated Science Assessment as ''[P]opulations that have a greater likelihood of experiencing health effects related to exposure to an air pollutant (e.g., PM) due to a variety of factors including, but not limited to: Genetic or developmental factors, race, gender, lifestage, lifestyle (e.g., smoking status and nutrition) or preexisting disease; as well as population-level factors that can increase an individual's exposure to an air pollutant (e.g., PM) such as socioeconomic status [SES], which encompasses reduced access to health care, low educational attainment, residential location, and other factors (U.S. EPA, 2009a, p. 8–1).

With regard to morbidity effects, currently available studies provide evidence that older adults have heightened responses, especially for cardiovascular-related effects, and children have heightened responses for respiratory-related effects (U.S. EPA, 2009a, p. 2–23). In considering respiratory-related effects in children associated with long-term PM exposures, the Policy Assessment recognizes that our understanding of effects on lung development has been strengthened based on newly available evidence that is consistent and coherent across different study designs, locations, and research groups (U.S. EPA, 2011a, p. 2–28). The strongest evidence comes from the extended follow-up for the Southern California Children's Health Study which includes several new studies that report positive associations between long-term exposure to $PM_{2.5}$ and respiratory morbidity, particularly for such endpoints as lung function growth, respiratory symptoms (e.g., bronchitic symptoms), and respiratory disease incidence (U.S. EPA, 2009a, section 7.3; McConnell et al, 2003; Gauderman et al., 2004; Islam et al., 2007). These analyses provide evidence that $PM_{2.5}$-related effects persist into early adulthood and are more robust and larger in magnitude than previously reported. With regard to respiratory effects in children associated with short-term exposures to $PM_{2.5}$, currently available studies provide stronger evidence of respiratory-related hospitalizations with larger effect estimates observed among children. In addition, reductions in lung function (i.e., FEV_1) and increases in respiratory symptoms and medication use associated with PM exposures have been reported among asthmatic children (U.S. EPA, 2009a, sections 6.3.1, 6.3.2.1, and 8.4.9).

A number of health conditions have been found to put individuals at greater risk for adverse effects following exposure to PM. The currently available evidence confirms and strengthens evidence in the last review that individuals with underlying cardiovascular and respiratory diseases are more susceptible to PM exposures (U.S. EPA, 2009a, section 8.1.6; U.S. EPA, 2011a, section 2.2.1). There is also emerging evidence that people with diabetes, who are at risk for cardiovascular disease, as well as obese individuals, may have increased susceptibility to PM exposures (U.S. EPA, 2009a, section 8.1.6.4). As discussed in section 8.1.6 of the Integrated Science Assessment, this body of evidence includes findings from epidemiological and human clinical studies that associations with mortality or morbidity are greater in those with pre-existing conditions, and also includes evidence from toxicological studies using animal models of cardiopulmonary disease.

Stronger evidence is available in this review than the last indicating that people from lower socioeconomic strata are an at-risk population relative to PM exposures (U.S. EPA, 2009a, section 8.1.7; U.S. EPA, 2011a, section 2.2.1). Persons with lower socioeconomic status (SES)[42] have been generally found to have a higher prevalence of pre-existing diseases; limited access to medical treatment; and increased nutritional deficiencies, which can increase this population's risk to PM-related effects.

Investigation of potential genetic susceptibility has provided evidence that individuals with specific genetic differences are more susceptible to PM-related effects (U.S. EPA, 2009a, pp. 8–7 to 8–9). More research is needed to better understand the relationship between genetic effects and potential susceptibility to PM-related effects (U.S. EPA, 2011a, p. 2–109).

In summary, there are several at-risk populations that may be especially susceptible or vulnerable to PM-related effects. 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. The available evidence does not generally allow distinctions to be drawn between the PM indicators in terms of whether populations are more at-risk to a particular size fraction (i.e., $PM_{2.5}$ and $PM_{10-2.5}$).

4. Potential $PM_{2.5}$-Related Impacts on Public Health

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 as described in section III.B.3. 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. In addition, it appears that mortality risks are not limited to the very frail. Taken together, these results suggest that exposure to ambient $PM_{2.5}$ concentrations can have substantial public health impacts.

With regard to at-risk populations in the United States, approximately 7 percent of adults (approximately 16 million adults) and 9 percent of children (approximately 7 million children) have asthma (U.S. EPA 2009a, Table 8–3; CDC, 2008[43]). In addition, approximately 4 percent of adults have been diagnosed with chronic bronchitis and approximately 2 percent with emphysema (U.S. EPA, 2009a, Table 8–3). Approximately 11 percent of adults have been diagnosed with heart disease, 6 percent with coronary heart disease, 23 percent with hypertension, and 8 percent with diabetes (U.S. EPA, 2009a, Table 8–3). In addition, approximately 3 percent of the U.S. adult population has suffered a stroke (U.S. EPA, 2009a, Table 8–3). Therefore, large portions of the United States population are in groups that may be at increased risk to health effects associated with exposures to ambient $PM_{2.5}$. The size of the potentially at-risk population suggests that exposure to ambient $PM_{2.5}$ has significant impact on public health in the United States.

C. Quantitative Characterization of Health Risks

1. Overview

In this review, the quantitative risk assessment builds on the approach used and lessons learned in the last review and focuses 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 are largely the same as those articulated in the risk assessment conducted for the last review. These goals include: (1) To provide estimates of the potential magnitude of premature mortality and/or selected morbidity effects in the population associated with recent ambient level 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, including, where data were available, consideration of impacts on at-risk

[42] Socioeconomic status is a composite measure that usually consists of economic status, measured by income; social status measured by education; and work status measured by occupation (U.S. EPA, 2009a, p. 8–14).

[43] For percentages, see *http://www.cdc.gov/ASTHMA/nhis/06/table4-1.htm.* For population estimates, see *http://www.cdc.gov/ASTHMA/nhis/06/table3-1.htm.*

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 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 I.B.3.

2. Summary of Design Aspects

Based on a review of the evidence presented and assessed in the Integrated Science Assessment and criteria for selecting specific health effect endpoints discussed in the Risk Assessment (U.S. EPA, 2010a, section 3.3.1), the following broad categories of health endpoints were included in the quantitative risk assessment: (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 associated with short-term $PM_{2.5}$ exposure. 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 (U.S. EPA, 2010a, p. 3–29). The quantitative risk assessment estimates risks for various health effects in 15 urban study areas. The selection of urban study areas was based on a number of criteria including: (1) Consideration of urban study areas evaluated in the last PM risk assessment; (2) consideration of locations evaluated in key epidemiological studies; (3) preference for locations with relatively elevated annual and/or 24-hour $PM_{2.5}$ monitored concentrations; and (4) preference for including locations from different regions across the country, reflecting potential differences in $PM_{2.5}$ sources, composition, and potentially other factors which might impact $PM_{2.5}$-related risk (U.S. EPA, 2010a, section 3.3.2). Based on the results of several analyses examining the representativeness of these 15 urban study areas in the broader national context, the Risk 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 $PM_{2.5}$ 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).[44]

In order to estimate the incidence of a particular health effect associated with recent ambient conditions in a specific urban study area attributable to $PM_{2.5}$ exposures, as well as the change in incidence corresponding to a given change in $PM_{2.5}$ concentrations resulting from simulating just meeting current or alternative $PM_{2.5}$ standards, three elements are required (U.S. EPA, 2010a, section 3.1.1, Figures 3–2 and 3–3). These elements are: (1) Air quality information (including recent air quality data for $PM_{2.5}$ from ambient monitors for the selected location, estimates of background $PM_{2.5}$ concentrations appropriate for that location, and a method for adjusting the recent data to reflect patterns of air quality estimated to occur when the area just meets a given set of $PM_{2.5}$ standards); (2) relative risk-based concentration-response functions that provide an estimate of the relationship between the health endpoints of interest and ambient $PM_{2.5}$ concentrations; and (3) baseline health effects incidence rates and population data, which are needed to provide an estimate of the incidence of health effects in an area before any changes in $PM_{2.5}$ air quality.[45]

The Risk Assessment includes 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 provide information to evaluate and rank the potential impacts of key sources of uncertainty on the core risk estimates (U.S. EPA, 2010a, sections 3.5 and 4.3, Table 4–3). In addition, the sensitivity analyses represent a set of reasonable alternatives to the core set of risk estimates that fall within an overall set of plausible risk estimates surrounding the core estimates (U.S. EPA, 2010a, section 4.3.2).

Recent air quality was characterized for the 15 urban study areas based on 24-hour $PM_{2.5}$ concentrations measured for 3 years (i.e., 2005, 2006, and 2007) as described in section 3.2.1 of the Risk Assessment. Different methodologies were then used to simulate conditions for just meeting the current or alternative $PM_{2.5}$ standards (U.S. EPA, 2010a, section 3.2.3). This included using the single rollback approach used in the risk assessment conducted for the last review which reflects a uniform regional pattern of reductions in ambient $PM_{2.5}$ concentrations across monitors (i.e., proportional rollback approach). The proportional rollback approach was used in generating the core risk estimates (U.S. EPA, 2010a, section 3.2.3.1). In sensitivity analyses, the Risk Assessment also applied two alternative rollback approaches (i.e., hybrid and locally-focused rollback approaches)[46] to better characterize

[44] 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 have relatively low $PM_{2.5}$ concentrations (e.g., urban areas in Florida) and, consequently, the Risk Assessment concludes failure to include these areas in the set of urban study areas is unlikely to exclude high $PM_{2.5}$-risk locations (U.S. EPA, 2010a, section 4.4.1).

[45] Incidence rates express the occurrence of a disease or event (e.g., death, hospital admission) in a specific period of time, usually per year. Rates are expressed either as a value per population group (e.g., the number of cases in Philadelphia County) or a value per number of people (e.g., the number of cases per 10,000 residents in Philadelphia County), and may be age- and/or sex-specific. Incidence rates vary among geographic areas due to differences in populations characteristics (e.g., age distribution) and factors promoting illness (e.g., smoking rates, air pollution concentrations). The baseline incidence rate provides an estimate of the incidence rate (i.e., number of cases of the health effect per year, usually per 10,000 or 100,000 general population) in the assessment location unrelated to changes in ambient $PM_{2.5}$ concentrations in that location (U.S. EPA, 2010a, section 3.4).

[46] The hybrid rollback approach involves a combination of an initial step of a more localized reduction in ambient $PM_{2.5}$ concentrations at source-oriented monitors followed by a regional pattern of reduction across all monitors in a study

potential variability in the way air quality in urban areas responds to programs put in place to meet the current or alternative $PM_{2.5}$ standards. In considering the three rollback approaches collectively, the proportional and locally-focused methods are approaches that are more likely to represent ''bounding'' scenarios related to the spatial pattern of future reductions in ambient $PM_{2.5}$ concentrations. In contrast, the hybrid approach, in principle, reflects a more plausible or representative rollback strategy since it: (1) Reflects consideration for site-specific information regarding larger $PM_{2.5}$ sources and their potential impact on source-oriented monitors and (2) combines elements of more locally-focused and regionally-focused patterns of reductions (U.S. EPA, 2010a, section 3.2.3).

The peak-to-mean ratio of ambient $PM_{2.5}$ concentrations within a study area informs the type of rollback approach used to simulate just meeting the current or alternative suites of standards to determine the magnitude of the reduction in annual mean $PM_{2.5}$ concentrations for that study area and consequently the degree of risk reduction.[47] For example, study areas with relatively high peak-to-mean ratios are likely to have greater estimated risk reductions for the current suite of standards (depending on the combination of 24-hour and annual design values), and such locations can be especially sensitive to the type of rollback approach used, with the proportional rollback approach resulting in notably greater estimated risk reduction compared with the locally-focused rollback approach. In contrast, study areas with lower peak-to-mean ratios typically experience greater risk reductions when simulating just meeting the current or alternative annual-standard level than with simulating just meeting the current or alternative 24-hour standard level (again depending on the combination of 24-hour and annual design values). In addition, the type of rollback approach used will tend to have less of an impact on the magnitude of risk reductions for study areas with lower peak-to-mean ratios. Consideration of these two factors helps to inform an understanding of the nature and pattern of estimated risk reductions and risk remaining upon simulation of just meeting the current and alternative suites of standards across the urban study areas (U.S. EPA, 2010a, section 5.2.1).

The concentration-response functions used in the risk assessment were based on findings from epidemiological studies that have relied on fixed-site, population-oriented, ambient monitors as a surrogate for actual ambient $PM_{2.5}$ exposures. The risk assessment addresses risks attributable to anthropogenic sources and activities (i.e., risk associated with concentrations above policy-relevant background).[48] This approach of estimating risks in excess of background was judged to be more relevant to policy decisions regarding ambient air quality standards than risk estimates that include effects potentially attributable to $PM_{2.5}$ concentrations that are not associated with North American anthropogenic emissions.

In modeling risk associated with long- and short-term $PM_{2.5}$ exposures, the Risk Assessment initially focused on selecting concentration-response functions from multi-city studies.[49] Concentration-response functions from two single-city studies provided coverage for additional health effect endpoints (i.e., emergency department visits for cardiovascular and/or respiratory effects) associated with short-term $PM_{2.5}$ exposures (U.S. EPA, 2010a, p. 3–37).

With regard to modeling risks associated with long-term $PM_{2.5}$ exposure, concentration-response functions used in the risk model are all based on cohort studies, in which a cohort of individuals is followed over time. In the core analysis, estimated premature mortality risk associated with long-term $PM_{2.5}$ concentrations used concentration-response functions from the extended ACS study (Krewski et al., 2009). This study had a number of advantages including: analyses that expanded upon previous publications presenting evaluations of the ACS long-term cohort study and extending the follow-up period to eighteen years; a rigorous examination of different model forms for estimating effect estimates; coverage for a range of ecological variables (e.g., social, economic, and demographic factors) which allowed for consideration of whether these factors confound or modify the relationship between $PM_{2.5}$ exposure and mortality; and updated and expanded data sets on incidence and exposure (U.S. EPA, 2010a, p 2–9 and 3–38).

As discussed in section III.B.3, persons of lower socioeconomic status have been identified as an at-risk population. The ACS study cohort does not provide representative coverage for persons of lower-socioeconomic status and, thus, the Risk Assessment concludes that using the concentration-response functions from this study may result in risk estimates that are biased low (U.S. EPA, 2010a, p. 5–7). Therefore, concentration-response functions from a reanalysis of the Harvard Six Cities study (Krewski et al., 2000) were used in a sensitivity analysis to better support generalizing the results of the risk assessment across the broader national population.[50]

While being mindful that the use of concentration-response functions from Krewski et al. (2009) introduces potential for low bias in the core risk estimates, the Policy Assessment also recognizes many strengths of this study and reasons for its continued use for generating the core risk estimates, including: consideration of a large number of metropolitan statistical areas, inclusion of two time periods for the air quality data which allowed us to consider different exposure windows, and analysis of a wide range of concentration-response function models. Therefore, the Risk Assessment concludes that concentration-response functions obtained from this study had the greatest overall support and were appropriate to incorporate in the core risk model (U.S. EPA, 2010a, p. 3–38).

area (U.S. EPA, 2010a, section 3.2.3.2). The locally-focused rollback approach involves a focused reduction of concentrations only at those monitors exceeding the current or alternative 24-hour standard levels (U.S. EPA, 2010a, section 3.2.3.3).

[47] The peak-to-mean ratio of ambient $PM_{2.5}$ concentrations also has a direct bearing on whether the 24-hour or annual standard will be the generally controlling standard for a particular study area, with higher peak-to-mean ratios generally being associated with locations where the 24-hour standard is likely the controlling standard.

[48] Policy-relevant background estimates used in the risk assessment model were based on information presented in the Integrated Science Assessment (U.S. EPA, 2009a, section 3.7, Table 3–23) and discussed in the Risk Assessment (U.S. EPA, 2010a, section 3.2.2). These values were generated based on a combination of Community Multiscale Air Quality model (CMAQ) and Goddard Earth Observing System (GEOS)-Chem modeling (U.S. EPA, 2009a, section 3.7.1.2; U.S. EPA, 2010a, section 3.2.2).

[49] As noted in section 3.3.3 of the Risk Assessment, multi-city studies have a number of advantages over single-city studies including: increased statistical power providing effect estimates with relatively greater precision and reduced problems with publication bias (i.e., in which studies with statistically insignificant or negative results are less likely to get published than those with positive and/or statistically significant results).

[50] As noted in the last review, the ACS study population has persons generally representative of a higher SES (e.g., higher educational status) relative to the Harvard Six Cities study population (12 percent versus 28 percent of the cohort had less than a high school education, respectively) (U.S. EPA, 2004, p. 8–118). The Policy Assessment concludes that the Harvard Six Cities study cohort may provide a more representative sample of the broader national population than the ACS study cohort (U.S. EPA, 2011a, p. 2–40).

In the core analysis, for modeling health endpoints associated with long-term exposure, the Risk Assessment concluded that modeling risks down to policy-relevant background would require substantial extrapolation of the estimated concentration-response functions below the range of the data on which they were estimated (i.e., the lowest measured levels reported in the epidemiological studies were substantially above policy-relevant background). Therefore, the Risk Assessment concluded it was most appropriate in the core analysis to estimate risk only down to the lowest measured level to avoid introducing additional uncertainty into the analysis (U.S. EPA, 2010a, 3–1 to 3–3).[51] A sensitivity analysis comparing the impact of estimated risks down to policy-relevant background rather than down to the lowest measured level (U.S. EPA, 2010a, section 3.5.4.1) used annual estimates of policy-relevant background values for specific geographic regions (U.S. EPA, 2010a, section 3.2.2, Table 3–2).

With regard to modeling risks associated with short-term $PM_{2.5}$ exposure, concentration-response functions from two time-series studies were selected as the primary studies to support the core analysis. Concentration-response functions from Zanobetti and Schwartz (2009) were used in estimating premature non-accidental, cardiovascular-related, and respiratory-related mortality. Concentration-response functions from Bell et al. (2008) were used in estimating cardiovascular-related and respiratory-related hospital admissions. In addition, concentration-response functions from two single-city studies were used to estimate emergency department visits for cardiovascular and/or respiratory illnesses associated with short-term $PM_{2.5}$ exposure (Tolbert et al., 2007; Ito et al., 2007; U.S. EPA, 2010a, p. 3–37).

For modeling health endpoints associated with short-term $PM_{2.5}$ exposure, the Risk Assessment estimates risk down to policy-relevant background exclusively using quarterly values to represent the appropriate block of days within a simulated year (U.S. EPA, 2010a, section 3.2.2, Table 3–2).

To estimate the change in incidence of a health endpoint associated with a given change in $PM_{2.5}$ concentrations, information on the baseline incidence of that endpoint is needed (U.S. EPA, 2010a, section 3.4). In calculating a baseline incidence rate to be used with a concentration-response function from a given epidemiological study, the Risk Assessment matched the counties, age grouping, and International Classification of Diseases (ICD) codes used in that study (U.S. EPA, 2010a, section 3.4.2).

An important component of a population health risk assessment is the characterization of both uncertainty and variability.[52] The design of the risk assessment includes a number of elements to address these issues, including using guidance from the World Health Organization (WHO, 2008) as a framework for developing the approach used for characterizing uncertainty in the analyses (U.S. EPA, 2010a, section 3.5).

The Risk Assessment considers key sources of variability that can impact the nature and magnitude of risks associated with simulating just meeting current and alternative standard levels across the urban study areas (U.S. EPA, 2010a, section 3.5.2). These sources of variability include those that contribute to differences in risk across urban study areas, but do 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 focuses on factors that not only introduce variability into risk estimates across study areas, but also play 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 are likely to affect population risks and the degree to which they were (or were not) fully captured in the design of the risk assessment are discussed in section 3.5.2 of the Risk Assessment. These sources include: $PM_{2.5}$ composition; intra-urban variability in ambient $PM_{2.5}$ concentrations; 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; co-pollutant exposures; factors related to demographic and socioeconomic status; behavioral differences across urban study areas (e.g., time spent outdoors); baseline incidence rates; and 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 (U.S. EPA, 2010a, pp. 3–67 to 3–69).

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 (U.S. EPA, 2010a, sections 3.5.3 and 3.5.4). The quantitative sensitivity analyses informed our understanding of sources of uncertainty that may have a moderate to large impact on the core risk estimates including: (1) Characterizing intra-urban population exposure in the context of epidemiology 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 associate with long-term $PM_{2.5}$ exposures; and (8) potential variation in effect estimates reflecting compositional differences in $PM_{2.5}$ (U.S. EPA, 2011a, section 5.1.4). In addition to identifying sources of uncertainty with a moderate to large impact on the core risk estimates, the single and multi-element sensitivity analyses also produced a set of reasonable alternative risk estimates that allowed us to place the results of the core analysis in context with regard to uncertainty and potential bias (U.S. EPA, 2010a, section 5.1.4). The qualitative uncertainty analysis supplemented the quantitative sensitivity analyses by allowing coverage for sources of uncertainty that could not be readily included in the sensitivity analysis (U.S. EPA, 2010a, section 3.5.3).

With respect to the long-term exposure-related mortality risk

[51] To provide consistency for the different concentration-response functions selected from the long-term exposure studies, and, in particular, to avoid the choice of lowest measured levels unduly influencing the results of the risk assessment, the Risk Assessment concluded it was appropriate to select a single lowest measured level—5.8 $\mu g/m^3$ from the later exposure period evaluated in Krewski et al. (2009)—to use in estimating risks associated with long-term $PM_{2.5}$ exposures (U.S. EPA, 2010a, p. 3–3).

[52] *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).

estimates,[53] the most important sources of uncertainty identified in the quantitative sensitivity analyses included: selection of concentration-response functions; modeling risk down to policy-relevant background versus lowest measured level; and the choice of rollback approach used to simulate just meeting current or alternative standards (U.S. EPA, 2011a, p. 2–39). With regard to the qualitative analysis of uncertainty, the following sources were identified as potentially having a large impact on the core risk estimates for the long-term exposure-related mortality: characterization of intra-urban population exposures; impact of historical air quality; and potential variation in effect estimates reflecting differences in $PM_{2.5}$ composition (U.S. EPA, 2011a, p. 2–39).

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). Two additional analyses examined potential bias and overall confidence in the risk estimates. The first analysis explored potential bias in the core risk estimates by considering a set of alternative reasonable risk estimates generated as part of a sensitivity analysis. The second analysis compared the annual mean $PM_{2.5}$ concentrations associated with simulating just meeting the current and alternative suites of standards with the air quality distribution used in deriving the concentration-response functions applied in modeling mortality risk. 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).

3. Risk Estimates and Key Observations

As discussed below, three factors figure prominently in the interpretation of the risk estimates associated with simulating just meeting the current and alternative suites of standards, including: (1) The importance of changes in annual mean $PM_{2.5}$ concentrations for a specific study area in estimating changes in risks related to both long- and short-term exposures associated with recent air quality conditions and air quality simulated to just meet the current and alternative suites of $PM_{2.5}$ standards; (2) the ratio of peak- to-mean ambient $PM_{2.5}$ concentrations in a study area; and (3) the spatial pattern of ambient $PM_{2.5}$ reductions that result from using different approaches to simulate just meeting the current standard levels (i.e., rollback approaches). The latter two factors are interrelated and influence the degree of risk reduction estimated under the current suite of standards.

The magnitude of both long- and short-term exposure-related risk estimated to remain upon just meeting the current suite of standards is strongly associated with the simulated change in annual mean $PM_{2.5}$ concentrations. The role of annual mean $PM_{2.5}$ concentrations in driving long-term exposure-related risk estimates is intuitive given that risks are modeled using the annual mean air quality metric.[54] The fact that short-term exposure-related risk estimates are also driven by changes in long-term mean $PM_{2.5}$ concentrations is less intuitive, since changes in mean 24-hour $PM_{2.5}$ concentrations are used to estimate changes in risk for this time period.[55] Analyses show that short-term exposure-related risks are 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 (U.S. EPA, 2010a, section 3.1.2.2). Consequently, the largest part of the estimates of short-term exposure-related risk is related to the changes in the portion of the distribution of short term $PM_{2.5}$ exposures that are well represented by changes in the annual mean. Therefore, the Policy Assessment focuses on changes in annual mean $PM_{2.5}$ concentrations to inform our understanding of patterns of both long- and short-term exposure-related risk estimates across the set of urban study areas evaluated in the quantitative risk assessment (U.S. EPA, 2011a, pp. 2–36 to 2–37).

In estimating $PM_{2.5}$-related risks likely to remain upon simulation of just meeting the current annual and 24-hour standards in the 15 urban study areas, the Risk Assessment focuses on the 13 areas that would likely not have met the current suite of $PM_{2.5}$ standards based on recent air quality (2005 to 2007). These 13 areas have annual and/or 24-hour design values that are above the levels of the current standards (U.S. EPA, 2010a, Table 3–3).[56] Based on the core risk estimates for these areas, using the proportional rollback approach, the Policy Assessment makes the following key observations regarding the magnitude of risk remaining upon simulation of just meeting the current suite of standards:

(1) *Long-term exposure-related mortality risk estimated to remain upon just meeting the current standards are significant:* Premature mortality related to ischemic heart disease attributable to long-term $PM_{2.5}$ exposure was estimated to range from less than 100 to approximately 2,000 cases per year across the urban study areas. The variability in these estimates reflects, to a

[53] Given increased emphasis placed in this analysis on long-term exposure-related mortality, the uncertainty analyses completed for this health endpoint category were more comprehensive than those conducted for analyses of short-term exposure-related mortality and morbidity. This reflects, to some extent, limitations in the epidemiological data available for addressing uncertainty in the latter categories (U.S. EPA, 2010a, section 3.5.4.2).

[54] As noted in section 3.2.1 of the Risk Assessment (U.S. EPA, 2010a), estimates of long-term exposure-related mortality are actually based on an annual mean $PM_{2.5}$ concentration that is the average across monitors in a study area (i.e., based on the composite monitor distribution). Therefore, in considering changes in long-term exposure-related mortality, it is most appropriate to compare composite monitor estimates generated for a study area under each alternative suite of standards considered. The annual mean at the highest reporting monitor (i.e., based on the maximum monitor distribution) for a study area is the annual design value. The annual design value is used to determine the percent reduction in $PM_{2.5}$ concentrations required to meet a particular standard. Both types of air quality estimates are provided in Table 3–4 of the Risk Assessment (U.S. EPA, 2010a, pp. 3–25 to 3–27).

[55] Estimates of short-term $PM_{2.5}$ exposure-related mortality and morbidity are based on composite monitor 24-hour $PM_{2.5}$ concentrations. However, similar to the case with long-term exposure-related mortality, under the current rules, it is the 98th percentile 24-hour concentration estimated at the maximum monitor (the 24-hour design value) that will determine the degree of reduction required to meet a given 24-hour standard level (U.S. EPA, 2011a, p. 2–37).

[56] Of the 15 urban study areas, only Dallas and Phoenix have both annual and 24-hour design values below the levels of the current standards based on 2005–2007 air quality data (U.S. EPA, 2010a, Table 3–3).

great extent, differences in the size of study area populations. These estimates represent from 4 to 17% of all mortality related to ischemic heart disease in a given year for the urban study areas evaluated, representing a measure of risk that takes into account differences in population size and baseline mortality rates (U.S. EPA, 2011a, p. 2–43, Table 2–2). These estimates of risk for mortality related to ischemic heart disease associated with long-term $PM_{2.5}$ exposure would likely be in a range of thousands of deaths per year for the 15 urban study areas[57] (U.S. EPA, 2011a, pp. 2–46 to 2–47). Based on these risk estimates for premature mortality related to ischemic heart disease alone, the Policy Assessment concludes that risks estimated to remain upon simulation of just meeting the current suite of standards are important from a public health standpoint (U.S. EPA, 2011a, p. 2–47). The Risk Assessment also includes estimated risks for premature mortality related to cardiopulmonary effects and lung cancer, which increase the total annual incidence of mortality attributable to long-term $PM_{2.5}$ exposure (see U.S. EPA, 2010a, section 4.2.1).

(2) *Short-term exposure-related mortality risk estimated to remain upon just meeting the current standards are much smaller than long-term exposure-related mortality risks:* Cardiovascular-related mortality associated with short-term $PM_{2.5}$ exposure was estimated to range from less than 10 to 500 cases per year across the urban study areas. These estimates represent approximately 1 to 2 percent of total cardiovascular-related mortality in a given year for the urban study areas evaluated (U.S. EPA, 2011a, p. 2–43, Table 2–3). 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 substantially lower, up to an order of magnitude smaller, for short-term exposure-related mortality (U.S. EPA, 2011a, p. 2–47).

(3) *Short-term exposure-related morbidity risk estimated to remain upon just meeting the current standards indicate hospitalizations are significantly larger for cardiovascular-related rather than respiratory-related events and emergency department visits for asthma-related events are significant:* Cardiovascular-related hospitalizations were estimated to range from approximately 10 to 800 cases per year across the study areas, which are less than 1 percent of total cardiovascular-related hospitalizations (U.S. EPA, 2011a, p. 2–43, Table 2–3). Respiratory-related hospital admissions attributable to short-term $PM_{2.5}$ exposure were significantly smaller than those related to cardiovascular events (U.S. EPA, 2010a, Tables E–102 and E–111). Cardiovascular- and respiratory-related hospital admissions together ranged up to approximately 1,000 admissions per year across the urban study areas. The estimated incidence of asthma-related emergency department visits is several times larger than the estimates of cardiovascular- and respiratory-related hospital admissions (U.S. EPA, 2011a, p. 2–47; U.S. EPA, 2010a, Tables E–118 to E–123

(4) *Substantial variability exists in the magnitude of risk remaining across urban study areas:* Estimated risks remaining upon just meeting the current suite of standards vary substantially across study areas, even when considering risks normalized for differences in population size and baseline incidence rates. This variability is a consequence of the substantial differences in the annual mean $PM_{2.5}$ concentrations across study areas that result from simulating just meeting the current standards. This is important because, as discussed above, annual mean concentrations are highly correlated with both long- and short-term exposure-related risk. The variability in annual mean $PM_{2.5}$ concentrations occurred primarily in those study areas in which the 24-hour standard was the generally controlling standard. In such areas, the variability in estimated risks across study areas was largest when regional patterns of reductions in $PM_{2.5}$ concentrations were simulated, using the proportional rollback approach, as was done in the core analysis. Less variability was observed when more localized patterns of $PM_{2.5}$ reductions were simulated using the locally-focused rollback approach, as was done in a sensitivity analysis. When simulations were done using the locally-focused rollback approach, estimated risks remaining upon just meeting the current suite of standards were appreciably larger than those estimated in the core analysis (U.S. EPA, 2011a, p. 2–46; U.S. EPA, 2010a, section 4.3.1.1).

(5) *Simulation of just meeting the current suite of standards results in annual mean $PM_{2.5}$ concentrations well below the current standard for some study areas:* In simulating just meeting the current suite of standards, the resulting composite monitor annual mean $PM_{2.5}$ concentrations ranged from about 15 $\mu g/m^3$ (for those study areas in which the annual standard was controlling) down to as low as about 8 $\mu g/m^3$ (for those study areas in which the 24-hour standard was the generally controlling standard or the annual mean concentration was well below 15 $\mu g/m^3$ based on recent air quality) (U.S. EPA, 2011a, p. 2–46).

Reductions in risk associated with simulating air quality to just meet alternative standard levels were also estimated in this review (U.S. EPA, 2010a, sections 4.2.2, 5.2.2, and 5.2.3; U.S. EPA, 2011a, section 2.3.4.2). The estimated percent of risk reductions are depicted graphically in the Policy Assessment (US 2011a, Figures 2–11 and 2–12), showing patterns of estimated risk reductions associated with alternative suites of standards.[58] These figures also depict the level of confidence associated with the risk estimates generated for simulating just meeting the current standards as well as alternative standard levels considered. As would be expected, patterns of increasing estimated risk reductions are generally observed as either the annual or 24-hour standard, or both, are reduced over the ranges considered in the Risk Assessment. A number of the key observations regarding the magnitude of risk remaining upon simulation of just meeting the alternative suites of standards are analogous to the observations identified above for simulation of just meeting the current standards (U.S. EPA, 2011a, pp. 2–97 to 2–100).

With regard to characterizing estimates of $PM_{2.5}$-related risk associated with simulation of alternative standards, the Policy Assessment recognizes that greater overall confidence is associated with estimates of *risk reduction* than for estimates of *absolute risk remaining* (U.S. EPA, 2011a, p. 2–94). Furthermore, the Policy Assessment recognizes 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 (U.S. EPA, 2011a, p. 2–97). In addition, the Policy Assessment observes that in considering the overall confidence associated with the quantitative analyses, the Risk Assessment recognizes that: (1) Substantial variability exists in the magnitude of risk remaining across urban study areas and (2) in general, higher confidence is 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.

The variability in risk is a consequence of the substantial differences in the annual mean $PM_{2.5}$ concentrations across urban study areas that result from simulating just meeting current or alternative standards. As $PM_{2.5}$ concentrations decrease from the mean $PM_{2.5}$ concentrations, the Risk Assessment concludes there is decreasing confidence in the risk estimates (U.S. EPA, 2010a, p. 5–16). As lower long-term mean $PM_{2.5}$ concentrations are simulated (i.e., ambient concentrations further from

[57] Premature mortality for all causes attributed to $PM_{2.5}$ exposure was estimated to be in a range 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).

[58] Patterns of risk reduction across alternative annual standard levels, in terms of percent change relative to risk estimates upon simulating just meeting the current standards, are similar for all health endpoints modeled (i.e., all-cause, ischemic heart disease-related, and cardiopulmonary-related mortality). This similarity reflects the fact that the concentration-response functions used in the quantitative risk assessment are close to linear across the range of ambient $PM_{2.5}$ concentrations evaluated. However, estimated incidence will vary by health endpoint (U.S. EPA, 2011a, pp. 2–93 to 2–94, footnote 70).

recent air quality conditions), the potential variability in such factors as the spatial pattern of ambient $PM_{2.5}$ reductions (i.e., rollback) increases, thereby introducing greater uncertainty into the simulation of composite monitor annual mean $PM_{2.5}$ concentrations, and, consequently, in the risk estimates (U.S. EPA, 2010a, Appendix J).

Based on consideration of the composite monitor annual mean $PM_{2.5}$ concentrations involved in estimating long-term exposure-related mortality, the Risk Assessment has higher confidence in using those concentrations that generally fall well within the range of ambient $PM_{2.5}$ concentrations considered in fitting the concentration-response functions used (i.e., within one standard deviation of the mean $PM_{2.5}$ concentration reported in Krewski et al. (2009) for 1999–2000) as inputs to the risk model. For example, with the exception of one urban study area, those areas estimated to have risk reductions using alternative annual standard levels of 13 and 14 μg/m^3 had simulated composite monitor annual mean concentrations ranging from approximately 10.6 to 13.3 μg/m^3. With lower alternative annual standard levels of 12 μg/m^3 and 10 μg/m^3, the composite monitor annual mean values ranged from approximately 9.0 to 11.4 μg/m^3 and 7.6 and 8.9 μg/m^3, respectively. These concentrations are towards the lower end of the range of ACS data (in some cases approaching the lowest measured level) used in fitting the concentration-response functions, particularly for an annual standard level of 10 μg/m^3, and, thus, the Policy Assessment concludes there is less confidence in the risk estimates associated with these levels compared with those for the higher alternative annual standard levels considered (U.S. EPA, 2011a, p. 2–99). Thus, while simulation of risks for an alternative annual standard level of 10 μg/m^3 suggests that additional risk reductions could be expected with alternative annual standards below 12 μg/m^3, the Policy Assessment recognizes that there is potentially greater uncertainty associated with these risk estimates compared with estimates generated for the higher alternative annual standard levels considered in the quantitative risk assessment, since these estimates required simulation of relatively greater reductions in ambient $PM_{2.5}$ concentrations (U.S. EPA, 2011a, p. 2–98).

The results of simulating alternative suites of $PM_{2.5}$ standards including a combination of alternative annual and 24-hour standard levels suggest 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 the alternative 24-hour standard is highly variable (U.S. EPA, 2010a, section 4.2.2). Thus, the Risk Assessment concludes more consistent reductions in estimated risk and consequently degrees of public health protection are estimated to result from simulating just meeting the alternative annual standard levels considered (U.S. EPA, 2010a, pp. 5–15 to 5–16). Furthermore, the Policy Assessment concludes that the urban study areas with the greatest degree of estimated reduction associated with simulating just meeting alternative 24-hour standard levels of 30 and 25 μg/m^3 also had the lowest estimated annual mean $PM_{2.5}$ concentrations, and, therefore, there was substantially lower confidence in these risk estimates (U.S. EPA, 2011a, pp. 2–99 to 2–100).

Based on the consideration of both the qualitative and quantitative assessments of uncertainty, the Risk Assessment concludes 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 Risk Assessment conclude 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 [59] (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 recognizes that the currently available scientific information includes evidence for a broader range of health endpoints and at-risk populations beyond those included in the quantitative risk assessment, including lung function growth and respiratory symptoms in children and reproductive and developmental effects (U.S. EPA, 2011a, section 2.2.1).

In considering the set of quantitative risk estimates and related uncertainties and limitations related to long- and short-term $PM_{2.5}$ exposure discussed above together with consideration of the health endpoints which could not be quantified, the Policy Assessment concludes this information provides 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 (U.S. EPA, 2011a, p. 2–47). Furthermore, while the alternative 24-hour standard levels considered (when controlling) did result in additional estimated risk reductions beyond those estimated for alternative annual standards alone, these additional estimated reductions are highly variable, in part due to different rollback approaches. Conversely, the Risk Assessment recognizes 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

The initial issue to be addressed in the current review of the primary $PM_{2.5}$ standards is whether, in view of the additional information now available, the existing standards should be retained or revised. In evaluating whether it is appropriate to retain or revise the current suite of standards, the Administrator considered the scientific information from the last review and the broader body of evidence and information now available. The Administrator has taken into account both evidence- and risk-based considerations in developing conclusions on the adequacy of the current primary $PM_{2.5}$ standards. Evidence-based considerations (section III.D.1) 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). The risk-based considerations (section III.D.2) 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). The advice received from CASAC is discussed in section III.D.3. Finally, the Administrator's proposed conclusion on the adequacy of the current $PM_{2.5}$ primary standards is provided in section III.D.4.

[59] Most of the alternative model specifications supported by the currently available scientific information produced risk estimates that are higher (by up to a factor of 2 to 3) than the core risk estimates (U.S. EPA, 2011a, pp. 2–40 and 2–41).

1. Evidence-Based Considerations in the Policy Assessment

In light of the health evidence described above, specifically with regard to factors contributing to greater susceptibility to health effects associated with ambient $PM_{2.5}$ exposures, the Policy Assessment considers the extent to which the currently available scientific evidence reports associations between fine particle exposures and health effects that extend to air quality concentrations that are lower than had previously been observed or that have been observed in areas that would likely meet the current suite of $PM_{2.5}$ standards (U.S. EPA, 2011a, section 2.2.1). As noted above, the Integrated Science Assessment concludes there is no evidence to support the existence of a discernible threshold below which effects would not occur (U.S. EPA, 2009a, section 2.4.3).

a. Associations With Long-term $PM_{2.5}$ Exposures

With regard to associations observed in long-term $PM_{2.5}$ exposure studies, the Policy Assessment recognizes that extended follow-up analyses of the ACS and Harvard Six Cities studies provide 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 μg/m^3 across 50 metropolitan areas for 1979–1983 (Pope et al., 1995; Krewski et al., 2000).[60] 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 μg/m^3 in the original monitoring period (1979–1983) to 14.0 μg/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 μg/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 with a long-term mean $PM_{2.5}$ concentration of 18.0 μg/m^3 for 1980–1985 (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/m^3 for 1980–1988[61] (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).

New cohort studies provide 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 greater in magnitude (U.S. EPA, 2011a, pp. 2–32 to 2–33). The WHI study reported positive and most often statistically significant associations between long-term $PM_{2.5}$ exposure and cardiovascular-related mortality, with much larger relative risk estimates than in the ACS and Harvard Six Cities studies, as well as morbidity effects at an aggregate long-term mean $PM_{2.5}$ concentration of 12.9 μg/m^3 for 2000 (Miller et al., 2007).[62] 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/m^3 and 14.1 μg/m^3, respectively, for 2000–2002. The MCAPS 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/m^3, although no association was reported for the western region with an aggregate long-term $PM_{2.5}$ median concentration of 13.1 μg/m^3 (U.S. EPA, 2009a, p. 7–88; Zeger et al., 2008).[63] 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/m^3 and 13.7 μg/m^3, 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/m^3 (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/m^3. 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/m^3 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 concludes evidence is suggestive of a causal relationship, the Policy Assessment notes a limited number of birth outcome studies that reported positive and statistically significant effects related to aggregate long-term mean $PM_{2.5}$ concentrations

[60] The study periods referred to in the Policy Assessment (U.S. EPA, 2011a) and in this proposed 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 status data that were included.

[61] Aggregate mean concentration provided by study author (personal communication from Dr. Francine Laden, 2009).

[62] Miller et al. (2007) studied postmenopausal women without previous cardiovascular disease in 36 study areas from 1994 to 1998, with a median follow-up period of six years. The ambient $PM_{2.5}$ monitor nearest to a study subject's residence (within 30 miles or 48 kilometers) was identified and used to assign long-term mean $PM_{2.5}$ concentrations to each subject. The annual average concentration in the year 2000 was the primary exposure measure because of the substantially increased network of monitors in that year, as compared with previous years. Miller et al. (2007) reported a long-term mean $PM_{2.5}$ concentration across study areas of 13.5 μg/m^3. This concentration was presented in the Integrated Science Assessment (U.S. EPA, 2009a, Figure 2–2, Table 7–8) and discussed in the second draft Policy Assessment (U.S. EPA, 2010f, Figure 2–4). In response to a request from the EPA for additional information on the air quality data used in selected epidemiological studies (Hassett-Sipple and Stanek, 2009), study investigators provided updated air quality data for the study period. The updated long-term mean $PM_{2.5}$ concentration provided by the study authors was 12.9 μg/m^3 (personal communication from Cynthia Curl, 2009; Stanek et al., 2010). The EPA notes that this updated long-term mean concentration matches the composite monitor approach annual mean calculated by staff for the year of air quality data (i.e., 2000) considered by the study investigators (Hassett-Sipple et al., 2010, Attachment A, p. 6). The updated air quality data for the Women's Health Initiative study was presented and considered in the final Policy Assessment (U.S. EPA, 2011a, p. 2–32). The Policy Assessment notes that in comparison to other long-term exposure studies, the WHI study was more limited in that it was based on only one year of air quality data (U.S. EPA, 2011a, p. 2–82).

[63] 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/m^3. 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).

down to approximately 12 μg/m³ (U.S. EPA, 2011a, p. 2–33).

Collectively, the Policy Assessment concludes that currently available evidence provides support for associations between long-term $PM_{2.5}$ exposure and mortality and morbidity effects that extend to air quality concentrations that are lower than had previously been observed, with aggregate long-term mean $PM_{2.5}$ concentrations extending to well below the level of the current annual standard. These studies evaluated a broader range of health outcomes in the general population and in at-risk populations than were considered in the last review, and include extended follow-up for prospective epidemiological studies that were important in the last review as well as additional evidence in important new cohorts.

b. Associations With Short-term $PM_{2.5}$ Exposures

In light of the mixed findings reported in single-city, short-term exposure studies, the Policy Assessment places 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 recognizes that long-term mean concentrations reported in new multi-city U.S. and Canadian studies provide evidence of associations between short-term $PM_{2.5}$ exposure and mortality at similar air quality distributions than 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 indicate the association between short-term exposure to $PM_{2.5}$ and total mortality and cardiovascular- and respiratory-related mortality is 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 notes 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 μg/m³ (personal communication with Dr. Antonella Zanobetti, 2009).[64]

With regard to cardiovascular and respiratory morbidity effects, in the first analysis of the MCAPS 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).[65] In an extended analysis of the MCAPS study, 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 indicate that effects are occurring in areas that would meet the current standards but also suggest 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 concludes that the findings from short-term $PM_{2.5}$ exposure studies provide 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 are 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, the Policy Assessment first concludes that there is 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 addresses the question of whether the available evidence supports consideration of standards that are more protective than the current standards. In so doing, the Policy Assessment considers whether there is 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 provide 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 recognizes that important limitations and uncertainties associated with this expanded body of scientific evidence, noted above in section III.B.2, need 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 concludes 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 concludes this evidence provides strong support for considering fine particle standards that would afford increased protection beyond that

[64] 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).

[65] This sub-analysis was not included in the original publication (Dominici et al., 2006a). 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.

afforded by the current standards (U.S. EPA, 2011a, p. 2–35).

2. Summary of Risk-Based Considerations in the Policy Assessment

In addition to evidence-based consideration, the Policy Assessment also considers 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 notes 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; [66] 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 concludes these risks are important from a public health standpoint (U.S. EPA, 2011a, p. 2–47). This conclusion reflects consideration of both the severity and the magnitude of the effects. For example, the risk assessment indicates 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 [67] (U.S. EPA, 2011a, pp. 2–46 to 2–47). Moreover, additional risks are 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 quantitative assessments of uncertainty completed as part of the quantitative risk assessment, the Risk Assessment concludes that it is 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 above provides 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).

In considering the risks estimated to occur upon simulating just meeting the current $PM_{2.5}$ standards, the Policy Assessment concludes that these estimated risks can reasonably be judged to be important from a public health perspective and provide strong support for consideration of alternative standards that would provide increased protection beyond that afforded by the current $PM_{2.5}$ standards (U.S. EPA, 2011a, p. 2–48).

3. CASAC Advice

CASAC, based on their review of drafts of the Integrated Science Assessment, the Risk Assessment, and the Policy Assessment, has 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).

4. Administrator's Proposed Conclusions Concerning the Adequacy of the Current Primary $PM_{2.5}$ Standards

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 staff conclusions and associated rationales presented in the Policy Assessment, views expressed by CASAC, and public comments. In particular, the Administrator recognizes that the Integrated Science Assessment concludes 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. Moreover, the Administrator reflects that these effects have 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. *See American Trucking Associations* v. *EPA,* 283 F. 3d at 369, 376 (revision of level of existing standards justified when effects are observed in areas that meet those standards). With regard to the results of the quantitative risk assessment, the Administrator notes that the Risk Assessment concludes that the risks estimated to remain upon simulation of just meeting the current standards are important from a public health standpoint in terms of both the severity and magnitude of the effects.

Based on her consideration of these conclusions, as well as consideration of CASAC's conclusion that the evidence and risk assessment clearly call into question the adequacy of the public health protection provided by the current $PM_{2.5}$ NAAQS, the Administrator provisionally concludes that the current primary $PM_{2.5}$ standards, taken together, are not requisite to protect public health with an adequate margin of safety and that revision is needed to provide increased public health protection. The Administrator provisionally concludes that the scientific evidence and information on risk provide strong support for consideration of alternative standards that would provide increased public health protection beyond that afforded by the current $PM_{2.5}$ standards.

[66] 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).

[67] 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).

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 concludes that it is 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, 2011, p. 2–50).

The Policy Assessment also considers the expanded body of evidence available in this review to consider whether there is sufficient evidence to support a separate standard for ultrafine particles [68] or whether there is 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 concludes this evidence is still very limited and largely focused on exposure to diesel exhaust, for which the Integrated Science Assessment concludes it is unclear if 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 notes 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 recognizes 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 concludes that the currently available evidence is suggestive of a causal relationship between short-term exposures to ultrafine particles and cardiovascular and respiratory effects. Furthermore, the Integrated Science Assessment concludes that evidence is 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 recognizes a national characterization of concentrations, temporal and spatial patterns, and trends is not possible at this time, and the availability of ambient ultrafine measurements to support health studies is 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 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 suggest 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

[68] 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).

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 concludes that this information is 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 concludes 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, there are 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). Data from the CSN provide 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).[69] The CSN provides $PM_{2.5}$ speciation measurements generally on a one-in-three or one-in-six day sampling schedule and, thus, do not capture data every day at most sites.[70]

The Policy Assessment recognizes that several new multi-city studies evaluating short-term exposures to fine particle constituents are now available. These studies continue 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 notes the most significant new evidence is 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., 2006). Using health data from a cohort of U.S. military veterans and $PM_{2.5}$ measurement data from the CSN, Lipfert et al. (2006) 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 associated with a range of health endpoints, the Integrated Science Assessment reports that the currently available evidence suggests associations between cardiovascular effects and a number of specific $PM_{2.5}$–related source categories, specifically 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. These studies include a study that 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). There is less consistency in associations observed between sources of fine particles and respiratory health effects, which may be partially due to the fact that fewer studies have evaluated respiratory-related outcomes and measures. However, there is 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). Respiratory effects relating to the crustal/soil/road dust and traffic sources of PM have been observed in asthmatic children and adults (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). 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 morality 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

[69] 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).

[70] 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).

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 concludes 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 concludes 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 concludes 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 concludes 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 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 proposes to retain $PM_{2.5}$ as the indicator for fine particles. Further, the Administrator provisionally concludes 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. Furthermore, the Administrator also provisionally concludes that the currently available scientific information does 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.

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 $PM_{2.5}$.

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 concludes 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 notes 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}, $PM_{10-2.5}$, 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 is much sparser than for cardiovascular effects and continues to be very limited. The Integrated Science Assessment concludes 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 concludes 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 provide 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 observes 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 concludes that there is no basis to consider a seasonal averaging time separate from a 24-hour averaging time.

Based on the above considerations, the Policy Assessment concludes that the currently available information provides strong support for consideration of retaining current annual and 24-hour averaging timers but does not provide support for considering alternative averaging times (U.S. EPA, 2011a, p. 2–58). In addition, CASAC considers 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). The Administrator concurs with the staff conclusions and CASAC advice and proposes 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 concludes, consistent with conclusions reached in the Policy Assessment and by CASAC, that the currently available information is 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.

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, we consider whether currently available information supports consideration of alternative 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 (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 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 discussed in section III.B.3, 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 is 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, would provide appropriate public health protection.

In considering the potential for disproportionate impacts on at-risk populations, the Policy Assessment recognizes an update of an air quality analysis conducted for the last review (U.S. EPA, 2011a, pp. 2–59 to 60; Schmidt, 2011a, Analysis A). This analysis focuses on determining if 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 considers whether persons of lower socioeconomic status 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, 2011a, Analysis A). Recognizing the limitations of such cross-sectional analyses, the Policy Assessment observes 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 concludes 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 concludes that it is appropriate to consider revising the form of the annual $PM_{2.5}$ standard such that it does 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 [71] (U.S. EPA, 2011a, p. 2–60).

The CASAC agreed with staff conclusions that it is ''reasonable'' for the EPA to eliminate the spatial averaging provisions (Samet, 2010d, p. 2). Further, in CASAC's comments on

[71] As discussed in section VIII.B.1 below, the EPA is proposing to revise several terms associated with $PM_{2.5}$ monitor placement. Specifically, the EPA is proposing to revoke the term ''community-oriented'' and replace it with the term ''area-wide'' monitoring.

the first draft Policy Assessment, they 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 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 proposes to revise the form of the annual $PM_{2.5}$ standard to eliminate the use of spatial averaging. Thus, the Administrator proposes 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[72] 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.

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.[73]

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 considers 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 provides evidence that the 98th percentile value is a more stable metric than the 99th percentile (U.S. EPA, 2011a, Figure 2–2, p. 2–62).

The Agency recognizes 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.[74] As in previous reviews, the EPA recognizes that a concentration-based form, compared to an exceedance-based form, is 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 concludes that a concentration-based form, when averaged over three years, provides 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 proposes to retain the 98th percentile form of the 24-hour standard. The Administrator provisionally concludes 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.

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 exposures 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 $\mu g/m^3$ [75] was challenged and on judicial review, the D.C. 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. Approach Used in the Policy Assessment

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 uses an approach that integrates evidence-based and risk-based considerations, takes into account CASAC advice, and considers 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, for the reasons discussed below, the Policy Assessment concludes it is 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 is 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.

[72] As discussed in section VIII.B.2.b below, the EPA proposes that $PM_{2.5}$ monitoring sites at micro- and middle-scale locations be comparable to the annual standard unless the monitoring site has been approved by the Regional Administrator as a ''relatively unique micro-scale, or localized hot-spot, or unique middle-scale site.''

[73] 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).

[74] 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. The context for the court's discussion is identical to that here; whether to adopt a 98th percentile form for a 24-hour primary $PM_{2.5}$ standard intended to provide supplemental protection for a generally controlling annual standard.

[75] Throughout this section, the annual standard level is denoted as an integer value for simplicity, although, as noted above in section II.B.1, Table 1, the standard level is defined to one decimal place, such that the current standard level is 15.0 $\mu g/m^3$. Alternative standard levels discussed in this section are similarly defined to one decimal place.

Beyond looking directly at the relevant epidemiologic evidence, the Policy Assessment considers the extent to which specific alternative $PM_{2.5}$ standard levels are 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.3 above, patterns of increasing estimated risk reductions are generally observed as either the annual or 24-hour standard, or both, are 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 observes, as discussed in section III.A.3, that analyses conducted for this and previous reviews demonstrate 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.3, the Risk Assessment observes 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 notes that while the results of simulating alternative suites of $PM_{2.5}$ standards including different combinations of alternative annual and 24-hour standard levels suggest 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 is highly variable, in part due to the choice of rollback approached used (U.S. EPA, 2010a, p. 5–17).

Therefore, the Policy Assessment concludes, consistent with CASAC advice (Samet 2010c, p. 1), that it is appropriate to set a ''generally controlling'' annual standard that will lower a wide range of ambient 24-hour concentrations. The Policy Assessment concludes 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 believes 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.

The Policy Assessment recognizes 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 concludes it is 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.

Based on the above considerations, the approach used in the Policy Assessment to identify alternative standard levels that are appropriate for consideration focuses on translating information from epidemiological studies into the basis for staff conclusions on levels. This approach is broader and more integrative than the general approach used by the EPA in previous reviews (see summary in section III.A.3 above; U.S. EPA, 2011a, sections 2.1.3 and 2.3.4.1) and reflects the more extensive and stronger body of scientific evidence now available on health effects related to long- and short-term $PM_{2.5}$ exposures, a more comprehensive quantitative risk assessment, and more extensive $PM_{2.5}$ air quality data. In considering the currently available information, the Policy Assessment focuses on identifying levels for an annual standard and a 24-hour standard that, in combination, provide protection against health effects associated with both long- and short-term $PM_{2.5}$ exposures. The Policy Assessment also considers the extent to which various combinations of annual and 24-hour standards reflect setting a generally controlling annual standard with a 24-hour standard providing supplemental protection (U.S. EPA, 2011a, sections 2.1.3, 2.3.4.1).

As discussed in the Policy Assessment, EPA staff recognizes that there is no single factor or criterion that comprises the ''correct'' approach for reaching conclusions on alternative standard levels for consideration, but rather there are various approaches that are reasonable to consider (U.S. EPA, 2011a, section 2.3.4.1). In reaching conclusions in the Policy Assessment on the ranges of standard levels that are appropriate to consider, staff considered the relative weight to place on different evidence. The Policy Assessment initially focuses on long- and short-term $PM_{2.5}$ exposure studies conducted in the U.S. and Canada and places the greatest weight on health outcomes judged in the Integrated Science Assessment as having evidence to support a causal or likely causal relationship. The Policy Assessment also considers the evidence for a broader range of health outcomes judged in the Integrated Science Assessment to have evidence suggestive of a causal relationship, specifically studies that focus on effects in susceptible populations, to evaluate whether this evidence provides support for considering lower alternative standard levels.

Several factors were taken into account in placing relative weight on the body of available epidemiological studies, for example, study characteristics, including study design (e.g., time period of air quality monitoring, control for potential confounders); strength of the study (in terms of statistical significance and precision of results); and availability of population-level and air quality distribution data. As noted above in section III.A.3, the Policy Assessment places greatest weight on information from multi-city epidemiological studies to inform staff conclusions regarding alternative annual standard levels. These studies have a number of advantages compared to single-city studies [76] that include providing representation of ambient $PM_{2.5}$ concentrations and potential health impacts across a range of diverse locations providing spatial coverage for different regions across the country, reflecting differences in $PM_{2.5}$ sources, composition, and potentially other exposure-related factors which might impact $PM_{2.5}$-related risks; lack of

[76] As discussed in section III.B.1 above, the Policy Assessment recognizes that single-city studies provide ancillary evidence to multi-city studies in support of calling into question the adequacy of the current suite of standards. However, in light of the mixed findings reported in single-city short-term $PM_{2.5}$ exposure studies, and the likelihood that these results are influenced by localized events and not representative of air quality across the country, the Policy Assessment places comparatively greater weight on the results from multi-city studies in considering alternative annual and 24-hour standard levels (U.S. EPA, 2011a, p. 2–64).

'publication bias' (U.S. EPA, 2004, p. 8–30); and consideration of larger study populations that afford the possibility of generalizing to the broader national population and provide higher statistical power than single-city studies to detect potentially statistically significant associations with relatively more precise effect estimates.

In reaching conclusions in the Policy Assessment regarding alternative 24-hour standard levels that are appropriate to consider, staff also considers relevant information from single-city short-term $PM_{2.5}$ exposure studies. Although, as discussed above, multi-city studies have greater power to detect associations and provide broader geographic coverage in comparison to single-city studies, the extent to which effects reported in multi-city short-term $PM_{2.5}$ exposure studies are associated with the specific short-term air quality in any particular location is unclear, especially when considering short-term concentrations at the upper end of the air quality distribution (i.e., at the 98th percentile value) for a given study area. In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the air quality in a given study area is more straightforward. Therefore, the Policy Assessment considers the results of both multi-city and single-city short-term exposure studies to inform staff conclusions regarding alternative levels that are appropriate to consider for a 24-hour standard that is intended to provide supplemental protection in areas where the annual standard may not offer appropriate protection against the effects of all short-term exposures (U.S. EPA, 2011a, pp. 2–62 to 2–65).

b. Consideration of the Annual Standard 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 are appropriate to consider focuses on characterizing the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in the epidemiological studies, and conversely where our confidence in the association becomes appreciably lower. The most direct approach to address this issue, consistent with CASAC advice (Samet, 2010c, p.10), is 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 three long-term $PM_{2.5}$ exposure studies reporting confidence intervals around concentration-response functions (i.e., Schwartz et al., 2008; Pope et al., 2002; Miller et al., 2007; U.S. EPA, 2011a, pp. 2–65 to 2–70 and Figure 2–3).[77] In its assessment of these studies, the Policy Assessment places greater weight on analyses that averaged across multiple concentration-response models since this approach represents a more robust examination of the underlying concentration-response relationship than analyses considering a single concentration-response model. Although these analyses of long-term exposure to $PM_{2.5}$ provide information on the lack of any discernible population threshold, only Schwartz et al. (2008) conducted a multi-model analysis to characterize confidence intervals around the estimated concentration-response relationship that can help inform at what $PM_{2.5}$ concentrations we have appreciably less confidence in the nature of the underlying concentration-response relationship. Although analyses of confidence intervals associated with concentration-response relationships can help inform consideration of alternative standard levels, the Policy Assessment concludes that the single relevant analysis now available is 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 explores other approaches that considered different statistical metrics to identify ranges of long-term mean $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in long- and short-term epidemiological studies, placing 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 recognizes 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 $PM_{2.5}$ exposure studies. The long-term mean concentrations represent air quality data typically used in epidemiological analyses and provide a direct link between $PM_{2.5}$ concentrations and the observed health effects. Further, these data are available for all long- and short-term exposure studies analyzed and, therefore, represent the data set available for the broadest set of epidemiological studies.

However, consistent with CASAC's comments on the second draft Policy Assessment[78] (Samet, 2010d, p. 2), in preparing the final Policy Assessment, 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 range of $PM_{2.5}$ concentrations down through which staff continued to have confidence in the associations observed in epidemiological studies and below which there is a comparative lack of data such that the staff's confidence in the relationship was appreciably less. This would also be the range of $PM_{2.5}$ concentrations which has the most influence on generating the health effect estimates reported in epidemiological studies. As discussed in section III.A.3 above, the Policy Assessment recognizes there is no one percentile value within a given distribution that is the most appropriate or ''correct'' way to characterize where our confidence in the associations becomes appreciably lower. The Policy Assessment concludes that focusing on concentrations within the lower quartile of a distribution, such as the range from the 25th to the 10th percentile, is reasonable to consider as a region within which we begin to have appreciably less confidence in the associations observed in epidemiological studies.[79] In staff's

[77] The EPA carefully analyzed the published evidence, but was unable to identify any short-term $PM_{2.5}$ exposure studies that characterized confidence intervals around concentration-response relationships. Nor did CASAC or public comments on this issue, as addressed in their comments on the second draft Policy Assessment, identify any additional analyses.

[78] 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).

[79] 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,

Continued

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 recognizes that there are 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 is 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 an appropriate surrogate for health event data.

In applying this approach, the Policy Assessment focuses on identifying the broader range 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, 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). For the three studies for which both health event and study population data were available, EPA staff analyzed the reliability of using study population data as a surrogate for health event data. Based on these analyses, 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 $\mu g/m^3$.[80] 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). By following the general approach used in previous PM NAAQS reviews, one could consider identifying alternative standard levels that are somewhat below the long-term mean $PM_{2.5}$ concentrations reported in these epidemiological studies.

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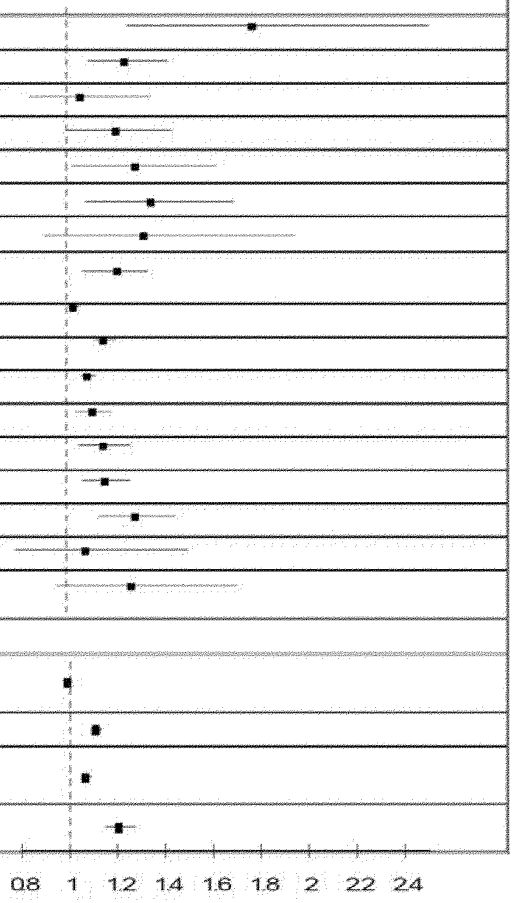
2005, pp. 5–22 to 5–23). In this review, the Policy Assessment noted the interrelatedness of the distributional statistics and a range of one standard deviation around the mean which contains approximately 68 percent of normally distributed data, in that one standard deviation below the mean falls between the 25th and 10th percentiles (U.S. EPA, 2011a, p. 2–71).

[80] 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).

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

Study	Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (μg/m^3) Author Reported Data			Effect Estimate (95% CI)
					Mean	Mean - 1SD	Range	
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	

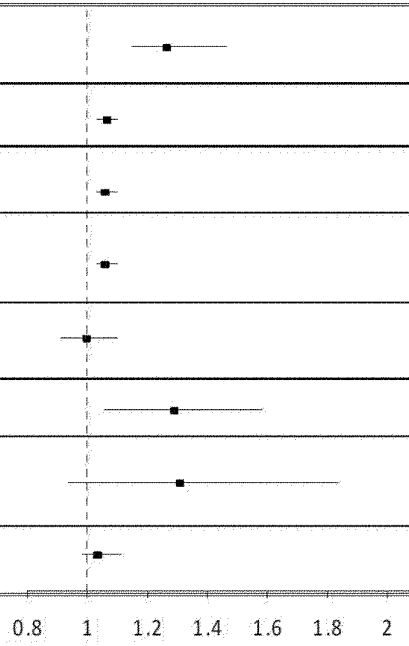


[a]Update of Miller et al. (2007) $PM_{2.5}$ data included in Curl, 2009
[b]Cohort included persons with cystic fibrosis age 6 and older, mean age: 18.4 yrs
[c]Estimated from data provided by study author (Laden, 2009)
[d]Median (IQR: Interquartile range); overall US reported median (IQR) of 13.2 μg/m^3 (11.1-14.9)

Source: US 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: US EPA, 2011a, Figure 2-5

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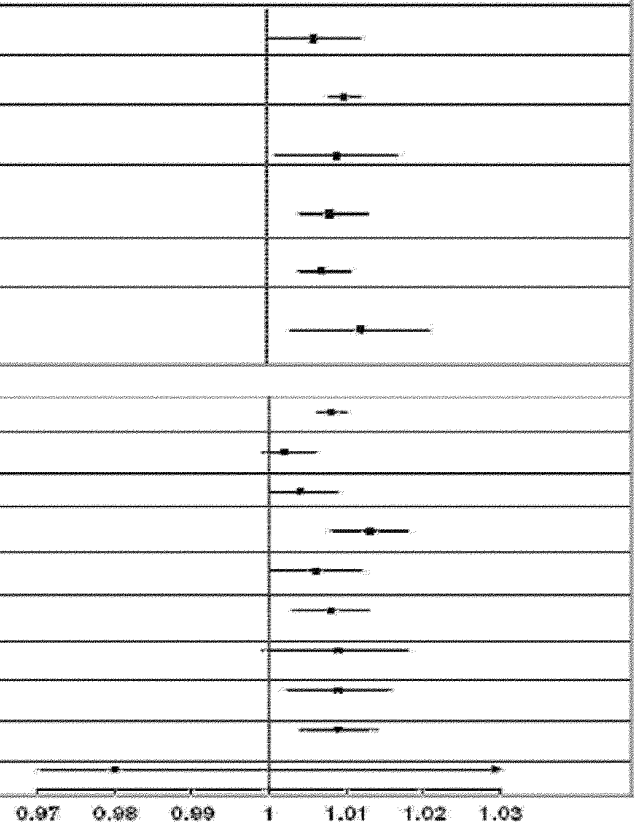
Figure 3. Summary of Effect Estimates (per 10 µg/m^3) and Air Quality Distributions for Multi-City, Short-term $PM_{2.5}$ Exposure Studies of the General Population and Older Adults

Study/Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (µg/m^3) Author Reported Data				Effect Estimate (95% CI)
				Mean	Mean - 1SD	Range	98th percentile	
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: US EPA, 2011a, Figure 2-6

With regard to consideration of additional information from epidemiological studies which is relevant to the second approach, EPA has 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 [81] (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. As noted above in section III.A.3 and discussed in the Policy Assessment, a policy approach that uses data based on composite monitor distributions to identify alternative standard levels, and then compares those levels to concentrations at appropriate maximum monitors to determine if an area meets a given standard, inherently has the potential to build in some margin of safety (U.S. EPA, 2011a, p. 2–14). In analyses conducted by EPA staff based on selected long- and short-term exposure studies, the Policy Assessment notes that the differences between the maximum and composite distributions were greater for studies with fewer years of air quality data (i.e., 1 to 3 years) and smaller numbers of study areas (i.e., 36 to 51 study areas). The differences in the maximum and composite monitor distribution were much smaller (i.e., generally within five percent) for studies with more years of air quality data (i.e., up to 6 years) and larger numbers of study areas (i.e., 112 to 204 study areas) (Hassett-Sipple et al., 2010; U.S. EPA, 2010f, section 2.3.4.1). Therefore, any margin of safety that may be provided by a policy approach that uses data based on composite monitor distributions to identify alternative standard levels, and then compares those levels to concentrations at appropriate maximum monitors to determine if an area meets a given standard, will vary depending upon the number of monitors and air quality distributions within a given area. See also, section III.A.3 above.

Figure 4 summarizes statistical metrics for those studies included in Figures 1, 2, and 3 that provide evidence of statistically significant $PM_{2.5}$-related effects, which are relevant to the two approaches for translating epidemiological evidence into standard levels discussed above. The top of Figure 4 includes information for *long-term* exposure studies evaluating health outcomes classified as having evidence of a *casual* or *likely casual 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 *casual* or *likely casual* 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.

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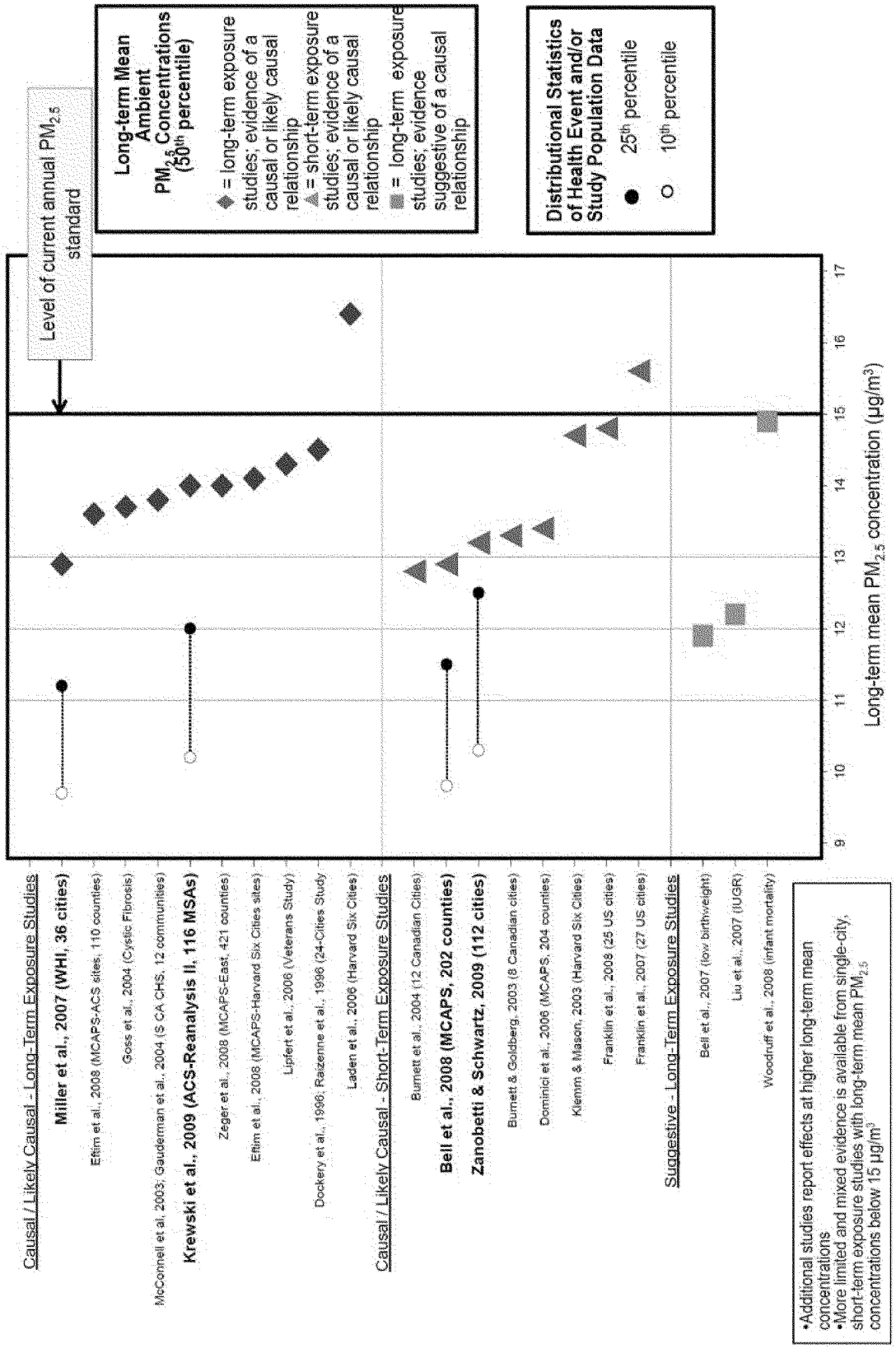
[81] Health event data (e.g., number of deaths, hospitalizations) occurring in a study population were obtained for three multi-city studies (Krewski et al., 2009; Zanobetti and Schwartz, 2009; Bell et al., 2008) and study population data were obtained for the same three studies and one additional study (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.

Figure 4. Translating Epidemiological Evidence from Multi-City Exposure Studies into an Annual $PM_{2.5}$ Standard



Source: US EPA, 2011a, Figure 2-8

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In looking first at the long-term mean $PM_{2.5}$ concentrations reported in the multi-city long-term exposure studies, as summarized at the top of Figure 4, the Policy Assessment observes positive and often statistically significant associations at long-term mean $PM_{2.5}$ concentrations ranging from 16.4 to 12.9 $\mu g/m^3$ [82] (Laden et al., 2006; Lipfert et al., 2006; Krewski et al., 2009; Goss et al., 2004; Miller et al.; 2007; Zeger et al., 2008; Eftim et al., 2008; Dockery et al., 1996; McConnell et al., 2003). In considering the one long-term $PM_{2.5}$ exposure study for which health event data are available (Krewski et al., 2009), the Policy Assessment observes that the long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25th and 10th percentiles of the distribution of mortality data are 12.0 $\mu g/m^3$ and 10.2 $\mu g/m^3$, respectively (Figure 4; U.S. EPA, 2011a, Figure 2–7; Rajan et al., 2011, Table 1). As identified above, although less directly relevant than event data, the number of participants within each study area can be used as a surrogate for health event data in relation to the distribution of $PM_{2.5}$ concentrations. The long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25th and 10th percentiles of the distribution of study participants for Miller et al. (2007) were 11.2 $\mu g/m^3$ and 9.7 $\mu g/m^3$, respectively (Figure 4; U.S. EPA, 2011a, Figure 2–7; Rajan et al., 2011, Table 1).

In then considering information from multi-city, short-term exposure studies reporting positive and statistically significant associations with these same broad health effect categories, as summarized in the middle of Figure 4, the Policy Assessment observes positive and statistically significant associations at long-term mean $PM_{2.5}$ concentrations in a similar range of 15.6 to 12.8 $\mu g/m^3$ (Franklin et al., 2007, 2008; Klemm and Mason, 2003; Burnett and Goldberg, 2003; Zanobetti and Schwartz, 2009; Burnett et al., 2004; Bell et al., 2008; Dominici et al., 2006a; see Figure 3). In considering the two multi-city, short-term $PM_{2.5}$ exposure studies for which health event data are available, the Policy Assessment observes that the long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25th and 10th percentiles of the distribution of deaths and cardiovascular-related hospitalizations are 12.5 $\mu g/m^3$ and 10.3 $\mu g/m^3$, respectively, for Zanobetti and Schwartz (2009), and 11.5 $\mu g/m^3$ and 9.8 $\mu g/m^3$, respectively, for Bell et al. (2008) (Figure 4; U.S. EPA, 2011a, Figure 2–7; Rajan et al., 2011, Table 1).

Taking into consideration additional studies of specific at-risk populations (i.e., children), the Policy Assessment expands its evaluation of the long-term exposure studies to include a broader range of health outcomes judged in the Integrated Science Assessment to have evidence suggestive of a causal relationship. This evidence was taken into account to evaluate whether it provides support for considering lower alternative levels than if weight were only placed on studies for which health effects have been judged in the Integrated Science Assessment to have evidence supporting a causal or likely causal relationship. The Policy Assessment makes note of a limited number of studies that provide emerging evidence for $PM_{2.5}$-related low birth weight and infant mortality, especially related to respiratory causes during the post-neonatal period. This more limited body of evidence, as summarized at the bottom of Figure 4, indicates positive and often statistically significant effects associated with long-term $PM_{2.5}$ mean concentrations in the range of 14.9 to 11.9 $\mu g/m^3$ (Woodruff et al., 2008; Liu et al., 2007; Bell et al., 2007; see Figure 2). As illustrated in Figure 2, although Parker and Woodruff (2008) did not observe an association between quarterly estimates of exposure to $PM_{2.5}$ and low birth weight in a multi-city U.S. study, other U.S. and Canadian studies did report positive and statistically significant associations between $PM_{2.5}$ and low birth weight at lower ambient concentrations (Bell et al., 2007; Liu et al., 2007).[83] There remain significant limitations (e.g., identifying the etiologically relevant time period) in the evaluation of evidence on the relationship between $PM_{2.5}$ exposures and birth outcomes (U.S. EPA, 2009a, pp. 7–48 and 7–56) which should be taken into consideration in reaching judgments about how to weigh these studies of potential impacts on specific susceptible populations in considering alternative standard levels that provide protection with an appropriate margin of safety.

With respect to carcinogenicity, mutagenicity, and genotoxicity (evidence suggestive of a causal relationship), the strongest evidence currently available is from long-term prospective cohort studies that report positive associations between $PM_{2.5}$ and lung cancer mortality. At this time, 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, in selecting alternative standard levels appropriate to consider, the Policy Assessment noted that, in providing protection against mortality and cardiovascular and respiratory effects it is reasonable to anticipate that protection will also be provided for carcinogenicity, mutagenicity, and genotoxicity effects (U.S. EPA, 2011a, p. 2–78).

In summarizing the currently available evidence and air quality information within the context of identifying potential alternative annual standard levels for consideration, the Policy Assessment first notes that the Integrated Science Assessment concludes there is no evidence of a discernible population threshold below which effects would not occur. Thus, health effects may occur over the full range of concentrations observed in the epidemiological studies. In the absence of any discernible thresholds, the general approach used in the Policy Assessment for identifying alternative standard levels that would provide appropriate protection against effects observed in epidemiological studies has focused on the central question of identifying the range of $PM_{2.5}$ concentrations below the long-term mean concentrations where we continue to have confidence in the associations observed in epidemiological studies.

In considering the evidence, the Policy Assessment recognizes 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, considerations of different alternative standard levels could be supported.

[82] As discussed in section III.D.1.a above, the lowest long-term mean $PM_{2.5}$ concentration reported in the long-term exposure studies was based on updated air quality data for Miller et al. (2007). As noted in the Policy Assessment, these air quality data were based on only one year of ambient measurements (2000) and in comparison to other long-term exposure studies that considered multiple years of air quality data, were much more limited (U.S. EPA, 2011a, pp. 2–81 to 2–82).

[83] As noted in section 7.4 of the Integrated Science Assessment, Parker et al. (2005) reported that over a 9-month exposure period (mean $PM_{2.5}$ concentration of 15.4 $\mu g/m^3$) a significant decrease in birth weight was associated with infants in the highest quartile of $PM_{2.5}$ exposure as compared to infants exposed in the lowest quartile.

Given the currently available evidence and considering the various approaches discussed above, the Policy Assessment concludes it is 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, a standard level of 12 μg/m³, at the upper end of this range, is somewhat below the long-term mean $PM_{2.5}$ concentrations reported in all the 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, 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 corresponds with approximately the 25th percentile of the available distributions of health events data in the studies for which population-level information was available.[84] In addition, a level of 12 μg/m³ would reflect some consideration of studies that provide more limited evidence of reproductive and developmental effects, which are suggestive of a causal relationship, in that it is about at the same level as the lowest long-term mean $PM_{2.5}$ concentrations reported in such studies (see Figure 4).

Alternatively, an annual standard level of 11 μg/m³, at the lower end of this range, is 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 is within the range of $PM_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of all the available distributions of such data.[85] In addition, a level of 11 μg/m³ is 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 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 concludes that the available evidence does 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 considers the extent to which the available evidence provides a basis for considering alternative annual standard levels above 12 μg/m³. As discussed below, the Policy Assessment concludes that it could be reasonable to consider a standard level up to 13 μg/m³ based on a policy approach that tends to weigh 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 is placed on long-term exposure studies as a basis for an annual standard level. A level of 13 μg/m³ is 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 is the WHI study (Miller et al., 2007). As noted in section III.D.1.a above, the Policy Assessment observes that in comparison to other long-term exposure studies, the WHI study was more limited in that it was based on only one year of air quality data (U.S. EPA, 2011a, pp. 2–81 to 2–82). Thus, to the extent that less weight is placed on the WHI 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, the Policy Assessment notes that a level of 13 μg/m³ is below the long-term mean $PM_{2.5}$ concentrations reported in most such studies, but is above the long-term means of 12.8 and 12.9 μg/m³ reported in Burnett et al. (2004) and Bell et al. (2008), respectively. In considering these studies, the Policy Assessment finds no basis to conclude that these two studies are 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 concludes 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, such that taken together the suite of $PM_{2.5}$ standards 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 notes 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.2 above, 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 is too uncertain to support consideration of any lower level.

Beyond evidence-based considerations, the Policy Assessment also considered the extent to which quantitative risk assessment supports consideration of these alternative standard levels or provides 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, noting 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

[84] As outlined in section III.A.3, the Policy Assessment considers the 25th percentile to be the start of the range of $PM_{2.5}$ concentrations below the mean within which the data become appreciably more sparse and, thus, where our confidence in the associations observed in epidemiological studies begins to become appreciably less.

[85] As discussed in section III.A.3, the Policy Assessment identifies the range from the 25th to the 10th percentiles as a reasonable range to consider, in that it is a range where we have appreciably less confidence in the associations observed in epidemiological studies (U.S. EPA, 2011a, p. 2–12).

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 concludes that consideration of alternative annual standard levels in the range of 13 to 11 μg/m³ may be appropriate. Furthermore, the Policy Assessment concludes that the currently available evidence most strongly supports 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 concludes 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 would also reflect placing weight on information from studies that help 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 is appreciably less at lower concentrations.

c. Consideration of the 24-Hour Standard in the Policy Assessment

As recognized in section III.A.3 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 concludes that it is 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 considers 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 takes into account information from multi-city studies as well as single-city studies. The Policy Assessment considers 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 considers information on the long-term mean $PM_{2.5}$ concentrations from these studies.

In addition to considering the epidemiological evidence, the Policy Assessment also considers 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 help 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 recognizes that to the extent these studies were conducted in areas that likely did not meet one or both of the current standards, such studies do 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 places 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, the Policy Assessment observes 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 Policy Assessment notes 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 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). To the extent that consideration is given to revising the level of the annual standard, as discussed above in section III.E.4.b, the Policy Assessment recognizes 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 work in conjunction with an annual standard to provide appropriate public health protection, the Policy Assessment notes that to the extent that the level of the annual standard is 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 effects observed in these multi-city studies (U.S. EPA, 2011a, p. 2–84).

In summary, the Policy Assessment concludes that the multi-city, short-term exposure studies generally provide support for retaining the 24-hour standard level at 35 μg/m³ 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 concludes that the multi-city studies provide 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 in conjunction with 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 are appropriate to consider, the Policy Assessment also takes into account relevant information from single-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures. The Policy Assessment recognizes that these studies may provide additional insights regarding impacts on susceptible populations and/or on areas with isolated peak concentrations. Although, as discussed in section III.E.4.a above, multi-city studies have advantages over single-city studies in terms of statistical power to detect associations and broader geographic coverage as well as other factors such as less likelihood of publication bias, reflecting differences in $PM_{2.5}$ sources, composition, and potentially other factors that could impact $PM_{2.5}$-related effects, multi-city studies often present overall effect estimates rather than single-city effect estimates. Since short-term air quality can vary considerably across cities, the extent to which effects reported in multi-city studies are associated with short-term air quality in any particular location is uncertain, especially when considering short-term concentrations at the upper end of the distribution of daily $PM_{2.5}$ concentrations (i.e., at the 98th percentile value). In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the air quality in a given study area is more straightforward to establish. Therefore, the Policy Assessment also considers evidence from single-city, short-term exposure studies to inform staff conclusions regarding alternative levels that are appropriate to consider for a 24-hour standard that is intended to provide supplemental protection in areas where the annual standard may not provide an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures.

As discussed above for the multi-city studies, the Policy Assessment takes into account both the 24-hour $PM_{2.5}$ concentrations in the single-city studies, focusing on the 98th percentile air quality values, as well as the long-term mean $PM_{2.5}$ concentrations. The Policy Assessment considers single-city studies conducted in areas that would likely have met the current suite of $PM_{2.5}$ standards as most useful for informing staff conclusions related to the level of the 24-hour standard (U.S. EPA, 2011a, Figure 2–9). The Policy Assessment notes that additional single-city studies summarized in that Figure 2–9 were conducted in areas that would likely have met one but not both of the current $PM_{2.5}$ standards. To the extent changes in air quality designed to just meet the current suite of $PM_{2.5}$ standards are undertaken, one could reasonably anticipate additional public health protection will occur in these study areas. Therefore, the Policy Assessment concludes that these studies are not helpful to inform staff conclusions regarding alternative standard levels that are appropriate to consider (U.S. EPA, 2011a, p. 2–87).

With regard to single-city studies that were conducted in areas that would likely have met both the current 24-hour and annual standards, the Policy Assessment first considers studies that reported positive and statistically significant associations. In considering this group of studies, the Policy Assessment notes Mar et al. (2003) reported a positive and statistically significant association for premature mortality in Phoenix with a long-term mean concentration of 13.5 μg/m³ in conjunction with a 98th percentile value of 32.2 μg/m³ (U.S. EPA, 2011a, Figure 2–9). To the extent that consideration is given to revising the level of the annual standard, within a range of 13 to 11 μg/m³, as discussed above, additional protection would be provided for the effects observed in this study (U.S. EPA, 2011a, p. 2–87).

Four additional studies reported positive and statistically significant associations with 98th percentile values within a range of 31.2 to 25.8 μg/m³ and long-term mean concentrations within a range of 12.1 to 8.5 μg/m³ (Delfino et al., 1997; Peters et al., 2001; Stieb et al., 2000; and Mar et al., 2004; U.S. EPA, 2011a, Figure 2–9). Delfino et al. (1997) reported statistically significant associations between $PM_{2.5}$ and respiratory emergency department visits for older adults (greater than 64 years old) but not young children (less than 2 years old), in one part of the study period (summer 1993) but not the other (summer 1992). Peters et al. (2001) reported a positive and statistically significant association between short-term exposure to $PM_{2.5}$ (2-hour and 24-hour averaging times) and onset of acute myocardial infarction in Boston. Stieb et al. (2000) reported positive and statistically significant associations with cardiovascular- and respiratory-related emergency department visits in Saint John, Canada, in single pollutant models but not in multi-pollutant models (U.S. EPA, 2004, pp. 8–154 and 8–252 to 8–253). Mar et al. (2004) reported a positive and statistically significant association for short-term $PM_{2.5}$ exposures in relation to respiratory symptoms among children but not adults in Spokane, however, this study had very limited statistical power because of the small number of children and adults evaluated.

The Policy Assessment also considers short-term single-city $PM_{2.5}$ exposure studies that reported positive but nonstatistically significant associations for cardiovascular and respiratory endpoints in areas that would likely have met both the current 24-hour and annual standards. The 98th percentile values reported in these studies ranged from 31.6 to 17.2 μg/m³ and the long-term mean concentrations ranged from 13.0 to 7.0 μg/m³ (U.S. EPA, 2011a, Figure 2–9). These studies included consideration of cardiovascular-related mortality effects in Phoenix (Wilson et al., 2007), asthma medication use in children in Denver (Rabinovitch et al., 2006), hospital admissions for hemorrhagic and ischemic stroke in Edmonton, Canada (Villeneuve et al., 2006), and hospital admissions for ischemic stroke/transient ischemic attack in Nueces County, TX (Lisabeth et al., 2008).

Lastly, the Policy Assessment considers single-city studies conducted in areas that would likely have met both the current 24-hour and annual standards that reported null findings. The 98th percentile values reported in these studies ranged from 29.6 to 24.0 μg/m³ and the long-term mean concentrations ranged from 10.8 to 8.5 μg/m³ (U.S. EPA, 2011a, Figure 2–9). These studies reported no associations with short-term $PM_{2.5}$ exposures and cardiovascular-related hospital admissions and respiratory-related emergency department visits (Slaughter et al., 2005) and cardiovascular-related emergency department visits (Schreuder et al., 2006) in Spokane; asthma exacerbation in children in Denver (Rabinovitch et al., 2004); and hospital admissions for transient ischemic attack in Edmonton, Canada (Villeneuve et al., 2006).

Viewing the evidence as a whole, the Policy Assessment observes a 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. Many of these studies had significant limitations (e.g., limited statistical power, limited exposure data) or equivocal results (i.e., mixed results within the same study area) as briefly identified above and discussed in more detail in the Policy Assessment (U.S. EPA, 2011a, p. 2–88). Other studies reported positive but not statistically

significant results or null associations also in areas that would likely have met the current suite of $PM_{2.5}$ standards. Overall, the entire body of results from these single-city studies is mixed, particularly as 24-hour 98th percentile concentrations go below 35 μg/m³.

Although a number of single-city studies report 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 greater and, thus, the Policy Assessment concludes there is less confidence in using these studies as a basis for setting the level of a standard. Therefore, the Policy Assessment concludes that the multi-city short-term exposure studies provide the strongest evidence to inform decisions on the level of the 24-hour standard, and the single-city studies do 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 takes into account air quality information based on county-level 24-hour and annual design values to understand the implications of the alternative standard levels supported by the currently available scientific evidence, as discussed in section III.E.4.b above. As discussed in section III.A.3 above, the Policy Assessment concludes that a policy goal which includes 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, is 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. Therefore, the Policy Assessment considers the extent to which different combinations of alternative annual and 24-hour standard levels based on the evidence would support this policy goal (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 examines 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 concludes 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 represent 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 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 concludes 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 would recognize 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).

The Policy Assessment also recognizes an alternative approach to considering the evidence that provides some support for revising the level below 35 μg/m³, perhaps as low as 30 μg/m³ (U.S. EPA, 2011a, p. 2–92). This alternative 24-hour standard level would be more compatible with an alternative annual standard of 13 μg/m³ based on placing greater weight on one multi-city short-term exposure study (Bell et al., 2008) that reported positive and statistically significant effects at a 98th percentile value less than 35 μg/m³ (i.e., 34.2 μg/m³) in conjunction with a long-term mean concentration less than 13 μg/m³ (i.e., 12.9 μg/m³).

Beyond evidence-based considerations, the Policy Assessment also considered the extent to which the quantitative risk assessment supports consideration of retaining the current 24-hour standard level or provides 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 provides 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 does 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 concludes that while it is appropriate to consider an alternative 24-hour standard level within a range of 35 to 30 μg/m³, the currently available evidence most strongly supports 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).

d. 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 are appropriate to consider, including consideration of the combination of these standards supported by the available information (Samet, 2010d, p. ii). Specifically, 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 (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/m^3 for the annual standard, in conjunction with retaining the current 24-hour $PM_{2.5}$ standard level of 35 μg/m^3; alternatively, revising the level of the 24-hour standard to 30 μg/m^3 in conjunction with an annual standard level of 11 μg/m^3) ''may not be adequately inclusive'' and ''[i]t was not clear why, for example a daily standard of 30 μg/m^3 should only be considered in combination with an annual level of 11 μg/m^3'' (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, EPA staff conducted additional analyses and modified their conclusions regarding alternative standard levels that are appropriate to consider. The staff conclusions in the final Policy Assessment (U.S. EPA, 2011a, section 2.3.4.4) differ 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, the EPA analyzed additional population-level data obtained from several study investigators. In commenting on draft staff conclusions in the second draft Policy Assessment, CASAC did not have an opportunity to review the staff analyses of distributional statistics to identify the broader range of $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in epidemiological studies (Rajan et al., 2011). In addition, CASAC was not aware of the revised long-term mean $PM_{2.5}$ concentration in the WHI study as discussed in section III.D.1.a above or the staff's inclusion of that value in its evaluation of the evidence (i.e., in Figures 1 and 4 above and related discussion). The WHI study is the only long-term cohort study that provides information regarding effects classified as having evidence of a causal or likely causal relationship associated with a long-term $PM_{2.5}$ concentration below 13 μg/m^3. Furthermore, CASAC did not have an opportunity to review the staff's revised rationale for the combinations of alternative standards suggested in the final Policy Assessment.

e. Administrator's Proposed Conclusions on the Primary $PM_{2.5}$ Standard Levels

In reaching her conclusions regarding appropriate alternative standard levels to consider, 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 and the advice of CASAC. As an initial matter, the Administrator agrees with the 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 $PM_{2.5}$. This is consistent with the approach taken in the review completed in 1997, in contrast to considering each standard separately, as was done in the review completed in 2006. Furthermore, based on the evidence and quantitative risk assessment, the Administrator provisionally concludes 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 concludes 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.

In reaching decisions on alternative standard levels to propose, the Administrator judges that it is most appropriate to examine where the evidence of associations observed in the epidemiological studies is strongest and, conversely, where she has 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 recognizes 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 takes note that these studies, along with evidence available in the last review, provide 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 recognizes 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 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 at ambient concentrations similar to those previously observed (as summarized in Figure 3).

The newly available scientific evidence builds 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 recognizes that the weight of evidence, as evaluated in the Integrated Science Assessment, is strongest for health endpoints classified as having evidence of a causal relationship. These relationships include those between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects. She recognizes that the weight of evidence is also strong for health endpoints classified as having evidence of a likely causal relationship, which include those between long- and short-term $PM_{2.5}$ exposures and respiratory effects. In addition, the Administrator makes 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.

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 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 recognizes, in taking note of CASAC advice and the distributional statistics analysis discussed in section III.E.4.b above and in the Policy Assessment, that there is significantly greater confidence in observed associations over certain parts of the air quality distributions in the studies, and conversely, that there is 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.d above, the Administrator generally agrees that it is appropriate to consider a level for an annual standard that is 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 is strongest at and around the long-term average where the data in the study are most concentrated, she understands that this approach does not provide a bright line for reaching decisions about appropriate standard levels. The Administrator notes that long-term mean $PM_{2.5}$ concentrations are available for each study considered and, therefore, represent the most robust data set to inform her decisions on appropriate annual standard levels. She also notes that the overall study mean $PM_{2.5}$ concentrations are 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 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 understands that it is appropriate to consider the weight of evidence for the health endpoints evaluated in such studies in giving weight to this information.

Based on the information summarized in Figure 4 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 observes 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 $\mu g/m^3$ down to the lowest mean concentration in such studies of 12.9 $\mu g/m^3$ (in Miller et al., 2007). She observes 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 $\mu g/m^3$ down to 12.8 $\mu g/m^3$ (in Burnett et al., 2004). With regard to effects classified as providing evidence suggestive of a causal relationship, the Administrator observes 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 $\mu g/m^3$ (in Bell et al., 2007).[86]

The Administrator also considers 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 understands 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 within which the data become appreciably more sparse and, thus, where her confidence in the associations observed in epidemiological studies would become appreciably less. As discussed in section III.E.4.b above and summarized in Figure 4, the Administrator takes note of additional population-level data that are available for four studies (Krewski et al., 2009; Miller et al., 2007; Bell et al., 2008; Zanobetti and Schwartz, 2009), each of which report 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 observes that these values range from somewhat above to somewhat below 12 $\mu g/m^3$ (Figure 4). The Administrator recognizes that these four studies represent some of the strongest evidence available within the overall body of scientific evidence and notes 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). However, the Administrator also recognizes that additional population-level data are available for only these four studies and, therefore, she believes that these studies comprise a more limited data set than one based on long-term mean $PM_{2.5}$ concentrations for which data are available for all studies considered, as discussed above. In considering this information, the Administrator notes 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

[86] 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.

studies can help to inform selection of an appropriate annual standard level.

The Administrator recognizes, as summarized in section III.B.2 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 fixed monitor sites, and the nature, magnitude, and confidence in 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. The Administrator also recognizes 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.

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 standard levels are appropriate to propose, the Administrator recognizes, as did EPA staff in the Policy Assessment, that there is no single factor or criterion that comprises the ''correct'' approach to weighing the various types of available evidence and information, but rather there are various approaches that are appropriate to consider. The Administrator further recognizes 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 leads the Administrator to consider various approaches to weighing the evidence so as to identify appropriate standard levels to propose. In so doing, the Administrator encourages 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 notes the advice of CASAC that the currently available scientific information, including epidemiological and toxicological evidence as well as risk and air quality information, provides 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 recognizes that the Policy Assessment concludes 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 concludes that the evidence most strongly supports 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 observes that CASAC did not express support for any specific levels or combinations of standards within in these ranges, although she recognizes that CASAC did not have an opportunity to review additional information and analyses presented in the final Policy Assessment prepared in response to CASAC's recommendations on the second draft Policy Assessment. Nor did CASAC have an opportunity to review the EPA staff's revised rationale for the combinations of alternative standards presented in the final document.

In considering the extent to which the currently available evidence and information provide support for specific standard levels within the ranges identified by CASAC and the Policy Assessment as appropriate for consideration, the Administrator initially considers standard levels within the range of 13 to 11 $\mu g/m^3$ for the annual standard. In so doing, the Administrator first considers 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 and discussed more broadly above. She notes 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 notes that the evidence of an association in any such study is 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 are available for each study considered and, therefore, represent the most robust data set to inform her decisions on appropriate annual standard levels. Further, she is mindful that this approach does not provide a bright line for reaching decisions about appropriate standard levels.

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 notes 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 notes 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 considers additional 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 notes 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 notes 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 notes that there is 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 becomes appreciably less.

In considering mean $PM_{2.5}$ concentrations and distributional analyses from the various sets of epidemiological studies noted above, the Administrator is 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 uses 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 is set, concentrations at appropriate maximum monitors within an area are generally used to determine if an area meets a given standard.

The Administrator also recognizes 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 remain in the evidence and information being considered in this review. The Administrator notes that the extent to which these uncertainties influence judgments about appropriate annual standard levels within the range of 13 to 11 $\mu g/m^3$ 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 concludes that it is appropriate to propose to set a level for the primary annual $PM_{2.5}$ standard within the range of 12 to 13 $\mu g/m^3$. The Administrator provisionally concludes 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 concludes 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 recognizes that setting an annual standard level at the lower end of this range would reflect an approach that places 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 place more emphasis on the remaining uncertainties in the evidence to avoid potentially overestimating public health improvements, and would generally support a view that the uncertainties remaining in the evidence are too great to warrant setting a lower annual standard level.

While the Administrator recognizes that CASAC advised, and the Policy Assessment concluded, that the available scientific information provides support for considering a range that extended down to 11 $\mu g/m^3$, she concludes that proposing such an extended range would reflect a public health policy approach that places more weight on relatively limited evidence and more uncertain information and analyses than she considers appropriate at this time. Nonetheless, the Administrator solicits comment on a level down to 11 $\mu g/m^3$ 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 recognizes that potential air quality changes associated with meeting an annual standard set at a level within the range of 12 to 13 $\mu g/m^3$ will result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures. However, the Administrator recognizes 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 $\mu g/m^3$, the Administrator provisionally 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, 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, the Administrator has 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 agrees 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 recognizes that to the extent these studies were conducted in areas that likely did not meet one or both of the current standards, such studies do 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 anticipates that additional public health protection will occur. Therefore, the Administrator has 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 has also considered whether or not these studies were conducted in areas that would likely have met an annual standard level of 12 to 13 $\mu g/m^3$ to inform her decision regarding an appropriate 24-hour standard level. As discussed in section III.E.4.a, 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. The Administrator views the single-city, short-term exposure studies as a much

more limited data set providing mixed results and, therefore, she has less confidence in using these 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 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 values averaged across study areas in the range of 45.8 to 34.2 $\mu g/m^3$ (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 anticipated for the effects observed in the three multi-city studies with 98th percentile values greater than 35 $\mu g/m^3$ (Burnett et al., 2004; Burnett and Goldberg, 2003; Franklin et al., 2008). In the three additional studies with 98th percentile values below 35 $\mu g/m^3$, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 $\mu g/m^3$, the Administrator notes that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 $\mu g/m^3$, 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 $\mu g/m^3$, as discussed above, the Administrator recognizes 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 $\mu g/m^3$, and in two of these three studies in conjunction with an annual standard level of 13 $\mu g/m^3$. She notes that the study-wide mean concentrations are 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 believes it would be reasonable to conclude that revision to the 24-hour standard would not be warranted in conjunction with an annual standard within this range. Based on the above considerations related to the epidemiological evidence, the Administrator provisionally concludes that it is appropriate to retain the level of the 24-hour standard at 35 $\mu g/m^3$, in conjunction with a revised annual standard level in the proposed range of 12 to 13 $\mu g/m^3$.

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 retaining the 24-hour standard level at 35 $\mu g/m^3$ in conjunction with an annual standard level within the proposed range of 12 to 13 $\mu g/m^3$. She has considered whether this suite of standards would meet a public health policy goal which includes 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 concludes that this approach is 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 recognizes that there is no annual standard within the proposed range of levels, when combined with a 24-hour standard at the proposed level of 35 $\mu g/m^3$, for which the annual standard would be the generally controlling standard in all areas of the country. She further observes that such a suite of $PM_{2.5}$ standards with an annual standard level of 12 $\mu g/m^3$ 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 $\mu g/m^3$ 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 $\mu g/m^3$.

Taking the above considerations into account, the Administrator proposes to revise the level of the primary annual $PM_{2.5}$ standard from 15.0 $\mu g/m^3$ to within the range of 12.0 to 13.0 $\mu g/m^3$ and to retain the 24-hour standard level at 35 $\mu g/m^3$. 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 recognizes 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 is solicited, must be clearly responsive to the issues raised by the D.C. Circuit's remand of the 2006 primary annual $PM_{2.5}$ standard. Furthermore, the final suite of standards will reflect the Administrator's 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.

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 $\mu g/m^3$ and to propose retaining the 24-hour standard level at 35 $\mu g/m^3$, the Administrator solicits 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 solicits public comment on alternative annual standard levels down to 11 $\mu g/m^3$ 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 plays in considering the appropriate annual and 24-hour levels, the Administrator solicits public comment on issues related to translating epidemiological evidence into standards, including approaches for addressing the uncertainties and

limitations associated with this evidence.

F. Administrator's Proposed 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 proposes to revise the current primary $PM_{2.5}$ standards. Specifically, the Administrator proposes to revise: (1) The level of the primary annual $PM_{2.5}$ standard to a level within the range of 12.0 to 13.0 $\mu g/m^3$ 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 allowance 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 proposes to retain the level and form of the primary 24-hour $PM_{2.5}$ standard to provide supplemental protection for areas with high peak $PM_{2.5}$ concentrations. The Administrator provisionally concludes that such a revised suite of standards, including a revised annual standard together with the current 24-hour standard, could provide requisite protection against health effects potentially associated with long- and short-term $PM_{2.5}$ exposures. The Administrator is not proposing any revisions to the current $PM_{2.5}$ indicator and the annual and 24-hour averaging times for the primary $PM_{2.5}$ standards. Data handling conventions are specified in proposed revisions to appendix N, as discussed in section VII below. The Administrator solicits comment on all aspects of this proposed decision.

IV. Rationale for Proposed Decision on Primary PM_{10} Standard

This section presents the rationale for the Administrator's proposed decision to retain the current 24-hour PM_{10} standard to continue to provide public health protection against short-term exposures to thoracic coarse particles, that is inhalable particles which can penetrate into the trachea, bronchi, and deep lungs and which are in the size range of 2.5 to 10 µm ($PM_{10-2.5}$). As discussed more fully below, this rationale 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 thoracic coarse particles in the ambient air. This proposal also takes 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 health evidence presented in 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 and Policy Assessment at public meetings, in separate written comments, and in CASAC's letters to the Administrator; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately. The EPA notes that the final decision for retaining or revising the current primary PM_{10} standard is a public health policy judgment made by the Administrator. The Administrator's final decision will draw upon scientific information and analyses related to health effects; judgments about uncertainties that are inherent in the scientific evidence and analyses; CASAC advice; and comments received in response to this proposal.

In presenting the rationale for the proposed decision to retain the current primary PM_{10} standard, this section begins with background information on EPA's past reviews of the PM NAAQS and the general approach taken to review the current PM_{10} 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), and the Administrator's proposed conclusions regarding the adequacy of the current primary PM_{10} standard (section IV.E). Section IV.F summarizes the Administrator's proposed decision with regard to the primary PM_{10} NAAQS.

A. Background

The following sections discuss previous reviews of the PM NAAQS (section IV.A.1), the litigation of the 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). 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). Thus, the EPA concluded that a PM_{10} standard could provide requisite protection against effects associated with particles in the size range of 2.5 to 10 µm.[87] 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, it was judged 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 newly adopted $PM_{2.5}$ standards.

[87] With regard to the 24-hour PM_{10} standard, the EPA retained the indicator, averaging time, and level (150 $\mu g/m^3$), but revised the form (i.e., from one-expected-exceedance to the 99th percentile).

In May 1998, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit found ''ample support'' for 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 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 $PM_{10-2.5}$.[88] 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 decision that it was requisite to provide protection from exposure to all thoracic coarse PM, regardless of its origin, rejecting 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 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 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 to 96, October 17, 2006). 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 $PM_{2.5}$, potentially increasing the toxicity of thoracic coarse particles in urban areas (*Id.*). Given the evidence that the existing PM_{10} standard afforded requisite protection with an adequate margin of safety, the Agency retained the level and form of the 24-hour PM_{10} standard.[89]

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 $PM_{10-2.5}$ 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.

In the same rulemaking, the EPA also included a new FRM for the measurement of $PM_{10-2.5}$ in the ambient air (71 FR 61212 to 61213, October 17, 2006). Although the standard for thoracic coarse particles does not use a $PM_{10-2.5}$ indicator, the new FRM for $PM_{10-2.5}$ was established to provide a basis for approving FEMs and to promote the gathering of scientific data to support future reviews of the PM

[88] 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).

[89] 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.

NAAQS (71 FR 61202/3, October 17, 2006).

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 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 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 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 accorded 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 EPA's decision to revoke the annual PM_{10} standard. Specifically, the court stated the following:

> 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 Policy Assessment for 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 basic elements of the NAAQS: Indicator, averaging time, form, and level.

In contrast to previous reviews, where PM_{10} studies conducted in locations where PM_{10} is comprised predominantly of $PM_{10-2.5}$ were considered (U.S. EPA, 2005, pp. 5–49 to 5–50), the focus in the current review is on $PM_{10-2.5}$ studies. It is difficult to interpret PM_{10} studies within the context of a standard meant to protect against exposures to $PM_{10-2.5}$ because PM_{10} is comprised of both fine and coarse particles, even in locations with the highest concentrations of $PM_{10-2.5}$ (U.S. EPA, 2011a, Figure 3–4). In light of the considerable uncertainty in the extent to which PM_{10} effect estimates reflect associations with $PM_{10-2.5}$ versus $PM_{2.5}$, together with the availability in this review of a number of studies that evaluated associations with $PM_{10-2.5}$ and the fact that the Integrated Science Assessment weight of evidence conclusions for thoracic coarse particles were based on studies of $PM_{10-2.5}$, the EPA focuses in this review on studies that have specifically evaluated $PM_{10-2.5}$.

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, section 2.4.3). As a result, any approach to 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.

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 $PM_{10-2.5}$. 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 $PM_{10-2.5}$ health risks, would introduce significant uncertainty into a $PM_{10-2.5}$ 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 $PM_{10-2.5}$ risks is not supportable at this time (U.S. EPA, 2010a, p. 2–6).

B. Health Effects Related to Exposure to Thoracic Coarse Particles

The following sections discuss available information on the health effects associated with exposures to $PM_{10-2.5}$, including the nature of such health effects (section IV.B.1), the impacts of sources and composition on particle toxicity (section IV.B.2), ambient PM_{10} concentrations in $PM_{10-2.5}$ study locations (section IV.B.3), at-risk populations (section IV.B.4), and limitations and uncertainties (section IV.B.5).

1. Nature of Effects

Since the conclusion of the last review, the Agency has developed a more formal framework for reaching causal inferences from the body of scientific evidence. As discussed above in section III.B.1, this framework uses a five-level hierarchy that classifies the overall weight of evidence using the following categorizations: Causal relationship, likely to be a causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (U.S. EPA, 2009a, section 1.5). Applying this framework to thoracic coarse particles, the Integrated Science Assessment concludes 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 (U.S. EPA, 2009a, section 2.3.3).[90] In contrast, the Integrated Science Assessment concludes that available evidence is ''inadequate'' to infer a causal relationship between long-term $PM_{10-2.5}$ exposures and various health effects (U.S. EPA, 2009a, sections 7.2 to 7.6). Similar to the judgment made in the 2004 AQCD regarding long-term exposures (U.S. EPA, 2004, p. 9–79), the Integrated Science Assessment states, ''To date, a sufficient amount of evidence does not exist in order to draw conclusions regarding the health effects and outcomes associated with long-term exposure to $PM_{10-2.5}$'' (U.S. EPA, 2009a, section 2.3.4). Given these weight of evidence conclusions in the Integrated Science Assessment, EPA's consideration of the scientific evidence for $PM_{10-2.5}$ focuses on effects that have been linked with short-term exposures. The evidence supporting a link between short-term thoracic coarse particle exposures and adverse health effects is discussed in detail in the Integrated Science Assessment (U.S. EPA, 2009a, Chapter 6) and is summarized briefly below for mortality (section IV.B.1.a), cardiovascular effects (section IV.B.1.b), and respiratory effects (section IV.B.1.c).

a. Short-Term $PM_{10-2.5}$ Exposure and Mortality

The Integrated Science Assessment assesses a number of multi-city and single-city epidemiological studies that have evaluated associations between mortality and short-term $PM_{10-2.5}$ concentrations (U.S. EPA, 2009a, Figure 6–30 presents $PM_{10-2.5}$ mortality studies assessed in the last review and the current review). Different studies have used different approaches to estimate ambient $PM_{10-2.5}$. Some studies have used the difference between PM_{10} and $PM_{2.5}$ mass, either measured at co-located monitors (e.g., Lipfert et al., 2000; Mar et al., 2003; Ostro et al., 2003; Sheppard et al., 2003; Wilson et al., 2007) or as the difference in county-wide average concentrations (Zanobetti and Schwartz, 2009), while other studies have measured $PM_{10-2.5}$ directly with dichotomous samplers (e.g., Burnett and Goldberg, 2003; Fairley et al., 2003; Burnett et al., 2004; Klemm et al., 2004). Despite differences in the approaches used to estimate ambient $PM_{10-2.5}$ concentrations, the majority of multi- and single-city studies have reported positive associations between $PM_{10-2.5}$ and mortality, though most of these associations were not statistically significant (U.S. EPA, 2009a, Figure 6–30).

One important $PM_{10-2.5}$ study conducted since the last review of the PM NAAQS is the U.S. multi-city study by Zanobetti and Schwartz (2009), which reported positive and statistically significant associations with $PM_{10-2.5}$ for all-cause, cardiovascular-related, and respiratory-related mortality (U.S. EPA, 2009a, section 6.5.2.3). In this study, effect estimates for all-cause and respiratory-related mortality remained statistically significant in co-pollutant models that included $PM_{2.5}$, while the effect estimate for cardiovascular-related mortality remained positive but not statistically significant. Several other multi-city studies have reported positive, but not statistically significant, $PM_{10-2.5}$ effect estimates for mortality (U.S. EPA, 2009a, Figure 6–30).

When risk estimates in the study by Zanobetti and Schwartz (2009) were evaluated by climatic region (U.S. EPA, 2009a, Figure 6–28), a mix of positive and negative $PM_{10-2.5}$ effect estimates were reported in the regions that typically have the highest ambient $PM_{10-2.5}$ concentrations (i.e., regions corresponding to the western and southwestern U.S.). Regional effect estimates from western regions of the United States were generally not statistically significant. Positive and statistically significant effect estimates were more often reported in regions that typically have lower $PM_{10-2.5}$ concentrations (i.e., regions generally corresponding to the eastern half of the U.S.) (Schmidt and Jenkins, 2010 for $PM_{10-2.5}$ concentrations). In addition, single-city empirical Bayes-adjusted effect estimates (calculated using the methods discussed in Le Tertre et al., 2005) for the 47 cities evaluated by Zanobetti and Schwartz (2009) were generally positive, though typically not statistically significant (U.S. EPA, 2009a, Figure 6–29).

Of the available single-city $PM_{10-2.5}$ mortality studies, most reported positive, but not statistically significant, $PM_{10-2.5}$ effect estimates (U.S. EPA, 2009a, Figure 6–30). Of the three studies that did report statistically significant effect estimates (Mar et al., 2003; Ostro et al., 2003; Wilson et al., 2007), Ostro et al. (2003) reported that $PM_{10-2.5}$ effect estimates remained statistically significant in co-pollutant models that included either ozone or NO_2. The single-city studies by Mar et al. (2003) and Wilson et al. (2007) did not utilize co-pollutant models.

b. Short-Term $PM_{10-2.5}$ Exposure and Cardiovascular Effects

The Integrated Science Assessment assesses a number of studies that have evaluated the link between short-term ambient concentrations of thoracic coarse particles and cardiovascular effects. Single- and multi-city epidemiological studies generally report positive associations between short-term $PM_{10-2.5}$ concentrations and hospital admissions or emergency department visits for cardiovascular causes (U.S. EPA, 2009a, sections 2.3.3 and 6.2.12.2). However, as is the case for the mortality studies, most of these positive associations are not statistically significant. In addition, most $PM_{10-2.5}$ effect estimates remained positive, but not statistically significant, in co-pollutant models that included either

[90] The Integrated Science Assessment discusses the framework for causality determinations (U.S. EPA, 2009a, section 1.5). 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).

gaseous or particulate co-pollutants (U.S. EPA, 2009a, Figure 6–5).

An important cardiovascular morbidity study published since the last review of the PM NAAQS is the U.S. multi-city study by Peng et al. (2008). This study evaluates hospital admissions and emergency department visits for cardiovascular disease in Medicare patients (MCAPS, Peng et al., 2008). The authors report a positive and statistically significant association between 24-hour $PM_{10-2.5}$ concentrations and cardiovascular disease hospitalizations in a single pollutant model using air quality data for 108 U.S. counties with co-located PM_{10} and $PM_{2.5}$ monitors. The magnitude of this effect estimate was larger in counties with higher degrees of urbanization and larger in the eastern U.S. than the western U.S., though this regional difference was not statistically significant (Peng et al., 2008). The $PM_{10-2.5}$ effect estimate was reduced only slightly in a co-pollutant model that included $PM_{2.5}$, but it was no longer statistically significant (U.S. EPA, 2009a, sections 2.3.3, 6.2.10.9).

In addition to this U.S. multi-city study, positive associations reported for short-term $PM_{10-2.5}$ exposures and cardiovascular-related morbidity reached statistical significance in a multi-city study in France (Host et al., 2007) and single-city studies in Detroit (Ito, 2003) and Toronto (Burnett et al., 1999) (U.S. EPA, 2009a, Figures 6–2 and 6–3). In contrast, associations were positive but not statistically significant in single-city studies conducted in Atlanta (Metzger et al., 2004; Tolbert et al., 2007) and Boston (Peters et al., 2001) (and for some endpoints in Detroit (Ito, 2003)) (U.S. EPA, 2009a, Figures 6–1 to 6–3, and 6–5).

The plausibility of the positive associations reported for $PM_{10-2.5}$ and cardiovascular-related hospital admissions and emergency department visits receives some measure of support from a small number of controlled human exposure studies that have reported alterations in heart rate variability following short-term exposure to $PM_{10-2.5}$ (Gong et al., 2004; Graff et al., 2009); by short-term $PM_{10-2.5}$ epidemiological studies reporting positive associations with cardiovascular-related mortality; by a small number of recent epidemiological studies that have examined dust storm events and reported increases in cardiovascular-related emergency department visits and hospital admissions (see below); and by associations with other cardiovascular effects including heart rhythm disturbances and changes in heart rate variability (U.S. EPA, 2009a, sections 2.3.3 and 6.2.12.2). The few toxicological studies that examined the effect of $PM_{10-2.5}$ on cardiovascular health effects used intratracheal instillation and, as a result, provide only limited evidence on the biological plausibility of $PM_{10-2.5}$ induced cardiovascular effects (U.S. EPA, 2009a, sections 2.3.3 and 6.2.12.2).

c. Short-Term $PM_{10-2.5}$ Exposure and Respiratory Effects

The Integrated Science Assessment also assesses a number of studies that have evaluated the link between short-term ambient concentrations of thoracic coarse particles and respiratory effects. This includes recent studies conducted in the U.S., Canada, and France (U.S. EPA, 2009a, section 6.3.8), including the U.S. multi-city study of Medicare patients by Peng et al. (2008). As discussed above, Peng estimated $PM_{10-2.5}$ concentrations as the difference between PM_{10} and $PM_{2.5}$ concentrations measured by co-located monitors. The authors reported a positive, but not statistically significant, $PM_{10-2.5}$ effect estimate for respiratory-related hospital admissions. Single-city studies have reported positive, and in some cases statistically significant, $PM_{10-2.5}$ effect estimates for respiratory-related hospital admissions and emergency department visits (U.S. EPA, 2009a, Figures 6–10 to 6–15). Some of these $PM_{10-2.5}$ respiratory morbidity studies have reported positive and statistically significant $PM_{10-2.5}$ effect estimates in co-pollutant models that included gaseous pollutants while others reported that $PM_{10-2.5}$ effect estimates remain positive, but not statistically significant, in such co-pollutant models (U.S. EPA, 2009a, Figure 6–15).

A limited number of epidemiological studies have focused on specific respiratory morbidity outcomes and reported both positive and negative, but generally not statistically significant, associations between $PM_{10-2.5}$ and lower respiratory symptoms, wheeze, and medication use (U.S. EPA, 2009a, sections 2.3.3.1 and 6.3.1.1; Figures 6–7 to 6–9). Although controlled human exposure studies have not observed an effect on lung function or respiratory symptoms in healthy or asthmatic adults in response to short-term exposure to $PM_{10-2.5}$, healthy volunteers have exhibited increases in markers of pulmonary inflammation.[91] Toxicological studies using inhalation exposures are still lacking, but pulmonary injury and inflammation has been reported in animals after intratracheal instillation exposure (U.S. EPA, 2009a, section 6.3.5.3) and, in some cases, $PM_{10-2.5}$ was found to be more potent than $PM_{2.5}$.

2. Potential Impacts of Sources and Composition on $PM_{10-2.5}$ Toxicity

In the absence of a systematic national effort to characterize $PM_{10-2.5}$ components, relatively little information (e.g., compared to fine particles) is available in the current review to inform consideration of the potential for composition to impact $PM_{10-2.5}$ toxicity. Given this, the Integrated Science Assessment concludes that currently available evidence is insufficient to draw distinctions in toxicity based on composition and notes that recent studies have reported that PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from a variety of sources is associated with adverse health effects (U.S. EPA, 2009a, section 2.4.4).

As discussed above, positive associations between short-term $PM_{10-2.5}$ concentrations and mortality and morbidity have been reported in a number of urban locations in the U.S., Canada, and Europe. While little is known about how $PM_{10-2.5}$ composition varies across these locations or about how that variation could affect particle toxicity (U.S. EPA, 2009a, sections 2.3.3, 2.3.4, 2.4.4), a number of trace elements (e.g., chromium, cobalt, nickel, copper, zinc, arsenic, selenium, and lead) have been detected in $PM_{10-2.5}$ from urban locations (U.S. EPA, 2004, section 3.2.4).

An indication of the sources of some of these trace elements (e.g., metals such as lead, copper, and zinc) in ambient $PM_{10-2.5}$ samples has been obtained by examining urban runoff (U.S. EPA, 2004, section 3.2.4). Wind-abrasion on building siding and roofs (coatings such as lead paint and building material such as brick, metal, and wood siding); brake wear (brake pads contain significant quantities of copper and zinc); tire wear (zinc is used as a filler in tire production); and burning engine oil could all produce particles containing metals (U.S. EPA, 2004, section 3.2.4). Once deposited on the ground, these elements can be resuspended with other material as $PM_{10-2.5}$. In addition, resuspended crustal particles may become contaminated with trace elements and other components from previously deposited fine PM (e.g., metals from smelters or steel mills, PAHs from automobile exhaust, pesticides from agricultural lands) (U.S. EPA, 2004, section 8.5, p. 8–344).

In considering the potential for $PM_{10-2.5}$ composition to impact toxicity,

[91] $PM_{10-2.5}$ controlled human exposure studies have not been conducted in children.

it is useful to consider studies conducted in locations where $PM_{10-2.5}$ composition is expected to be very different from that in typical urban locations. Specifically, a small number of studies have examined the health impacts of dust storm events (U.S. EPA, 2009a, sections 6.2.10.1 and 6.5.2.3). Although these studies do not link specific particle constituents to health effects, they do provide some information on the toxicity of particles of non-urban crustal origin. Several of these studies have reported positive and statistically significant associations between dust storm events and morbidity or mortality, including the following:

(1) Middleton et al. (2008) reported that dust storms in Cyprus were associated with a statistically significant increase in risk of hospitalization for all causes and a non-significant increase in hospitalizations for cardiovascular disease.

(2) Chan et al. (2008) studied the effects of Asian dust storms on cardiovascular-related hospital admissions in Taipei, Taiwan and reported a statistically significant increase associated with 39 Asian dust events. Evaluating the same data, Bell et al. (2008) also reported positive and statistically significant associations between hospitalization for ischemic heart disease and $PM_{10-2.5}$.

(3) Perez et al. (2008) tested the hypothesis that outbreaks of Saharan dust exacerbate the effects of $PM_{10-2.5}$ on daily mortality in Spain. During Saharan dust days, the $PM_{10-2.5}$ effect estimate was larger than on non-dust days and it became statistically significant, whereas it was not statistically significant on non-dust days.

In addition, a study in Coachella Valley by Ostro et al. (2003) reported statistically significant associations in a location where thoracic coarse particles are expected to be largely due to windblown dust.

In contrast to the studies noted above, some dust storm studies have reported associations that were not statistically significant. Specifically, Bennett et al. (2006) reported on a dust storm in the Gobi desert that transported PM across the Pacific Ocean, reaching western North America in the spring of 1998. The authors reported no excess risk of cardiovascular-related or respiratory-related hospital admissions associated with the dust storm in the population of British Columbia's Lower Fraser Valley (Bennett et al., 2006). In addition, Yang et al. (2009) reported that hospitalizations for congestive heart failure were elevated during or immediately following 54 Asian dust storm events, though effect estimates were not statistically significant.

3. Ambient PM_{10} Concentrations in $PM_{10-2.5}$ Study Locations

As discussed above, a 24-hour PM_{10} standard is in place to protect public health against exposures to $PM_{10-2.5}$. Given this, the EPA considers ambient PM_{10} concentrations in locations where $PM_{10-2.5}$ health studies have been conducted (U.S. EPA, 2011a, section 3.2.1). Specifically, the Agency considers study locations for which ambient PM_{10} data are available for comparison to the current standard,[92] including study locations evaluated in single-city U.S. studies, in Bayes-adjusted single-city analyses of the U.S. locations assessed by Zanobetti and Schwartz (2009), in single-city studies conducted outside the U.S., and in recent U.S. multi-city studies (Peng et al., 2008; Zanobetti and Schwartz, 2009).

In considering 24-hour PM_{10} concentrations in locations of specific $PM_{10-2.5}$ epidemiological studies, the EPA has focused primarily on U.S. study locations where single-city analyses have been conducted (U.S. EPA, 2011a, sections 3.2.1 and 3.3.4). While multi-city studies are particularly important when drawing conclusions about health effect associations,[93] it can be difficult to use these studies to link air quality in a given location to health effects in that same location. Multi-city studies often present overall effect estimates rather than single-city effect estimates, while short-term air quality can vary considerably across cities. Therefore, the extent to which effects reported in multi-city studies are associated with the short-term air quality in any particular location is uncertain, especially when considering short-term concentrations at the upper end of the distribution of daily concentrations for pollutants with relatively heterogeneous spatial distributions such as $PM_{10-2.5}$ and PM_{10} (U.S. EPA, 2009a, section 2.1.1.2). In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the short-term air quality in a given city is more straightforward to establish. As a result, in considering 24-hour PM_{10} concentrations in locations of epidemiological studies, the EPA has focused primarily on single-city studies and single-city analyses of the locations evaluated in the multi-city study by Zanobetti and Schwartz (2009) (U.S. EPA, 2011a, sections 3.2.1 and 3.3.4).

Of the 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).[94] 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). Amongst 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, $PM_{10-2.5}$ effect estimates were both positive and negative, with most not statistically significant (U.S. EPA, 2011a, Figure 3–3).

As discussed above, $PM_{10-2.5}$ effect estimates for mortality were generally positive but not statistically significant in Bayes-adjusted single-city analyses in the locations evaluated by Zanobetti and Schwartz (U.S. EPA, 2009a, Figure 6–30). These effect estimates were generally similar in magnitude and precision, particularly for cardiovascular-related mortality, across a wide range of estimated $PM_{10-2.5}$ concentrations (U.S. EPA, 2009a, Figure 6–29). In most of the cities evaluated (37 of the 45 for which appropriate PM_{10} air quality data were available for comparison to the current standard, as described in Schmidt and Jenkins (2010) and Jenkins (2011), PM_{10} concentrations were below those that would have been allowed by the current PM_{10} standard (U.S. EPA, 2011a, section 3.2.1). Of these 37 cities that would likely have met the current PM_{10} standard during

[92] As discussed in more detail in the Policy Assessment (U.S. EPA, 2011a), these analyses are based on comparison of the one-expected-exceedance concentration-equivalent design values in study locations to the level of the current standard. The one-expected-exceedance concentration-equivalent design value is used as a surrogate concentration for comparison to the standard level in order to gain insight into whether a particular area would likely have met or violated the current PM_{10} standard. Therefore, locations with one-expected-exceedance concentration-equivalent design values below the level of the current PM_{10} standard (i.e., 150 $\mu g/m^3$) would likely meet that standard (U.S. EPA, 2011a, section 3.2.1).

[93] Multi-city studies assess $PM_{10-2.5}$-associated health effects among large study populations and provide enhanced power to detect $PM_{10-2.5}$-associated health effects. In addition, multi-city studies often provide spatial coverage for different regions across the country, reflecting differences in $PM_{10-2.5}$ sources, composition, and potentially other factors that could impact $PM_{10-2.5}$-related effects. These factors make multi-city studies particularly important when drawing conclusions about health effect associations.

[94] See a previous footnote above and the Policy Assessment (U.S. EPA, 2011a, section 3.2.1) for an explanation of how PM_{10} air quality in study locations was compared to the current PM_{10} standard.

the study period, positive and statistically significant $PM_{10-2.5}$ effect estimates were reported in three locations (Chicago, Pittsburgh, Birmingham). Of the eight cities likely to have violated the current PM_{10} standard during the study period, $PM_{10-2.5}$ effect estimates were positive and statistically significant in three (Detroit, St. Louis, Salt Lake City).

In considering $PM_{10-2.5}$ epidemiological studies conducted in Canada and elsewhere outside the U.S., the EPA notes that PM_{10} air quality information beyond that published by the study authors is generally not available. The available PM_{10} concentration data for these study areas is typically not appropriate for comparison to the current PM_{10} standard (i.e., concentrations are averaged across monitors, rather than from the highest monitor in the study area, and/or concentrations are reported as means or medians). However, in a small number of cases it is possible to draw conclusions based on available air quality information about whether a study area would likely have met or violated the current PM_{10} standard.

For example, Lin et al. (2002) reported positive and statistically significant associations between $PM_{10-2.5}$ and asthma hospital admissions in children in Toronto (U.S. EPA, 2009a; Figures 6–12 and 6–15). The authors reported a maximum PM_{10} concentration measured at a single monitor in the study area of 116 $\mu g/m^3$, indicating that the PM_{10} air quality in Toronto during this study would have been allowed by the current 24-hour PM_{10} standard.[95]

In contrast Middleton et al. (2008), who reported that dust storms in Cyprus were associated with a statistically significant increase in risk of hospitalization for all causes and a non-significant increase in hospitalizations for cardiovascular diseases, reported a maximum 24-hour PM_{10} concentration of 1,371 $\mu g/m^3$. Thus, the dust storm-associated increases in hospitalizations reported in this study occurred in an area with PM_{10} concentrations that were likely well above those allowed by the current standard. Other dust storm studies did not report maximum 24-hour PM_{10} concentrations from individual monitors, though the studies by Chan et al. (2008) and Bell et al. (2008), which reported positive and statistically significant associations between dust storm metrics and cardiovascular-related hospital admissions, reported that 24-hour PM_{10} concentrations, averaged across monitors, exceeded 200 $\mu g/m^3$. It is likely that peak concentrations measured at individual monitors in these studies were much higher and, therefore, 24-hour PM_{10} concentrations in these study areas were likely above those allowed by the current standard.

In addition to the single-city studies discussed above, multi-city averages of PM_{10} one-expected-exceedance concentration-equivalent design values[96] for recent U.S. multi-city studies were 110 $\mu g/m^3$, for the locations evaluated by Zanobetti and Schwartz (2009), and 100 $\mu g/m^3$, for the locations evaluated by Peng et al. (2008) (U.S. EPA, 2011a, section 3.2.1). As discussed above, the extent to which multi-city $PM_{10-2.5}$ effect estimates are associated with the air quality in any particular location is uncertain.

4. At-Risk Populations

Specific groups within the general population are likely at increased risk for suffering adverse effects following $PM_{10-2.5}$ exposures. As discussed in section III.B.3 above, in this proposal, the term ''at-risk'' is the all encompassing term used for groups with specific factors that increase the risk of PM-related health effects in a population.

Although studies have primarily used exposures to PM_{10} or $PM_{2.5}$ to investigate potential at-risk populations, the available evidence suggests that the identified factors also increase risk from $PM_{10-2.5}$[97] (U.S. EPA, 2009a, section 8.1.8). As discussed in section III.B.3 above, at-risk populations include those with preexisting heart and lung diseases (e.g., asthma), 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 (U.S. EPA, 2009a, section 2.4.1 and Table 8–2).

Given the range of at-risk groups, the population potentially affected by $PM_{10-2.5}$ is large. In the United States, approximately 7 percent of adults (approximately 16 million adults) and 9 percent of children (approximately 7 million children) have asthma (U.S. EPA, 2009a, Table 8–3; CDC, 2008[98]). In addition, approximately 4 percent of adults have been diagnosed with chronic bronchitis and approximately 2 percent with emphysema (U.S. EPA, 2009a, Table 8–3). Approximately 11 percent of adults have been diagnosed with heart disease, 6 percent with coronary heart disease, 23 percent with hypertension, and 8 percent with diabetes (U.S. EPA, 2009a, Table 8–3). In addition, approximately 3 percent of the U.S. adult population has suffered a stroke (U.S. EPA, 2009a, Table 8–3). Therefore, although exposures to ambient $PM_{10-2.5}$ have not been well characterized on a national scale, the size of the potentially at-risk population suggests that ambient $PM_{10-2.5}$ could have a significant impact on public health in the United States.

5. Limitations and Uncertainties Associated With the Currently Available Evidence

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, are discussed below.

The Integrated Science Assessment concludes that an important uncertainty in interpreting $PM_{10-2.5}$ epidemiological studies is the potential for confounding by co-occurring pollutants, particularly $PM_{2.5}$. This issue 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

[95] This is the case because the maximum monitored 24-hour PM_{10} concentration (116 $\mu g/m^3$) was below the level of the current PM_{10} standard (150 $\mu g/m^3$).

[96] The one-expected-exceedance concentration-equivalent design value is used as a surrogate concentration for comparison to the standard level in order to gain insight into whether a particular area would likely have met or violated the current PM_{10} standard. Therefore, locations with one-expected-exceedance concentration-equivalent design values below the level of the current PM_{10} standard (i.e., 150 $\mu g/m^3$) would likely meet that standard (U.S. EPA, 2011a, section 3.2.1).

[97] Although the Integrated Science Assessment notes that in $PM_{10-2.5}$ studies of respiratory-related hospital admissions and emergency department visits, ''the strongest relationships were observed among children'' (U.S. EPA, 2009a, section 2.3.3.1). As discussed above (section III.B.3), children may be more at increased risk for effects associated with ambient PM exposures because, compared to adults, children typically spend more time outdoors and at higher activity levels; they have exposures that result in higher doses per body weight and lung surface area; and there is the potential for irreversible effects on the developing lung (U.S. EPA, 2009a, section 8.1.1.2).

[98] For percentages, see *http://www.cdc.gov/ASTHMA/nhis/06/table4-1.htm.* For population estimates, see *http://www.cdc.gov/ASTHMA/nhis/06/table3-1.htm.*

experimental evidence (i.e., controlled human exposure and animal toxicology studies) available to support the plausibility of 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.

Another important uncertainty is related to exposure error. The Integrated Science Assessment concludes that ''there is greater spatial variability in $PM_{10-2.5}$ concentrations than $PM_{2.5}$ concentrations, resulting in increased exposure error for the larger size fraction'' (U.S. EPA, 2009a, p. 2–8) and that 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).

In addition, there is uncertainty in the air quality estimates used in $PM_{10-2.5}$ epidemiological studies (U.S. EPA, 2009a, sections 2.3.3, 2.3.4) and, therefore, in the ambient $PM_{10-2.5}$ concentrations that are associated with mortality and morbidity. 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.[99] Given these limitations in routine monitoring, epidemiological studies have employed different approaches for estimating $PM_{10-2.5}$ concentrations. For example, several of the studies discussed above, including the multi-city study by Peng et al. (2008), estimated $PM_{10-2.5}$ by taking the difference between mass measured at co-located PM_{10} and $PM_{2.5}$ monitors while the study by Zanobetti and Schwartz (2009) used the difference between county-wide average PM_{10} and $PM_{2.5}$ concentrations. In addition, a small number of studies have directly measured $PM_{10-2.5}$ concentrations with dichotomous samplers (e.g., Burnett et al., 2004; Villeneuve et al., 2003; Klemm et al., 2004). 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 with a dichotomous sampler or by calculating the difference using co-located samplers (U.S. EPA, 2009a, section 6.5.2.3).[100] 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 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).

Another uncertainty results from the relative lack of 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). As discussed above, a few recent studies have evaluated associations between health effects and particles of non-urban, crustal origin by evaluating the health impacts of dust storm events. Though these studies provide some information on the health effects of ambient particles that likely differ in composition from the particles of urban origin that are typically studied, 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).

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 $PM_{10-2.5}$ (U.S. EPA, 2009b, Appendix H). The decision not to conduct a $PM_{10-2.5}$ risk assessment for the current review was based on consideration of several key uncertainties, including the following:

(1) Concerns that monitoring data that would be used in a $PM_{10-2.5}$ risk assessment (i.e., for the period 2005 to 2007) would not match ambient monitoring data used in the underlying epidemiological studies providing concentration-response functions.

(2) Uncertainty in the prediction of ambient levels under current and alternative standard levels.

(3) Concerns that locations used in the risk assessment may not be representative of areas experiencing the most significant 24-hour peak $PM_{10-2.5}$ concentrations (and consequently, may not capture locations with the highest risk).

(4) Concerns about the relatively small (i.e., compared to $PM_{2.5}$) health effects database that supplies the concentration-response relationships.

When considered together, the limitations outlined above resulted in the conclusion that a quantitative $PM_{10-2.5}$ risk assessment would not significantly enhance the review of the NAAQS for coarse-fraction PM. Specifically, these limitations would likely result in sufficient uncertainty in the resulting risk estimates to significantly limit their utility to inform policy-related questions, including the assessment of whether the current standard is protective of public health and characterization of the degree of additional public health protection potentially afforded by alternative standards. 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.

C. Consideration of the Current and Potential Alternative Standards in the Policy Assessment

The following sections discuss EPA's consideration of whether to revise the current PM_{10} standard, as well as our consideration of potential alternative

[99] The EPA has required $PM_{10-2.5}$ mass monitoring, as part of the NCore network, beginning January 1, 2011 at approximately 80 stations. The NCore network is a multi-pollutant network that includes measurements of particles, gases, and meteorology (71 FR 61236, October 17, 2006). NCore monitoring stations are located away from direct emissions sources that could substantially impact the detection of area-wide concentrations. The network is comprised of stations in both urban and rural areas. Urban NCore stations are generally to be located at an urban or neighborhood scale to provide exposure concentrations that are expected to be representative of the metropolitan area. Rural NCore stations are to be located, to the maximum extent practicable, at a regional or larger scale away from any large local emission source, so that they represent ambient concentrations over an extensive area (U.S. EPA, 2011a, Appendix B, section B.4).

[100] In addition, several sources of uncertainty can be specifically associated with $PM_{10-2.5}$ concentrations that are estimated based on co-located monitors. For example, the potential for differences among operational flow rates and temperatures for PM_{10} and $PM_{2.5}$ monitors add to the potential for exposure misclassification. As discussed in Appendix B of the Policy Assessment (U.S. EPA, 2011a, sections B.2 and B.3), PM_{10} data are often reported at standard temperature and pressure (STP) while $PM_{2.5}$ is reported at local conditions (LC). In these cases, the PM_{10} data should be adjusted to LC when estimating $PM_{10-2.5}$ concentrations. In many of the epidemiological studies that estimated $PM_{10-2.5}$ concentrations based on co-located monitors, it is not made explicitly clear whether this adjustment was made, adding to the overall uncertainty in the $PM_{10-2.5}$ concentrations that are associated with health effects.

standards, drawing from such considerations in the Policy Assessment (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 (section IV.C.2.a), averaging time (section IV.C.2.b), form (section IV.C.2.c), and level (section IV.C.2.d).

1. Consideration of the Current Standard in the Policy Assessment

As discussed above, a 24-hour PM_{10} standard is in place 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 EPA considers 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 EPA notes 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 notes 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 3.2.1):

(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 in 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 characterize.

(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 concludes 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 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 $PM_{10-2.5}$. Although such an approach to considering the adequacy of the current standard would recognize the positive, and in some cases statistically significant, associations between $PM_{10-2.5}$ 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 notes that, when considering the uncertainties and limitations in the $PM_{10-2.5}$ health evidence and air quality information, the EPA judged that it would not be 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 notes an alternative approach to considering the evidence and its uncertainties would place emphasis on the following:

(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 concludes 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 concludes 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.

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 $PM_{10-2.5}$. These considerations are discussed below in terms of indicator, averaging time, form, and level.

a. Indicator

As noted above, PM_{10} includes both $PM_{10-2.5}$ and $PM_{2.5}$, with the relative contribution of each to PM_{10} mass varying across locations and over time. In the most recent review completed in 2006, the EPA concluded that the PM_{10} indicator remained appropriate in large part because a PM_{10} standard would provide some measure of protection against exposures to all $PM_{10-2.5}$ regardless of source or location, while also targeting protection to urban areas, where the evidence of effects from exposure to coarse PM is the strongest (71 FR at 61196, October 17, 2006). As noted above, the court explicitly endorsed this reasoning. 559 F. 3d at 535–36.

In considering the indicator in the current review, the Policy Assessment evaluated the extent to which PM_{10} is comprised of $PM_{10-2.5}$ across locations and over time. Based on the air quality analyses in the Integrated Science Assessment (U.S. EPA, 2009a, section 3.5.1.1) and Schmidt and Jenkins (2010), and based on the concentration estimates of Zanobetti and Schwartz (2009), the Policy Assessment notes that $PM_{10-2.5}$ typically makes up a larger portion of PM_{10} mass in the western United States, with the southwest region having the highest ratios of $PM_{10-2.5}$ to PM_{10}. In addition, the ratios of $PM_{10-2.5}$ to PM_{10} across the U.S. tended to be higher on days with relatively high PM_{10} concentrations than on days with more typical PM_{10} concentrations (i.e., comparing days with concentrations at or above the 95th percentile to all days) (U.S. EPA, 2011a, section 3.3.1, Figure 3–4). Given this, the Policy Assessment concludes that high daily PM_{10} concentrations are driven, at least in part, by elevated $PM_{10-2.5}$ mass and that a PM_{10} standard focusing on the upper end of the distribution of daily PM_{10} concentrations could effectively control ambient $PM_{10-2.5}$ concentrations (U.S. EPA, 2011a, p. 3–28).

The Policy Assessment also considered the appropriateness of a PM_{10} standard, given that such a standard allows lower $PM_{10-2.5}$ concentrations in areas with higher fine particle concentrations (urban areas) than areas with lower fine particle concentrations (rural areas) (U.S. EPA, 2011a, section 3.3.1). In considering this issue, the Policy Assessment notes that most of the evidence for positive associations between $PM_{10-2.5}$ and morbidity and mortality, particularly evidence for these associations at relatively low concentrations of $PM_{10-2.5}$, comes from a number of studies conducted in locations where the $PM_{10-2.5}$ is expected to be largely of urban origin (U.S. EPA, 2009a, Chapter 6). Although some studies have reported positive associations between relatively high concentrations of particles of non-urban origin (i.e., crustal material from windblown dust in non-urban areas, see above) and mortality and morbidity, the Policy Assessment notes that the extent to which these associations would remain at the lower particle concentrations more typical of U.S. and Canadian urban study locations remains uncertain.[101]

Given these considerations, and given the increased potential for coarse particles in urban areas to become contaminated by toxic components of fine particles from urban/industrial sources (U.S. EPA, 2004 at 8–344; 71 FR 61196, October 17, 2006), the Policy Assessment concludes that it is reasonable to consider an indicator that targets control to areas with the types of ambient mixes generally present in urban areas. The Policy Assessment notes that such an indicator would focus control on areas with ambient mixes known with greater certainty to be associated with adverse health effects and, therefore, would provide public health benefits with the greatest degree of certainty. Therefore, as in the last review, the Policy Assessment reaches the conclusion that a PM_{10} indicator would appropriately target protection to those locations where the evidence is strongest for associations between adverse health effects and exposures to thoracic coarse particles (U.S. EPA, 2011a, p. 3–29).

In contrast, the Policy Assessment notes that a $PM_{10-2.5}$ indicator, for a standard set at a single unvarying level, would not achieve this targeting, given that allowable thoracic coarse particle concentrations would be the same regardless of the location or the likely sources of PM. Therefore, given the currently available evidence, one possible result of using a $PM_{10-2.5}$ indicator would be a standard that is overprotective in rural areas and/or underprotective in urban areas (*Id.*).

Given all of the above considerations, the Policy Assessment concludes that the available evidence supports consideration in the current review of a PM_{10} indicator for a standard that protects against exposures to thoracic coarse particles. The Policy Assessment further concludes that consideration of alternative indicators (e.g., $PM_{10-2.5}$) in future reviews is desirable and could be informed by additional research (U.S. EPA, 2011a, section 3.5).

b. Averaging Time

Based primarily on epidemiological studies that reported positive associations between short-term (24-hour) $PM_{10-2.5}$ concentrations and mortality and morbidity, the Administrator concluded in the last review that the available evidence supported a 24-hour averaging time for a standard intended to protect against exposures to thoracic coarse particles. In contrast, given the relative lack of studies supporting a link between long-term exposures to thoracic coarse particles and morbidity or mortality (U.S. EPA, 2004, Chapter 9), the Administrator further concluded that an annual coarse particle standard was not warranted at that time (71 FR 61198–61199, October 17, 2006).

In the current review, the Policy Assessment notes the conclusions from the Integrated Science Assessment regarding the weight of evidence for short-term and long-term $PM_{10-2.5}$ exposures as well as the studies on which those conclusions are based. Specifically, as discussed above, the Integrated Science Assessment concludes 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 (U.S. EPA, 2009a, section 2.3.3). This conclusion is based largely on epidemiological studies which have primarily evaluated associations between 24-hour $PM_{10-2.5}$ concentrations and morbidity and

[101] Other than the dust storm studies, we note that the study in Coachella Valley by Ostro et al. (2003) reported statistically significant associations in a location where thoracic coarse particles are expected to be largely due to windblown dust. Specifically, we note the CASAC conclusion in the last review that ''studies from Ostro et al. showed significant adverse health effects, primarily involving exposures to coarse-mode particles arising from crustal sources'' (Henderson, 2005b). In considering this study, we also note the relatively high PM_{10} concentrations in the study area (U.S. EPA, 2011a, Figure 3–2), which would not have met the current PM_{10} standard.

mortality (e.g., U.S. EPA, 2009a, Figure 2–3), though a small number of controlled human exposure studies have reported effects following shorter exposures (i.e., 2-hours) to $PM_{10-2.5}$ (U.S. EPA, 2009a, sections 6.2.1.2 and 6.3.3.2). In contrast, with respect to long-term exposures, the Integrated Science Assessment concludes that available evidence is inadequate to infer a causal relationship with all health outcomes evaluated (U.S. EPA, 2009a, section 2.3). Specifically, the Integrated Science Assessment states, ''To date, a sufficient amount of evidence does not exist in order to draw conclusions regarding the health effects and outcomes associated with long-term exposure to $PM_{10-2.5}$'' (U.S. EPA, 2009a, section 2.3.4).

In considering these weight-of-evidence determinations, the Policy Assessment concludes that, at a minimum, they suggest the importance of maintaining a standard that protects against short-term exposures to thoracic coarse particles. Given that the majority of the evidence supporting the link between short-term $PM_{10-2.5}$ and morbidity and mortality is based on 24-hour average thoracic coarse particle concentrations, the Policy Assessment concludes that the evidence available in this review continues to support consideration of a 24-hour averaging time for a PM_{10} standard meant to protect against effects associated with short-term exposures to $PM_{10-2.5}$ (U.S. EPA, 2011a, p. 3–31).

The Policy Assessment further concludes that the available evidence does not support consideration of an annual thoracic coarse particle standard at this time. In reaching this conclusion, the Policy Assessment also notes that, to the extent a short-term standard requires areas to reduce their 24-hour ambient particle concentrations, long-term concentrations would also be expected to decrease (*Id.*). Therefore, a 24-hour standard meant to protect against short-term exposures to thoracic coarse particles would also be expected to provide some protection against potential effects associated with long-term exposures to ambient concentrations.

c. Form

The ''form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains that standard. As discussed above, in the last review the Administrator retained the one-expected exceedance form of the primary 24-hour PM_{10} standard. This decision was linked to the overall conclusion that ''the level of protection from coarse particles provided by the current 24-hour PM_{10} standard remains requisite to protect public health with an adequate margin of safety'' (71 FR 61202, October 17, 2006). Because revising either the level or the form of the standard would have altered the protection provided, the Administrator concluded that such changes ''would not be appropriate based on the scientific evidence available at this time'' (71 FR 61202). Therefore, the decision in the last review to retain the one-expected-exceedance form was part of the broader decision that the existing 24-hour standard provided requisite public health protection.

In the current review, the Policy Assessment considers the form of the standard within the context of the overall decision on whether, and if so how, to revise the current 24-hour PM_{10} standard. Given the conclusions above regarding the appropriate indicator and averaging time for consideration for potential alternative standards, the Policy Assessment considers potential alternative forms for a 24-hour PM_{10} standard.

Although the selection of a specific form must be made within the context of decisions on the other elements of the standard, the Policy Assessment notes that the EPA generally favors concentration-based forms for short-term standards. In 1997, the EPA established a 98th percentile form for the 24-hour $PM_{2.5}$ standard and, in 2010, the EPA established a 98th percentile form for the primary 1-hour NO_2 standard (62 FR 38671, July 18, 1997; 75 FR 6474, February 9, 2010) and a 99th percentile form for the primary 1-hour SO_2 standard (75 FR 35541, June 22, 2010).[102] In making these decisions, the EPA noted that, compared to an exceedance-based form, a concentration-based form is 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. In addition, when averaged over three years, these concentration-based forms were judged to provide an appropriate balance between limiting peak pollutant concentrations and providing a stable regulatory target, facilitating the development of stable implementation programs.

These considerations are also relevant in the current review of the 24-hour PM_{10} standard. Specifically, the Policy Assessment concludes that it is appropriate to consider concentration-based forms that would provide a balance between limiting peak pollutant concentrations and providing a stable regulatory target. To accomplish this, it would be appropriate to consider forms from the upper end of the annual distribution of 24-hour PM_{10} concentrations.[103] However, given the potential for local sources to have important impacts on monitored PM_{10} concentrations (U.S. EPA, 2009a, section 2.1.1.2), the Policy Assessment also notes that it would be appropriate to consider forms that, when averaged over three years, would be expected to promote the stability of local implementation programs.[104] In considering these issues in the most recent review of the primary NO_2 NAAQS, the Policy Assessment notes that a 98th percentile form was adopted, rather than a 99th percentile form, due to the potential for ''instability in the higher percentile concentrations'' near local sources (75 FR 6493, February 9, 2010).[105] [106]

In considering the potential appropriateness of a 98th percentile form in the current review, the Policy Assessment notes that, compared to the current PM_{10} standard, attainment status for a PM_{10} standard with a 98th percentile form would be based on a more stable air quality statistic and would be expected to be less influenced by relatively rare events that can cause elevations in PM_{10} concentrations over short periods of time (Schmidt, 2011b).

[102] As noted above (section IV.A.1.a), in the 1997 review the EPA revised the form of the 24-hour PM_{10} standard to the 99th percentile. However, the D.C. Circuit Court vacated the revised rule, based on EPA's retention of the PM_{10} indicator, and the 1987 standards remained in place (including the one-expected-exceedance form for the 24-hour standard).

[103] With regard to this conclusion, the Policy Assessment also notes that $PM_{10-2.5}$ is likely to make a larger contribution to PM_{10} mass on days with relatively high PM_{10} concentrations than on days with more typical PM_{10} concentrations (see above).

[104] As noted in section III.E.3.b above, stability of implementation programs has been held to be a legitimate consideration in determining a NAAQS (*American Trucking Associations* v. *EPA,* 283 F. 3d at 374 to 75).

[105] See also, ATA III, 283 F. 3d at 374–75 (upholding 98th percentile form since ''otherwise States would have to design their pollution control programs around single high exposure events that may be due to unusual meteorological conditions alone, rendering the programs less stable—and hence, we assume, less effective—than programs designed to address longer-term average conditions.''). In contrast, in the recently completed review of the primary SO_2 NAAQS, a 99th percentile form was adopted. However, in the case of SO_2, the standard was intended to limit 5-minute exposures and a 99th percentile form was markedly more effective at doing so than a 98th percentile form (75 FR 35540 to 41, June 22, 2010).

[106] Similar considerations are noted in section III.E.3.b above, with regard to the form of the primary 24-hour $PM_{2.5}$ standard.

Specifically, the Policy Assessment notes that in areas that monitor PM_{10} every six days, every three days, or every day the PM_{10} concentrations that are comparable to the current standard level are, respectively, the highest, 2nd highest, or 4th highest 24-hour PM_{10} concentrations measured during a three year period. In contrast, for the same monitoring frequencies, the PM_{10} concentrations that would be comparable to the level of a standard with a 98th percentile form would be the three-year average of the 2nd highest, 3rd highest, or 7th/8th highest 24-hour PM_{10} concentrations measured during a single year (U.S. EPA, 2011a, p. 3–33).

In further considering this issue the Policy Assessment notes that, compared to the current one-expected-exceedance form, a concentration-based form specified as a percentile of the annual distribution of PM_{10} concentrations (e.g., such as a 98th percentile form) would be expected to better compensate for missing data and less-than-daily monitoring. This is a particularly important consideration in the case of PM_{10} because, depending largely on ambient concentrations, the frequency of PM_{10} monitoring differs across locations (i.e., either daily, 1 in 2 days, 1 in 3 days, or 1 in 6 days) (U.S. EPA, 2011a, section 1.3 and Appendix B). As discussed in earlier reviews of the PM NAAQS (e.g., 62 FR 38671, July 18, 1997), an area's attainment status for a standard with a 98th percentile form would be based directly on monitoring data rather than on a calculated value adjusted for missing data or less-than-every-day monitoring, as is the case with the current one-expected-exceedance form.

In light of all of the above considerations, the Policy Assessment concludes that, 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 (U.S. EPA, 2011a, p. 3–34).[107]

In their review of the second draft Policy Assessment, CASAC noted that such a change in form ''will lead to changes in levels of stringency across the country'' and recommended that this issue be explored further (Samet, 2010d). In considering this issue, the Policy Assessment acknowledges that, given differences in PM_{10} air quality distributions across locations (U.S. EPA, 2009a, Table 3–10), a revised standard with a 98th percentile form would likely target public health protection to some different locations than does the current standard with its one-expected-exceedance form (U.S. EPA, 2011a, p. 3–34). The final Policy Assessment notes that a further consideration with regard to the appropriateness of revising the form of the current PM_{10} standard is the extent to which, when compared with the current standard, a revised standard with a 98th percentile form would be expected to target public health protection to areas where we have more confidence that ambient $PM_{10-2.5}$ is associated with adverse health effects (*Id.,* p. 3–34 to 3–35).

In giving initial consideration to this issue, the Policy Assessment used recent PM_{10} air quality concentrations (i.e., from 2007–2009) to identify counties that would meet, and counties that would violate, the current PM_{10} standard as well as potential alternative standards with 98th percentile forms (Schmidt, 2011b).[108] [109] In some cases, counties that would violate the current standard do so because of a small number of ''outlier'' days (e.g., as few as one such day in three years) with PM_{10} concentrations well-above more typical concentrations (Schmidt, 2011b). Mean and 98th percentile PM_{10} and $PM_{10-2.5}$ concentrations were higher in counties that would have violated a revised standard with a 98th percentile form but met the current standard [110] than in counties that violated the current standard, but would have met a revised standard with a 98th percentile form (Schmidt, 2011b). This analysis suggests that, to the extent a revised PM_{10} standard with a 98th percentile form could target public health protection to different areas than the current standard, those areas preferentially targeted by a revised standard generally have higher ambient concentrations of thoracic coarse particles. The issue of targeting public health protection is considered further in section 3.3.4 of the Policy Assessment (U.S. EPA, 2011a) and below, within the context of considering specific potential alternative standard levels for a 24-hour PM_{10} standard with a 98th percentile form.

d. Level

As noted above, the Policy Assessment concluded that, to the extent it is judged in the current review that the 24-hour PM_{10} standard does not provide adequate public health protection against exposures to thoracic coarse particles, potential alternative standards could be considered. The Policy Assessment considers potential alternative levels for a 24-hour PM_{10} standard with a 98th percentile form. To inform consideration of this issue, the Policy Assessment considers the available scientific evidence and air quality information (U.S. EPA, 2011a, section 3.3.4).

i. Evidence-Based Considerations in the Policy Assessment

As discussed above, in considering the evidence as it relates to potential alternative standard levels, the Policy Assessment first considers the relative weight to place on specific epidemiological studies, including the weight to place on the uncertainties associated with those studies. The Policy Assessment considers several factors in placing weight on specific epidemiological studies including the extent to which studies report statistically significant associations with $PM_{10-2.5}$ and the extent to which the reported associations are robust to co-pollutant confounding, in particular confounding by $PM_{2.5}$. In addition, the Policy Assessment considers the extent to which associations with $PM_{10-2.5}$ can be linked to the air quality in a specific location. With regard to this, as noted above, the Policy Assessment places the greatest weight on information from single-city analyses.

In considering PM air quality in study locations, the Policy Assessment also notes that the available evidence does not support the existence of thresholds, or lowest-observed-effects levels, in terms of 24-hour average concentrations (U.S. EPA, 2009a, section 2.4.3).[111] In the absence of an apparent threshold, for purposes of identifying a range of

[107] As noted above, local sources can have important impacts on monitored PM_{10} concentrations. In the recent review of the NO_2 primary NAAQS, where this was also an important consideration, a 98th percentile form was adopted, rather than a 99th percentile form, due to the potential for ''instability in the higher percentile concentrations'' near local sources (75 FR 6493, February 9, 2010). A similar conclusion in the current review led the Policy Assessment to focus on the 98th percentile rather than the 99th percentile, in considering potential alternative forms for a PM_{10} standard.

[108] Section 3.3.4 of the Policy Assessment (U.S. EPA, 2011a) discusses potential alternative standard levels that would be appropriate to consider in conjunction with a revised standard with a 98th percentile form.

[109] The memo by Schmidt (2011b) identifies specific counties that are expected to meet, and counties that are not likely to meet the current standard and potential alternative standards with 98th percentile forms.

[110] This analysis considered a revised PM_{10} standard with a 98th percentile form and a level from the middle of the range discussed in section 3.3.4 of the Policy Assessment (i.e., 75 $\mu g/m^3$) (U.S. EPA, 2011a).

[111] Most studies that have evaluated the potential for thresholds have focused on PM_{10} or $PM_{2.5}$. However, there is no scientific basis for drawing different conclusions for $PM_{10-2.5}$.

standard levels potentially supported by the health evidence, the Policy Assessment focuses on the range of PM_{10} concentrations that have been measured in locations where U.S. epidemiological studies have reported associations with $PM_{10-2.5}$ (U.S. EPA, 2009a, Figures 6–1 to 6–30 for studies).

In single-city mortality studies, as well as the single-city analyses of the locations evaluated by Zanobetti and Schwartz (2009), positive and statistically significant $PM_{10-2.5}$ effect estimates were reported in some locations with 98th percentile PM_{10} concentrations ranging from 200 μg/m^3 to 91 μg/m^3 (U.S. EPA, 2011a, section 3.3.4). Lower PM_{10} concentrations were present in locations where positive, but not statistically significant, effect estimates were reported and when averaged across locations evaluated in the multi-city study by Zanobetti and Schwartz (2009) (U.S. EPA, 2011a, section 3.3.4).

Among U.S. morbidity studies, Ito (2003) reported a positive and statistically significant $PM_{10-2.5}$ effect estimate for hospital admissions for ischemic heart disease in Detroit, where the 98th percentile PM_{10} concentration (102 μg/m^3) was also within this range (U.S. EPA, 2011a, section 3.3.4 and Figure 3–6). $PM_{10-2.5}$ effect estimates in this study remained positive, and in some cases statistically significant, in co-pollutant models with gaseous pollutants (U.S. EPA, 2009a, Figures 6–5 and 6–15). Lower PM_{10} concentrations were present in locations where positive, but not statistically significant, effect estimates were reported and when averaged across locations evaluated in the multi-city study by Peng et al. (2008) (U.S. EPA, 2011a, section 3.3.4).

ii. Air Quality-based Considerations in the Policy Assessment

In addition to the evidence-based considerations described above, the Policy Assessment estimated the level of a 24-hour PM_{10} standard with a 98th percentile form that would approximate the degree of protection, on average across the country, provided by the current 24-hour PM_{10} standard with its one-expected-exceedance form. The initial approach to estimating this ''generally equivalent'' 98th percentile PM_{10} concentration was to use EPA's Air Quality System (AQS)[112] as the basis for evaluating correlations between 98th percentile PM_{10} concentrations and one-expected-exceedance concentration equivalent design values (Schmidt and Jenkins, 2010).[113] Based on these correlations, using monitoring data from 1988 to 2008, a 98th percentile PM_{10} concentration of 87 μg/m^3 is, on average, generally equivalent to the current standard level (U.S. EPA, 2011a, Figure 3–7). However, given the variability in the distributions of PM_{10} concentrations across locations (U.S. EPA, 2009a, Table 3–10; Schmidt and Jenkins, 2010), the range of equivalent concentrations varies considerably (95 percent confidence interval ranges from 63 to 111 μg/m^3) (Schmidt and Jenkins, 2010). As a consequence, the Policy Assessment notes that in some locations a 98th percentile standard with a level of 87 μg/m^3 would likely be more protective than the current standard while in other locations it would likely be less protective than the current standard.[114]

The Policy Assessment also evaluates regional differences in the relationship between 98th percentile PM_{10} concentrations and one-expected-exceedance concentration equivalent design values (U.S. EPA, 2011a, Figure 3–8), based on air quality data from 1988 to 2008. The 98th percentile PM_{10} concentrations that are, on average, generally equivalent to the current standard level ranged from just below 87 μg/m^3 in the Southeast, Southwest, upper Midwest, and outlying areas (i.e., generally equivalent 98th percentile PM_{10} concentrations ranged from 82 to 85 μg/m^3 in these regions) to just above 87 μg/m^3 in the Northeast, industrial Midwest, and southern California (i.e., generally equivalent 98th percentile PM_{10} concentrations ranged from 88 to 93 μg/m^3 in these regions) (Schmidt, 2011b). However, within each of these regions there is considerable variability in the ''generally equivalent'' 98th percentile PM_{10} concentration across monitoring sites (U.S. EPA, 2011a, Figure 3–8).

To provide a broader perspective on the relationship between the current standard and potential alternative standards with 98th percentile forms, the Policy Assessment also compares the size of the populations living in counties with PM_{10} one-expected-exceedance concentration-equivalent design values greater than the current standard level to the size of the populations living in counties with 98th percentile PM_{10} concentrations above different potential alternative standard levels (based on air quality data from 2007 to 2009[115]). Such comparisons can be considered as surrogates for comparisons of the breadth of public health protection provided by the current and potential alternative standards. Based on these comparisons, a 98th percentile PM_{10} standard with a level between 75 and 80 μg/m^3 would be most closely equivalent to the current standard. That is, compared to the number of people living in counties that would violate the current PM_{10} standard, a similar number live in counties that would violate a revised 24-hour PM_{10} standard with a 98th percentile form and a level between 75 and 80 μg/m^3 (U.S. EPA, 2011a, Table 3–2). However, there is considerably more variability across regions in the potential alternative standard that, based on this analysis, would be generally equivalent to the current PM_{10} standard (U.S. EPA, 2011a, section 3.3.4).

Given the variability in the relationship between the current standard and potential alternative standards with 98th percentile forms, the Policy Assessment concludes that no single potential alternative standard level, for a revised standard with a 98th percentile form, would provide public health protection equivalent to that provided by the current standard, consistently over time and across locations.

One consequence of this variability, as noted above in the discussion of the form of the standard, would be that a 24-hour PM_{10} standard with a 98th percentile form and a revised level would likely target public health protection to some different locations than does the current standard. Therefore, in further considering the appropriateness of revising the form and level of the current PM_{10} standard, the

[112] See *http://www.epa.gov/ttn/airs/airsaqs/*.

[113] As discussed above, the one-expected-exceedance concentration-equivalent design value is used as a surrogate concentration for comparison to the standard level in order to gain insight into whether a particular area would likely have met or violated the current PM_{10} standard. Therefore, locations with one-expected-exceedance concentration-equivalent design values below the level of the current PM_{10} standard (i.e., 150 μg/m^3) would likely meet that standard (U.S. EPA, 2011a, section 3.2.1).

[114] The ''generally equivalent'' concentration also differs depending on the years of monitoring data used. For example, when this analysis was restricted to only the most recent years available (i.e., 2007 to 2009), the ''generally equivalent'' 98th percentile PM_{10} concentration was 78 μg/m^3. Given the temporal variability in the relationship between the current standard level and 98th percentile PM_{10} concentrations, and the potential for the ''generally equivalent'' 98th percentile concentration to vary year-to-year, staff concluded that it remains appropriate to consider the correlation analyses that use the broader range of available monitoring years (i.e., 1998–2008), as these analyses are likely to be more robust than analyses based on a shorter period of time.

[115] These analyses are based on three years of air quality data in order to simulate the requirements for determining whether areas attain or violate the current PM_{10} standard, which requires consideration of 3 years of air quality data.

Policy Assessment considered the extent to which, when compared with the current standard, a revised PM_{10} standard would be expected to target public health protection to areas where we have more confidence that $PM_{10-2.5}$ is associated with adverse health effects. To address this question, the Policy Assessment considered the potential impact of revising the form and level of the PM_{10} standard in locations where health studies have reported associations with $PM_{10-2.5}$.

The Policy Assessment initially considers U.S. study locations that would likely have met the current PM_{10} standard during the study period and where positive and statistically significant associations with $PM_{10-2.5}$ were reported. Only Birmingham, Chicago, Pittsburgh, and Detroit [116] met these criteria. During study periods, none of these areas would likely have met a 98th percentile 24-hour PM_{10} standard with a level at or below 87 μg/m³ (U.S. EPA, 2011a, section 3.3.4 and Table 3–3).

The Policy Assessment also considered U.S. locations where health studies have reported positive associations (both statistically significant and non-significant) between $PM_{10-2.5}$ and mortality or morbidity. Such positive associations were reported in 47 locations that would likely have met the current PM_{10} standard during the study period.[117] Of these 47 locations, 13 would likely not have met a 98th percentile 24-hour PM_{10} standard with a level at 87 μg/m³, 20 would likely not have met a 98th percentile 24-hour PM_{10} standard with a level of 75 μg/m³, and 31 would likely not have met a 98th percentile 24-hour PM_{10} standard with a level of 65 μg/m³ (U.S. EPA, 2011a, section 3.3.4).

In addition to the above analyses, the Policy Assessment also considered locations where health studies reported positive associations with $PM_{10-2.5}$ and where ambient PM_{10} concentrations were likely to have exceeded those allowed under the current PM_{10} standard during the study period. Nine locations met these criteria.[118] Of these locations, all would also likely have exceeded a 98th percentile PM_{10} standard with a level at or below 87 μg/m³ (U.S. EPA, 2011a, section 3.3.4).

Therefore, among U.S. study locations where $PM_{10-2.5}$-associated health effects have been reported, some areas met the current standard but would likely have violated a 98th percentile PM_{10} standard with a level at or below 87 μg/m³. In contrast, the locations that violated the current standard would also likely have violated a 98th percentile PM_{10} standard with a level at or below 87 μg/m³. Given this, the Policy Assessment concludes that, compared to the current PM_{10} standard, a 24-hour PM_{10} standard with a 98th percentile form could potentially better target public health protection to locations where we have more confidence that ambient $PM_{10-2.5}$ concentrations are associated with mortality and/or morbidity (U.S. EPA, 2011a, pp. 3–45 to 3–46).

iii. Integration of Evidence-Based and Air Quality-Based Considerations in the Policy Assessment

In considering the integration of the evidence and air quality information within the context of identifying potential alternative standard levels for consideration, the Policy Assessment first notes the following:

(1) Analyses of air quality correlations suggest that a 98th percentile 24-hour PM_{10} concentration as high as 87 μg/m³ could be considered generally equivalent to the current PM_{10} standard, over time and across the country.

(2) A 98th percentile 24-hour PM_{10} standard with a level at or below 87 μg/m³ would be expected to maintain PM_{10} and $PM_{10-2.5}$ concentrations below those present in U.S. locations where single-city studies have reported $PM_{10-2.5}$ effect estimates that are positive and statistically significant (lowest concentration in such a location was 91 μg/m³). Although some single-city studies have reported positive $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations below 87 μg/m³, these effect estimates were not statistically significant.

(3) Multi-city average 98th percentile PM_{10} concentrations were below 87 μg/m³ for recent U.S. multi-city studies, which have reported positive and statistically significant $PM_{10-2.5}$ effect estimates. However, the extent to which effects reported in multi-city studies are associated with the short-term air quality in any particular location is highly uncertain.

(4) Epidemiological studies have reported positive, and in a few instances statistically significant, associations with $PM_{10-2.5}$ in some locations likely to have met the current PM_{10} standard but not a PM_{10} standard with a 98th percentile form and a level at or below 87 μg/m.[3]

To the extent the above considerations are emphasized, the Policy Assessment notes that a standard level as high as about 85 μg/m³, for a 24-hour PM_{10} standard with a 98th percentile form, could be supported. 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. Given this, when compared to the current standard, a 24-hour PM_{10} standard with a 98th percentile form and a level at or below 85 μg/m³ could have the effect of focusing public health protection on locations where there is more confidence that $PM_{10-2.5}$ is associated with mortality and/or morbidity.

Given the above, the Policy Assessment concludes that a 98th percentile standard with a level as high as 85 μg/m³ could be considered to the extent that more weight is placed on the appropriateness of focusing public health protection in areas where positive and statistically significant associations with $PM_{10-2.5}$ have been reported, and to the extent less weight is placed on $PM_{10-2.5}$ effect estimates that are not statistically significant and/or that reflect estimates across multiple cities. The Policy Assessment notes that it could be judged appropriate to place less weight on $PM_{10-2.5}$ effect estimates that are not statistically significant given the relatively large amount of uncertainty that is associated with the broader body of $PM_{10-2.5}$ health evidence, including uncertainty in the extent to which health effects evaluated in epidemiological studies result from exposures to $PM_{10-2.5}$ itself, rather than one or more co-occurring pollutants. This uncertainty, as well as other uncertainties discussed above, are reflected in the Integrated Science Assessment conclusions that the evidence is ''suggestive'' of a causal relationship (i.e., rather than ''causal'' or ''likely causal'') between short-term $PM_{10-2.5}$ and mortality, respiratory effects, and cardiovascular effects. In addition, the Policy Assessment concludes that it could be appropriate to place less weight on 98th percentile PM_{10} concentrations averaged across multiple cities, given the uncertainty in

[116] Positive and statistically significant $PM_{10-2.5}$ effect estimates for Birmingham, Chicago, and Pittsburgh are reported in the Integrated Science Assessment (U.S. EPA, 2009a, Figure 6–29; from cities evaluated by Zanobetti and Schwartz, 2009). Effect estimates for Detroit are reported by Ito et al. (2003).

[117] Philadelphia (Lipfert et al., 2000), Detroit (Ito et al., 2003), Santa Clara (CA) (Fairley et al., 2003), Seattle (Sheppard et al., 2003), Atlanta (Klemm et al., 2004), Spokane (Slaughter et al., 2005), Bronx and Manhattan (NYS DOH, 2006), and 39 of the cities evaluated by Zanobetti and Schwartz (2009) (U.S. EPA, 2009a, Figure 6–29).

[118] Pittsburgh (Chock et al., 2000), Coachella Valley (CA) (Ostro et al., 2003), Phoenix (Mar et al., 2003; Wilson et al., 2007), and 6 of the cities evaluated by Zanobetti and Schwartz (2009) (U.S. EPA, 2009a, Figure 6–29).

linking multi-city effect estimates with the air quality in any particular location.

However, the Policy Assessment also notes that, overall across the U.S., based on recent air quality information (i.e., 2007–2009), fewer people live in counties with 98th percentile 24-hour PM_{10} concentrations above 85 μg/m^3 than in counties likely to exceed the current PM_{10} standard (U.S. EPA, 2011a, Table 3–2 and p. 3–48). These results could be interpreted to suggest that a 98th percentile standard with a level of 85 μg/m^3 would decrease overall public health protection compared to the current standard. Based on this 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 μg/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. To the extent these population counts are emphasized in comparing the public health protection provided by the current and potential alternative standards, and to the extent it is judged appropriate to set a revised standard that provides at least the level of public health protection that is provided by the current standard based on such population counts, the Policy Assessment concludes that it would be appropriate to consider standard levels in the range of approximately 75 to 80 μg/m^3 (*Id.*).

The Policy Assessment concludes that alternative approaches to considering the evidence could also lead to consideration of standard levels below 75 μg/m^3. 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/m^3. 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.5 above), 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 multi-city averages of 98th percentile PM_{10} concentrations in the locations evaluated by Zanobetti and Schwartz (2009) and Peng et al. (2008) were 77 and 68 μg/m^3, respectively. Both of these multi-city studies reported positive and statistically significant $PM_{10-2.5}$ effect estimates that remained positive in co-pollutant models that included $PM_{2.5}$, though only Zanobetti and Schwartz (2009) reported $PM_{10-2.5}$ effect estimates that remained statistically significant in such co-pollutant models. Despite uncertainties in the extent to which effects reported in these multi-city studies are associated with the short-term air quality in any particular location, emphasis could be placed on these multi-city associations. The Policy Assessment concludes 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/m^3 (U.S. EPA, 2011a, p. 3–48). A standard level of 65 μg/m^3 would be expected to provide a substantial margin of safety against health effects that have been associated with $PM_{10-2.5}$ and, as discussed above, could better focus (compared to the current standard) public health protection on areas where health studies have reported associations with $PM_{10-2.5}$.

In considering potential alternative standard levels below 65 μg/m^3, the Policy Assessment notes that, as discussed above, 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/m^3 than in locations with 98th percentile PM_{10} concentrations below 65 μg/m^3. Specifically, the Policy Assessment notes the following (*Id.,* p. 3–49):

(1) Epidemiological studies, either single-city or multi-city, have not reported positive and statistically significant $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations (multi-city average 98th percentile concentrations in the case of multi-city studies) at or below 65 μg/m^3.

(2) Although some single-city morbidity studies have reported positive, but not statistically significant, associations with $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations below 65 μg/m^3, the results of U.S. morbidity studies were generally less consistent than those of mortality studies, with some $PM_{10-2.5}$ effect estimates being positive while others were negative (i.e., negative effect estimates were reported in several studies conducted in Atlanta, where the 98th percentile PM_{10} concentrations ranged from 67 μg/m^3 to 71 μg/m^3).

(3) Although Bayes-adjusted single-city $PM_{10-2.5}$ effect estimates were positive, but not statistically significant, in some locations with PM_{10} concentrations below 65 μg/m^3, these effect estimates were based on the difference between community-wide PM_{10} and $PM_{2.5}$ concentrations. As discussed above, it is not clear how these estimates of $PM_{10-2.5}$ concentrations compare to those more typically used in other studies to calculate $PM_{10-2.5}$ effect estimates. At present, few corroborating studies are available that use other approaches (i.e., co-located monitors, dichotomous samplers) to estimate/measure $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations below 65 μg/m^3.

In light of these 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 concludes that while it could be judged appropriate to consider standard levels as low as 65 μg/m^3, it is not appropriate, based on the currently available body of evidence, to consider standard levels below 65 μg/m^3.

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).[119] 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). 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 current

[119] With regard to limitations and uncertainties in the evidence, CASAC endorsed the ISA 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).

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 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 $\mu g/m^3$ (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 $\mu g/m^3$'' (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 $\mu g/m^3$. CASAC used this information as the basis for their conclusion that a 98th percentile standard between 75 and 80 $\mu g/m^3$ 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 $\mu g/m^3$ in order to increase public health protection, relative to that provided by the current standard (Samet 2010d, p. ii).

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 notes 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 above, the Administrator provisionally concludes that the available evidence continues 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 $PM_{10-2.5}$. In drawing conclusions as to whether the current PM_{10} standard is 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 has considered:

(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, in the last review the EPA concluded 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 an adequate margin of safety (71 FR 61197, October 17, 2006). In that review, the EPA concluded that 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). In litigation of the decisions from the last review, the D.C. Circuit affirmed the conclusion that it was appropriate 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 current review, the Administrator judges that the expanded body of scientific evidence 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 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). While $PM_{10-2.5}$ 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).

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 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 point, 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 (see above) 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 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 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 provisionally concludes that it remains appropriate to maintain a standard that 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 provisionally 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.[120] [121]

In reaching this initial 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). 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 judges 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 notes that the Policy Assessment discusses 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 in detail (section IV.C.1), lead to different

[120] 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 D.C. 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.

[121] 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.

conclusions regarding the appropriateness of the degree of public health protection provided by the current PM_{10} standard. The Administrator further notes 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;

(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 used 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 notes that when the available $PM_{10-2.5}$ scientific evidence and its associated uncertainties are considered, the Integrated Science Assessment concludes 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 notes that she is proposing 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). The suggestive judgment for $PM_{10-2.5}$ reflects the greater degree of uncertainty associated with this body of evidence, as discussed above in detail (sections IV.B.5 and IV.C.1) 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.

(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 provisional 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.

With regard to this provisional 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 the single-city analyses for the locations evaluated in the multi-city study by Zanobetti and Schwartz (2009), the Administrator notes that associations in most of these 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 above, 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 with a dichotomous sampler or by calculating the difference using co-located samplers (U.S. EPA,

2009a, section 6.5.2.3).[122] For these reasons, the Administrator notes that there is considerable uncertainty in interpreting the associations 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 provisional conclusions:

(1) Given 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; given 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 given 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; 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.[123]

(2) Given 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, the degree of public health protection provided by the current standard is not greater than warranted.[124]

In reaching these provisional conclusions, the Administrator notes that the Policy Assessment also discusses 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).[125] 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

[122] As noted in section IV.B.5 above and in the Policy Assessment (U.S. EPA, 2011a, p. 3–16), there are also important uncertainties in estimates of ambient $PM_{10-2.5}$ concentrations based on the difference between PM_{10} mass and $PM_{2.5}$ mass, as measured at co-located monitors.

[123] 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 D.C. 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 provisional 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.

[124] 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 at 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.

[125] 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.

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 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 reaches 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 proposes to retain the current PM_{10} standard in order to protect against health effects associated with short-term exposures to $PM_{10-2.5}$.

The Administrator recognizes that her proposed conclusions and decision to retain the current PM_{10} standard differ 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 welcomes 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.

F. Administrator's Proposed Decision on the Primary PM_{10} Standard

For the reasons discussed above, and taking into account the information and assessments presented in the Integrated Science Assessment and the Policy Assessment and the advice and recommendations of CASAC, the Administrator proposes to retain the current primary PM_{10} standard. The Administrator solicits comment on all aspects of this 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.

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.[126] The current AQI has been in use since its inception in 1999.[127] 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 dioxide, PM and sulfur dioxide. The AQI is also recognized internationally as a proven tool to effectively communicate air quality information to the public. In fact, many countries have created similar indices based on the AQI.

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). Decisions about the pollutant concentrations at which to set the various AQI breakpoints that delineate the various AQI categories for each pollutant specific sub-index within the AQI draw directly from the underlying health information that supports the NAAQS review.

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 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 and can encourage the public to take actions that will reduce air pollution on days when levels are projected to be at levels of concern to local communities. Thus, these programs have significantly broadened the ways in which state and local agencies can meet the nationally uniform AQI reporting requirements, and are contributing to state and local efforts to provide community health protection and to attain or maintain compliance with the NAAQS. The EPA and state and local agencies recognize that these programs are interrelated with AQI reporting and with the information on the effects of air pollution on public health that is generated through the periodic review, and revision when appropriate, of the NAAQS.

In recognition of the proposed change to the primary annual $PM_{2.5}$ standard summarized in section III.F above, the EPA proposes a conforming change to the $PM_{2.5}$ sub-index of the AQI to be

[126] See *http://www.airnow.gov/.*

[127] 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.

consistent with the proposed change to the annual standard. The health effects information that supports the proposed decisions on the $PM_{2.5}$ standards, as discussed in section III.B above, is also the basis for the proposed decisions on the AQI discussed below in this section. The EPA intends to finalize conforming changes to the AQI in conjunction with the Agency's final decisions on the primary annual and 24-hour $PM_{2.5}$ standards, if revisions to such standards are promulgated.

With respect to an AQI value of 50, as discussed above, the historical approach is to set it at the same level of the annual standard, if there is one. This is consistent with the current AQI sub-index for $PM_{2.5}$, in which the current AQI value of 50 is set at 15 μg/m^3, consistent with the level of the current primary annual $PM_{2.5}$ standard. The EPA sees no basis for deviating from this approach in this review. Thus, the EPA proposes to set an AQI value of 50 within a range of 12 to 13 μg/m^3, 24-hour average, consistent with the proposed annual $PM_{2.5}$ standard level (section III.F). The final AQI value of 50 will be set at the level of the annual $PM_{2.5}$ standard that is promulgated.

With respect to an AQI value of 100, which is the basis for advisories to individuals in sensitive groups, there are 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 the other sub-indices as noted above, is to set an AQI value of 100 at the same level as the short-term standard. The EPA recognizes 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. 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 proposes to use this approach to set the AQI value of 100 at 35 μg/m^3, 24-hour average, consistent with the proposal to retain the current 24-hour $PM_{2.5}$ standard (section III.F). If the 24-hour standard is set at a different level, the EPA proposes to set an AQI value of 100 at the level of the 24-hour $PM_{2.5}$ standard that is promulgated.

An alternative approach is 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/m^3, 24-hour average,[128] when the 24-hour standard level was 65 μg/m^3. 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 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. The EPA is soliciting 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 recognizes that some state and local air quality agencies have expressed support for this alternative approach. Using this alternative approach could result 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 above. The EPA encourages state and local air quality agencies that use the AQI to comment on both the approach and the level at which to set an AQI value of 100 together with any supporting rationale.

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/m^3, 24-hour average. In considering what level to propose for an AQI value of 150, we believe that the health effects evidence indicates that the level of 55 μg/m^3, 24-hour average, is appropriate to use[129] in conjunction with an AQI value of 100 set at the proposed level of 35 μg/m^3. Thus, if the EPA sets an AQI value of 100 at the $PM_{2.5}$ level of 35 μg/m^3, 24-hour average, the Agency proposes to set an AQI value of 150 at the $PM_{2.5}$ level of 55 μg/m^3, 24-hour average. If, however, the EPA decides to set an AQI value of 100 at a lower level, then the EPA would adjust an AQI value of 150 proportionally. 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, EPA concludes the use of a proportional adjustment would be appropriate.

With respect to an AQI value of 500, a review of the history of the AQI value of 500 for PM_{10} and of the AQI value of 500 for $PM_{2.5}$ is useful background. The current AQI value of 500 for PM_{10} was set in 1987 at the level of 600 μg/m^3, 24-hour average, on the basis of increased mortality associated with historical wintertime pollution episodes in London (52 FR 24687 to 24688, July 1, 1987). Particle concentrations during these episodes, measured by the British Smoke method, were in the range of 500 to 1000 μg/m^3. In the 1987 rulemaking that established the upper bound index value for PM_{10}, the EPA cited a generally held opinion that the British Smoke method measures PM with a cutpoint of approximately 4.5 microns (52 FR 24688, July 1, 1987). In establishing this value for PM_{10}, the EPA assumed that concentrations of PM_{10}, which includes both coarse and fine particles, during episodes of concern, would be about 100 μg/m^3 higher than the PM concentration measured in terms of British Smoke (52 FR 24688, July 1, 1987). The upper bound index value of 600 μg/m^3 was developed by selecting the lower end of the range of harmful concentrations during the historical wintertime pollution episodes in London (500 μg/m^3) and adding a margin of 100 μg/m^3 to account for this measurement difference. The current $PM_{2.5}$ concentration corresponding to an AQI value of 500 set in the 1999 rulemaking is 500 μg/m^3, 24-hour average.[130] Because there were few $PM_{2.5}$ monitoring data available at that time, the decision was based on the stated assumption that PM concentrations measured by the British Smoke method were approximately equivalent to $PM_{2.5}$ concentrations. In considering whether it is appropriate to retain or revise the AQI value of 500 for $PM_{2.5}$, the EPA notes that the 1999 rulemaking was based on an assumption of approximate equivalence between the British Smoke

[128] Currently, we are cautioning members of sensitive groups at the AQI value of 100 at 35 μg/m^3, 24-hour average, consistent with more recent guidance from EPA with regard to the development of State emergency episode contingency plans (Harnett, 2009, Attachment B).

[129] 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.

[130] We note that a level of 350 μg/m^3 is recommended for an AQI value of 500 in the more recent EPA guidance (Harnett, 2009, Attachment B).

method and the current $PM_{2.5}$ method. This assumption is not entirely consistent with the view cited in 1987 that the British Smoke method has a size cutpoint of 4.5 microns (52 FR 24688, July 1, 1987), such that it would be reasonable to expect based on considering size cutpoint alone that a level of 500 μg/m^3 based on the British Smoke method would generally be equivalent to a somewhat lower level based on the current $PM_{2.5}$ method. Nonetheless, more recent comparisons between British Smoke and $PM_{2.5}$ measurement methods (Heal, et al., 2005; Chaloulakou, et al., 2005) suggest that on average British Smoke can be less than or more than $PM_{2.5}$, but generally represents a larger fraction in the seasons and locations when $PM_{2.5}$ predominantly results from directly emitted carbonaceous particles such as from combustion sources. More generally, the EPA recognizes that extremely high PM concentrations that would most likely be associated with combustion sources (e.g., coal burning in historic the London event, wildfires in contemporary U.S. environments) are typically dominated by fine particles, such that there may be very little difference between these measurement methods at such high levels.

Further, in considering the body of more recent health effects evidence available in this review, the EPA concludes that there is little information about more recent air pollution episodes similar to the wintertime pollution episodes in London and associated impacts on community health upon which to base a decision. Thus, the EPA concludes that it remains appropriate to use the historical wintertime pollution episodes in London as the basis for setting an AQI value of 500 for $PM_{2.5}$ as described above because it is still the best available directly relevant information. Nonetheless, the EPA takes note of a limited number of more recent studies cited in the Integrated Science Assessment that evaluated wood smoke health impacts which found effects such as cardiovascular morbidity and mortality as well as respiratory effects, albeit at much lower levels (U.S. EPA, 2009a, sections 6.2 and 6.6). These more recent health studies may provide some support for considering a lower $PM_{2.5}$ level for an AQI value of 500.

Based on the above considerations, the EPA concludes that it is appropriate to propose to retain the current level of 500 μg/m^3, 24-hour average, for the AQI value of 500. The EPA solicits comment on alternative approaches to setting a level for the AQI value of 500 and on alternative levels that commenters believe may be appropriate as well as supporting information and rationales for such alternative levels. The EPA also solicits 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.

For the intermediate breakpoints in the AQI between the values of 150 and 500, the EPA proposes $PM_{2.5}$ concentrations that generally reflect a linear relationship between increasing index values and increasing $PM_{2.5}$ values. 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 suggest 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 proposed breakpoints for the $PM_{2.5}$ sub-index.[131] 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—PROPOSED BREAKPOINTS FOR $PM_{2.5}$ SUB-INDEX

AQI category	Index values	Proposed breakpoints (μg/m^3, 24-hour average)
Good	0–50	0.0–(12.0–13.0)
Moderate	51–100	(12.1–13.1)–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 proposing to retain the 500 level for the AQI as described above, we note that the EPA is not proposing to establish 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 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.

VI. Rationale for Proposed Decisions on the Secondary PM Standards

This section presents the rationale for the Administrator's proposed decisions to revise the current suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related

[131] As discussed in section VII.C below, the EPA is also proposing to update 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.

visibility impairment while retaining the current secondary $PM_{2.5}$ and PM_{10} standards to address the other welfare effects considered in this review. In particular, this section presents background information on EPA's previous and current reviews of the secondary PM standards (section VI.A), information on visibility impairment (section VI.B), conclusions on the adequacy of the current secondary $PM_{2.5}$ standards to protect against PM-related visibility impairment (section VI.C), conclusions on alternative standards to protect against PM-related visibility impairment (section VI.D), conclusions on secondary PM standards to address other PM-related welfare effects (section VI.E), and a summary of the Administrator's proposed decisions on the secondary PM standards (section VI.F).

A. Background

The current suite of secondary PM standards is identical to the current suite of primary PM standards, 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 builds upon and broadens the approaches used in previous PM NAAQS reviews. The following discussion focuses particularly on the current $PM_{2.5}$ 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 current approach 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, utilize different ways to consider the underlying body of scientific evidence. They also reflect an evolution in EPA's understanding of the nature of the effect on public welfare from visibility impairment, from an approach focusing only on Federal Class I area visibility impacts to a more multifaceted approach that also considers PM-related impacts on non-Federal Class I area visibility, such as in urban areas. This evolution has occurred in conjunction with the expansion of available PM data and information from associated studies of public perception, valuation, and personal comfort and well-being.

In 1997, the EPA revised the identical primary and secondary 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 regional differences. These differences included several factors that influence visibility 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 these considerations, the EPA assessed potential visibility improvements in urban areas and on a regional scale that would result from attainment of the new primary standards for $PM_{2.5}$. The agency concluded that the spatially averaged form of the annual $PM_{2.5}$ standard was well suited to the protection of visibility, which involves effects of $PM_{2.5}$ throughout an extended viewing distance across an urban area. Based on air quality data available at that time, many urban areas in the Northeast, Midwest, and Southeast, as well as Los Angeles, were expected to see perceptible improvement in visibility if the annual $PM_{2.5}$ primary standard were attained. The EPA also concluded that attainment of the 24-hour $PM_{2.5}$ standard in some areas would be expected to reduce, to some degree, the number and intensity of ''bad visibility'' days, resulting in improvement in the 20 percent of days having the greatest impairment over the course of a year.

Having concluded that attainment of the annual and 24-hour $PM_{2.5}$ primary standards would lead to visibility improvements in many eastern and some western urban areas, the EPA also considered whether these standards could provide potential improvements to visibility on a regional scale. Based on information available at the time, the EPA concluded that attainment of secondary $PM_{2.5}$ standards set identical to the primary $PM_{2.5}$ standards would be expected to result in 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 then considered the potential effectiveness of a regional haze program, required by sections 169A and 169B of the CAA [132] 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 a nationally applicable secondary NAAQS. The regional haze visibility goal is more protective than a secondary NAAQS since the goal addresses any anthropogenic impairment rather than just impairment at levels determined to be adverse to 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

[132] 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.

emissions of pollutants that impair visibility in many of these areas.

For these reasons, 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, in conjunction with a regional haze program 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, 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 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 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 EPA's decision lacked a reasoned basis. First, they asserted that EPA never determined what level of visibility was ''requisite to protect the public welfare.'' They argued that 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 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 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 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 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 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 broadens 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 is taking 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 are appropriate for consideration in this review. As in past reviews, the EPA is also considering 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 recognizes that such an approach is the most appropriate and effective means of addressing the public welfare effects associated with visibility impairment in areas across the country.

The Policy Assessment draws from the qualitative evaluation of all studies discussed in the Integrated Science Assessment (U.S. EPA, 2009a). Specifically, the Policy Assessment considers the extensive new air quality and source apportionment information available from the regional planning organizations, long-standing evidence of PM effects on visibility, and public preference studies 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 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. On these bases, the Policy Assessment again focuses assessments on visibility conditions in urban areas.

The conclusions in the Policy Assessment reflect 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 takes into account the four basic elements of the NAAQS: indicator, averaging time, level, and form.

B. PM-Related Visibility Impairment

As discussed below, the rationale for the Administrator's proposed decision regarding secondary PM standards to protect against visibility impairment focuses on those considerations most influential in the Administrator's proposed decisions, including consideration of: (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 outlines key information contained in the Integrated Science Assessment, the Visibility Assessment and the Policy Assessment on: (1) 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 and (2) public perceptions and attitudes about visibility impairment and the impacts of visibility impairment on public welfare.

1. Nature of PM-Related Visibility Impairment

New research conducted by regional planning organizations in support of the Regional Haze Rule, as 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. Additional by-products of this research include 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. Information from both of these sources of PM data, while useful, has not however changed the fundamental and long understood science characterizing the contribution of PM, especially fine particles, to visibility impairment. This science, briefly summarized below, provides the basis for the Integrated Science Assessment designation of the relationship between PM and visibility impairment as causal.

a. 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. 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 is quantified by a light extinction coefficient with units of 1/distance, which is often expressed in the technical literature as 1/(1 million meters) or inverse megameters (abbreviated Mm^{-1}). When PM is present in the air, its contribution to light extinction typically greatly exceeds that of gases.

The amount of light extinction contributed by PM depends on the particle size distribution and composition, as well as its particle concentration. If details of the ambient particle size distribution and composition (including the mixing of components) are known, Mie theory can be used to accurately calculate PM light extinction (U.S. EPA, 2009a, chapter 9). However, routine monitoring rarely includes measurements of particle size and composition information with sufficient detail for such calculations. To make estimation of light extinction more practical, visibility scientists have developed a much simpler algorithm, known as the IMPROVE algorithm,[133] to estimate light extinction using routinely monitored fine particle ($PM_{2.5}$) speciation and coarse particle mass ($PM_{10-2.5}$) data. In addition, relative humidity information is needed to estimate the contribution by liquid water that is in solution with hygroscopic PM components (U.S. EPA, 2009a, section 9.2.2.2; U.S. EPA, 2010b, chapter 3). 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 light extinction conditions.[134] 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. 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. They have been evaluated by comparing the algorithm estimates of light extinction with coincident optical measurements. 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.

$$b_{ext} \approx 3 \times f(RH) \times [Sulfate] + 3 \times f(RH) \times [Nitrate] + 4 \times [Organic\ Mass] + 10 \times [Elemental\ Carbon] + 1 \times [Fine\ Soil] + 0.6 \times [Coarse\ Mass] + 10$$

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. The dry extinction efficiency for particulate organic mass is larger than those for particulate sulfate and nitrate principally because the density of the dry inorganic compounds is higher than that assumed for the PM organic mass components.

For the first two terms, ''sulfate'' is defined in terms of ammonium sulfate and ''nitrate'' is defined in terms of ammonium nitrate. Since IMPROVE does not include ammonium ion monitoring, the assumption is made that all sulfate is fully neutralized ammonium sulfate and all nitrate is assumed to be ammonium nitrate.[135] Though often reasonable, neither assumption is always true (see U.S. EPA, 2009a, section 9.2.3.1). In the eastern U.S. during the summer there is insufficient ammonia in the atmosphere to neutralize the sulfate fully. Fine particle nitrates can include sodium or calcium nitrate, which are the fine particle fraction of generally much coarser particles due to nitric acid interactions with sea salt at near-coastal areas (sodium nitrate) or nitric acid interactions with calcium carbonate in crustal aerosol (calcium nitrate). Despite the simplicity of the 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.

The $f(RH)$ term 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

[133] 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).

[134] 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.

[135] To calculate ammonium sulfate, multiply the CSN measurement of the sulfate ion by 1.375. To calculate ammonium nitrate, multiply the CSN measurement of the nitrate ion by 1.29 (Lowenthal and Kumar, 2006).

approximately 85 percent where their total light extinction efficiency exceeds the 10 m^2/g associated with elemental carbon (EC). Based on this algorithm, particulate sulfate and nitrate are estimated to have comparable light extinction efficiencies (i.e., the same dry extinction efficiency and *f*(RH) water growth terms), so on a per unit mass concentration basis at any specific relative humidity they are treated as equally effective contributors to visibility effects.

As noted above, 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. 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 high relative humidity conditions.[136]

With regard to the fifth and sixth terms, the fine soil component is based on measurement of five elements: Aluminum (Al), silicon (Si), calcium (Ca), iron (Fe), and titanium (Ti).[137] 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 $PM_{10-2.5}$.

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) has been developed. It employs a more complex split-component mass extinction efficiency to correct biases believed to be related to particle size distributions, a sea salt term that can be important for remote coastal areas, a different multiplier for organic carbon for purposes of estimating organic carbonaceous material,[138] and site-specific Rayleigh light scattering terms in place of a universal Rayleigh light scattering value. These features of the revised IMPROVE algorithm are described in section 9.2.3.1 of the Integrated Science Assessment, which also presents a comparison of the estimates produced by the two algorithms for rural areas. Compared to the original algorithm, the revised IMPROVE algorithm can yield higher estimates of current light extinction levels in urban areas on days with relatively poor visibility (Pitchford, 2010). This difference is primarily attributable to the split-component mass extinction efficiency treatment in the revised algorithm rather than to the inclusion of a sea salt term or the use of site-specific Rayleigh scattering values.

As mentioned above, particles are not the only contributor to ambient visibility conditions. Light scattering by gases also occurs in ambient air. Under pristine atmospheric conditions, naturally occurring gases such as elemental nitrogen and oxygen cause what is known as Rayleigh scattering. Rayleigh scattering depends on the density of air, which is a function primarily of the elevation above sea level, and can be treated as a site-dependent constant. The Rayleigh scattering contribution to light extinction is only significant under pristine conditions. The only other commonly occurring atmospheric gas to appreciably absorb light in the visible spectrum is nitrogen dioxide. Nitrogen dioxide forms in the atmosphere from nitrogen oxide emissions associated with combustion processes. These combustion processes also emit PM at levels that generally contribute much higher light extinction than the nitrogen dioxide (i.e., nitrogen dioxide absorption is generally less than approximately 5 percent of the light extinction, except where emission controls remove most of the PM prior to releasing the remaining gases to the atmosphere). The final term in the IMPROVE algorithm of 10 Mm^{-1} is known as the Rayleigh scattering term and accounts for light scattering by the natural gases in unpolluted air. The remainder of this section focuses on the contribution of PM, which is typically much greater than that of gases, to ambient light extinction, unless otherwise specified.

In the following discussions, visual air quality is characterized in terms of both light extinction, as discussed above, and an alternative scale for characterizing visibility—the deciview scale—that is defined directly in terms of light extinction (expressed in units of Mm^{-1}) by the following equation:[139]
Deciview (dv) = 10 ln (b_{ext}/10 Mm^{-1}).

The deciview scale is frequently used in the scientific and regulatory 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.

b. 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). Generally, low mixing heights at night and during the early morning hours tend to trap locally produced emissions, which are diluted as the mixing height increases due to heating during the day. Low temperatures and high relative humidity at night are conducive to the presence of ammonium nitrate particles and water growth by hygroscopic particles compared with the generally higher temperatures and lower relative humidity later in the day. These combine to make early morning the most likely time for peak urban light extinction. Superimposed on such systematic time-of-day variations are the effects of synoptic meteorology (i.e., those associated with changing weather) and regional-scale air quality that can generate peak light extinction impacts any time of day. The net effects of the systematic urban- and larger-scale variations are that peak daytime PM light extinction levels can occur any time of day, although in many areas they most often occur 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

[136] The IMPROVE algorithm does not explicitly separate the light-scattering and light-absorbing effects of elemental carbon.

[137] Consistent with calculations used in the IMPROVE network and the Regional Haze Program, the fine soil component is calculated using the following formula:

Fine Soil = 2.20 × [Al] + 2.49 × [Si] + 1.63 × [Ca] + 2.42 × [Fe] + 1.94 × [Ti].

[138] The revised IMPROVE algorithm uses a multiplier of 1.8 instead of 1.4 as used in the original algorithm for the mean ratio of organic mass to organic carbon.

[139] 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 a negative deciview values when the $PM_{2.5}$ concentration is very low.

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.

c. Periods During the Day of Interest for Assessment of Visibility

Visibility is typically associated with daytime periods because people are outside more during the day than at night and there are more viewable scenes at a distance during the day than at night. The Policy Assessment recognizes, however, that physically PM light extinction behaves the same at night as during the day, 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. These effects produce the visual result of a reduction in the number of visible stars and the disappearance of diffuse or subtle phenomena such as the Milky Way. The extinction of starlight is a secondary and minor effect also caused by increased PM scattering and absorption.

However, there are significant and important differences between daytime and nighttime visual environments with regard to how light extinction per se relates to visual air quality (or visibility) and public welfare. First, daytime visibility has dominated the attention of those who have studied the visibility effects of air pollution, particularly in urban areas. As a result, little research has been conducted on nighttime visibility and the state of the science is not comparable to that associated with daytime visibility impairment. As noted in the Policy Assessment, no urban-focused preference or valuation studies providing information on public preferences for nighttime visual air quality have been identified (U.S. EPA, 2011a, p. 4–17). Second, in addition to air pollution, nighttime visibility is affected by the addition of light into the sight path from numerous sources, including anthropogenic light sources in urban environments such as artificial outdoor lighting, which varies dramatically across space, and natural sources including the moon, planets, and stars. Light sources and ambient light conditions are typically five to seven orders of magnitude dimmer at night than in sunlight. Moonlight, like sunlight, introduces light throughout an observer's sight path at a constant angle. On the other hand, dim starlight emanates from all over the celestial hemisphere while artificial lights are concentrated in cities and illuminate the atmosphere from below. These different light sources will yield variable changes in visibility as compared to what has been established for the daytime scenario, in which a single source, the sun, is by far the brightest source of light. Third, the human psychophysical response (e.g., how the human eye sees and processes visual stimuli) at night is expected to differ (U.S. EPA, 2009a, section 9.2.2).

Given the above, 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). Thus, the Policy Assessment focuses its assessments of PM visibility impacts in urban areas on daylight hours. For simplicity, and because perceptions and welfare effects from light extinction-related visual effects during the minutes of actual sunrise and sunset have not been explored, daylight hours are defined as those hours entirely after the local sunrise time and before the local sunset time.

In so doing, the Policy Assessment notes that the 24-hour averaging time used in the Regional Haze Program includes nighttime conditions (U.S. EPA, 2011a, p. 4–18). It also notes, however, that the goal of the Regional Haze Program is to address any manmade impairment of visibility without regard to distinctions between daylight and nighttime conditions. Moreover, because of the lack of strong diurnal patterns in most Federal Class I areas, both nighttime and daylight visibility are strongly correlated with 24-hour average visibility conditions, so a 24-hour averaging period is suitable for driving both daylight and nighttime visibility towards their natural conditions. Also, the focus on 24-hour average visibility allows the Regional Haze Program to make use of more practically obtained ambient speciated PM measurements of adequate accuracy than if a shorter averaging period were used, which is an important consideration especially given the remoteness of many Federal Class I area monitoring sites and given the low PM concentrations that must be measured accurately in such areas.

In addition, when natural conditions such as fog and rain cause poor visibility, it can be reasonably assumed that the light extinction properties of the air that are attributable to air pollution are not important from a public welfare perspective. Thus, it is appropriate to give special treatment to such periods when considering whether current $PM_{2.5}$ standards adequately protect public welfare from PM-related visibility impairment. In evaluating alternative sub-daily standards, the Policy Assessment addresses this issue by screening out hours with particularly high relative humidity. As discussed further below, the Policy Assessment uses a relative humidity screen of 90 percent on the basis that it serves as a reasonable surrogate for excluding hours affected by fog and rain (U.S. EPA, 2011a, p. 4–18).

d. Exposure Durations of Interest

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 has 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. A momentary glance at an image of a scene (i.e., less than a minute) is enough for study participants to judge the acceptability or unacceptability of the viewed visual air quality conditions. Moreover, individual participants in general consistently judge the acceptability of same-scene images that differed only with respect to light extinction levels when these images were presented repeatedly for such short periods. That is, individuals generally did not say that a higher-light extinction image was acceptable while saying a lower-light extinction, same-scene image was unacceptable, even though they could not compare images side-to-side. However, the Policy Assessment does not have information about what assumptions, if any, the participants may have made about the duration of exposure in determining the acceptability of the images and EPA staff 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.

In the absence of such studies, the Policy Assessment considers 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. In such circumstances, the viewer may consciously evaluate how the visual air quality at that time either enhances or diminishes the experience or view. However, the public also 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). These scenes, whether iconic or generic, may not be consciously viewed for their scenic value and may not even be noticed for periods comparable to what would be the case during purposeful visits to scenic visits, but their visual air quality may still affect a person's sense of wellbeing. 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 wellbeing.''

Some people have mostly intermittent opportunities on a daily basis (e.g., during morning and/or afternoon commutes) to experience ambient visibility conditions because they spend much of their time indoors without access to windows. For such people a view of poor visual air quality during their morning commute may provide their perception of the day's visibility conditions until the next time they venture outside during daylight hours later or perhaps the next day. Other people have exposure to visibility conditions throughout the day, conditions that may differ from hour to hour. A day with multiple hours of visibility impairment would likely be judged as having a greater impact on their wellbeing than a day with just one such hour followed by clearer conditions.

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 logical to conclude 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 judges 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. This approach would recognize that at least some but not all of the population of an area will actually be exposed to this worst hour and that some of the people who are exposed to this worst hour may not have an opportunity to observe clearer conditions in other hours if they were to occur. Moreover, because visibility conditions and people's daily activities on work/school days both tend to follow the same diurnal pattern day after day, those who are exposed only to the worst hour will tend to have this experience day after day.

For another group of observers, those who have access to visibility conditions often or continuously throughout the day, the impact of the day's visibility conditions on their welfare may be based on the varying visibility conditions they observe 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. Based on these considerations, the Policy Assessment judges that it would also be appropriate to use a maximum multi-hour daylight period for evaluating the adequacy of the current suite of secondary standards (U.S. EPA, 2011a, p. 4–20).

The above discussion is based on what people see, which is determined by the extinction of light along the paths between observers and the various objects they view. A related but separate issue is what measurement period is relevant, if what will be measured is the light extinction property or the PM concentration of the local air at a fixed site. Light extinction conditions at a fixed site can change quickly (i.e., in less than a minute). Sub-hourly variations in light extinction determined at any point in the atmosphere are likely the result of small-scale spatial pollution features (i.e., high concentration plumes that have just been generated in the immediate vicinity due to local sources or that have been transported by the wind across that point). These small-scale pockets of air causing short periods of higher light extinction at the fixed site likely do not determine the visual effect for scenes with longer sight paths. In contrast, atmospheric sight path-averaged light extinction which is pertinent to visibility impacts generally changes more slowly (i.e., tens of minutes generally), because a larger air mass must be affected by a broader set of emission sources or the larger air mass must be replaced by a cleaner or dirtier air mass due to the wind operating over time. At typical wind speeds found in U.S. cities, an hour corresponds to a few tens of kilometers of air flowing past a point, which is similar to sight path lengths of interest in urban areas. Based on the above considerations, the Policy Assessment concludes hourly average light extinction would generally be reasonably representative of the net visibility effect of the spatial pattern of light extinction levels, especially along site paths that generally align with the wind direction (U.S. EPA, 2011a, p. 4–21).

2. Public Perception of Visibility Impairment

As noted in the Integrated Science Assessment, 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 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.'' 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.[140] 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.[141] 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. Urban visibility preference studies for four urban areas were reviewed in the Visibility Assessment (U.S. EPA, 2010b, chapter 2) 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 includes 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 answered while viewing a set of images of various urban visual air quality conditions.

The approaches used in the four studies are similar and are 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

[140] 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.

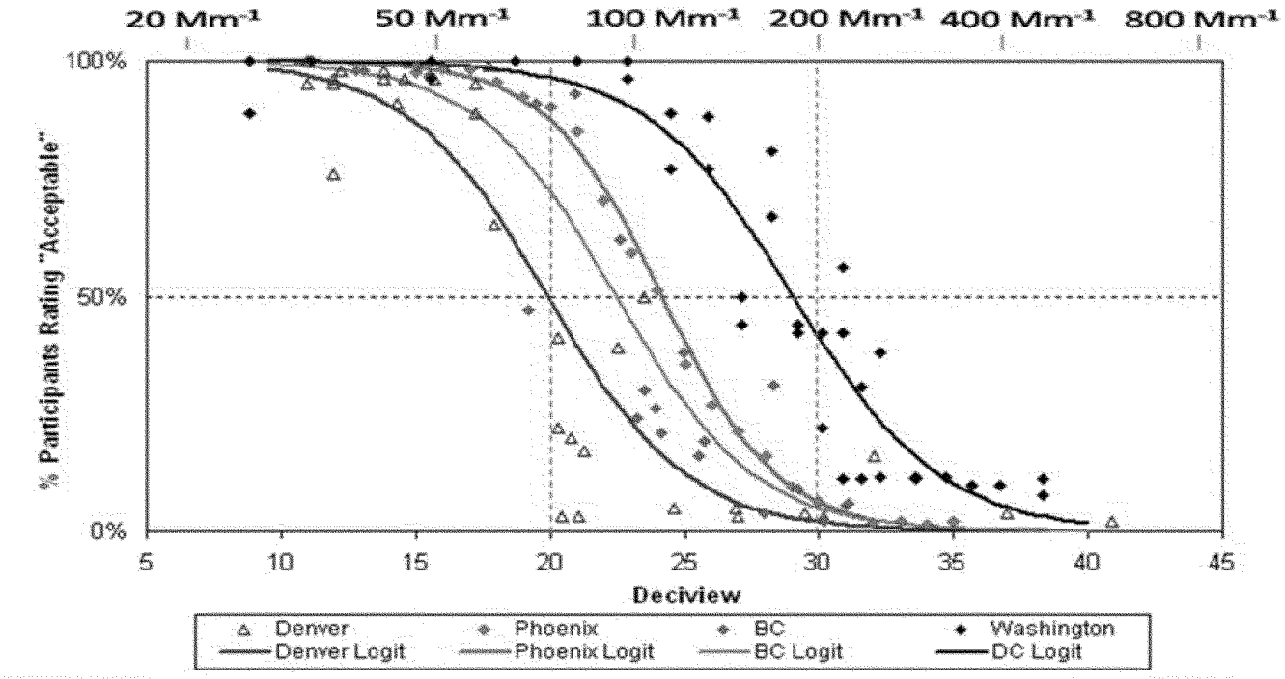
[141] By ''characteristics of the scene'' the EPA means the distance(s) between the viewer and the object(s) of interest, the shapes and colors of the objects, the contrast between objects and the sky or other background, and the inherent interest of the objects to the viewer. Distance is particularly 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.

extinction than do images representing higher levels.

Given the similarities in the approaches used, it is 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, variations in the specific materials and methods used in each study introduce uncertainties that should also be considered when interpreting the results of these comparisons. Key differences between the studies include: (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 the criterion as a useful index for comparison between studies. The results of each individual 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.[142] 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.[143]

Figure 5. Summary of Results of Urban Visibility Studies in Four Cities, Showing the Identified Range of the 50% Acceptance Criteria[144]



Source: US EPA, 2011a, Figure 4-2; US 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. 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

[142] Only 47 percent of the British Columbia participants rated a 19.2 dv photograph as acceptable.

[143] 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.

[144] 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.

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 4–1 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 by the Policy Assessment in a range from 20 dv to 30 dv (75 to 200 Mm^{-1})[145] 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). 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 least noisy preference results and the most representative selection of participants. Based on the currently available information, the Policy Assessment concludes 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% 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,[146] 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 continues to be used in this 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 notes that the term CPL is meant only to indicate target levels of visibility within a range that EPA staff feels is appropriate for consideration that could, in conjunction with other elements of the standard, including indicator, averaging time, and form, 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 considers whether they represent a true regional distinction in preferences for urban visibility conditions between western and eastern U.S. There is 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.[147] 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 notes 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 and many areas in the eastern U.S., and possibly some areas in the western U.S. as well. 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. Based on the currently available information, the Policy Assessment concludes 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 concludes 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

[145] 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 considers 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 reflect the unrounded values.

[146] Rayleigh scatter is light scattering by atmospheric gases which is on average about 10 Mm^{-1}.

[147] 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.

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 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 concludes 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 supports this set of CPLs for consideration by the EPA in this review. CASAC notes 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. CASAC concludes that this range of levels is ''adequately supported by the evidence presented'' (Samet, 2010d, p. iii).

C. Adequacy of the Current Standards for PM-Related Visibility Impairment

As noted above, visibility impairment occurs during periods with fog or precipitation irrespective of the presence or absence of PM. While it is a popular notion that areas with many foggy or rainy days are ''dreary'' places to live compared to areas with more sunny days per year, the Policy Assessment has no basis for taking into account how the occurrence of such days might modify the effect of pollution-induced hazy days on public welfare. It is logical that periods with naturally impaired visibility due to fog or precipitation should not be treated as having PM-impaired visibility. Moreover, depending on the specific indicator, averaging time, and measurement approach used for the NAAQS, foggy conditions might result in measured or calculated indicator values that are higher than the light extinction actually caused by PM.[148] Therefore, in order to avoid precipitation and fog confounding estimates of PM visibility impairment, and as advised by CASAC as part of its comments on the first draft Visibility Assessment, the assessment of visibility conditions was restricted to daylight hours with relative humidity less than or equal to 90 percent when evaluating sub-daily alternative standards (U.S. EPA, 2010b, section 3.3.5, Appendix G).

The EPA recognizes that not all periods with relative humidity above 90 percent have fog or precipitation. Removing those hours from consideration for a secondary PM standard would involve a tradeoff between the benefits of not including many of the hours with meteorological causes of visibility impacts and the loss of public welfare protection of not including some hours with high relative humidity without fog or precipitation, where the growth of hygroscopic PM into large solution droplets results in enhanced PM visibility impacts. For the 15 urban areas included in the assessment for which meteorological data were obtained to allow an examination of the co-occurrence of high relative humidity and fog or precipitation, a 90 percent relative humidity cutoff criterion is effective in that on average less than 6 percent of the daylight hours are removed from consideration, yet those hours have 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. Based on these findings, the Policy Assessment concludes that it is appropriate that a sub-daily standard intended to protect against PM-related visibility impairment would be defined in such a way as to exclude hours with relative humidity greater than approximately 90 percent, regardless of measured values of light extinction or PM (U.S. EPA, 2011a, p. 4–29).

1. Visibility Under Current Conditions

Recent visibility conditions have been characterized in the Policy Assessment in terms of PM-related light extinction[149] levels for the 15 urban areas[150] that were selected for analysis in the Visibility Assessment. Hourly average PM-related light extinction was analyzed in terms of both PM_{10} and $PM_{2.5}$ light extinction. These recent visibility conditions were then compared to the CPLs identified above. From Figure 4–3 and Table 4–2 in the Policy Assessment (U.S. EPA, 2010b, Figure 3–8 and Table 3–7, respectively) it can be seen that among these 14 urban areas, those in the East and in California tend to have a higher frequency of visibility conditions estimated to be above the high CPL compared with those in the western U.S. Both the figure and table are based on data from the 2005 to 2007 time period and exclude hours with relative humidity greater than 90 percent. These displays indicate that all 14 urban areas have daily maximum hourly PM_{10} light extinction values that are 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 are estimated to exceed the high CPL from about 20 percent to over 60 percent of the days. It is also noted that all 14 of the urban areas are estimated to exceed the low CPL from about 40 percent to over 90 percent of the days.

The Policy Assessment repeats 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), as described in Policy Assessment Appendix F. Figure 4–4 and Table 4–3 in the Policy Assessment present the same type of information as do Figure 4–3 and Table

[148] One example of an indicator and measurement approach for which indicator values could be higher than true PM light extinction as a result of fog would be a light extinction indicator measured in part by an unheated nephelometer, which is an optical instrument for measuring PM light scattering from an air sample as it flows through a measurement chamber. Raindrops would be removed by the initial size-selective inlet device, although some particles associated with fog may be small enough that they might pass through the inlet and enter the measurement chamber of the instrument. This would result in a reported scattering coefficient that does not correspond to true PM light extinction. Direct measurement of light extinction using an open-path instrument would be even more affected by both fog and precipitation.

[149] 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% 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% cutpoint of 2.5 μm diameter.

[150] 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. 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, is not representative of the urban area and resulted in unrealistically large $PM_{10-2.5}$ values. The EPA staff considers these comments credible and has set aside the St. Louis assessment results for PM_{10} light extinction. Thus, results and statements in this Policy Assessment regarding PM_{10} light extinction apply to only the other 14 areas. However, results regarding $PM_{2.5}$ light extinction in most cases apply 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.

4–2, respectively. While the estimates of the percentage of daily maximum hourly $PM_{2.5}$ light extinction values exceeding the CPLs are somewhat lower than for PM_{10} light extinction, the patterns of these estimates across the study areas are similar. More specifically, except for the two Texas and the non-California western urban areas, all of the other urban areas are estimated to exceed the high CPL from about 10 percent up to about 50 percent of the days based on $PM_{2.5}$ light extinction, while all 15 areas are estimated to exceed the low CPL from over 10 percent to over 90 percent of the days.

2. Protection Afforded by the Current Standards

The Policy Assessment also conducted analyses to assess the likelihood that PM-related visibility impairment would exceed the various CPLs for a scenario based on simulating just meeting the current suite of $PM_{2.5}$ secondary standards: 15 μg/m^3 annual average $PM_{2.5}$ concentration and 35 μg/m^3 24-hour average $PM_{2.5}$ concentration with a 98th percentile form, averaged over three years. As described in the Visibility Assessment, the steps needed to model meeting the current NAAQS involve explicit consideration of changes in $PM_{2.5}$ components. First, the Policy Assessment applied proportional rollback to all the $PM_{2.5}$ monitoring sites in each study area, taking into account policy-relevant background $PM_{2.5}$ mass, to ''just meet'' the current NAAQS scenario for the area as a whole, not just at the visibility assessment study site. The quantitative health risk assessment document (U.S. EPA, 2010a) describes this air quality roll-back procedure in detail. The degree of rollback (i.e., the percentage reduction in non-policy-relevant background $PM_{2.5}$ mass) is controlled by the highest annual or 24-hour design value, which in most study areas is from a site other than the site used in this visibility assessment.[151] The relevant result from this analysis is the percentage reduction in non-policy-relevant background $PM_{2.5}$ mass needed to ''just meet'' the current NAAQS, for each study area. These percentage reductions are shown in Table 4–4 of the Visibility Assessment. It was noted that Phoenix and Salt Lake City meet the current $PM_{2.5}$ NAAQS under current conditions and require no reduction. $PM_{2.5}$ levels in these two cities were not ''rolled up.'' Second, for each day and hour for each $PM_{2.5}$ component, the Policy Assessment subtracted the policy-relevant background concentration from the current conditions concentration to determine the non- policy-relevant background portion of the current conditions concentration. Third, the Policy Assessment applied the same percentage reduction from the first step to the non- policy-relevant background portion of each of the five $PM_{2.5}$ components and added back the policy-relevant background portion of the component. Finally, the Policy Assessment applied the original IMPROVE algorithm, using the reduced $PM_{2.5}$ component concentrations, the current conditions $PM_{10-2.5}$ concentration for the day and hour, and relative humidity for the day and hour to calculate the PM_{10} light extinction.

In these analyses, the Policy Assessment has 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 display 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 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 show 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 are estimated to exceed the high CPL from about 8 percent up to over 30 percent of the days and the middle CPL from about 30 percent up to about 70 percent of the days, while all areas except Phoenix are estimated to exceed the low CPL from 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 are estimated to exceed the high CPL from about 4 percent up to over 15 percent of the days and the middle CPL from about 15 percent up to about 45 percent of the days, while all areas except Phoenix are estimated to exceed the low CPL from over 10 percent to about 75 percent of the days. A similar set of figures and tables have been 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 into account the above considerations, the Policy Assessment concludes that the available information in this review, as described above and in the Visibility Assessment and Integrated Science Assessment, clearly calls 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 supports consideration of alternative standards to provide appropriate protection (U.S. EPA, 2011a, p. 4–39).

This conclusion is based in part on the large percentage of days, in many urban areas, 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 is simulated to just meet the current $PM_{2.5}$ standards, greater than 10 percent of the days are estimated to 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 exceed the highest CPL ranges from over 10 percent to over 30 percent. Similarly, when the middle CPL of 25 dv is considered, greater than 30 percent up to approximately 70 percent of the days are estimated to exceed 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 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 exceeding the middle CPL in terms of $PM_{2.5}$ light extinction. For the lowest CPL of 20 dv, the percentages of days estimated to exceed that CPL are even higher for all cases considered. Based on all of the above, the Policy Assessment concludes 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 exceeds 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 concludes that use of the current indicator of $PM_{2.5}$ mass, in conjunction

[151] The selection of the site used to assess visibility was driven by the need for several types of PM data, and for most study areas the site with the highest annual or 24-hour design value did not have the needed types of data.

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 confounded by 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 notes 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, as discussed above in section 4.1.2.

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 concludes 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).

3. CASAC Advice

Based on its review of the second draft Policy Assessment, CASAC concludes 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 notes 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 states, 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).

4. Administrator's Proposed Conclusions on the Adequacy of Current Standards for PM-Related Visibility Impairment

In considering whether the current suite of secondary $PM_{2.5}$ standards is requisite to protect the public welfare against PM-related visibility impairment primarily in urban areas, the Administrator has taken 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 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. As an initial matter, the Administrator recognizes the clear causal relationship between PM in the ambient air and impairment of visibility. She takes note of the evidence from the visibility preference studies, and the rationale for determining a range of candidate protection levels based on those studies. She notes the relatively large number of days 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, the Administrator concludes that such information provides 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 concludes 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 recognizes 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. She recognizes that 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 plays a central role in determining the relationship between the mix of PM in the ambient air and impairment of visibility. The Administrator notes that such considerations were reflected in CASAC's advice to set a distinct secondary standard that would more directly reflect the relationship between ambient PM and visibility impairment. The Administrator also notes that such considerations were reflected in the court's remand of the current secondary $PM_{2.5}$ standards. Based on the above considerations, the Administrator provisionally concludes that the current secondary $PM_{2.5}$ standards, taken together, are neither sufficiently protective nor are they suitably structured to provide an appropriate degree of public welfare protection from PM-related visibility impairment, primarily in urban areas. Thus, the Administrator has considered alternative standards by looking at each of the elements of the standards—indicator, averaging time, form, and level—as discussed below.

D. Consideration of Alternative Standards for Visibility Impairment

1. Indicator

a. Alternative Indicators Considered in the Policy Assessment

As described below, the Policy Assessment considers three indicators: The current $PM_{2.5}$ mass indicator and two alternative indicators, including directly measured $PM_{2.5}$ light extinction and calculated $PM_{2.5}$ light extinction (U.S. EPA, 2011a, section 4.3.1.1).[152] 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 speciated $PM_{2.5}$ mass and measured relative humidity.[153]

The Policy Assessment concludes 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 $PM_{2.5}$ characteristic that is most relevant and directly related to PM-related visibility effects (U.S. EPA, 2011a,

[152] In the second draft Policy Assessment, the calculated $PM_{2.5}$ light extinction indicator was referred to as speciated $PM_{2.5}$ mass calculated light extinction.

[153] In 2009, the D.C. Circuit remanded the secondary $PM_{2.5}$ standards to the Agency in part because the EPA did not address the problem that a $PM_{2.5}$ mass-based standard using a daily averaging time would be confounded by regional differences in relative humidity, although EPA had acknowledged this problem. The EPA notes that the light extinction indicators considered in the Policy Assessment explicitly took into account differences in relative humidity in areas across the country (U.S. EPA, 2011a, section 4.3.1).

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 $PM_{10-2.5}$ is a minor contributor to visibility impairment most of the time, although at some locations (U.S. EPA, 2010b, Figure 3–13 for Phoenix) $PM_{10-2.5}$ can be a major contributor to urban visibility effects. Few urban areas conduct continuous $PM_{10-2.5}$ monitoring. For example, among the 15 urban areas assessed in this review, only four areas had collocated continuous PM_{10} data allowing calculation of hourly $PM_{10-2.5}$ data for 2005 to 2007. In the absence of $PM_{10-2.5}$ air quality information from a much larger number of urban areas across the country, it is not possible at this time to know in how many urban areas $PM_{10-2.5}$ is a major contributor to urban visibility effects, though 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. $PM_{10-2.5}$ is generally less homogenous in urban areas than $PM_{2.5}$, making it more challenging to select sites that would adequately represent urban visibility conditions. While it would be possible to include a $PM_{10-2.5}$ 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).

The basis for considering each of these three indicators is discussed below. The discussion also addresses monitoring data requirements for directly measured $PM_{2.5}$ light extinction and for calculated $PM_{2.5}$ light extinction. The following discussion also takes into consideration different averaging times since the combination of indicator and averaging time is relevant to understanding the monitoring data requirements. Consideration of alternative averaging times is addressed more specifically in section VI.D.2 on averaging time.

i. $PM_{2.5}$ Mass

$PM_{2.5}$ 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. Blank and loaded filters are weighed to determine 24-hour $PM_{2.5}$ mass. Continuous $PM_{2.5}$ monitoring produces hourly average mass concentrations and is conducted at about 900 locations. About 180 of these locations employ newer model continuous instruments that have been approved by EPA as FEMs, although the Policy Assessment notes that FEM approval has been based only on 24-hour average, not hourly, $PM_{2.5}$ mass. 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.[154] 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.[155]

The overall performance of 1-hour average $PM_{2.5}$ mass as a predictor of PM-related visibility impairment as indicated by PM_{10} calculated light extinction can be seen in scatter plots shown in Figure 4–9 of the Policy Assessment for two illustrative urban areas, Pittsburgh and Philadelphia (Similar plots for all 14 urban areas that have estimates of PM_{10} light extinction are in Appendix D, Figure D–2 of U.S. EPA, 2010b). These illustrative examples demonstrate the large variations in hourly PM_{10} light extinction corresponding to any specific level of hourly $PM_{2.5}$ mass concentration as well as differences in the statistical average relationships (depicted as the best fit lines) between cities. This poor correlation between hourly PM_{10} light extinction and hourly $PM_{2.5}$ mass is not due to any great extent to the contribution of $PM_{10-2.5}$ to light extinction, but rather is 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. This contributes to the noisiness of the data on the relationship 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.

As part of the Visibility Assessment, an assessment was conducted that estimated PM_{10} light extinction levels that may prevail if areas were simulated to just meet a range of alternative secondary standards based on hourly $PM_{2.5}$ mass as the indicator. Appendix E of the Policy Assessment contains the results of this rollback-based assessment. This assessment quantifies the projected uneven protection, noted qualitatively above, that would result from the use of 1-hour average $PM_{2.5}$ mass as the indicator.

ii. Directly Measured $PM_{2.5}$ Light Extinction

PM light extinction is the major contributor to light extinction, which is the property of the atmosphere that is most directly related to visibility effects. It differs from light extinction by the nearly constant contributions for Rayleigh (or clean air) light scattering and the minor contributions by NO_2 light absorption. The net result is that 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. Direct measurement of $PM_{2.5}$ light extinction can be accomplished 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). 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.

As part of the Visibility Assessment, an assessment was conducted that estimated PM_{10} light extinction levels that may prevail in 14 urban study areas if the areas were simulated to just meet a secondary standard based on directly measured hourly PM_{10} light extinction as the indicator (U.S. EPA, 2010b,

[154] FRM filters are stabilized in a laboratory at fixed temperature and relative humidity levels, which alters whatever water content was present on the filter when removed from the sampler. FEM instruments are designed to meet performance criteria compared to FRM measurements, and accordingly typically manage temperature and/or humidity at the point of measurement to levels that are not the same as ambient conditions.

[155] As discussed below, 24-hour average $PM_{2.5}$ chemical component mass is measured at about 200 CSN sites.

section 4.3).[156] As would be expected, this assessment indicated that a secondary standard based on a directly measured PM_{10} light extinction indicator would provide the same percentage of days having values above the level of the standard in each of the areas, with the percentage being dependent on the statistical form of the standard. The Policy Assessment considers this assessment reasonably informative for a directly measured $PM_{2.5}$ light extinction indicator as well, because in most of the assessment study areas PM_{10} light extinction is dominated by $PM_{2.5}$ 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 produced a White Paper on Particulate Matter (PM) Light Extinction Measurements (U.S. EPA, 2010g), and solicited comment on the White Paper from the Ambient Air Monitoring and Methods Subcommittee (AAMMS) of CASAC. In its review of the White Paper (Russell and Samet, 2010a), the CASAC AAMMS made the recommendation that consideration of direct measurement should be limited to $PM_{2.5}$ light extinction as this can be accomplished by a number of commercially available instruments and because $PM_{2.5}$ is generally responsible for most of the PM visibility impairment in urban areas. The CASAC AAMMS indicated that it is technically more challenging at this time to accurately measure the $PM_{10-2.5}$ component of light extinction.

The CASAC AAMMS also commented on the capabilities of currently available instruments, and expressed optimism regarding the near-term development of even better instruments for such measurement than are now commercially available. 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 EPA develop performance-based approval criteria for direct measurement methods in order to put all approaches on a level playing field. Such criteria would necessarily include procedures and pass/fail requirements for demonstrating that the performance criteria have been met. For example, instruments might be required to demonstrate their performance in a wind tunnel, where the concentration of $PM_{2.5}$ components, and thus of $PM_{2.5}$ light extinction, could be controlled to known values. It might also be possible to devise approval testing procedures based on operation in ambient air, although knowing the true light extinction level (without in effect treating some particular instrument as if it were the FRM) would be more challenging. 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.

iii. Calculated $PM_{2.5}$ Light Extinction

As discussed above in section VI.B.1 above, $PM_{2.5}$ light extinction can be calculated from 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 also be used for a NAAQS focused on protecting against PM-related visibility impairment primarily in urban areas. This could use the type of data that is routinely collected from the urban CSN[157] in combination with climatological relative humidity data as used in the Regional Haze Program (U.S. EPA, 2011a, Appendix G, section G.2). This calculation procedure, using the original IMPROVE light extinction equation presented above in section VI.B.1 on a 24-hour basis (or the revised IMPROVE equation), does not require $PM_{2.5}$ mass concentration measurements.

Alternatively, a conceptually similar approach could be applied in urban areas on an hourly or multi-hour basis. Applying this conceptual approach on a sub-daily basis would involve translating 24-hour speciation data into hourly estimates of species concentrations, and using 24-hour average species concentrations in conjunction with hourly $PM_{2.5}$ mass concentrations. This translation can be made using more or less complex alternative approaches, as discussed below.

The approach used to generate hourly PM_{10} light extinction for the Visibility Assessment was a relatively more complex method for implementing such a conceptual approach. It involved the use of the original IMPROVE algorithm[158] with estimates of hourly $PM_{2.5}$ components derived from day-specific 24-hour and hourly measurements of $PM_{2.5}$ mass, 24-hour measurements of $PM_{2.5}$ composition, hourly measurements of $PM_{2.5}$ mass and (for some but not all study sites) hourly $PM_{10-2.5}$ mass, along with hourly relative humidity information (U.S. EPA, 2010b, section 3.3). The Visibility Assessment approach also involved the use of output from a chemical transport modeling run to provide initial estimates of diurnal profiles for $PM_{2.5}$ components at particular sites. The Visibility Assessment approach entailed numerous and complex data processing steps to generate hourly $PM_{2.5}$ composition information from these less time-resolved data, including application of a mass-closure approach, referred to as the SANDWICH approach[159] (Frank, 2006), to adjust for nitrate retention differences between FRM and CSN filters, which is a required step for consistency with the IMPROVE algorithm and for estimating organic carbonaceous material via mass balance.[160] The EPA staff employed complex custom software to do these data processing steps.

While the complexity of the approach used in the Visibility Assessment was reasonable for assessment purposes at 15 urban areas, the Policy Assessment recognizes that a relatively more simple approach would be more straightforward and have greater transparency, and thus should be considered for purposes of a national standard.[161] Therefore, the Policy Assessment evaluated the degree to which simpler approaches would correlate with the results of the highly complex method used in the Visibility Assessment. This evaluation of two specific simpler approaches (described briefly below and in more detail in U.S. EPA, 2011a, Appendix F, especially Table F–1) demonstrated that the $PM_{2.5}$ portions of the PM_{10} light extinction

[156] This assessment was conducted prior to staff's decision to focus on $PM_{2.5}$ light extinction indicators in the Policy Assessment.

[157] 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).

[158] The original IMPROVE algorithm was selected for the described analysis in the Visibility Assessment because of its simplicity relative to the revised algorithm.

[159] Sulfate, adjusted nitrate, derived water, inferred carbonaceous mass (SANDWICH) approach.

[160] Daily temperature data were also used as part of the SANDWICH method.

[161] 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.

values developed for the Visibility Assessment can be well approximated using the same IMPROVE algorithm applied to hourly $PM_{2.5}$ composition values that were much more simply generated than with the method used in the Visibility Assessment.

The simplified approaches examined were aimed at calculating hourly $PM_{2.5}$ light extinction using the original IMPROVE algorithm (see section VI.B.1.a. above) excluding the Rayleigh term for light scattering by atmospheric gases and the term for $PM_{10\text{-}2.5}$.[162] These approaches, including a description of the sources of the data and steps required to determine calculated $PM_{2.5}$ light extinction for these simplified approaches, are described in more detail in the Policy Assessment (U.S. EPA, 2011a, pp. 4–46 to 48, Appendix F, Table F–2). Also, Table F–1 of Appendix F of the Policy Assessment compares and contrasts each of these approaches with the Visibility Assessment approach and with each other.

The hourly $PM_{2.5}$ light extinction values generated by using either simplified approach are comparable to those developed for use in the Visibility Assessment as indicated by the regression statistics for scatter plots of the paired data (i.e., the slopes of the regression equation and the R^2 values are near 1 as shown in U.S. EPA, 2011a, Appendix F, Tables F–3 and F–4). Appendix F notes that both approaches underestimate $PM_{2.5}$ light extinction on some days in a few study areas, which the Policy Assessment attributes to the occurrence of very high nitrate concentrations and the failure of the FRM-correlated/adjusted FEM instrument to report the entire nitrate mass. Nevertheless, the Policy Assessment concludes that each of these simplified approaches provides reasonably good estimates of $PM_{2.5}$ light extinction and each is appropriate to consider as the indicator for a distinct hourly or multi-hour secondary standard (U.S. EPA, 2011a, p. 4–48).

In addition, the Policy Assessment notes that there are variations of these simplified approaches that may also be appropriate to consider. For example, some variations that may improve the correlation with actual ambient light extinction in certain areas of the country include the use of the split-component mass extinction efficiency approach from the revised IMPROVE algorithm,[163] the use of more refined value(s) for the organic carbon multiplier (see U.S. EPA, 2011a, Appendix F),[164] and 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. Other variations may serve to simplify the calculation of $PM_{2.5}$ light extinction values, such as those suggested by CASAC for consideration, including the use of historical monthly or seasonal speciation averages as well as speciation estimates on a regional basis (Samet, 2010d, p. 11). Some of these variations would also be appropriate to consider in conjunction with a 24-hour average calculated $PM_{2.5}$ light extinction indicator, including the use of the revised IMPROVE algorithm, the use of an alternative value for the organic carbon multiplier (e.g., 1.6), and the use of historical monthly or seasonal, or regional, speciation averages.

As mentioned above, as part of the Visibility Assessment, an assessment was conducted of PM_{10} light extinction levels that would prevail if areas met a standard based on directly measured hourly PM_{10} light extinction as the indicator. This assessment indicated that a standard based on a directly measured PM_{10} light extinction indicator would provide the same percentage of days having indicator values above the level of the standard across areas, with the percentage being dependent on the statistical form of the standard. This assessment was based on the more complex Visibility Assessment approach to estimating PM_{10} light extinction, rather than the simpler approaches for estimating $PM_{2.5}$ light extinction. Nevertheless, the generally close correspondence between design values for $PM_{2.5}$ light extinction developed consistent with the Visibility Assessment approach and design values based on the simplified approaches (U.S. EPA, 2011a, Appendix F, Figure F–5) suggest that the findings regarding the protection offered by alternative PM_{10} light extinction standards using directly measured light extinction would also hold quite well for standards based on the simplified indicators.[165] Thus, the Policy Assessment concludes that the use of a calculated $PM_{2.5}$ light extinction indicator would provide a much higher degree of uniformity in terms of the visibility levels across the country than is possible using $PM_{2.5}$ mass as the indicator (U.S. EPA, 2011a, p. 4–49). This is due to the fact that the $PM_{2.5}$ mass indicator does not account for the effects of humidity and $PM_{2.5}$ composition differences between various regions, while a calculated $PM_{2.5}$ light extinction indicator directly incorporates those effects.

The inputs that would be necessary to use either simplified approach to calculate a sub-daily $PM_{2.5}$ light extinction indicator (e.g., 1- or 4-hour averaging time) include $PM_{2.5}$ chemical speciation, relative humidity, and hourly $PM_{2.5}$ mass measurements. In defining a standard in terms of calculated light extinction, the criteria for allowable protocols for these calculations would need to be specified. It would be appropriate to base these criteria on the protocols utilized in the IMPROVE [166] and CSN networks, as well as sampling and analysis protocols for ambient relative humidity sensors, and approved FEM mass monitors for $PM_{2.5}$. Any approach to approving methods for use in calculating a light extinction indicator should take advantage of the existing inventory of monitoring and analysis methods.

The CSN measurements have a strong history of being reviewed by CASAC technical committees, both during their initial deployment about ten years ago (Mauderly 1999a,b) and during the more recent transition to carbon sampling that is consistent with the IMPROVE protocols (Henderson, 2005c). Because the methods for the CSN are well documented in a nationally implemented Quality Assurance Project Plan (QAPP) and accompanying standard operating procedures (SOPs), are validated through independent performance testing, and are used to meet multiple data objectives (e.g., source apportionment, trends, and as an input to health studies), consideration

[162] The original IMPROVE algorithm was the basis for the approaches considered in the Policy Assessment to maintain comparability to the estimates developed in the Visibility Assessment. This allowed the effects of other simplifications relative to the Visibility Assessment approach to be better discerned.

[163] 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.

[164] 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.

[165] The degree of emission reduction needed to meet a standard is tightly tied to the degree to which the design value exceeds the level of the standard.

[166] Several monitoring agencies utilize IMPROVE in urban areas to meet their chemical speciation monitoring needs. These sites are known as IMPROVE-protocol stations.

should be given to an approach that utilizes the existing methods as the basis for criteria for allowable sampling and analysis protocols for purposes of a calculated light extinction indicator. Such an approach of basing criteria on the current CSN and IMPROVE methods provides a nationally consistent way to provide the chemical species data used in the light extinction calculation, while preserving the opportunity for improved methods for measuring the chemical species. For relative humidity, in conjunction with either hourly, multi-hour, or 24-hour average calculated $PM_{2.5}$ light extinction, consideration should be given to simply using criteria based on available relative humidity sensors such as already utilized by the National Oceanic and Atmospheric Administration (NOAA) at routine weather stations. These relative humidity sensors are already widely used by a number of monitoring agencies and can be easily compared to other relative humidity measurements.[167] Finally, the simplified approaches for a sub-daily averaging period depend on having values of hourly $PM_{2.5}$ mass, as discussed below.

Since 2008, EPA has approved several $PM_{2.5}$ continuous mass monitoring methods as FEMs.[168] These methods have several advantages over filter-based FRMs, such as producing hourly data and the ability to report air quality information in near real-time. However, initial assessments of the data quality as operated by state and local monitoring agencies have had mixed results. A recent assessment of continuous FEMs and collocated FRMs conducted by EPA staff (Hanley and Reff, 2011) found some sites and continuous FEM instruments to have an acceptable degree of comparability of 24-hour average $PM_{2.5}$ mass values derived from continuous FEMs and filter-based FRMs, while others had poor data quality that would not meet current data quality objectives. The EPA is working closely with the monitoring committee of the National Association of Clean Air Agencies (NACAA), instrument manufacturers, and monitoring agencies to document and communicate best practices on these methods to improve quality and consistency of resulting data. It should be noted that performance testing submitted to EPA for purposes of designating the $PM_{2.5}$ continuous methods as FEMs, and the recent assessment of collocated FRMs and continuous FEMs, are both based on 24-hour sample periods. Therefore, the EPA does not have similar performance data for continuous $PM_{2.5}$ FEMs for 1-hour or 4-hour averaging periods, nor is there an accepted practice to generate performance standards for these time periods.[169] Until issues regarding the comparability of 24-hour $PM_{2.5}$ mass values derived from continuous FEMs and filter-based FRMs 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 and speciated $PM_{2.5}$ mass values from 24-hour filter-based samplers. Section 4.3.2.1 of the Policy Assessment discusses another reason for such caution, based on a preliminary assessment of hourly data from continuous FEMs (U.S. EPA, 2011a, pp. 4–52 to 4–54).

This section has addressed the types of measurements that would be necessary to support a calculated $PM_{2.5}$ light extinction indicator for either 24-hour or sub-daily (e.g., 1-hour and 4-hour) averaging periods. Considerations related specifically to each of these alternative averaging times, in conjunction with a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, are discussed further in section 4.3.2 of the Policy Assessment.

iv. Conclusions in the Policy Assessment

Taking the above considerations and CASAC's advice into account, the Policy Assessment concludes that consideration should be given to establishing a new calculated $PM_{2.5}$ light extinction indicator (U.S. EPA, 2011a, p. 4–51). This conclusion takes into consideration the available evidence that demonstrates 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. While a secondary standard that uses a $PM_{2.5}$ mass indicator could be set to provide additional protection from $PM_{2.5}$-related visibility impairment, the Policy Assessment concludes that the advantages of using a calculated $PM_{2.5}$ light extinction indicator make it the preferred choice (U.S. EPA, 2011a, p. 4–51). In addition, the Policy Assessment recognizes 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, it concludes that 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).

Further, the Policy Assessment concludes 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). In either case, it would be appropriate to base criteria for allowable monitoring and analysis protocols to obtain $PM_{2.5}$ speciation measurements on the protocols utilized in the IMPROVE and CSN networks. Further, in the case of a calculated $PM_{2.5}$ light extinction indicator defined on a sub-daily basis, it would be appropriate to consider using the simplified approaches described, or some variations on these approaches. In reaching this conclusion, as discussed above, the Policy Assessment notes that 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, the mixed results of data quality assessments on a 24-hour basis, as well as the near absence of performance data for sub-daily averaging periods, increases 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.

b. CASAC Advice

Based on its review of 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 concludes 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

[167] For the purposes of using relative humidity measurements to derive multi-hour or 24-hour average $PM_{2.5}$ calculated light extinction, the non-linear f(RH) enhancement factor should be developed separately for each hour and then averaged over the desired multi-hour period. This averaging approach is consistent with derivation of climatological f(RH) factors used by the IMPROVE program and for the Regional Haze rule.

[168] The EPA maintains a list of designated Reference and Equivalent Methods on its Web site at: *http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-list.pdf.*

[169] 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.

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 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).[170]

c. Administrator's Proposed Conclusions on Indicator

In reaching a proposed conclusion on the appropriate indicator for a standard intended to protect against PM-related visibility impairment, as an initial matter, the Administrator concurs 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. However, she also recognizes that while instruments currently exist that can directly measure $PM_{2.5}$ light extinction, they are not an appropriate option in this review because a suitable specification of the equipment or performance-based verification procedures cannot be developed in the time frame of this review.

Taking the above considerations and CASAC advice into account, the Administrator provisionally concludes 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), is an appropriate indicator to replace the current $PM_{2.5}$ mass indicator. Such an indicator, referred to as a $PM_{2.5}$ visibility index, appropriately reflects the relationship between ambient PM and PM-related light extinction, based on the analyses discussed above and incorporation of factors based on measured $PM_{2.5}$ speciation concentrations and relative humidity data. In addition, this addresses, in part, the issues raised in the court's remand of the 2006 $PM_{2.5}$ standards. The Administrator also notes 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 the above considerations, the Administrator proposes 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 proposes that such an index be based on the original IMPROVE algorithm in conjunction with climatological relative humidity data as used in the Regional Haze Program. A more detailed discussion of the steps involved in the calculation of $PM_{2.5}$ visibility index values is presented in section VII.A.5 below.

The Administrator solicits comment on all aspects of the proposed indicator. In particular, the Administrator solicits comment on 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. The Administrator also solicits comment on alternatively using the revised IMPROVE algorithm rather than the original IMPROVE algorithm the use of alternative values for the organic carbon multiplier in conjunction with either the original or revised IMPROVE algorithm; the use of historical monthly, seasonal, or regional speciation averages; and on alternative approaches to determining relative humidity, as discussed above. Further, in conjunction with an hourly or multi-hour indicator, comment is solicited on variations on the simplified approaches discussed above and on other approaches that may be appropriate to consider for such an indicator.

2. Averaging Times

a. Alternative Averaging Times

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, as discussed above in section VI.B.1 and in section 4.2.1 of the Policy Assessment, and the nature of inputs to the calculation of $PM_{2.5}$ light extinction, as discussed above in section VI.D.1 and in section 4.3.1 of the Policy Assessment. Based on this information, the Policy Assessment considered both sub-daily (1- and 4-hour averaging times) and 24-hour averaging times, as discussed below. In considering sub-daily averaging times, the Policy Assessment also addressed what diurnal periods and ambient relative humidity conditions would be appropriate to consider in conjunction with such an averaging time.

i. Sub-daily

As an initial matter, in considering sub-daily averaging times, the Policy Assessment took 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. While perception of change in visibility can occur in less than a minute, meaningful changes to path-averaged light extinction occur more slowly. As discussed above and in section 4.2.1 of the Policy Assessment, one hour is a short enough averaging period to result in indicator values that are close to the maximum one- or few-minute visibility impact that an observer could be exposed to within the hour. Further, a 1-hour averaging time could reasonably characterize the visibility effects experienced by the segment of the population that experiences infrequent short-term exposures during peak visibility impairment periods in each area/site. Based on the above considerations, the initial analyses conducted in the Policy Assessment as part of the Visibility Assessment to support consideration of alternative standards 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 notes 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 concludes that since a calculated $PM_{2.5}$ light extinction indicator relies in part on measured $PM_{2.5}$ mass, as discussed above and in section 4.3.1 of the Policy Assessment, it is also appropriate to consider a multi-hour averaging time in

[170] 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).

conjunction with such an indicator (U.S. EPA, 2011a, p. 4–53).

Thus, the Policy Assessment has considered multi-hour averaging times, on the order of a few hours as illustrated by a 4-hour averaging time. Such averaging times 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 recognizes 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 recognizes 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 concludes 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).

Additionally, as part of the review of data from all continuous FEM $PM_{2.5}$ instruments operating at state/local monitoring sites, as discussed above, the Policy Assessment notes that the occurrence of questionable outliers in 1-hour data submitted to AQS from continuous FEM $PM_{2.5}$ instruments has been observed at some of these sites (Evangelista, 2011). Some of these outliers are questionable simply by virtue of their extreme magnitude, as high as 985 $\mu g/m^3$, whereas other values are questionable because they are 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.[171] The nature and frequency of questionable 1-hour FEM data collected in the past two years are being investigated. At this time, the Policy Assessment notes 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 notes 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.

In considering an appropriate diurnal period for use in conjunction with a sub-daily averaging time, the Policy Assessment recognizes that nighttime visibility impacts, described in the Integrated Science Assessment (U.S. EPA, 2009a, section 9.2.2) are significantly different from daytime impacts and are not sufficiently well understood to be included at this time. As a result, consistent with CASAC advice (Samet, 2010c, p. 4), the Policy Assessment concludes that it would be appropriate to define a sub-daily standard in terms of only daylight hours at this time (U.S. EPA, 2011a, p. 4–54). In the Visibility Assessment, daylight hours were defined to be those morning hours having no minutes prior to local sunrise and afternoon hours having no minutes after local sunset. This definition ensures the exclusion of periods of time where the sun is not the primary outdoor source of light to illuminate scenic features.

In considering the well-known interaction of PM with ambient relative humidity conditions, the Policy Assessment recognizes that PM is not generally the primary source of visibility impairment during periods with fog or precipitation. In order to reduce the probability that hours with a high degree of visibility impairment caused by fog or precipitation are unintentionally used for purposes of determining compliance with a standard, the Policy Assessment determined that a relative humidity screen that excludes daylight hours with average relative humidity above approximately 90 percent is appropriate (U.S. EPA, 2001, pp. 4–54 to 4–55; see also U.S. EPA, 2010b, section 3.3.5, Appendix G). For example, for the 15 urban areas[172] included in the Visibility Assessment, a 90 percent relative humidity cutoff criterion proved effective in that on average less than 6 percent of the daylight hours were removed from consideration, yet those same hours had on average 10 times the likelihood of rain, 6 times the likelihood of snow/sleet, and 34 times the likelihood of fog compared with hours with 90 percent or lower relative humidity. However, not all periods with relative humidity above 90 percent have fog or precipitation. The Policy Assessment recognizes that removing those hours from consideration involves a tradeoff between the benefits of avoiding many of the hours with meteorological causes of visibility impacts and not counting some hours without fog or precipitation in which high humidity levels (e.g., greater than 90 percent) lead to the growth of hygroscopic PM to large solution droplets resulting in larger PM visibility impacts.

ii. 24–Hour

As discussed in section 4.3.1 of the Policy Assessment and below, 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 over relying on continuous $PM_{2.5}$ monitoring data. However, the Policy Assessment recognizes 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, as discussed above and in section 4.3.2.1 of the Policy Assessment. Thus, consideration of a 24-hour averaging time depends 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, as discussed below in this section. Further, since a 24-hour averaging time combines daytime and nighttime periods, the Policy Assessment recognizes that the public preference studies do not directly provide a basis for identifying an appropriate level of protection, in terms of 24-hour average light extinction, based on judgments of acceptable daytime visual air quality obtained in

[171] 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.

[172] The 90 percent relative humidity cap assessment was conducted as part of the Visibility Assessment on all 15 of the urban areas, including St. Louis.

those studies. Thus, consideration of a 24-hour averaging time also depends upon developing an approach to translate the candidate levels of protection derived from the public preference studies, which the Policy Assessment has interpreted on an hourly or multi-hour basis, to a candidate level of protection defined in terms of a 24-hour average calculated light extinction, as discussed in section.VI.D.4 below.

To determine whether $PM_{2.5}$ 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, the Policy Assessment performed comparative analyses of 24-hour and 4-hour averaging times in conjunction with a calculated $PM_{2.5}$ indicator.[173] These analyses are presented and discussed in Appendix G, section G.4 of the Policy Assessment. 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 calculations used the original IMPROVE algorithm and long-term (1988 to 1997) average relative humidity conditions, to calculate monthly average values of the relative humidity term in the IMPROVE algorithm, consistent with the approach used for the Regional Haze Program. Similar to the approach used to assess a sub-daily visibility index discussed in section VI.2.a.i above, these 1988–1997 humidity data are similarly screened to remove the effect of high hourly relative humidity. In this case, any relative humidity value great than 95 percent was treated as 95 percent. Because 10-years of hourly data were used to produce a single humidity term for each month, the EPA believes that the resulting monthly average of the humidity term is sufficient and appropriate to reduce the effects of fog or precipitation. Based on these analyses, scatter plots comparing 24-hour and 4-hour calculated $PM_{2.5}$ light extinction are shown 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). It can be seen, as expected, that there is some scatter around the regression line for each city, because the calculated 4-hour light extinction includes day-specific and hour-specific influences that are not captured by the simpler 24-hour approach. The Policy Assessment notes that this scatter could be reduced by the use of same-day hourly relative humidity data to calculate a 24-hour average value of the relative humidity term in the IMPROVE algorithm. In the Policy Assessment, scatter plots are also shown for the annual 90th percentile values, based on data from 2007 to 2009, for 4-hour and 24-hour calculated $PM_{2.5}$ light extinction across all 15 cities (U.S. EPA, 2011a, Figure G–7) and for the 3-year design values across all 15 cities (U.S. EPA, 2011a, Figure G–8). These analyses 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.[174]

iii. Conclusions in the Policy Assessment

Taking the above considerations and CASAC's advice into account, the Policy Assessment concludes that it is appropriate to consider in this review a 24-hour averaging time, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and an appropriately specified standard level (U.S. EPA, 2011a, p. 4–57). This conclusion reflects the judgment 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 average basis. This conclusion is also predicated on consideration of a 24-hour average standard level, as discussed below and in section 4.3.4 of the Policy Assessment, that is appropriately translated from the CPLs derived from the public preference studies, which the Policy Assessment has interpreted as providing information on the acceptability of daytime visual air quality over an hourly or multi-hour exposure period.

A 24-hour average calculated $PM_{2.5}$ light extinction indicator would avoid data quality uncertainties that have recently been associated with currently available instruments for measurement of hourly $PM_{2.5}$ mass. The particular 24-hour indicator considered by the Policy Assessment uses the original IMPROVE algorithm and long-term relative humidity conditions to calculate $PM_{2.5}$ light extinction. 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.

Further, the Policy Assessment concludes 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 that have been raised by the recent EPA study of continuous FEMs (U.S. EPA, 2011a, p. 4–58). 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 concludes 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 concludes 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).

b. CASAC Advice

As noted above, in its review of the first draft Policy Assessment, CASAC concludes 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

[173] 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).

[174] The EPA staff note that the R^2 value (0.44) for Houston was notably lower than for the other cities.

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 indicator when calculated on a sub-daily basis.

In considering this advice, the Policy Assessment first notes that CASAC did not have the benefit of EPA's recent assessment of the data quality issues associated with the use of continuous FEMs as the basis for hourly $PM_{2.5}$ mass measurements. The Policy Assessment also notes that since earlier drafts of this Policy Assessment did not include 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.

c. Administrator's Proposed Conclusions on Averaging Time

In reaching a proposed conclusion on the appropriate averaging time for a standard intended to protect against PM-related visibility impairment, the Administrator has taken into account the information discussed above with regard to analyses and conclusions presented in the final Policy Assessment as well as the views of CASAC based on its reviews of the first and second drafts of the Policy Assessment. As an initial matter, the Administrator recognizes 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 recognizes 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 recognizes the desirability of a sub-daily averaging time, she has 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 recognizes that the Policy Assessment concludes 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 (U.S. EPA, 2011a, p. 4–57). In light of this finding, the Administrator proposes to set a distinct secondary standard with a 24-hour averaging time in conjunction with a $PM_{2.5}$ visibility index.

Further, in light of the desirability of a sub-daily averaging time, the Administrator solicits comment on a sub-daily (e.g., 4-hour) averaging time and related data quality issues associated with currently available monitoring instrumentation. In so doing, the Administrator notes that CASAC's advice on averaging times was predicated in part on the capabilities of available monitoring instrumentation as CASAC understood them when it provided its advice.

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 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 concludes it is 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 concludes 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 notes 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 finds 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 that was considered in the Visibility Assessment for a sub-daily (i.e., 1-hour) averaging time is whether to include all daylight hours or only the maximum daily daylight hour. This consideration would also be relevant for a multi-hour (e.g., 4-hour) averaging time, although such an analysis was not included in the Visibility Assessment. The maximum daily daylight 1-hour or multi-hour form is 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 does not have information regarding the fraction of the public that has only one or a few opportunities to experience visibility during the day, nor does 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 Visibility Assessment analyses included both the maximum daily hour and the all daylight hours forms. The Policy Assessment observed a close correspondence between the level of protection afforded for all 15 urban areas in the assessment by the maximum daily daylight 1-hour approach using the 90th percentile form and the all daylight hours approach combined with the 98th percentile form (U.S. EPA, 2010b, section 4.1.4). On this basis, the Policy Assessment notes that the 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). The Policy Assessment also notes that 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 concludes that it is 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 concludes that it is 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.

Based on its review of the second draft Policy Assessment, CASAC did not provide advice as to a specific form that would be appropriate, but 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, the Administrator provisionally concludes that a 90th percentile form, averaged over 3 years, is appropriate, and proposes such a form in conjunction with a $PM_{2.5}$ visibility index and a 24-hour averaging time.

4. Level

In considering alternative levels for a new standard that would provide requisite protection against PM-related visibility impairment primarily in urban areas, the Policy Assessment has taken into account the evidence- and impact-based considerations discussed above and in section 4.2.1 of the Policy Assessment, 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 this information in the context of a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, discussed above and in the Policy Assessment section 4.3.1; with alternative averaging times of 24-hours or multi-hour, sub-daily periods (e.g., 4-hours), discussed above and in Policy Assessment section 4.3.2; and a 90th percentile-based form, discussed above and in section 4.3.3 of the Policy Assessment.

As part of the Policy Assessment's assessment of the adequacy of the current standards, summarized in section VI.B. above and in Policy Assessment section 4.2.1, it 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 Policy Assessment notes that CASAC agreed that this was an appropriate range of levels to consider for such a standard (Samet, 2010d, p. 11).[175] The Policy Assessment also recognizes 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 is 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.

As an initial matter, in considering alternative levels for a sub-daily standard based directly on the four preference study results, the Policy Assessment notes that the individual

[175] In 2009, the D.C. 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.

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. As discussed above and in section 4.2.1 of the Policy Assessment, the Phoenix study was by far the best of the studies, providing somewhat more support for the middle CPL. In considering the results from these studies, the Policy Assessment recognizes that the 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 recognizes 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 concludes, as did CASAC, that these studies are appropriate to use for this purpose (U.S. EPA, 2011a, p. 4–61).

In considering potential alternative levels for a 24-hour standard, the Policy Assessment explores various approaches to adjusting the CPLs derived directly from the preference studies, as presented and discussed in Appendix G of the Policy Assessment, especially section G–5. 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 so doing, staff recognized that there are multiple approaches for estimating generally equivalent levels on a city-specific or national basis, and that the inherent spatial and temporal variability in relative humidity and fine particle composition across cities leads to a set of alternative estimates of levels that may be construed as being generally equivalent on a national basis.

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 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 Table G–6 of Appendix G,[176] in considering estimates aggregated or averaged over all 15 cities as well as the range of city-specific estimates for the various approaches considered, 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.[177]

Some of the approaches used in these analyses focused on comparing 24-hour and 4-hour light extinction values in each of the 15 urban areas, whereas other approaches focused on comparisons based on using aggregated data across the urban areas. Two of these approaches, which used regressions of city-specific annual 90th percentile light extinction values or 3-year light extinction design values, gave nearly identical results and were considered by staff to be most appropriate for further consideration. These approaches (shown in U.S. EPA, 2011a, Appendix G, Figures G–7 and G–8, referred to as Approaches A and B) were preferred by staff based on the high R^2 values of the regressions and because the regressions were determined by data from days with $PM_{2.5}$ light extinction conditions in the range of 20 to 40 dv. This contrasted with the other approaches that were influenced by $PM_{2.5}$ light extinction conditions well below this range. Based on these analyses (presented in Appendix G of the Policy Assessment), the Policy Assessment notes that the single approach thought by staff to be more appropriate for further consideration (referred to as Approach B in Appendix G) yielded adjusted 24-hour CPLs of 21, 25, and 28 dv as being levels that are generally equivalent in an aggregate or central tendency sense to 4-hour CPLs of 20, 25, and 30 dv.[178]

Two of the approaches yielded not only estimates of generally equivalent levels on an aggregated basis but also city-specific estimates (referred to as Approaches C and E in Appendix G) that showed greater variability than the aggregated estimates. 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 shown in Tables G–7 and G–8, Appendix G of the Policy Assessment, for Approaches C and E, respectively). 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 more broadly considering alternative standard levels that would be appropriate for a nationally applicable secondary standard focused on protection from PM-related urban visibility impairment based on either a 24-hour or multi-hour, sub-daily (e.g., 4-hour) averaging time, the Policy Assessment was mindful of the important limitations in the available evidence from public preference studies. While the Policy Assessment concluded, consistent with CASAC advice, that it is appropriate to consider a distinct secondary $PM_{2.5}$ standard to address PM-related visibility impairment focused primarily in urban areas based on the evidence from public preference studies, it also recognized that there are a number of uncertainties and limitations associated with the preference studies that have served as a basis for selecting an appropriate range of levels to consider, as discussed above

[176] 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.

[177] 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.

[178] To provide some perspective in considering these results (U.S. EPA, 2011a, Appendix G, Table G–6), the Policy Assessment notes that 1 dv is about the amount that persons can distinguish when viewing scenic vistas, and that a difference of 1 dv is equivalent to about a 10 percent difference in light extinction expressed in Mm^{-1}.

in section VI.B.2. 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 Policy Assessment was mindful 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, and that there is the possibility that there could be regional differences in individual preferences for VAQ.

Given the uncertainties and limitations noted above, the EPA broadly solicits comment on the strengths and limitations associated with these 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). In particular, the EPA solicits comment on the following specific aspects of the public preference studies and on how these studies should appropriately be considered in this review. Recognizing that all of these studies evaluated a 50 percent acceptability criterion as the basis for reaching judgments in the context of each study, the EPA requests comment on the extent to which this 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. Recognizing that these studies vary in the extent to which the study participants may be representative of the broader study area population, the EPA requests comment on how this aspect of the study designs should appropriately be weighed in the context of considering these studies in reaching proposed conclusions on a distinct secondary NAAQS. The EPA also solicits comment on 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.

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.

Based on the above considerations, the Policy Assessment concludes 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 concludes 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 judges that such standards would provide appropriate protection against PM-related visibility impairment primarily in urban areas. The Policy Assessment notes 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 concludes 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 above considerations, taking into account the conclusions in the Policy Assessment and the extent to which those conclusions reflected consideration of CASAC advice during the development of the Policy Assessment, as an initial matter, the Administrator provisionally concludes that it is 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 concludes 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 is supported by the available information and is generally consistent with the advice of CASAC. The option of setting such a 24-hour standard 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. 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.

In light of these provisional conclusions, the Administrator proposes to set 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 based on one of two options. One option is to set the level of such a standard at 30 dv and the other option is to set the level at 28 dv. In so doing, the

Administrator solicits comment on each of these levels and on the various approaches to identifying generally equivalent levels discussed above upon which the alternative proposed levels are based. Recognizing that there was some support for consideration of a broader range of levels, the Administrator also solicits comment on a range of levels down to 25 dv in conjunction with a 24-hour averaging time. Further, having solicited comment on a sub-daily (e.g., 4-hour) averaging time, the Administrator also solicits comment on a range of alternative levels from 30 to 25 dv in conjunction with such a sub-daily averaging time.

Finally, as we have indicated, 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). We invite comment on how the Administrator should weigh those uncertainties as well as any additional comments and information to inform her consideration of these uncertainties.

E. Other PM-Related Welfare Effects

In the 2006 review, the Administrator 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. To provide a level of protection for 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).

In that review, the 2004 AQCD concluded that regardless of size fraction, particles containing nitrates and sulfates have the greatest potential for widespread environmental significance (U.S. EPA, 2004, sections 4.2.2 and 4.2.3.1). Considerable supporting evidence was available that indicated a significant role of oxides of nitrogen and sulfur, and their transformation products in acidification and nutrient enrichment of terrestrial and aquatic ecosystems (71 FR 61209, October 17, 2006). The recognition of these ecological effects, coupled with other considerations detailed below, led EPA to initiate a joint review of the secondary NO_2 and SO_2 NAAQS that is considering the gaseous and particulate species of oxides of nitrogen and sulfur with respect to the ecosystem-related welfare effects that result from the deposition of these pollutants and transformation products.

This section presents the Policy Assessment's conclusions with regard to the current suite of secondary PM standards to protect against non-visibility PM-related welfare effects. Specifically, the Policy Assessment has assessed the relevant information related to effects of atmospheric PM on the environment, including effects on climate, ecological effects, and materials. Non-visibility welfare-based effects of oxides of nitrogen and sulfur are divided between two NAAQS reviews; (1) PM NAAQS review and, (2) the joint secondary NAAQS review for oxides of nitrogen (NO_X) and oxides of sulfur (SO_X).[179] The scope of each document and the compounds of nitrogen and sulfur considered in each review are summarized in this section and in Table 5–1 of the Policy Assessment.

In reviewing the current suite of secondary PM standards, the Policy Assessment considers all PM-related effects that are not being covered in the ongoing NO_X/SO_X review, including visibility impairment (U.S. EPA, 2011a, chapter 4), climate forcing effects (U.S. EPA, 2011a, section 5.2), ecological effects (U.S. EPA, 2011a, section 5.3), and materials damage (U.S. EPA, 2011a, section 5.4). By excluding the effects associated with deposited particulate matter components of NO_X and SO_X and their transformation products which are addressed fully in the NO_X/SO_X secondary review, the discussion of ecological effects of PM has been narrowed to focus on effects associated with the deposition of metals and, to a lesser extent, organics (U.S. EPA, 2011a, section 5.3). With regard to the materials section, because the NO_X/SO_X review is not considering materials, the discussion includes particles and gases that are associated with the presence of ambient NO_X and SO_X, as well as reduced forms of nitrogen such as ammonia and ammonium ions for completeness.

In contrast, the proposed rulemaking for the joint NO_X/SO_X secondary review (76 FR 46084, August 1, 2011) focuses on the welfare effects associated with exposures from deposited particulate and gaseous forms of oxides of nitrogen and sulfur and related nitrogen- and sulfur-containing compounds and transformation products on ecosystem receptors, including effects of acidifying deposition associated with particulate nitrogen and sulfur. In addition, the NO_X/SO_X secondary review includes evidence related to direct ecological effects of gas-phase NO_X and SO_X.

1. Climate

Information and conclusions about what is currently known about the role of PM in climate is summarized in Chapter 9 of the Integrated Science Assessment (U.S. EPA, 2009a). The Integrated Science Assessment concludes ''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). The Policy Assessment summarizes and synthesizes the policy-relevant science in the Integrated Science Assessment for the purpose of helping to inform consideration of climate aspects in the review of the secondary PM NAAQS (U.S. EPA, 2011a, section 5.2). This discussion is summarized below.

Atmospheric PM (referred to as aerosols [180] in the remainder of this section to be consistent with the Integrated Science Assessment) affects multiple aspects of climate. These include absorbing and scattering of incoming solar radiation, alterations in terrestrial radiation, effects on the hydrological cycle, and changes in cloud properties (U.S. EPA, 2009a, section 9.3.1). Major aerosol components that contribute to climate processes include black carbon (BC),

[179] For the purposes of this discussion, NO_X and SO_X refers to all oxides of nitrogen and all oxides of sulfur, respectively.

[180] In the sections of the Integrated Science Assessment included from IPCC AR4 and CCSP SAP2.3 (U.S. EPA, 2009a, section 9.3), the term ''aerosols'' is more frequently used than ''PM'' and that word is retained in the Policy Assessment (U.S. EPA, 2011a, section 5.2) and in this section of the preamble.

organic carbon (OC), sulfates, nitrates, and mineral dusts. There is a considerable ongoing research effort focused on understanding aerosol contributions to changes in global mean temperature and precipitation patterns. The Climate Change Research Initiative identified research on atmospheric concentrations and effects of aerosols as a high research priority (National Research Council, 2001) and the IPCC 2007 *Summary for Policymakers* states that anthropogenic contributions to aerosols remain the dominant uncertainty in radiative forcing (IPCC, 2007). The current state of the science of climate alterations attributable to PM is in flux as a result of continually updated information.

Global climate change has increasingly been the focus of intense international research endeavors. As discussed in chapter 5 of the Policy Assessment, major efforts are underway to understand the complexities inherent in atmospheric aerosol interactions and to decrease uncertainties associated with climate estimations.

Aerosols have direct and indirect effects on climate processes. The direct effects of aerosols on climate result mainly from particles scattering light away from Earth into space, directly altering the radiative balance of the Earth-atmosphere system. This reflection of solar radiation back to space decreases the transmission of visible radiation to the surface of the Earth and results in a decrease in the heating rate of the surface and the lower atmosphere. At the same time, absorption of either incoming solar radiation or outgoing terrestrial radiation by particles, primarily BC, results in an increased heating rate in the lower atmosphere. Global estimates of aerosol direct radiative forcing (RF) were recently summarized using a combined model-based estimate (Forster et al., 2007). The overall, model-derived aerosol direct RF was estimated in the IPCC AR4 as -0.5 (-0.9 to -0.1) watts per square meter (W/m^2), with an overall level of scientific understanding of this effect as ''medium low'' (Forster et al., 2007), indicating a net cooling effect in contrast to greenhouse gases (GHGs) which have a warming effect.

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). The direct effect of radiative scattering by atmospheric particles exerts an overall net cooling of the atmosphere, while particle absorption of solar radiation leads to warming. For example, the presence of OC and sulfates decrease warming from sunlight by scattering shortwave radiation back into space. Such a perturbation of incoming radiation by anthropogenic aerosols is designated as aerosol climate forcing, which is distinguished from the aerosol radiative effect of the total aerosol (natural plus anthropogenic). The aerosol climate forcing and radiative effect are characterized by large spatial and temporal heterogeneities due to the wide variety of aerosol sources, the spatial non-uniformity and intermittency of these sources, the short atmospheric lifetime of aerosols (relative to that of the greenhouse gases), and processing (chemical and microphysical) that occurs in the atmosphere. For example, OC can be warming (positive forcer) when deposited on or suspended over a highly reflective surface such as snow or ice but, on a global average, is a negative forcer in the atmosphere.

More information has also become available on indirect effects of aerosols. Particles in the atmosphere indirectly affect both cloud albedo (reflectivity) and cloud lifetime by modifying the cloud amount, and microphysical and radiative properties (U.S. EPA, 2009a, section 9.3.6.4). The RF due to these indirect effects (cloud albedo effect) of aerosols is estimated in the IPCC AR4 to be -0.7 (-1.8 to -0.3) W/m^2 with the level of scientific understanding of this effect as ''low'' (Forster et al., 2007). Aerosols act as cloud condensation nuclei (CCN) for cloud formation. Increased particulates in the atmosphere available as CCN with no change in moisture content of the clouds have resulted in an increase in the number and decrease in the size of cloud droplets in certain clouds that can increase the albedo of the clouds (the Twomey effect). Smaller particles slow the onset of precipitation and prolong cloud lifetime. This effect, coupled with changes in cloud albedo, increases the reflection of solar radiation back into space. The altitude of the clouds also affects cloud radiative forcing. Low clouds reflect incoming sunlight back to space but do not effectively trap outgoing radiation, thus cooling the planet, while higher elevation clouds reflect some sunlight but more effectively can trap outgoing radiation and act to warm the planet (U.S. EPA, 2009a, section 9.3.3.5).

The total negative RF due to direct and indirect effects of aerosols computed from the top of the atmosphere, on a global average, is estimated at -1.3 (-2.2 to -0.5) W/m^2 in contrast to the positive RF of +2.9 (+3.2 to +2.6) W/m^2 for anthropogenic GHGs (IPCC 2007, p. 200).

The understanding of the magnitude of aerosol effects on climate has increased substantially in the last decade. Data on the atmospheric transport and deposition of aerosols indicate a significant role for PM components in multiple aspects of climate. Aerosols can impact glaciers, snowpack, regional water supplies, precipitation, and climate patterns (U.S. EPA, 2009a, section 9.3.9). Aerosols deposited on ice or snow can lead to melting and subsequent decrease of surface albedo (U.S. EPA, 2009a, section 9.3.9.2). Aerosols are potentially important agents of climate warming in the Arctic and other locations (U.S. EPA, 2009a, section 9.3.9). Carbonaceous aerosols emitted from intermittent fires can occur at large enough scales to affect hemispheric aerosol concentrations. In addition to incidental fires, routine biomass burning, usually associated with agriculture in eastern Europe, has also been shown to contribute to hemispheric concentrations of carbonaceous aerosols and is therefore recognized as having a significant impact on $PM_{2.5}$ concentrations and climate forcing (U.S. EPA, 2009a, section 9.3.7).

A series of studies available since the last review examines the role of aerosols on local and regional scale climate processes (U.S. EPA, 2009a, section 9.3.9.3). Studies on the South Coast Air Basin (SCAB) in California indicate aerosols may reduce near-surface wind speeds, which, in turn reduce evaporation rates and increase cloud lifetimes. The overall impact can be a reduction in local precipitation (Jacobson and Kaufmann, 2006). Conditions in the SCAB impact ecologically sensitive areas including the Sierra Nevadas. Precipitation suppression due to aerosols in California (Givati and Rosenfield, 2004) and other similar studies in Utah and Colorado found that mountain precipitation decreased by 15 to 30 percent downwind of pollution sources. Evidence of regional-scale impacts of aerosols on meteorological conditions in other regions of the U.S. is lacking.

Advances in the understanding of aerosol components and how they contribute to climate change have enabled refined global forcing estimates of individual PM constituents. The global mean radiative effect from individual components of aerosols was estimated for the first time in the IPCC AR4 where they were reported to be (all in W/m^2 units): -0.4 (+0.2) for sulfate, -0.05 (+0.05) for fossil fuel-derived OC, +0.2 (+0.15) for fossil fuel derived BC, +0.03 (+0.12) for biomass burning, -0.1

(+0.1) for nitrates, and −0.1 (+0.2) for mineral dust (U.S. EPA, 2009a, section 9.3.10). Sulfate and fossil fuel-derived OC cause negative forcing whereas BC causes positive forcing because of its highly absorbing nature (U.S. EPA, 2009a, 9.3.6.3). Although BC comprises only a small fraction of anthropogenic aerosol mass load and aerosol optical depth (AOD), its forcing efficiency (with respect to either AOD or mass) is an order of magnitude stronger than sulfate and particulate organic matter (POM), so its positive shortwave forcing largely offsets the negative direct forcing from sulfate and POM (IPCC, 2007; U.S. EPA, 2009a, 9.3.6.3). Global loadings for nitrates and anthropogenic dust remain very difficult to estimate, making the radiative forcing estimates for these constituents particularly uncertain (U.S. EPA, 2009a, section 9.3.7).

Improved estimates of anthropogenic emissions of some aerosols, especially BC and OC, have promoted the development of improved global emissions inventories and source-specific emissions factors useful in climate modeling (Bond et al. 2004). Recent data suggests that BC is one of the largest individual warming agents after carbon dioxide (CO_2) and perhaps methane (CH_4) (Jacobson 2000; Sato et al., 2003; Bond and Sun 2005). There are several studies modeling BC effects on climate and/or considering emission reduction measures on anthropogenic warming detailed in section 9.3.9 of the Integrated Science Assessment. In the U.S., most of the warming aerosols are emitted by biomass burning and internal engine combustion and much of the cooling aerosols are formed in the atmosphere by oxidation of SO_2 or volatile organic compounds (VOCs) (U.S. EPA, 2009a, section 3.3). Fires release large amounts of BC, CO_2, CH_4 and OC (U.S. EPA, 2009a, section 9.3.7).

Based on the above newly available scientific information on climate-aerosol relationships, the Policy Assessment concludes that aerosols alter climate processes directly through radiative forcing and by indirect effects on cloud brightness, changes in precipitation, and possible changes in cloud lifetimes (U.S. EPA, 2011a, p. 5–10). Further, the Policy Assessment notes 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). In light of this information, the Policy Assessment considered the appropriateness of the current secondary standards defined in terms of $PM_{2.5}$ and PM_{10} indicators, for providing protection against potential climate effects of aerosols. 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 Policy Assessment concludes that 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).

Further, in light of the uncertainties associated with the spatial and temporal heterogeneity of PM components that contribute to climate forcing and the uncertainties associated with measurement of aerosol components, the inadequate consideration of aerosol impacts in climate modeling and the insufficient data on local and regional microclimate variations and the heterogeneity of cloud formations, the Policy Assessment concludes 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). Based on these considerations, the Policy Assessment concludes 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).[181]

2. Ecological Effects

Information on what is currently known about ecological effects of PM is summarized in Chapter 9 of the Integrated Science Assessment (U.S. EPA, 2009a). Four main categories of ecological effects are identified in the Integrated Science Assessment: Direct effects, effects of PM-altered radiative flux, indirect effects of trace metals, and indirect effects of organics. Exposure to PM for direct effects occurs via deposition (e.g., wet, dry or occult) to vegetation surfaces, while indirect effects occur via deposition to ecosystem soils or surface waters where the deposited constituents of PM then interact with biological organisms. Both fine and coarse-mode particles may affect plants and other organisms; however, PM size classes do not necessarily relate to ecological effects (U.S. EPA, 1996). More often, the chemical constituents drive the ecosystem response to PM (Grantz et al., 2003). The trace metal constituents of PM considered in the ecological effects section of the Integrated Science Assessment are cadmium (Cd), copper (Cu), chromium (Cr), mercury (Hg), nickel (Ni) and zinc (Zn). Ecological effects of lead (Pb) in particulate form are covered in the Air Quality Criteria Document for Lead (U.S. EPA, 2006). The organics included in the ecological effects section of the PM Integrated Science Assessment are persistent organic pollutants (POPs), polyaromatic hydrocarbons (PAHs), and polybromiated diphenyl ethers (PBDEs).

Ecological effects of PM 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.

The Integrated Science Assessment states that overall, 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 based on information from the previous review and limited new findings in this review (U.S. EPA, 2009a, sections 2.5.3 and 9.4.7). However the Integrated Science Assessment also finds, in many cases, it is 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.

Ecological effects of PM must then be evaluated to determine if they are known or anticipated to have an adverse impact on public welfare. Characterizing a known or anticipated adverse effect to public welfare is an important component of developing any secondary NAAQS. The most recent secondary NAAQS reviews have assessed changes in ecosystem structure or processes using a weight-of-evidence approach that uses both quantitative and qualitative data. A paradigm useful in evaluating ecological adversity is the concept of ecosystem services. Ecosystem services consist of the varied and numerous ways that ecosystems are important to human welfare. Ecosystems provide many goods and services that are of vital importance for the functioning of the biosphere and

[181] This conclusion would apply for both the secondary (welfare-based) and the primary (health-based) standards.

provide the basis for the delivery of tangible benefits to human society. An EPA initiative to consider how ecosystem structure and function can be interpreted through an ecosystem services approach has resulted in the inclusion of ecosystem services in the NO_X/SO_X Risk and Exposure Assessment (U.S. EPA, 2009h). The Millennium Ecosystem Assessment (MEA) defines these to include supporting, provisioning, regulating, and cultural services (Hassan et al., 2005).

An important consideration in evaluating biologically adverse effects of PM and linkages to ecosystem services is that many of the MEA categories overlap and any one pollutant may impact multiple services. For example, deposited PM may alter the composition of soil-associated microbial communities, which may affect supporting services such as nutrient cycling. Changes in available soil nutrients could result in alterations to provisioning services such as timber yield and regulating services such as climate regulation. If enough information is available, these alterations can be quantified based upon economic approaches for estimating the value of ecosystem services. Valuation may be important from a policy perspective because it can be used to compare the benefits of altering versus maintaining an ecosystem. Knowledge about the relationships linking ambient concentrations and ecosystem services can be used to inform a policy judgment on a known or anticipated adverse public welfare effect.

The Policy Assessment seeks to build upon and focus this body of science using the concept of ecosystem services to qualitatively evaluate linkages between biologically adverse effects and particulate deposition. This approach is similar to that taken in the NO_X/SO_X Risk and Exposure Assessment in which the relationship between air quality indicators, deposition of nitrogen and sulfur, ecologically relevant indicators, and effects on sensitive receptors are linked to changes in ecosystem structure and services (U.S. EPA, 2009h). This approach considers the benefits received from the resources and processes that are supplied by ecosystems. Several ecosystem components (e.g., plants, soils, water, and wildlife) are impacted by PM air pollution, which may alter the services provided by the ecosystems in question. Key scientific evidence regarding PM effects on plants, soil and nutrient cycling, wildlife, and water available since the last review is summarized below to evaluate how this information has improved understanding of ecosystem responses to PM.

a. Plants

As primary producers, plants play a pivotal role in energy flow through ecosystems. Ecosystem services derived from plants include all of the categories (supporting, provisioning, regulating, and cultural) identified in the MEA (Hassan et al., 2005). Vegetation supports other ecosystem processes by cycling nutrients through food webs and serving as a source of organic material for soil formation and enrichment. Trees and plants provide food, wood, fiber, and fuel for human consumption. Flora help to regulate climate by sequestering CO_2, and control flooding by stabilizing soils and cycling water via uptake and evapotranspiration. Plants are significant in aesthetic, spiritual, and recreational aspects of human interactions.

Particulate matter can adversely impact plants and ecosystem services provided by plants by deposition to vegetative surfaces (U.S. EPA, 2009a, section 9.4.3). Particulates deposited on the surfaces of leaves and needles can block light, altering the radiation received by the plant. PM deposition can obstruct stomata limiting gas exchange, damage leaf cuticles, and increase plant temperatures. This level of PM accumulation is typically observed near sources of heavy deposition such as smelters and mining operations (U.S. EPA, 2009a, section 9.4.3). Plants growing on roadsides exhibit impact damage from near-road PM deposition, having higher levels of organics and heavy metals, and accumulate salt from road de-icing during winter months (U.S. EPA, 2009a, sections 9.4.3.1 and 9.4.5.7).

In addition to damage to plant surfaces, deposited PM can be taken up by plants from soil or foliage. The ability of vegetation to take up heavy metals and organics is dependent upon the amount, solubility, and chemical composition of the deposited PM. Uptake of PM by plants from soils and vegetative surfaces can disrupt photosynthesis, alter pigments and mineral content, reduce plant vigor, decrease frost hardiness, and impair root development. The Integrated Science Assessment indicates that there are little or no effects on foliar processes at ambient levels of PM (U.S. EPA, 2009a, sections 9.4.3 and 9.4.7). However, damage due to atmospheric pollution can occur near individual point sources or under conditions where plants are subjected to multiple stressors.

Although all heavy metals can be directly toxic at sufficiently high concentrations, only Cu, Ni, and Zn have been documented as being frequently toxic to plants (U.S. EPA, 2004), while toxicity due to Cd, Co, and Pb has been observed less frequently (Smith, 1990; U.S. EPA, 2009a, section 9.4.5.3). In general, plant growth is negatively correlated with trace metal and heavy metal concentration in soils and plant tissue (Audet and Charest, 2007). Trace metals, particularly heavy metals, can influence forest growth. Growth suppression of foliar microflora has been shown to result from iron (Fe), aluminum (Al), and Zn. These three metals can also inhibit fungal spore formation, as can Cd, Cr, magnesium (Mg), and Ni (see Smith, 1990). Metals cause stress and decreased photosynthesis (Kucera et al., 2008) and disrupt numerous enzymes and metabolic pathways (Strydom et al., 2006). Excessive concentrations of metals result in phytotoxicity.

New information since the last review provides additional evidence of plant uptake of organics (U.S. EPA, 2009a, section 9.4.6). An area of active study is the impact of PAHs on provisioning ecosystem services due to the potential for human and other animal exposure via food consumption (U.S. EPA, 2009a, section 9.4.6 page 9–190). The uptake of PAHs depends on the plant species, site of deposition, physical and chemical properties of the organic compound, and prevailing environmental conditions. It has been established that most bioaccumulation of PAHs by plants occurs via leaf uptake, and to a lesser extent, through roots. Differences between species in uptake of PAHs confound attempts to quantify impacts to ecosystem provisioning services.

Plants as ecosystem regulators can serve as passive monitors of pollution (U.S. EPA, 2009a, section 9.4.2.3). Lichens and mosses are sensitive to pollutants associated with PM and have been used with limited success to show spatial and temporal patterns of atmospheric deposition of metals (U.S. EPA, 2009a, section 9.4.2.3). A limitation to employing mosses and lichens to detect for the presence of air pollutants is the difference in uptake efficiencies of metals between species. Thus, quantification of ecological effects is not possible due to the variability of species responses (U.S. EPA, 2009a, section 9.4.2.3).

A potentially important regulating ecosystem service of plants is their capacity to sequester contaminants (U.S. EPA, 2009a, section 9.4.5.3). Ongoing research on the application of plants to environmental remediation efforts are

yielding some success in removing heavy metals and organics from contaminated sites (phytoremediation) with tolerant plants such as the willow tree (*Salix* spp.) and members of the family Brassicaceae (U.S. EPA, 2009a, section 9.4.5.3). Tree canopies can be used in urban locations to capture particulates and improve air quality (Freer-Smith et al., 2004). Plant foliage is a sink for Hg and other metals and this regulating ecosystem service may be impacted by atmospheric deposition of trace metals.

An ecological endpoint (phytochelatin concentration) associated with presence of metals in the environment has been correlated with the ecological effect of tree mortality (Grantz et al., 2003). Metal stress may be contributing to tree injury and forest decline in the Northeastern U.S. where red spruce populations are declining with increasing elevation. Quantitative assessment of PM damage to forests potentially could be conducted by overlaying PM sampling data and elevated phytochelatin levels. However, limited data on phytochelatin levels in other species currently hinders use of this peptide as a general biomarker for PM.

The presence of PM in the atmosphere affects ambient radiation as discussed in the Integrated Science Assessment which can impact the amount of sunlight received by plants (U.S. EPA, 2009a, section 9.4.4). Atmospheric PM can change the radiation reaching leaf surfaces through attenuation and by converting direct radiation to diffuse radiation. Diffuse radiation is more uniformly distributed in a tree canopy, allowing radiation to reach lower leaves. The net effect of PM on photosynthesis depends on the reduction of photosynthetically active radiation (PAR) and the increase in the diffuse fraction of PAR. Decreases in crop yields (provisioning ecosystem service) have been attributed to regional scale air pollution, however, global models suggest that the diffuse light fraction of PAR can increase growth (U.S. EPA, 2009a, section 9.4.4).

b. Soil and Nutrient Cycling

Many of the major indirect plant responses to PM deposition are chiefly soil-mediated and depend on the chemical composition of individual components of deposited PM. Major ecosystem services impacted by PM deposition to soils include support services such as nutrient cycling, products such as crops and regulating flooding and water quality. Upon entering the soil environment, PM pollutants can alter ecological processes of energy flow and nutrient cycling, inhibit nutrient uptake to plants, change microbial community structure and, affect biodiversity. Accumulation of heavy metals in soils depends on factors such as local soil characteristics, geologic origin of parent soils, and metal bioavailability. It can be difficult to assess the extent to which observed heavy metal concentrations in soil are of anthropogenic origin (U.S. EPA, 2009a, section 9.4.5.1). Trace element concentrations are higher in some soils that are remote from air pollution sources due to parent material and local geomorphology.

Heavy metals such as Zn, Cu, and Cd and some pesticides can interfere with microorganisms that are responsible for decomposition of soil litter, an important regulating ecosystem service that serves as a source of soil nutrients (U.S. EPA, 2009a, sections 9.4.5.1 and 9.4.5.2). Surface litter decomposition is reduced in soils having high metal concentrations. Soil communities have associated bacteria, fungi, and invertebrates that are essential to soil nutrient cycling processes. Changes to the relative species abundance and community composition can be quantified to measure impacts of deposited PM to soil biota. A mutualistic relationship exists in the rhizophere (plant root zone) between plant roots, fungi, and microbes. Fungi in association with plant roots form mycorrhizae that are essential for nutrient uptake by plants. The role of mychorrizal fungi in plant uptake of metals from soils and effects of deposited PM on soil microbes is discussed in section 9.4.5.2 of the Integrated Science Assessment.

c. Wildlife

Animals play a significant role in ecosystem function including nutrient cycling and crop production (supporting ecosystem service), and as a source of food (provisioning ecosystem service). Cultural ecosystem services provided by wildlife include bird and animal watching, hunting, and fishing. Impacts on these services are dependent upon the bioavailability of deposited metals and organics and their respective toxicities to ecosystem receptors. Pathways of PM exposure to fauna include ingestion, absorption and trophic transfer. Bioindicator species (known as sentinel organisms) can provide evidence of contamination due to atmospheric pollutants. Use of sentinel species can be of particular value because chemical constituents of deposited PM are difficult to characterize and have varying bioavailability (U.S. EPA, 2009a, section 9.4.5.5). Snails readily bioaccumulate contaminants such as PAHs and trace metals. These organisms have been deployed as biomonitors for urban pollution and have quantifiable biomarkers of exposure including growth inhibition, impairment of reproduction, peroxidomal proliferation, and induction of metal detoxifying proteins (metallothioneins) (Gomet-de Vaufleury, 2002; Regoli, et. al, 2006). Earthworms have also been used as sensitive indicators of soil metal contamination.

Evidence of deposited PM effects on animals is limited (U.S. EPA, 2009a, section 9.4.5.5). Trophic transfer of pollutants of atmospheric origin has been demonstrated in limited studies. PM may also be transferred between aquatic and terrestrial compartments. There is limited evidence for biomagnifications of heavy metals up the food chain except for Hg which is well known to move readily through environmental compartments (U.S. EPA, 2009a, section 9.4.5.6). Bioconcentration of POPs and PBDEs in the Arctic and deep-water oceanic food webs indicates the global transport of particle-associated organics (U.S. EPA, 2009a, section 9.4.6). Salmon migrations are contributing to metal accumulation in inland aquatic systems, potentially impacting the provisioning and cultural ecosystem service of fishing (U.S. EPA, 2009a, section 9.4.6). Stable isotope analysis can be applied to establish linkages between PM exposure and impacts to food webs however, the use of this evaluation tool is limited for this ecological endpoint due to the complexity of most trophic interactions (U.S. EPA, 2009a, section 9.4.5.6). Foraging cattle have been used to assess atmospheric deposition and subsequent bioaccumulation of Hg and trace metals and their impacts on provisioning services (U.S. EPA, 2009a, section 9.4.2.3).

d. Water

New limited information on impacts of deposited PM on receiving water bodies indicate that the ecosystem services of primary production, provision of fresh water, regulation of climate and floods, recreational fishing and water purification are adversely impacted by atmospheric inputs of metals and organics (U.S. EPA, 2009a, sections 9.4.2.3 and 9.4.5.4). Deposition of PM to surfaces in urban settings increases the metal and organic component of storm water runoff (U.S. EPA, 2009a, sections 9.4.2.3). This atmospherically-associated pollutant burden can then be toxic to aquatic biota.

Atmospheric deposition can be the primary source of some organics and metals to watersheds. The contribution of atmospherically deposited PAHs to aquatic food webs was demonstrated in high elevation mountain lakes with no other anthropogenic contaminant sources (U.S. EPA, 2009a, section 9.4.6). Metals associated with PM deposition limit phytoplankton growth, impacting aquatic trophic structure. Long-range atmospheric transport of 47 pesticides and degradation products to the snowpack in seven national parks in the Western U.S. was recently quantified indicating PM-associated contaminant inputs to receiving waters during spring snowmelt (Hageman et al., 2006).

The recently completed Western Airborne Contaminants Assessment Project (WACAP) is the most comprehensive database on contaminant transport and PM depositional effects on sensitive ecosystems in the U.S. In this project, the transport, fate, and ecological impacts of anthropogenic contaminants from atmospheric sources were assessed from 2002 to 2007 in seven ecosystem components (air, snow, water, sediment, lichen, conifer needles and fish) in eight core national parks (Landers et al., 2008). The goals of the study were to identify where the pollutants were accumulating, identify ecological indicators for those pollutants causing ecological harm, and to determine the source of the air masses most likely to have transported the contaminants to the parks (U.S. EPA, 2009a, section 9.4.6). The study concluded that bioaccumulation of semi-volatile organic compounds was observed throughout park ecosystems (Landers et al., 2008). Findings from this study included the observation of an elevational gradient in PM deposition with greater accumulation at higher altitude areas of the parks. Furthermore, specific ecological indicators were identified in the WACAP that can be useful in assessing contamination on larger spatial scales.

In the WACAP study, bioaccumulation and biomagnification of airborne contaminants were demonstrated on a regional scale in remote ecosystems in the Western United States. Contaminants were shown to accumulate geographically based on proximity to individual sources or source areas, primarily agriculture and industry (Landers et al., 2008). Although this assessment focuses on chemical species that are components of PM, it does not specifically assess the effects of particulates versus gas-phase forms; therefore, in most cases it is difficult to apply the results to this assessment based on particulate concentration and size fraction (U.S. EPA, 2009a, section 9.4.6). There is a need for ecological modeling of PM components in different environmental compartments to further elucidate links between PM and ecological indicators.

Europe and other countries are using the critical load approach to assess pollutant effects at the level of the ecosystem. This type of assessment requires site-specific data and information on individual species responses to PM. In respect to trace metals and organics, there are insufficient data for the vast majority of U.S. ecosystems to calculate critical loads. However, a methodology is being presented in the NO_X/SO_X Secondary Risk and Exposure Assessment (U.S. EPA, 2010h) to calculate atmospheric concentrations from deposition that may be applicable to other environmental contaminants.

e. Effects Associated With Ambient PM Concentrations

As reviewed above, there is considerable data on impacts of PM on ecological receptors, but few studies that link ambient PM concentrations to observed effect. This is due, in part, to the nature, deposition, transport and fate of PM in ecosystems. PM is not a single pollutant, but a heterogeneous mixture of particles differing in size, origin and chemical composition (U.S. EPA, 2009a, section 9.4.1). The heterogeneity of PM exists not only within individual particles or samples from individual sites, but to even a greater extent, between samples from different sites. Since vegetation and other ecosystem components are affected more by particulate chemistry than size fraction, exposure to a given mass concentration of airborne PM may lead to widely differing plant or ecosystem responses, depending on the particular mix of deposited particles. Many of the PM components bioaccumulate over time in organisms or plants making correlations to ambient concentrations of PM difficult.

Bioindicator organisms demonstrated biological effects including growth inhibition, metallothionein induction and reproductive impairment when exposed to complex mixtures of ambient air pollutants (U.S. EPA, 2009a, section 9.4.5.5). Other studies quantify uptake of metals and organics by plants or animals. However, due to the difficulty in correlating individual PM components to a specific physiological response, these studies are limited. Furthermore, there may be differences in uptake between species such as differing responses to metal uptake observed in mosses and lichens (U.S. EPA, 2009a, section 9.4.2.3). PM may also biomagnify across trophic levels confounding efforts to link atmospheric concentrations to physiological endpoints (U.S. EPA, 2009a, section 9.4.5.6).

Evidence of PM effects that are linked to a specific ecological endpoint can be observed when ambient levels are exceeded. 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). Extensive research on biota near point sources provide some of the best evidence of ecosystem function impacts and demonstrates that deposited PM has the potential to alter species composition over long time scales. The Integrated Science Assessment indicates at 4 km distance, species composition of vegetation, insects, birds, and soil microbiota changed, and within 1 km only the most resistant organisms were surviving (U.S. EPA, 2009a, section 9.4.5.7).

f. Conclusions in the Policy Assessment

Based on the above discussions, the Policy Assessment made the following observations:

(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.

Taking into consideration the responses to specific questions regarding the adequacy of the current secondary PM standards for ecological effects, the Policy Assessment concludes that the available information is insufficient to assess the adequacy of the protection for ecosystems afforded by the current suite of PM secondary standards (U.S. EPA, 2011a, p. 5–24). Ecosystem effects linked to PM are difficult to determine because the changes may not be observed until

pollutant deposition has occurred for many decades. Because the high levels necessary to cause injury occur only near a few limited point sources and/or on a very local scale, protection against these effects alone may not provide sufficient basis for considering a separate secondary NAAQS based on the ecological effects of particulate metals and organics. Data on ecological responses clearly linked with atmospheric PM is not abundant enough to perform a quantitative analysis although the WACAP study may represent an opportunity for quantification at a regional scale. The Policy Assessment further concludes that available evidence is not sufficient for 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).

The Policy Assessment considered the appropriateness of continuing to use the $PM_{2.5}$ and PM_{10} size fractions as the indicators for protection of ecological effects of PM. The chemical constitution of individual particles can be strongly correlated with size, and the relationship between particle size and particle composition can be quite complex, making it difficult in most cases to use particle size as a surrogate for chemistry. At this time it remains to be determined as to what extent PM secondary standards focused on a given size fraction would result in reductions of the ecologically relevant constituents of PM for any given area. Nonetheless, in the absence of information that provides a basis for specific standards in terms of particle composition, the Policy Assessment concludes that 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).

3. Materials Damage

Welfare effects on materials associated with deposition of PM include both physical damage (materials damage effects) and impaired aesthetic qualities (soiling effects). Because the effects of PM are exacerbated by the presence of acidic gases and can be additive or synergistic due to the complex mixture of pollutants in the air and surface characteristics of the material, this discussion will also include those particles and gases that are associated with the presence of ambient oxides of nitrogen and oxides of sulfur, as well as reduced forms of nitrogen (such as ammonia and ammonium ions) for completeness. Building upon the information presented in the last PM Staff Paper (U.S. EPA, 2005), and including the limited new information presented in Chapter 9 of the PM Integrated Science Assessment (U.S. EPA, 2009a) and *Annex E. Effects of NO_Y, NH_X, and SO_X on Structures and Materials of the Integrated Science Assessment for Oxides of Nitrogen and Sulfur-Ecological Criteria* (U.S. EPA, 2008c) the following sections consider the policy-relevant aspects of physical damage and aesthetic soiling effects of PM on materials including metal and stone.

The Integrated Science Assessment concludes 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). Particles contribute to these physical effects because of their electrolytic, hygroscopic and acidic properties, and their ability to sorb corrosive gases (principally sulfur dioxide). In addition, the deposition of ambient PM can reduce the aesthetic appeal of buildings and objects through soiling. Particles consisting primarily of carbonaceous compounds cause soiling of commonly used building materials and culturally important items such as statues and works of art. Soiling is the deposition of particles on surfaces by impingement, and the accumulation of particles on the surface of an exposed material that results in degradation of its appearance (U.S. EPA, 2009a, section 9.5). Soiling can be remedied by cleaning or washing, and depending on the soiled material, repainting.

The majority of available new studies on materials effects of PM are from outside the U.S., however, they provide limited new data for consideration of the secondary standard.

Metal and stone are also susceptible to damage by ambient PM. Considerable research has been conducted on the effects of air pollutants on metal surfaces due to the economic importance of these materials, especially steel, Zn, Al, and Cu. Chapter 9 of the PM Integrated Science Assessment and Annex E of the NO_X/SO_X Integrated Science Assessment summarize the results of a number of studies on the corrosion of metals (U.S. EPA, 2009a; U.S. EPA, 2008c). Moisture is the single greatest factor promoting metal corrosion, however, deposited PM can have additive, antagonistic or synergistic effects. In general, sulfur dioxide is more corrosive than oxides of nitrogen although mixtures of oxides of nitrogen, sulfur dioxide and other particulate matter corrode some metals at a faster rate than either pollutant alone (U.S. EPA, 2008c, Annex E.5.2). Information from both the PM Integrated Science Assessment and NO_X/SO_X Integrated Science Assessment suggest that the extent of damage to metals due to ambient PM is variable and dependent upon the type of metal, prevailing environmental conditions, rate of natural weathering and presence or absence of other pollutants.

The PM Integrated Science Assessment and NO_X/SO_X Integrated Science Assessment summarize the results of a number of studies on PM and stone surfaces. While it is clear from the available information that gaseous air pollutants, in particular sulfur dioxide, will promote the deterioration of some types of stones under specific conditions, carbonaceous particles (non-carbonate carbon) and particles containing metal oxides may help to promote the decay process. Studies on metal and stone summarized in the Integrated Science Assessment do not show an association between particle size, chemical composition and frequency of repair.

A limited number of new studies available on materials damage effects of PM since the last review consider the relationship between pollutants and biodeterioration of structures associated with microbial communities that colonize monuments and buildings (U.S. EPA, 2009a, section 9.5). Presence of air pollutants may synergistically enhance microbial deterioration processes. The role of heterotrophic bacteria, fungi and cyanobacteria in biodeterioration varied by local meterological conditions and pollutant components.

Particulate matter deposition onto surfaces such as metal, glass, stone and paint can lead to soiling. Soiling results when PM accumulates on an object and alters the optical characteristics (appearance). The reflectivity of a surface may be changed or presence of particulates may alter light transmission. These effects can impact the aesthetic value of a structure or result in reversible or irreversible damage to statues, artwork and architecturally or culturally significant buildings. Due to soiling of building surfaces by PM, the frequency and duration of cleaning may be increased. Soiling affects the aesthetic appeal of painted surfaces. In addition to natural

factors, exposure to PM may give painted surfaces a dirty appearance. Pigments in works of art can be degraded or discolored by atmospheric pollutants, especially sulfates (U.S. EPA, 2008c, Annex E–15).

Formation of black crusts due to carbonaceous compounds and buildup of microbial biofilms results in discoloration of surfaces. Black crust includes a carbonate component derived from building material and OC and EC. In limited new studies quantifying the organic carbon and elemental contribution to soiling by black crust, organic carbon predominated over elemental carbon at almost all locations (Bonazza et al., 2005). Limited new studies suggest that traffic is the major source of carbon associated with black crust formation (Putaud et al., 2004) and that soiling of structures in Oxford, UK showed a relationship with traffic and nitrogen dioxide concentrations (Viles and Gorbushina, 2003). These findings attempt to link atmospheric concentrations of PM to observed damage. However, no data on rates of damage are available and all studies were conducted outside of the U.S.

Based on the above discussion, the Policy Assessment makes 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 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.

Revisiting the overarching policy question as to whether the available scientific evidence supports or calls into question the adequacy of the protection for materials afforded by the current suite of secondary PM standards, the Policy Assessment concludes that no new evidence in this review calls into question the adequacy of the protection for materials afforded by the current standard (U.S. EPA, 2011a, p. 5–29). PM effects on materials can play no quantitative role in considering whether any revisions of the secondary PM NAAQS are appropriate at this time. Nonetheless, in the absence of information that provides a basis for establishing a different level of control, the Policy Assessment concludes 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).

4. CASAC Advice

Regarding the other 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 concludes 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 notes 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 notes 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 concludes that the published literature is insufficient to support a national standard for PM effects on ecosystem services (Samet, 2010c, p.23). CASAC notes 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 concludes 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 notes 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.

5. Administrator's Proposed Conclusions on Secondary Standards for Other PM-related Welfare Effects

Based on the above considerations and the advice of CASAC, the Administrator provisionally concludes that it is not appropriate to establish any distinct secondary PM standards to address other non-visibility PM-related welfare effects. Nonetheless, the Administrator concurs 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, including ecological effects, effects on materials, and climate impacts. In the absence of information that would support any different standards, the Administrator proposes generally to retain the current suite of secondary PM standards[182] to address non-visibility welfare effects. These secondary standards were set identical to the primary PM standards in the last review. More specifically, the Administrator proposes 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 proposes to retain the level of the current standard and to revise the form of the standard by removing the option for spatial averaging for the reasons discussed below in section VII.A. 2. In so doing, she 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.

F. Administrator's Proposed Decisions on Secondary PM Standards

With regard to the secondary PM standards, the Administrator proposes 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 distinct secondary standard is defined

[182] 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.

in terms of a calculated $PM_{2.5}$ light extinction indicator, translated into the deciview scale, which is referred to as a $PM_{2.5}$ visibility index; a 24-hour averaging time; a 90th percentile form, averaged over 3 years; and a level set at one of two options—either 30 dv or 28 dv. The Administrator solicits comment on a range of levels for such a standard down to 25 dv, as well as on alternative standards to address PM-related visibility impairment, including a sub-daily averaging time (e.g., 4 hours) and associated alternative levels in the range of 30 to 25 dv. To address other non-visibility welfare effects, the Administrator proposes to revise the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging and to retain all other elements of the current suite of secondary PM standards.

VII. Interpretation of the NAAQS for PM

With regard to the NAAQS for $PM_{2.5}$, this section discusses EPA's proposed revisions to the data handling procedures in 40 CFR part 50, appendix N, for the proposed primary and secondary annual and 24-hour standards for $PM_{2.5}$ (referred to as $PM_{2.5}$ standards) and for the proposed distinct secondary standard for $PM_{2.5}$ to address PM-related visibility impairment (referred to as the $PM_{2.5}$ visibility index standard).[183] Appendix N describes the computations necessary for determining when these standards are met and also addresses which measurement data are appropriate for comparison to the proposed standards, as well as data reporting protocols, data completeness criteria, and rounding conventions.

As discussed in sections III and VI above, the EPA is proposing 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); (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 non-visibility-related welfare protection (section VI.F); and (3) establish a distinct secondary $PM_{2.5}$ visibility index standard (section VI.F). The EPA proposes to revise appendix N to conform to the proposed revisions to the standards. The Agency also proposes to make additional changes in the appendix N data handling provisions to codify existing practices currently included in guidance documents or implemented as EPA standard operating procedures as well as to provide greater clarity and consistency in the application of these provisions. The proposed revisions to appendix N are discussed in section VII.A below.

Section 1(b) of appendix N refers to special considerations that may be given to data resulting from exceptional events. An exceptional event is defined in 40 CFR 50.1 as an event that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. Air quality data that are determined to have been affected by an exceptional event under the procedural steps, substantive criteria, and schedule specified in section 50.14 may be excluded from consideration when EPA makes a determination that an area is meeting or violating the associated NAAQS. Proposed revisions to the schedule specified in section 50.14 for data flagging and submission of demonstrations for exceptional events data considered for initial area designations under the proposed revised primary and secondary PM standards are discussed in section VII.B below.

Several proposed updates and clarifications to the data handling provisions associated with AQI reporting in 40 CFR part 58, Appendix G are discussed in section VII.C below. These modifications reflect the proposed changes to the AQI sub-index for $PM_{2.5}$ as discussed in section V above and harmonize reporting procedures for AQI sub-indices for other criteria pollutants.

A. Proposed Amendments to Appendix N: Interpretation of the NAAQS for $PM_{2.5}$

As discussed below, the proposed revisions to appendix N corresponding to proposed changes in the standards addressed in sections III and VI above are: (1) Modification of the level of the primary annual $PM_{2.5}$ standard (sections VII.A.1 and VII.A.4); (2) modification of the form of the primary and secondary annual $PM_{2.5}$ standards to remove the option for spatial averaging (sections VII.A.2 and VII.A.4); and (3) addition of data handling procedures that detail how to make comparisons to the proposed secondary standard for $PM_{2.5}$ that addresses PM-related visibility impairment (section VII.A.5), as well as to summarize associated changes proposed in other sections of appendix N to accommodate this proposed standard (sections VII.A.1, VII.A.2, and VII.A.3). In addition to these three proposed appendix modifications that are discussed in depth in sections III and VI above, the EPA also proposes additional revisions to appendix N in order to: (1) Better align appendix N language and requirements with proposed 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 EPA standard operating procedures; and (4) provide enhanced clarity and consistency in the articulation and application of appendix N provisions. Key elements of the proposed revisions to appendix N are summarized in sections VII.A.1 through VII.A.5 below, where each of these preamble sections corresponds to the similarly numbered section in appendix N.

1. General

The EPA proposes to modify section 1.0 of appendix N to provide additional clarity regarding the scope and interpretation of the NAAQS for $PM_{2.5}$. This section would reference the proposed revisions to the primary annual $PM_{2.5}$ standard and the proposed revision to the form of the secondary annual $PM_{2.5}$ standard (40 CFR 50.18) and the proposed addition of a distinct secondary $PM_{2.5}$ visibility index standard (40 CFR 50.19). As summarized in section VI.F, the proposed secondary standard is defined in terms of a calculated $PM_{2.5}$ light extinction indicator, which would use 24-hour average speciated $PM_{2.5}$ mass concentration data, along with associated relative humidity information, to calculate light extinction, which would then be translated to the deciview scale (referred to as a $PM_{2.5}$ visibility index); a 24-hour averaging time; a 90th percentile form averaged over 3 years; and a level of either 30 dv or 28 dv. The result (i.e., the $PM_{2.5}$ visibility index design value) would be compared to the level of the standard. As noted earlier, the NAAQS indicator and proposed data handling procedures are similar to those of the Regional Haze Program. The EPA proposes to add to section 1.0 of appendix N, a reference to section 2.9 of appendix C to 40 CFR part 58 which identifies the acceptable methods for the speciated $PM_{2.5}$ mass concentration data. With regard to the appendix N term definitions which are delineated in this initial section, the EPA proposes to

[183] With regard to the PM_{10} NAAQS, as summarized in sections IV.F and VI.F, the EPA is proposing to retain the current primary and secondary PM_{10} standards. Data handling procedures for these PM_{10} standards would remain as presented in 40 CFR part 50, appendix K.

add, modify, or eliminate term definitions, as appropriate, in accordance with the proposed data handling rule revisions such as the addition of terms associated with the proposed secondary $PM_{2.5}$ visibility index standard and the modification of terms that referenced spatial averaging. Additional term definitions are also being added to reference otherwise unchanged appendix N logic in an effort to streamline the appendix text, enhance clarity and thus improve readability and understanding.

2. Monitoring Considerations

The EPA proposes revisions to section 2.0 of appendix N consistent with the proposed modification of the form of the primary annual $PM_{2.5}$ standard to remove the option for spatial averaging. As described in more detail in section III.E.3.a above, the EPA is proposing to remove this option as part of the form of the primary annual $PM_{2.5}$ standard. This proposed change is based on an analysis that indicates 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, while, as discussed in section VI.E.5 above, the EPA is proposing to retain the current secondary annual $PM_{2.5}$ standard to provide protection for non-visibility welfare effects, the EPA believes it would be reasonable and appropriate to align the data handling procedures for the primary and secondary annual $PM_{2.5}$ standards. Therefore, the EPA proposes to remove the option for spatial averaging for the secondary annual $PM_{2.5}$ standard consistent with the proposed change in the form of the primary annual $PM_{2.5}$ standard. The EPA 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.

Consistent with the proposed change to revise the forms of the primary and secondary annual $PM_{2.5}$ standards, the levels of the standards would be compared to measurements from each appropriate (i.e., ''eligible'') monitoring site in an area operated in accordance with the network technical requirements specified in 40 CFR 58.11, the operating schedule described in 40 CFR 58.12, and the special considerations for data comparisons to the NAAQS 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 this proposed change, the EPA proposes to remove all references to the spatial averaging option throughout appendix N.

3. Requirements for Data Use and Reporting for Comparisons With the NAAQS for $PM_{2.5}$

The EPA proposes to make changes to section 3.0 of appendix N to correspond with the proposed secondary $PM_{2.5}$ visibility index standard, to improve consistency with procedures used for other NAAQS, and to improve consistency with current standard operating procedures. Specifically, the EPA proposes revisions to this section regarding: (1) Requirements for reporting monitored aggregated $PM_{2.5}$ and speciated $PM_{2.5}$ mass concentration data; (2) clarification of monitoring data appropriate to compare to the $PM_{2.5}$ and $PM_{2.5}$ visibility index NAAQS; (3) clarification of procedures for using hourly concentrations to calculate 24-hour concentrations; and (4) clarification of procedures for combining monitoring data from collocated instruments into a single ''combined site'' record. Further, the EPA proposes to codify, in this same section, modifications to the $PM_{2.5}$ data handling provisions to make them consistent with recent changes made for other criteria pollutants. For example, data for which the certification deadline has passed, and the monitoring agency has not requested certification of the data, can nevertheless be used to determine compliance with the $PM_{2.5}$ NAAQS and the $PM_{2.5}$ visibility index NAAQS when EPA judges the data to be complete and accurate.

With regard to the criteria for reporting $PM_{2.5}$ concentrations, section 3.0 of appendix N specifies that $PM_{2.5}$ mass concentrations used for NAAQS comparisons shall be reported in units of $\mu g/m^3$ with the values truncated (not rounded) to one digit to the right of the decimal point (i.e., truncated to one decimal place). Since, to date, appendix N has dealt only with $PM_{2.5}$ mass concentrations, intrinsically these requirements have dealt only with that particular set of data.

With regard to the proposed secondary $PM_{2.5}$ visibility index standard, the EPA already has a requirement in 40 CFR 58.16 to report speciated $PM_{2.5}$ mass concentration data. This includes the nine required speciated $PM_{2.5}$ mass concentration inputs (i.e., sulfate, nitrate, OC (and related $PM_{2.5}$ OC which is reported OC with an adjustment for the organic carbon artifact present on a filter), EC, Al, Si, Ca, Fe, and Ti) used to calculate $PM_{2.5}$ visibility index values as described in section VII.A.5 below. Specifically, the EPA proposes to require that all nine parameters be used in the appendix N procedures in units of $\mu g/m^3$ with the values rounded to four decimal places (or three significant digits if the value is 0.1 $\mu g/m^3$ or larger). These rounding conventions are consistent with the AQS reporting protocols used in the CSN program, discussed in section VIII.A.2 below, which is proposed to be a major source of ambient data used in calculating $PM_{2.5}$ visibility index design values to compare to the level of proposed secondary NAAQS.

Monitoring sites eligible for comparison to the NAAQS for $PM_{2.5}$ include those following the network technical requirements specified in 40 CFR 58.11 as well as following the eligibility criteria specified in 40 CFR 58.30.[184] However, as discussed in section VIII.A.1 below, an analysis of the quality of data from two different methods used by FEMs has indicated that some sites with continuous $PM_{2.5}$ FEMs have an acceptable degree of comparability with collocated FRMs, while other FEMs have less acceptable data comparability that would not meet the performance criteria originally used to approve the FEMs (Hanley and Reff, 2011). Therefore, as explained in more detail in section VIII.B.3.b.ii below, the EPA is proposing to allow monitoring agencies to identify $PM_{2.5}$ FEMs that are not providing data of sufficient comparability to the FRM and, with EPA approval, to exclude the use of these data in making comparisons to the NAAQS for $PM_{2.5}$.[185]

[184] As discussed in more detail in section VIII.B.2.b below, the EPA is proposing to change the current presumption in 40 CFR 58.30 that micro- and middle-scale monitoring sites are ''unique'' and are comparable only to the 24-hour $PM_{2.5}$ standards, unless approved by the Regional Administrator to collectively identify a larger region of localized high ambient $PM_{2.5}$ concentrations. Today's proposal, if finalized, would change this presumption, such that micro- and middle-scale monitoring sites would not be presumed to be unique and, therefore, would be comparable to the annual $PM_{2.5}$ standards as well as the 24-hour $PM_{2.5}$ standards, unless the Regional Administrator determines that the micro- or middle-scale site is unique.

[185] 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 would also be allowed to exclude these data in making comparisons to the $PM_{2.5}$ and $PM_{2.5}$ visibility index NAAQS. Currently, there are no designated ARMs for $PM_{2.5}$.

With regard to data handling procedures for using hourly mass concentrations to calculate 24-hour average mass concentrations, current procedures are specific for handling aggregated $PM_{2.5}$ mass concentrations and are not currently relevant for handling the speciated $PM_{2.5}$ mass concentrations that would be used for calculating $PM_{2.5}$ visibility index design values for the proposed secondary standard. In considering data handling procedures for hourly speciated $PM_{2.5}$ mass concentrations, the EPA notes that the vast majority of speciation data collected across the country are from filter-based sampling methods which typically operate on a 24-hour sampling period. There are several monitoring sites reporting hourly speciation data, but even in these cases the methods employed only provide for a small number of speciation parameters (e.g., EC, OC, sulfate) to be reported. However, in anticipation that such continuous methods might be more widely implemented for the speciated $PM_{2.5}$ mass components in the future, the EPA proposes to add clarifying language to section 3.0(a) to indicate that the data handling procedures for using hourly concentration data to calculate 24-hour average concentration data would be applicable to both aggregated $PM_{2.5}$ mass concentrations and speciated $PM_{2.5}$ mass concentrations.

With respect to the procedures for combining monitored data from collocated instruments into a single ''combined site'' data record, the EPA proposes 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). The EPA is not proposing to change the procedures for calculating a combined site record [186] but rather the subsequent evaluation of whether the specific measurements are considered ''creditable'' or ''extra'' samples. 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.

Before the introduction of continuous $PM_{2.5}$ 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 continuous $PM_{2.5}$ FEMs to FRMs operated in some monitoring agency networks, and as briefly discussed above and in more detail in section VIII.A.1 below, many monitoring agencies have kept the FRM as the ''primary'' monitor while continuing to evaluate the continuous FEM monitor. In cases where the FRM either does not have a scheduled measurement or has a measurement that is invalidated and the continuous FEM data are available for use, and the continuous FEM data are not identified as not to be used (i.e., a special purpose monitor (SPM) in its first 24 months of operation) the FEM data will be substituted into the site record. In cases where the continuous FEM measurements are reported on the FRM ''off'' days, these data are technically considered ''extra'' samples.

In light of this practice, the EPA modified standing operating procedures and now proposes a conforming revision to section 3.0(e) whereby 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, consistent with current practices, if data from a collocated FEM are missing on an FRM ''off'' day (and no unscheduled FRM data are reported that day), the EPA proposes not to identify these as ''scheduled'' samples. Thus, reported data generated from the collocated continuous FEMs can only help increase data capture rates. The EPA specifically solicits comment on whether ''non-primary'' (i.e., collocated) FEM data should be combined with the primary data as part of the comparison to the NAAQS for $PM_{2.5}$.

The EPA proposes to utilize the same general procedures for combining speciated $PM_{2.5}$ mass concentration data from collocated monitors into a single ''combined site'' record as those specified for the $PM_{2.5}$ mass measurements.

4. Comparisons With the Annual and 24-Hour $PM_{2.5}$ NAAQS

Section 4.0 of appendix N specifies the procedures for comparing monitored data to the annual and 24-hour $PM_{2.5}$ standards. The EPA proposes 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.F) and to retain the current level of the secondary annual $PM_{2.5}$ standard (section VI.F), the EPA proposes to modify section 4.1(a) of appendix N to separately list the levels of the primary and secondary annual $PM_{2.5}$ standards. Additionally, consistent with the proposed decision 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 proposes to amend section 4.4 of appendix N to remove equations and associated instructions that relate to spatial averaging.

With regard to assessments of data completeness, the EPA proposes to include two additional data substitution tests [187] (making a total of three data substitution tests) 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 checks). Data substitution tests are diagnostic in nature; that is; they are only used in an illustrative manner to

[186] 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.

[187] 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'').

show that the NAAQS status based on incomplete data is reasonable. If an ''incomplete'' design value using substituted data passes the diagnostic test, this ''incomplete'' design value (without the data substitutions) is then considered the true actual ''complete'' design value. If an incomplete design value does not pass any stipulated data substitution test, then the original design value is still considered incomplete.

Currently, section 4.1(c) specifies one data substitution test for validating an otherwise incomplete design value. This diagnostic test is only applicable to the primary and secondary annual $PM_{2.5}$ standard and only applies in instances of a violation. The EPA proposes to modify the data completeness requirements by adding two additional data substitution tests for handling incomplete data sets in order to make the data handling procedures for $PM_{2.5}$ more consistent with the procedures used for other NAAQS pollutants and to codify existing practices currently included in guidance documents (U.S. EPA, 1999) and implemented as EPA standard operating procedures. The proposed additional data substitution tests would be applicable for making comparisons to the primary and secondary annual and 24-hour $PM_{2.5}$ standards. One of these tests uses collocated PM_{10} data to fill in ''slightly incomplete'' [188] data records, and the other uses quarter-specific maximum values to fill in ''slightly incomplete'' data records.

With regard to identifying annual 98th percentile concentrations for comparison to the primary and secondary 24-hour $PM_{2.5}$ standards, the EPA proposes to simplify the procedures used with an approved seasonal sampling schedule. Specifically, the EPA proposes to eliminate the use of a special formula for calculating annual 98th percentile concentrations with a seasonal sampling schedule and proposes to use only one method for calculating annual 98th percentile concentrations at all sites.

Currently, with an approved seasonal sampling schedule, a site typically samples as required 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. 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 (U.S. EPA, 1999), and, where appropriate, with official OAQPS design value calculations (71 FR 61211, October 17, 2006). In cases where there is a balanced [189] (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 collocate 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. The end result of combining collocated FRM and FEM data is effectively an ''every day'' site-based sampling frequency, resulting 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'' FEM data and there would be no need for the special formula for calculating annual 98th percentile concentrations on the combined site data.

The EPA notes that currently there are very few $PM_{2.5}$ FRM monitors that actually operate on an approved seasonal sampling schedule (only 15 sites out of approximately 1,000 total sites in 2010) and that almost half of these sites have a collocated $PM_{2.5}$ FEM monitor. For the most recent 3-year period (2008–2010), the annual 98th percentile concentrations calculated with the special formula at these 15 sites were approximately five percent lower than if the regular procedure was used. The EPA also notes that, in the last review, the Agency modified the monitoring requirements for areas with an FRM operating on a non-daily schedule such that, if the design values were within five percent of the 24-hour $PM_{2.5}$ NAAQS, such areas are 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). Thus, the EPA proposes to simplify the data handling procedures for sites operating on a seasonal sampling schedule by eliminating the special formula and all references to it based on: (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 requirements for every day sampling in areas with design values that are within five percent of the 24-hour $PM_{2.5}$ NAAQS; and (3) the EPA requirement that FRMs operating on an approved seasonal sampling schedule 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). Thus, the EPA proposes to use only one method for calculating annual 98th percentile concentrations for all sites, that being the ''regular'' table look-up method specified in section 4.5(a)(1) of appendix N. The EPA solicits comment on the proposal to eliminate the special formula for sites operating on a seasonal sampling schedule.

5. Data Handling Procedures for the Proposed Secondary $PM_{2.5}$ Visibility Index NAAQS

As summarized in section VI.F above, the EPA is proposing to establish a distinct secondary standard for $PM_{2.5}$ to address PM-related visibility impairment. The EPA is proposing to define this standard in terms of a $PM_{2.5}$ visibility index (section VI.D.1.c), which would use 24-hour average speciated $PM_{2.5}$ mass concentration and historic monthly average relative humidity data to calculate $PM_{2.5}$ light extinction, translated into the deciview scale, similar to the Regional Haze Program.

The EPA proposes to add a new section 5.0 to appendix N to detail the data handling procedures for calculating $PM_{2.5}$ visibility index design values and comparing these design values to the level of the proposed $PM_{2.5}$ visibility index NAAQS. These proposed procedures are drawn from and are generally consistent with the original approach used in the Regional Haze Program [U.S. EPA, 2003] and discussed

[188] ''Slightly incomplete'' is defined as less than 75 percent but greater than or equal to 50 percent data capture.

[189] 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.

in the Policy Assessment (U.S. EPA, 2011a, chapter 4, Appendix G).

As discussed in section VI.B.1.a above, visibility impairment is caused by the scattering and absorption of light by suspended particles and gases in the atmosphere. The combined effect of light scattering and absorption by both particles and gases is characterized as light extinction. The amount of light extinction contributed by PM depends on the particle size distribution and composition, as well as the concentrations of speciated components of ambient PM. To make estimation of light extinction more practical, visibility scientists have developed simple algorithms, referred to as the IMPROVE algorithms to relate speciated $PM_{2.5}$ concentrations to light extinction. 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.

The EPA proposes to define the $PM_{2.5}$ visibility index using a $PM_{2.5}$ light extinction indicator calculated on a 24-hour basis using the original IMPROVE algorithm without the terms for coarse mass and Rayleigh scatter. As discussed in section VI.D.1.c above, using such an index appropriately reflects the relationship between ambient PM and PM-related light extinction. When converting $PM_{2.5}$ light extinction values in Mm^{-1} to the deciview scale, the Rayleigh scattering term must be included to avoid the possibility of negative values.

Consistent with the analyses and terminology used in the Policy Assessment (U.S. EPA, 2011a, chapter 4, Appendix G), $PM_{2.5}$ light extinction ($PM_{2.5}$ b_{ext}) is defined as

$$\begin{aligned} PM_{2.5}\ b_{ext} = {} & 3 \times f(RH) \times [\text{Sulfate}] \\ & + 3 \times f(RH) \times [\text{Nitrate}] \\ & + 4 \times [\text{Organic Mass}] \\ & + 10 \times [\text{Elemental Carbon}] \\ & + 1 \times [\text{Fine Soil}] \end{aligned} \qquad \text{(appendix N, equation 6)}$$

The above formula is implemented using 24-hr speciated $PM_{2.5}$ concentration data together with monthly climatological relative humidity factors as outlined below. The six steps involved in the calculation of the $PM_{2.5}$ visibility index values are as follows:

(1) As discussed in Section VI.B.1.a above, ''sulfate'' is defined as ammonium sulfate and ''nitrate'' is defined as ammonium nitrate. Multiply 24-hour average speciation measurements of sulfate and nitrate ions by factors 1.375 and 1.29, respectively, to convert the reported ion concentrations into sulfate and nitrate ammonium concentrations (appendix N, equations 5a and 5b).

(2) Convert artifact adjusted measured OC, which is termed ''$PM_{2.5}$ OC'', into an estimate of organic mass (OM). The $PM_{2.5}$ OC is derived by subtracting the sampler-dependent OC measurement artifact from the measured OC.[190] The $PM_{2.5}$ OC is then multiplied by 1.4 to account for the additional mass of hydrogen, oxygen and other elements associated with the carbon in measured OC (appendix N, equation 5c).

(3) Calculate fine soil/crustal $PM_{2.5}$ (FS) component based on measurements of five soil derived elements (i.e., Al, Si, Ca, Fe, and Ti) together with multipliers to account for their normal oxides [191] (appendix N, equation 5d).

(4) Determine a representative long-term monthly average of hourly relative humidity hygroscopic growth factors, referred to as f(RH) values, at the speciation monitoring site, for each month of the year. There will be 12 such values for any monitoring site. The EPA proposes that the f(RH) values be selected using historical data. A spatial interpolation of historical relative humidity data is available which presents a gridded field of f(RH) values across the U.S. at a resolution of 0.25 degrees (SAIC, 2001). As discussed in section VI.D.2.a.ii above, these monthly average values were developed to support the Regional Haze Program and are based on considering any hour with relative humidity greater than 95 percent as 95 percent. Because 10 years of hourly data were used to produce a single humidity term for each month, the EPA believes that the resulting monthly average of the humidity term is sufficient and appropriate to reduce the effects of fog or precipitation. The EPA proposes that the 10-year climatological data base be used to specify the f(RH) value associated with the grid-point closest in distance to the speciation monitoring site.[192]

(5) Apply the original IMPROVE algorithm without the terms for coarse mass and Rayleigh scatter (appendix N, equation 6) to calculate a daily average $PM_{2.5}$ light extinction ($PM_{2.5}$ b_{ext}, in units of Mm^{-1}).

(6) To translate $PM_{2.5}$ light extinction to the deciview scale for making comparisons to the level of the proposed secondary $PM_{2.5}$ visibility index standard, the following equation, which includes the term for Rayleigh scattering term, is used:

$$PM_{2.5}\ \text{visibility index (dv)} = 10 \ln [(PM_{2.5}\ b_{ext}\ \text{in}\ Mm^{-1} + 10)/10] \qquad \text{(appendix N, equation 7)}$$

The EPA solicits comment on all aspects of the calculation of the $PM_{2.5}$ visibility index, $PM_{2.5}$ b_{ext}.

As discussed in section VI.D.3 above, the EPA is proposing a 90th percentile form, averaged over 3 years, for the proposed secondary $PM_{2.5}$ visibility index standard. Thus, 3 years of valid 24-hr speciated $PM_{2.5}$ mass concentration data would be required to calculate $PM_{2.5}$ visibility index design values. The proposed new section 5.0 for appendix N addresses data completeness requirements for speciated $PM_{2.5}$ mass concentrations (section 5.0(b)), specifically that $PM_{2.5}$ visibility index values be present for at least 11 creditable days of each quarter, for each of the three consecutive years. The 11 sample minimum is consistent with criteria specified for the current and proposed primary and secondary annual $PM_{2.5}$ standards (i.e., 40 CFR part 50, appendix N 4.1(b)) and, furthermore, has been used extensively for various PM characterization exercises (e.g., U.S. EPA, 2009a; U.S. EPA, 2011a). In addition, the proposed new section 5.0 outlines procedures for identifying annual 90th percentile $PM_{2.5}$ visibility index values (section 5.0(d)(3)) similar to procedures used to identify annual 98th percentile values for the primary

[190] In the IMPROVE program, artifact adjusted OC (i.e., $PM_{2.5}$ OC) is simply reported as OC. That is the value used to produce OM for haze calculations. For the CSN measurements, the OC artifact needed to convert measured OC into $PM_{2.5}$ OC is estimated from sampler-specific network-wide field blanks (Frank, 2012).

[191] Fine Soil = 2.2[Al] + 2.49[Si] + 1.63[Ca] + 2.42[Fe] + 1.94[Ti]

[192] To facilitate the use of relative humidity data, the EPA would make this ten-year climatological data base publically available on its Web site.

and secondary 24-hour $PM_{2.5}$ standards. In situations where a year does not contain the minimum 11 creditable samples in each quarter, the EPA proposes (in section 5.0) to still consider the identified 90th percentile index value to be valid if it, or a 3-year average of 90th percentile index values (i.e., a visibility impairment design value) including it, exceeds the level of the NAAQS. The EPA is not proposing any data substitution tests for $PM_{2.5}$ visibility index design values like those codified and proposed for the aggregated $PM_{2.5}$ mass standard design values; however, the EPA solicits comment on the inclusion of such data substitution tests.

With regard to rounding conventions, the EPA proposes that all decimal digits be retained in the intermediate steps of the calculation of the $PM_{2.5}$ light extinction indicator and that the $PM_{2.5}$ visibility index values be rounded to the nearest tenth deciview. Furthermore, the EPA proposes to round the 3-year average 90th percentile $PM_{2.5}$ visibility index design values to the nearest 1 dv for comparison to the level of the proposed secondary standard.

Consistent with current procedures for PM and the other criteria pollutants, the EPA plans to calculate design values for the proposed secondary $PM_{2.5}$ visibility index NAAQS using the procedures described above. The EPA plans to post these design values on its Web site.[193]

B. Exceptional Events

States [194] are responsible for identifying air quality data that they believe warrant special consideration, including data affected by exceptional events. States identify such data by flagging (making a notation in a designated field in the electronic data record) specific values in the AQS database. States must flag the data and submit supporting documentation showing that the data have been affected by exceptional events if they wish the EPA to consider excluding the data in regulatory decisions, including determining whether or not an area is attaining the proposed revised PM NAAQS.

All states and areas of Indian country that include areas that could exceed the proposed PM NAAQS and could therefore be designated as nonattainment for the proposed PM NAAQS have the potential to be affected by this rulemaking. Therefore, this action would apply to all states; to local air quality agencies to which a state has delegated relevant responsibilities for air quality management including air quality monitoring and data analysis; and to tribal air quality agencies where appropriate.

The ''Treatment of Data Influenced by Exceptional Events; Final Rule'' (72 FR 13560, March 22, 2007), known as the Exceptional Events Rule and codified at 40 CFR 50.14, contains generic deadlines for a state to submit to EPA specified information about exceptional events and associated air pollutant concentration data. A state must initially notify the EPA that data have been affected by an event by July 1 of the calendar year following the year in which the event occurred. This is done by flagging the data in AQS and providing an initial event description. The state must also, after notice and opportunity for public comment, submit a demonstration to justify any claim within three years after the quarter in which the data were collected. However, if a regulatory decision based on the data (for example, a designation action) is anticipated, the schedule to flag data in AQS and submit complete documentation to EPA for review may be shortened and all information must be submitted to the EPA no later than one year before the decision is to be made.

These generic deadlines in the Exceptional Events Rule are suitable after initial designations have been made under a NAAQS or when an area is to be redesignated, either from attainment to nonattainment or from nonattainment to attainment, and the redesignation status may depend on the excluded data. However, these same generic deadlines may need to be adjusted to accommodate the initial area designation process and schedule under a newly revised NAAQS. Until the level and form of the NAAQS have been promulgated, a state does not know whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met for a given event. In some cases, the generic deadlines, especially the deadlines for flagging some relevant data, may have already passed by the time the new or revised NAAQS is promulgated. In addition, it may not be feasible for information on some exceptional events that may affect final designations decisions to be collected and submitted to EPA at least one year in advance of the final designation decision. This scheduling constraint could have the unintended consequence of the EPA designating an area nonattainment because of uncontrollable natural or other qualified exceptional events.

The Exceptional Events Rule at section 50.14(c)(2)(vi) indicates ''when EPA sets a NAAQS for a new pollutant or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging exceptional event data, providing initial data descriptions and providing detailed data documentation in AQS for the initial designations of areas for those NAAQS.''

The EPA intends to promulgate the revised PM NAAQS in December 2012. State Governors (and tribes, if they choose) should submit designations recommendations by December 2013, based on air quality data from the years 2010 to 2012 or 2011 to 2013, if there are sufficient data for these years. Initial designations under the revised NAAQS would be made by December 2014 based on air quality data from the years 2011 to 2013. (See section IX.A for a more detailed discussion of the designation schedule.) Assuming this schedule, all events to be considered during the designations process would need to be flagged and fully documented by states one year prior to designations, or by December 2013, under the existing generic deadline in the Exceptional Events Rule. Without revision to 40 CFR 50.14, a state would not be able to flag and submit documentation regarding events that occurred in December 2013 by one year before designations are made in December 2014. The EPA believes this is not an appropriate restriction, and therefore is proposing revisions to 40 CFR 50.14.

The EPA proposes revisions to 40 CFR 50.14 only to change submission dates for information supporting claimed exceptional events affecting PM data for initial area designations under the proposed new and revised PM NAAQS. The proposed rule language at the end of this notice shows the changes that would apply assuming promulgation of the new and revised PM NAAQS in December 2012 and initial area designations by December 2014. For air quality data collected in 2010 or 2011, the EPA proposes 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 proposes to retain 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 proposes to revise to December 12, 2013 the deadline for submitting

[193] Design values calculated by the EPA are computed and published annually by EPA's OAQPS and reviewed in conjunction with the EPA Regional Offices. These values are available at: *http://www.epa.gov/airtrends/values.html.*

[194] References to ''state'' are meant to include state, local and tribal agencies responsible for implementing the Exceptional Events Rule.

documentation to justify PM-related exceptional events occurring in 2010 through 2012. The EPA believes these revisions/extensions will provide adequate time for states to review the impact of exceptional events from 2010 through 2012 on any revised standards, 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.

If a state intends the EPA to consider in the PM designations decisions whether PM data collected during 2013 have been affected by exceptional events, the EPA proposes that these data must be flagged by the generic Exceptional Event Rule deadline of July 1, 2014. The EPA proposes to revise to August 1, 2014 the deadline for submitting documentation to justify PM-related exceptional events occurring in 2013. The EPA believes that these deadlines provide states with adequate time to review and identify potential exceptional events that occur in calendar year 2013.

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 proposes to modify the schedule for data flagging and submission of demonstrations for exceptional events data considered for initial area designations under the proposed PM primary and secondary NAAQS as presented in Table 3. If the promulgation date for a revised PM NAAQS occurs on a different date than in December 2012, the EPA will revise the final PM exceptional event flagging and documentation submission deadlines accordingly, consistent with the logic of this proposal, to provide states with reasonably adequate opportunity to review, identify, and document exceptional events that may affect an area designation under a revised NAAQS. The EPA invites comment on these proposed changes, shown in Table 3, to the exceptional event data flagging and documentation submission deadlines for the proposed revised PM NAAQS.

TABLE 3—REVISED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN INITIAL AREA DESIGNATIONS FOR THE 2012 PM 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-Hour Standard (final level and promulgation date TBD)	2010 to 2011	July 1, 2013	December 12, 2013.
	2012	[a] July 1, 2013	December 12, 2013.
	2013	[a] July 1, 2014	August 1, 2014.
$PM_{2.5}$/Annual Standard (final level and promulgation date TBD)	2010 to 2011	July 1, 2013	December 12, 2013.
	2012	[a] July 1, 2013	December 12, 2013.
	2013	[a] July 1, 2014	August 1, 2014.
Secondary PM (final level and promulgation date TBD)	2010 to 2011	July 1, 2013	December 12, 2013.
	2012	[a] July 1, 2013	December 12, 2013.
	2013	[a] July 1, 2014	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 final initial area designations for revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by the EPA for redesignations to attainment. TBD = to be determined.

C. Proposed Updates for Data Handling Procedures for Reporting the Air Quality Index

The EPA is proposing to update appendix G of 40 CFR part 58 to clarify units, breakpoint precision, and truncation methods for AQI sub-indices. These changes are intended to harmonize the AQI reporting requirements with data handling provisions expressed elsewhere in 40 CFR part 50. Currently, the breakpoints for NO_2 and SO_2 in Table 2 of appendix G of 40 CFR part 58 are expressed in parts per million (ppm). The EPA proposes to change the sub-indices for NO_2 and SO_2 to be based on parts per billion (ppb) rather than ppm to be consistent with the units used for defining the current levels of the primary NO_2 and SO_2 NAAQS (75 FR 6474, February 9, 2010; 75 FR 35520, June 22, 2010). In addition, in modifying the sub-index for NO_2 to express the breakpoints in units of ppb, the EPA proposes to clarify the breakpoints for NO_2 in the Very Unhealthy and Hazardous ranges to include four rather than three significant digits to increase precision. Finally, the EPA proposes to modify appendix G to explicitly identify truncation methods for using ambient measured concentrations in AQI calculations.

VIII. Proposed Amendments to Ambient Monitoring and Reporting Requirements

The EPA proposes 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 proposing to support the proposed PM NAAQS summarized in sections III.F, IV.F, and VI.F above.

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

In 2006, the EPA finalized new testing and performance criteria for Class II and Class III FEMs (71 FR 61281 to 61289, October 17, 2006). Class II methods are equivalent methods for $PM_{2.5}$ or $PM_{10\text{-}2.5}$

that utilize a $PM_{2.5}$ sampler or $PM_{10-2.5}$ sampler in which integrated $PM_{2.5}$ samples or $PM_{10-2.5}$ samples are obtained from the atmosphere by filtration and are then subjected to a filter conditioning process followed by gravimetric mass determination. Class II equivalent methods are different from Class I equivalent methods because of substantial deviations from the design specifications of the sampler specified for reference methods in appendix L or appendix O (as applicable) of 40 CFR part 50. Class III refers to those methods for $PM_{2.5}$ or $PM_{10-2.5}$ that are employed to provide $PM_{2.5}$ or $PM_{10-2.5}$ ambient air measurements representative of one-hour or less integrated $PM_{2.5}$ or $PM_{10-2.5}$ concentrations, as well as 24-hour measurements determined as, or equivalent to, the mean of 24 one-hour consecutive measurements. These new testing and performance criteria were developed by the EPA and reviewed through consultation with the CASAC AAMMS [195] and then through proposal (71 FR 2710 to 2808, January 17, 2006) and final rulemaking in 2006 (71 FR 61236 to 61328, October 17, 2006). The performance criteria were designed to ensure enough stringency in testing that subsequently deployed monitors would provide data of expected quality (i.e., they would meet the data quality objectives), but not so stringent that instrument manufacturers would be discouraged from testing their instrument and seeking approval as a Class II or III equivalent method. At the time of this proposal, the EPA has approved two $PM_{10-2.5}$ Class II manual methods, one Class III $PM_{10-2.5}$ continuous method, and six Class III $PM_{2.5}$ continuous methods.[196]

While the EPA has approved these $PM_{2.5}$ Class III continuous FEMs, only two of those methods are deployed on a wide-enough basis across the country to support initial analyses of data quality and comparability to collocated FRM samplers. The Policy Assessment discusses an analysis of the quality of data from these two FEMs (U.S. EPA, 2011a, p. 4–50). This initial analysis found that some sites with continuous $PM_{2.5}$ FEMs have an acceptable degree of comparability with collocated FRMs, while others had less acceptable data comparability that would not meet the performance criteria used to approve the FEMs.

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-approved continuous $PM_{2.5}$ monitors and approved Class III 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. 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, reduce the use of manual, filter-based samplers to improve operational efficiency and 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 earlier, 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 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 some agencies are achieving acceptable data comparability and others are not, the EPA wants to ensure that all monitoring agencies have the appropriate information to maximize data quality from their $PM_{2.5}$ continuous FEMs before considering any changes to regulatory testing requirements intended to demonstrate equivalency of candidate Class III FEMs. Since we are still early in the process of learning the data comparability between approved $PM_{2.5}$ continuous methods and collocated FRMs (assessments across the country are only available for two of the six methods), and some of the agencies operating those methods are achieving acceptable data comparability, the EPA does not believe it is appropriate at this time to propose any modifications to either the performance or testing criteria in 40 CFR part 53 used to approve $PM_{2.5}$ continuous FEMs.

While EPA is not proposing any changes to the performance or testing criteria in 40 CFR part 53 used to approve $PM_{2.5}$ continuous FEMs, the EPA proposes an administrative change to part 53.9—''Conditions of designations.'' 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 $PM_{10-2.5}$ 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 methods work within performance criteria, which includes methods for $PM_{2.5}$ and $PM_{10-2.5}$; however, there is no specific reference to performance criteria for Class II and III $PM_{2.5}$ and $PM_{10-2.5}$ methods. Therefore, the EPA proposes to link the performance criteria referred to in 40 CFR part 53.35 associated with Class II and III $PM_{2.5}$ and $PM_{10-2.5}$ 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 $PM_{10-2.5}$ methods are available in table C–4 to subpart C of 40 CFR part 53.

2. Use of CSN Methods To Support the Proposed New Secondary $PM_{2.5}$ Visibility Index NAAQS

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 initial CSN began with a pilot of 13 sites in 2000 and grew rapidly over the next two years. Since 2006, the size of the CSN has remained relatively stable at approximately 200 stations.

The methods employed in the CSN are well documented and uniformly implemented across the country. However, between May 2007 and

[195] The EPA consulted with the CASAC AAMMS on several PM monitoring topics in a public meeting on September 21 and 22, 2005. Materials from this meeting can be found on EPA's Web site at: *http://www.epa.gov/ttn/amtic/casacinf.html.*

[196] A list of designated Reference and Equivalent methods is available on EPA's Web site at: *http://www.epa.gov/ttn/amtic/criteria.html.*

October 2009, the CSN transitioned to a new method of sampling and analyses for carbon that is consistent with the IMPROVE network methodology.[197] The CSN measurements have a strong history of being reviewed by CASAC technical committees, both during their initial deployment about ten years ago, and during the more recent transition to carbon sampling that is consistent with the IMPROVE protocols (Henderson, 2005c). The CSN network is described in the Policy Assessment (U.S. EPA, 2011a, Appendix B, section B.1.3).

As noted in section VI.D.1.c above, the proposed new secondary standard for $PM_{2.5}$ to address PM-related visibility impairment is defined in terms of a $PM_{2.5}$ visibility index, which would use $PM_{2.5}$ speciation measurement data. The EPA proposes that measurements using either the CSN or IMPROVE methods [198] be eligible for use to calculate $PM_{2.5}$ visibility index values. The EPA believes this proposed approach is appropriate because the methods for CSN and IMPROVE are well documented [199] in nationally implemented Quality Assurance Project Plans (QAPPs) and accompanying Standard Operating Procedures (SOPs) are validated through independent performance testing, and because numerous state, local, and tribal agencies are already experienced in the use of these methods.

With reference to CSN methods, the EPA is specifically not proposing to include testing or performance criteria for approval of CSN measurements as FRMs. The EPA believes that the proposed framework of using the current, well-documented set of CSN and IMPROVE methods provides a nationally consistent way to provide the chemical species data used in calculating $PM_{2.5}$ visibility index values, while preserving the flexibility for timely improvements to methods for measuring chemical species. Monitoring programs wishing to establish methods for chemical speciation in support of the proposed $PM_{2.5}$ visibility index would do so by following the methods and SOP's publically available on both the IMPROVE or the EPA (for CSN) Web sites.[200] The EPA solicits comment on this approach to include the CSN and IMPROVE measurements by reference and not require that such methods be approved as FRMs.

As discussed in section VII.A.5 above, the calculation of the $PM_{2.5}$ visibility index values would use historic monthly average relative humidity data based on a ten-year climatological data base. This data base would be based on measurements of relative humidity reported through NOAA at routine weather stations and not relative humidity measurements specific to the SLAMS stations.

B. Proposed Changes to 40 CFR Part 58 (Ambient Air Quality Surveillance)

1. Proposed Terminology Changes

The EPA proposes 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.

The EPA proposes to revoke the term ''community-oriented'' and replace it 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 proposes to replace this functional 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. The EPA proposes 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 proposes to revoke the term ''Community Monitoring Zone'' (CMZ) and 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 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 proposes to revoke this term and references to it since, as discussed in section VII.A.2 above, the EPA is proposing to eliminate all references to the spatial averaging option throughout appendix N.

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 a monitor that provides data for comparison to the NAAQS, only in the $PM_{2.5}$ monitoring requirements are additional restrictions prescribed within the monitoring rules.[201] 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 additionally be sited to represent area-wide locations. There is a related provision that provides for comparing sites at smaller scales to the annual NAAQS when the (micro- or middle-scale) site collectively identifies a larger region of localized high ambient $PM_{2.5}$ concentration.

The inclusion of these provisions in the $PM_{2.5}$ monitoring requirements since the 1997 promulgation of the $PM_{2.5}$

[197] In the IMPROVE program, artifact adjusted OC (i.e., $PM_{2.5}$ OC) is simply reported as OC. That is the value used to produce OM for haze calculations. For the CSN measurements, the OC artifact needed to convert measured OC into $PM_{2.5}$ OC is estimated from sampler-specific network-wide field blanks (Frank, 2012).

[198] Appendix C to 40 CFR part 58—*Ambient Air Quality Monitoring Methodology* is where EPA specifies the criteria pollutant monitoring methods which must be used at SLAMS and NCore, which are a subset of SLAMS.

[199] CSN documents are available at: *http://www.epa.gov/ttn/amtic/speciepg.html;* IMPROVE documents are available at: *http://vista.cira.colostate.edu/improve/Data/QA_QC/qa_qc_Branch.htm*).

[200] SOP's for the CSN program are available in Docket number EPA–HQ–OAR–2007–0492 and on EPA's Web site at: *http://www.epa.gov/ttn/amtic/specsop.html.* SOP's for the IMPROVE program are available in Docket number EPA–HQ–OAR–2007–0492 and on the IMPROVE Web site at: *http://vista.cira.colostate.edu/improve/publications/IMPROVE_SOPs.htm.*

[201] These are referenced in 40 CFR 58.30 (Special considerations for data comparisons to the NAAQS).

NAAQS and associated monitoring requirements has resulted in substantial ambiguity when the EPA and state, local, and tribal agencies consider the design of $PM_{2.5}$ monitoring networks as NAAQS are revised as well as how unmonitored locations should be treated in modeling exercises.[202] Accordingly, the EPA proposes to revise these particular $PM_{2.5}$ requirements for consistency with long-standing practices in all other NAAQS pollutant monitoring networks, and to ensure interpretation of the monitoring rules does not cause ambiguity in considering treatment of unmonitored areas. Each of these topics and our proposal to revoke or modify the requirements is described below.

a. Revoking Use of Population-Oriented as a Condition for Comparability of $PM_{2.5}$ Monitoring Sites to the NAAQS

The EPA proposes to revoke the requirement that $PM_{2.5}$ monitoring sites be ''population-oriented'' for comparison to the NAAQS. This requirement is inconsistent with our definition of ambient air which the NAAQS employ. 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 EPA's intention in proposing to revoke the requirement that $PM_{2.5}$ monitoring sites be ''population-oriented'' for comparison to the NAAQS is to ensure that the monitoring rules do not create an ambiguity in the use of data by having a different definition from the definition of ambient air in 40 CFR 50.1 itself. Also, EPA's proposal to revoke this term in no way changes the requirements in the $PM_{2.5}$ network design criteria, which will continue to focus on sites representing ''area-wide'' locations; thus continuing to represent locations with population exposure. While the use of the term ''population-oriented'' has little effect on how data from existing sites are treated (as explained below there are no remaining sites designated as not being ''population-oriented''), the inclusion of this requirement in the monitoring rules creates substantial ambiguity in how to treat potential locations of exposure such as in applying modeling across an area. By reverting to the long-standing definition of ambient air, the EPA will be able to more clearly define how to treat potential exposure receptors, regardless of whether monitoring exists or not.

In reviewing the impact that this proposed change might have on the nation's $PM_{2.5}$ monitoring network, the EPA notes that there are no remaining sites operating affirmatively as ''non population-oriented.'' 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. While a monitoring agency could still set up a new site in any area, including one in an area that does not meet the definition of population-oriented, which the EPA is proposing to revoke, there are other monitoring options that may provide more useful information and still result in data that are not comparable to the NAAQS; for instance, using a chemical speciation network sampler that provides chemical species information or continuous $PM_{2.5}$ monitor that provides high time-resolution data, but is not approved as an FEM. Even if a monitoring agency wanted to use an FRM, an agency could still operate a monitor for up to 24 months as an SPM without any risk of data being used for comparison to the NAAQS.

b. Applicability of Micro- and Middle-scale Monitoring Sites to the Annual $PM_{2.5}$ NAAQS

The EPA is clarifying language used to determine when $PM_{2.5}$ monitoring sites at micro- and middle-scale locations are comparable to the annual NAAQS. EPA's intent in clarifying this language is to provide consistency and predictability in the interpretation of the monitoring regulations to minimize the burden on state monitoring programs as they plan and implement their monitoring programs. The EPA's current rules, as specified in 40 CFR 58.30, 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.'' The EPA is clarifying 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. Mobile sources are rather ubiquitous and, as such, there are many locations throughout an urban area where elevated exposures could occur. Therefore, any potential location for a $PM_{2.5}$ monitoring site, even micro- and middle-scale sites near roadways would be eligible for comparison to the annual NAAQS. The EPA's existing definition of middle-scale for $PM_{2.5,}$ as specified in appendix D to 40 CFR part 58, already states, ''(2) *Middle scale*—People moving through downtown areas, or living near major roadways, encounter particle concentrations that would be adequately characterized by this spatial scale. Thus, measurements of this type would be appropriate for the evaluation of possible short-term exposure public health effects of particulate matter pollution. In many situations, monitoring sites that are representative of micro- or middle-scale impacts are not unique and are representative of many similar situations. This can occur along traffic corridors or other locations in a residential district. In this case, one location is representative of a number of small scale sites and is appropriate for evaluation of long-term or chronic effects. This scale also includes the characteristic concentrations for other areas with dimensions of a few hundred meters such as the parking lot and feeder streets associated with shopping centers, stadia, and office buildings.'' With the reference to ''traffic corridors'' and related text, the EPA emphasizes that this type of location, which is referred to as near-road, should not be considered ''unique.''

EPA and monitoring agencies already have a process for approving $PM_{2.5}$ monitoring sites as described in the Annual Monitoring Network Plan due to the applicable EPA Regional Office by July 1 of each year (described in 40 CFR 58.10). This existing process provides for identification of sites that are suitable and sites that are not suitable for comparison against the annual $PM_{2.5}$ NAAQS (§ 58.10(b)(7)). This clarifying language will provide consistency between the $PM_{2.5}$ design criteria described in appendix D to 40 CFR part 58 and the example provided in the special considerations for data comparisons to the NAAQS network design (§ 58.30). This clarifying

[202] Modeling can be associated with either PSD or transportation conformity as discussed in sections IX.F and IX.G, respectively, below.

language will help to ensure a more consistent identification and approval of sites, and therefore a reduction in burden to monitoring agencies and EPA as annual monitoring network plans are prepared, reviewed, public comments are considered, plans are approved and implemented, and data are ultimately used.

3. Proposed 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) [203] 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. To summarize some of these sites, here 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; (b) sites located to measure typical concentrations in areas of high population density; (c) sites located to determine the impact of significant sources or source categories on air quality; (d) sites located to determine general background concentration levels; and (e) sites located to determine the extent of regional pollutant transport among populated areas; and in support of secondary standards.

b. Primary $PM_{2.5}$ NAAQS

In this section, the EPA proposes 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.

i. Proposed Addition of a Near-road Component to the $PM_{2.5}$ Monitoring Network

The EPA believes 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, with the largest numbers of impacted populations in the largest CBSAs in the country (Ntziachristos et al., 2007; Ross et al., 2007; Yanosky et al., 2008; Zwack et al., 2011). To better understand the potential health impacts of these exposures, the EPA proposes to add a near-road component to the compliance network design for $PM_{2.5}$ monitoring. The EPA believes 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 recognizes that there are limitations in the ability of some of these PM 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 recognizes 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 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 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). EPA believes that by allowing State monitoring agencies to choose the FRM, FEM, or ARM method(s) that best fits their needs, whether filter-based or continuous, that the data will still be able to meet the objectives cited above while ensuring maximum flexibility for the States in the operation of their network.

Additionally, the EPA recognizes that the near-road sites would provide a valuable platform for evaluating emerging monitoring technologies and for measuring other pollutants besides $PM_{2.5}$ mass to enhance knowledge of exposure in the near road environment and to support the characterization and comparison of specific method readings in an emission-rich environment. Further, in its response to the EPA on a ''Review of the ''Near-road Guidance Document—Outline'' and ''Near-road Monitoring Pilot Study Objectives and Approach'' (U.S. EPA, 2010i), the CASAC AAMMS cited several other measurements that may be useful or potentially linked to health and welfare effects such as BC, ultrafine particles,

[203] 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.

and particle size distribution (Russell and Samet, 2010b, pp. xi and xii). The EPA agrees with these recommendations and encourages monitoring agencies to include these measurements, and others cited in the Subcommittee letter, where possible, in addition to the $PM_{2.5}$ mass measurement. The EPA also encourages monitoring agencies to explore partnerships with instrument manufacturers and researchers to use the sites to evaluate the performance of emerging $PM_{2.5}$ methods in the near-road environment, especially potential or current FEMs able to provide temporally resolved data and capture the semi-volatile components of $PM_{2.5}$. Such emerging $PM_{2.5}$ methods could be operated as SPMs to provide comparisons to the EPA approved methods supporting compliance to advance the understanding of instrument performance in the near-road environment. Monitoring agencies are also encouraged to partner with instrument manufacturers and researchers to operate monitors able to measure other PM properties relevant for the near-road environment (e.g., ultrafine particles, BC) to provide additional information about exposure to PM in this environment. The EPA is interested in supporting monitoring agencies willing to operate and report the data from these supplemental monitors. EPA notes that the implementation of additional measurements, while encouraged, is completely voluntary to ensure maximum flexibility for state monitoring programs. The EPA solicits comment on the best way to support such research efforts.

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. These long-term monitors will supplement shorter-term networks operated by researchers to support the tracking of long-term trends of near-road $PM_{2.5}$ mass concentrations and other pollutants in near-road environments. Therefore, the EPA proposes 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, this 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 have redundant monitors that could be relocated to the near-road environment, reducing costs for equipment and ongoing operation.[204] While only a single $PM_{2.5}$ 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 recognizes that the location of maximum concentration of $PM_{2.5}$ from roadway sources might differ from the maximum location of NO_2 or other pollutants, the EPA proposes 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 (e.g., average annual daily traffic and fleet mix by road segment) and significant thought and review has gone into its design, including pilot studies at two 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. Therefore, while there may be limitations to collocating the proposed 52 near-road $PM_{2.5}$ monitors with the NO_2 stations that will also host CO monitors, on balance, EPA believes this is the most efficient and beneficial approach for deployment of this component of the network. ThU.S. EPA is seeking to maximize the utility of the network while also reducing the burden on monitoring agencies that have already put significant effort into designing their near-road stations for NO_2 and CO.

The EPA notes that the 52 proposed near-road monitors represent a small number of the total approximate 900 operating $PM_{2.5}$ monitoring stations across the country. The EPA could consider proposing 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 corresponding less travelled roads, is expected to be very small. The EPA could also consider proposing 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 measurements to serve the monitoring objectives noted above. Since EPA has already finalized requirement of CO monitoring at near-road stations in CBSAs 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). Also, EPA wants to ensure there is minimal disruption to the existing network and moving more than the proposed 52 $PM_{2.5}$ monitors may lead to losing some valuable existing $PM_{2.5}$ stations. Therefore, EPA believes the 52 proposed near road monitoring stations represent the least burdensome, but most useful number of near-road monitoring stations to meet the monitoring objectives cited above for deployment across the country.

Ideally, near-road sites would be located at the elevation and distance from the road where maximum concentration of $PM_{2.5}$ occurs in this environment, and within reasonable proximity to an area-wide $PM_{2.5}$ compliance monitoring site at which a similar PM monitor is used (i.e., for comparison purposes). Although the EPA is not proposing that the near-road $PM_{2.5}$ monitors be located within a specific distance of area-wide sites, 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 $PM_{2.5}$.

The timeline to implement the proposed near-road $PM_{2.5}$ monitors should be as minimally disruptive to on-going operations of monitoring agency programs as possible, 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 are proposed to be collocated with the emerging near-road NO_2 network that is scheduled to be operational by January 1, 2013, the EPA believes it is appropriate to wait

[204] EPA Regional Administrator approval would be required prior to the discontinuation of SLAMS monitors, based on the criteria described in paragraph 58.14(c) to 40 CFR part 58.

until after the near-road NO_2 network is established before implementing the near-road $PM_{2.5}$ monitors. Therefore, the EPA proposes 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 believes this proposed deadline provides an appropriate amount of time for monitoring agencies to select existing $PM_{2.5}$ monitors suitable for relocation, receive EPA approval, and physically relocate the $PM_{2.5}$ monitor to the near-road NO_2 site. Based on this proposed timeline, complete data sets (i.e., 3-years representing 2015–2017), from $PM_{2.5}$ monitors in the near-road environment would be available to calculate site-level design values in 2018.

In summary, the EPA proposes to specifically include a near-road component in the $PM_{2.5}$ network design criteria for CBSA's of 1 million persons or greater, with at least one $PM_{2.5}$ monitor collocated with a near-road NO_2 and CO monitors by January 1, 2015. EPA believes that the 52 proposed $PM_{2.5}$ monitors to be collocated with NO_2 and CO monitors in the near-road environment represent the minimal number of sites needed to characterize $PM_{2.5}$ in representative near road environments of large population CBSA's. EPA believes that a number of $PM_{2.5}$ monitors can be moved from single pollutant locations to multi-pollutant locations in the near-road environment, thus encouraging efficiencies in operation by monitoring agencies and reducing the burden of continuing to support some of the existing single pollutant $PM_{2.5}$ stations. The EPA solicits comment on this approach, especially the proposed network design requirements; any alternative strategies that would provide comparable long-term characterization of $PM_{2.5}$ in area-wide locations of maximum concentration in the absence of a specific near-road compliance requirement for monitoring of $PM_{2.5}$; priorities for the collection of supplemental data at a small subset of near-road monitoring sites to enhance knowledge of particle exposure (e.g., non-compliance SPMs); and the interest of monitoring agencies (or other parties) in the collection of supplemental (e.g., non-compliance) measurements relevant for the near-road environment.

ii. Use of $PM_{2.5}$ Continuous FEMs at SLAMS

The EPA proposes that each agency specify their 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. The proposal also provides 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. The EPA has already approved six $PM_{2.5}$ continuous FEMs 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 section VI.D.1.a.iii above, 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 utilized, particularly for the objective of determining NAAQS compliance. Accordingly, we propose 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; 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). The EPA believes 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 believe it is 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 comparability. Accordingly, in the first year after this rule becomes effective, we propose 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.[205] 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, as evidenced by a prior collocation with an FRM) to ensure a data record is available for comparison to the NAAQS. In cases where a $PM_{2.5}$ continuous FEM was not

[205] Data from any $PM_{2.5}$ monitor being used to meet minimum monitoring requirements could not be restricted from NAAQS comparability.

meeting the expected performance criteria, and the Regional Administrator has approved that the FEM data will 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 stored separately 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 method 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 method across all seasons, assess the data quality, and in some cases resolve operational issues with the instrument, it may still leave some agencies with methods 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 is 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 as 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.

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 versus how instrument manufacturers conduct required FRM and FEM testing protocols. The details below summarize these issues. The EPA proposes 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 as comparable to the NAAQS. To accommodate how routine monitoring networks operate, the EPA proposes that agencies seeking to demonstrate insufficient data comparability in an assessment base the analysis 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 were helpful for understanding whether an intercept or slope was driving a potential bias in an instrument. Therefore, the EPA proposes 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 propose 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 proposes 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 as 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 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 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.

The EPA solicits comment on all aspects of this proposed approach of allowing monitoring agencies to recommend that $PM_{2.5}$ continuous FEM data should not be compared to the NAAQS, when demonstrated to not meet the performance criteria used to approve FEMs based on data in their own network, and as appropriate, approved by the EPA Regional Administrators as ineligible for comparison to the NAAQS.

c. Revoking $PM_{10-2.5}$ Speciation Requirements at NCore Sites

The EPA issued revisions to the Ambient Air Monitoring Regulations (40 CFR parts 53 and 58) on October 17, 2006 (71 FR 61236). In the 2006 final rule, the EPA required that $PM_{10-2.5}$ speciation be conducted at NCore multi-pollutant monitoring stations by January 1, 2011. $PM_{10-2.5}$ speciation at NCore was intended to support further research in the understanding of the chemical composition and sources of PM_{10}, $PM_{10-2.5}$ and $PM_{2.5}$ at a variety of urban and non-urban NCore locations.

Subsequent to the completion of the 2006 final monitoring rule, several technical issues were raised concerning the readiness of $PM_{10-2.5}$ speciation monitoring methodologies to support such a nation-wide deployment strategy. Based on these issues and as explained in detail below, the EPA proposes to revoke the requirement for $PM_{10-2.5}$ speciation monitoring as part of the current suite of NCore monitoring requirements. The requirement to monitor for $PM_{10-2.5}$ mass (total) at all NCore multi-pollutant sites remains. Monitoring was 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 $PM_{10-2.5}$ speciation monitoring, a public consultation with the CASAC AAMMS on monitoring issues related to $PM_{10-2.5}$ speciation was held in February 2009 (74 FR 4196, January 23, 2009). At that time, the subcommittee noted the lack of consensus on appropriate sampling and analytical methods for $PM_{10-2.5}$ speciation and expressed concern that the Agency's 2006 commitment to launch the $PM_{10-2.5}$ 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 $PM_{10-2.5}$ speciation monitoring techniques, the Agency did plan and implement a small pilot monitoring project to evaluate the available monitoring and analytical technologies and supplement the $PM_{10-2.5}$ speciation measurements that have mostly been done as part of other research efforts. The EPA expects that this field study will address the issues needed to develop a more robust, long-term $PM_{10-2.5}$ speciation monitoring plan.

The EPA pilot monitoring project will be completed in 2011, with plans to analyze the data and prepare a final report on findings and recommendations in 2012. At that time, the EPA will consider what $PM_{10-2.5}$ speciation sampling techniques, analytical methodologies, and network 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 targets such measurements in areas with higher levels of coarse particles. This latter type of strategy would be consistent with CASAC AAMMS members written comments that not all NCore sites would be adequate for $PM_{10-2.5}$ speciation and that more flexibility in $PM_{10-2.5}$ speciation network design would allow for a geographically diverse network to support health studies and research (Russell, 2009).

The EPA may consider reintroducing some $PM_{10-2.5}$ speciation monitoring requirements in a subsequent monitoring rulemaking or as part of a future review of the PM NAAQS. Until that time, the EPA believes it is appropriate to propose to revoke the current set of $PM_{10-2.5}$ speciation monitoring requirements. The EPA solicits comment on this proposed revision to monitoring requirements.

d. Measurements for the Proposed New $PM_{2.5}$ Visibility Index NAAQS

The EPA proposes requirements for sampling of $PM_{2.5}$ chemical speciation in states with large CBSAs. The CSN has been operating for approximately 10 years and as described earlier in this proposal already supports a number of important monitoring objectives. Since the CSN network is already well established in states with large CBSAs, the EPA believes that using the data from these existing sites as an input for calculating $PM_{2.5}$ visibility index values will help ensure that the network can continue to support existing objectives, while also supporting the proposed new secondary standard.

To ensure the CSN network can support its existing network objectives while also supporting the proposed new secondary $PM_{2.5}$ visibility index standard (section VI.F), the EPA proposes that each state with a CBSA over 1 million have measurements based on the methods in CSN (or IMPROVE), as discussed in section VII.A.5 above, in at least one of its CBSAs. For states with urban or suburban NCore Stations, their existing CSN measurements at all NCore sites would be appropriate to meet this proposed requirement. For states with multiple high population CBSAs, the EPA proposes that each CBSA with a population over 2.5 million people be required to have CSN measurements. The EPA does not believe it would be appropriate to require multiple cities in the same state to have CSN measurements for purposes of supporting the proposed new secondary $PM_{2.5}$ visibility index standard when these cities have relatively smaller populations (i.e., less than 2.5 million people) as the chemical species data may be similar across cities in the same state. The exception to this will be the most highly populated states and cities, which are either already covered by requirements for multiple NCore stations or the proposed population threshold of 2.5 million people. For example, the following high population states are already required to have multiple NCore stations: California, Florida, Illinois, Michigan, New York, North Carolina, Ohio, Pennsylvania, and Texas. The EPA also proposes that states be allowed to request alternative CBSAs to locate their CSN measurements, when the alternative location is better suited to support providing data for multiple monitoring objectives, including for the proposed new secondary $PM_{2.5}$ visibility index standard. For example, in some cases a large CBSA with a marine influence may have relatively cleaner air than a smaller inland CBSA in the same state with a lower population. In these cases, states may request an alternative location for their CSN measurements. The EPA solicits comment of these proposed requirements and on alternative requirements for CSN measurements to support the proposed new secondary $PM_{2.5}$ visibility index standard.

The EPA proposes that the network design criteria for CSN measurements focus on area-wide locations that are generally representative of long distances throughout a CBSA. For most CBSAs, this will mean that the existing inventory of CSN measurements can be used where the location of the sampling equipment is at an NCore station or other station(s) sited at the neighborhood or urban scale of representation. The EPA points out that while the existing $PM_{2.5}$ network design criteria established to support the primary $PM_{2.5}$ NAAQS focuses on the area-wide locations of expected maximum concentration, there would not necessarily be the same focus for the proposed new secondary $PM_{2.5}$ visibility index standard. One reason for this difference is that for urban visibility, we are interested in the impact of visibility degradation over as representative a location as possible as the impact of the aerosol is a function of an entire site path and not just one monitoring location within a CBSA. Also, the EPA is interested in leveraging as much of the existing inventory of CSN and IMPROVE measurements operating in CBSAs where they can support the proposed new secondary $PM_{2.5}$ visibility index standard.

The EPA considered the issue of siting measurements to support a new secondary standard to address PM-related visibility impairment during a consultation with the CASAC AAMMS (75 FR 4069, January 26, 2010). In its letter to the EPA, the CASAC AAMMS stated that ''the Subcommittee strongly favored collocation of extinction measurements with PM mass, PM speciation, and precursor gas measurements, identifying continuous

PM mass and speciation measurements as being of particular value. NCore multi-pollutant monitoring sites were identified as worth considering even though these would not necessarily capture maximum concentrations and visibility impairment in an urban area'' (Russell and Samet, 2010a, p. 18). The EPA notes that the Subcommittee also identified that ''[t]here was general support for making public communication an important consideration in network design, for example by selecting a monitoring site that can be associated with a vista that is recognized by a significant fraction of the local population'' (Russell and Samet, 2010a, p. 18). While the EPA agrees that siting associated with a recognizable vista would be a useful consideration for establishing new sites, the EPA does not believe it would be appropriate to include such a requirement for cities with existing sites as this may disrupt the use of data to meet other important monitoring objectives. The EPA also notes existing long-standing public communication tools such as the ''Haze-Cam'' network are already well suited for public communications of important vistas.[206] In addition to collocation with several important measurements at NCore as cited by the Subcommittee, the EPA is also encouraging monitoring agencies to add other important measurements such as commercially available technologies for light absorption and light scattering; however, the EPA does not believe these technologies should be specified by regulation.

Since EPA's proposal to require CSN (or IMPROVE) sampling is consistent with a network that is largely already in place, there is no expectation new sites will be needed. However, from time to time there is a disruption of sampling due to loss of a sites lease agreement or other circumstances. Therefore, for any state that does not have a minimally required CSN (or IMPROVE) set of measurements in place, the EPA proposes that these measurements be in place and sampling by January 1, 2015.

4. Proposed Revisions to the Quality Assurance Requirements for SLAMS, SPMs, and PSD

a. Quality Assurance Weight of Evidence

The EPA believes that the process by which monitoring organizations and the EPA use the appendix A of 40 CFR part 58 regarding quality assurance requirements in regulatory decision making needs to be articulated. Prior interpretations of appendix A have led to disqualification of data for noncompliance with a particular appendix A requirement. The proposed language described below, provides the interpretation the EPA would use moving forward.

The appendix A to 40 CFR part 58 requirements represent a portion of the quality control activities that are implemented by monitoring organizations to control data quality. The EPA believes that while 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 does not preclude the EPA from determining that data are of acceptable quality to be used for regulatory decision-making purposes. The EPA proposes to use a weight-of-evidence approach for determining whether the quality of data is appropriate for regulatory decision-making purposes. Furthermore, the suitability of data for any regulatory purpose also relies, in part, on several other quality-related requirements found elsewhere in 40 CFR part 58. These requirements include air monitoring methodology (appendix C), network design criteria (appendix D) and network design plans for SLAMS, probe siting criteria (appendix E), the reporting of data to AQS, data completeness, and data certification by the reporting organization. This weight of evidence approach recognizes that all measurement systems have uncertainty and there are numerous factors that can affect data quality at a particular monitoring site. The specific appendix A criteria are designed to provide a quantification of this uncertainty, support a framework for assessing such uncertainty against known data quality goals and to support corrective actions when necessary to control uncertainty back to acceptable levels. Accordingly, the EPA proposes 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.

b. Quality Assurance Requirements for the Chemical Speciation Network

The EPA proposes to include requirements for flow rate verifications and flow rate audits for the $PM_{2.5}$ CSN. These audits are currently being performed so, although they will 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 proposes that PSD sites would not be required to collocate a second set of instruments for speciated $PM_{2.5}$ mass monitoring.

The EPA performed an assessment of measurement uncertainty from the collocated CSN and IMPROVE stations using the proposed visibility index (Papp, 2012) and concluded that the current data quality goals for the $PM_{2.5}$ mass can be achieved for the proposed calculated light extinction indicator.

c. Waivers for Maximum Allowable Separation of Collocated $PM_{2.5}$ Samplers and Monitors

The EPA proposes to allow waivers for the maximum allowable distance associated with collocated $PM_{2.5}$ samplers and monitors. As described in section VIII.A.1 of this proposal, the EPA has already approved six Class III $PM_{2.5}$ continuous FEMs. Several of these approved FEMs are required to be installed in a shelter with sufficient control of heating and air conditioning to ensure stable operation of the instrument. In many cases monitoring agencies are installing these approved continuous FEMs in shelters where they already have gas analyzers operating. Some agencies operate filter-based samplers (e.g., $PM_{2.5}$ FRMs) on top of their shelter, while others operate platforms next to their shelter. In either case, 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, some installed in the shelter and some installed on a platform, are being sited at the same station.

The EPA believes that maintaining the current requirement of 1 to 4 meters for $PM_{2.5}$ samplers with flow rates of less than 200 liters/minute is useful since it ensures consistency with long-standing practices of collocation and ensures that any air drawn through collocated samplers is well within the operational precision of the instruments. However, the EPA also believes that instruments spaced farther apart could also be within the operational precision of the instruments, especially at sites located at larger scales of representation (e.g., neighborhood scale and larger). The EPA already defines a collocated scale in its document ''Guidance for Network Design and Optimum Site Exposure for $PM_{2.5}$ and PM_{10} (U.S. EPA, 1997). In this document, the EPA defines a collocated scale as 1 to 10 meters. The EPA believes that almost all agencies would

[206] See *http://www.hazecam.net/.*

be able to site collocated PM samplers and monitors within 10 meters. Therefore, the EPA proposes 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 solicits comment on this proposed change to allow waivers of the maximum allowable distance for collocated $PM_{2.5}$ samplers and monitors.

5. Proposed Probe and Monitoring Path Siting Criteria

a. Near-Road Component to the $PM_{2.5}$ Monitoring Network

The EPA proposes that the probe and siting criteria for the near-road component to 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 solicits comment on this proposed probe and siting criteria for the proposed near-road component to the $PM_{2.5}$ monitoring network design.

b. CSN Network

The EPA proposes to extend the existing probe and monitoring path siting criteria described in appendix E to 40 CFR part 58 for $PM_{2.5}$ FRMs and FEMs to the CSN measurements. The EPA believes that monitoring agencies are already following the probe and siting criteria for $PM_{2.5}$ when conducting CSN measurements; that is, at neighborhood, urban, and regional scale sites the probe height must be 2 to 15 meters above ground level. All other aspects of the existing $PM_{2.5}$ probe and siting criteria would also apply including minimum distances from horizontal supporting structures (i.e., greater than 2 meters) and minimum distance to the drip-line of a tree (i.e., greater than 10 meters). The IMPROVE program SOP (IMPROVE, 1996) on site selection already provides for meeting probe and siting criteria described in Appendix E. The EPA solicits comment on extending the existing probe and siting criteria for PM to the speciation measurements used to support the proposed new secondary $PM_{2.5}$ visibility index standard.

c. Reinsertion of Table E–1 to Appendix E

The EPA is proposing 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 EPA is utilizing this proposed rule to reinsert 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 submitted to EPA Regional Offices on or before July 1, 2010. The assessments are intended to provide a comprehensive look at each monitoring agencies 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.[207]

Since each state has completed their 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 thinks it is 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 solicits comment on ways to either streamline or add additional criteria for future assessments. Even if no changes to the requirements are recommended by any commenters, the EPA is especially interested in learning from monitoring agencies that may have ideas on how to improve future assessments. Such ideas may not necessarily have to be incorporated into regulation, but could be referred to in our guidance on network assessments (U.S. EPA, 2007b).

The EPA proposes 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 proposes to remove these references since, as discussed in section VII.A.2 above, the EPA is proposing to remove all references to the spatial averaging option throughout 40 CFR part 50 appendix N. Consistent with these changes, the EPA also proposes to remove references to community monitoring zones under the annual monitoring network plans described in 40 CFR 58.10.

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 a site that has a collocated continuous operating $PM_{2.5}$ monitor.[208] 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 proposing to revise the level of the primary annual $PM_{2.5}$ NAAQS. Accordingly, she is now considering whether this proposed change should result in any changes to sampling frequency requirements.

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 proposed strengthening of the primary annual

[207] 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.

[208] All NCore stations must operate on at least a one-in-three day sample frequency for filter-based PM sampling.

$PM_{2.5}$ 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 should be 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 proposes to revise this requirement in the following ways: (1) The EPA proposes that monitors would only be required to operate on a daily schedule if their 24-hour design values are within five percent of the 24-hour $PM_{2.5}$ NAAQS and the site has a design value that is not above the level of the annual $PM_{2.5}$ NAAQS. (2) The EPA proposes 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 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. The EPA solicits comment on these proposed changes to the required operating schedule for $PM_{2.5}$ SLAMS.

c. Data Reporting and Certification for CSN and IMPROVE Data

The EPA solicits comment on minor changes to reporting and certification of data associated with CSN and IMPROVE data. The chemical analyses of filters associated with CSN measurements results in reporting of data that are usually within three months of the sample collection. This fits within the existing reporting requirements for most ambient air measurements that data be reported within 90 days past the end of the previous quarterly reporting period (40 CFR 58.15). However, some agencies also use IMPROVE or their own internal laboratory for processing of chemical analyses. IMPROVE is known to validate and report its data on a schedule that is approximately 12 to 18 months after sample collection. At least one state laboratory continues to provide chemical analysis of filters associated with sites that are not NCore (**Note:** All NCore stations use either IMPROVE or the CSN National Laboratory contractor for their speciation laboratory analysis). Therefore, the EPA solicits comment on including the existing reporting requirements when reporting CSN measurements. In addition, the EPA also solicits comment on a longer reporting and certification [209] schedule specifically for CSN and IMPROVE that appropriately balances having sufficient time to analyze, validate, and report data with the need to have the data in sufficient time to use in assessments including calculating the proposed $PM_{2.5}$ visibility index values discussed in section VII.A.5 above. Since 2010, the EPA has required states to certify their data by May 1 of each year. Since in some cases chemical speciation data may not be fully validated and submitted to EPA by May 1 of a given year, the EPA solicits comment on having data certification of these speciation measurements take place by May 1 of the following year. For example, if the fourth quarter chemical speciation data were not fully available to certify by May 1 of the following year, it would be certified another 12 months after that. The EPA solicits comment on the reporting and certification schedules for chemical speciation data.

d. Requirements for Archiving Filters

The EPA proposes to extend the requirement for archival of $PM_{2.5}$, PM_{10}, and $PM_{10-2.5}$ 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 tool 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 current requirement of one-year is not sufficiently long for retrospective analysis of important episodes and for use in long-term epidemiology research. Since first requiring filter archival of low-volume PM filters in 1997, the EPA has always recommended longer filters archives 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 proposes to minimize the costs of retaining filters by only requiring cold storage during the first year after sample collection. Therefore, the EPA solicits comment on this proposal to extend the filter archival requirement from one to five years, but only require cold storage during the first year.

IX. Clean Air Act Implementation Requirements for the PM NAAQS

The proposed revisions to the primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS discussed in sections III.F and VI.F above, if finalized, would trigger a process under which states [210] will make recommendations to the Administrator regarding area designations, and the EPA will take final action on these designations. States will also be required to review, modify, and supplement their existing implementation plans. The proposed PM NAAQS revisions would also affect the applicable air permitting requirements and the transportation conformity and general conformity processes. This section provides background information for understanding the possible implications of the proposed NAAQS changes, and describes the EPA's plans for providing states necessary guidance or rules in a timely manner to clarify how they are affected and to assist their implementation efforts. This section also describes existing EPA interpretations of CAA requirements and other EPA guidance relevant to implementation of new or revised NAAQS. Relevant CAA provisions that provide potential flexibility with regard to meeting implementation timelines are also discussed.

This section also contains a discussion of several requirements of the stationary source construction permit programs under the CAA that may be affected by the proposed revisions of the PM NAAQS. These are

[209] Data certification requirements are described in 40 CFR 58.15.

[210] This and all subsequent references to ''state'' are meant to include state, local and tribal agencies responsible for the implementation of a $PM_{2.5}$ control program.

the PSD and Nonattainment New Source Review (NNSR) programs. To facilitate implementation of the PSD requirements, which would be the first of the implementation requirements to become applicable upon the effective date of the final NAAQS rule, the EPA proposes as part of this rulemaking to add a grandfathering provision to its regulations that would apply to certain PSD permit applications that are pending on the effective date of the revised PM NAAQS. If the proposed NAAQS revisions are finalized, this rule could be finalized at the same time as the revised NAAQS. This section also discusses other possible actions under consideration to facilitate implementation of the PSD and NNSR programs (see section IX.F).

The EPA intends to propose additional appropriate regulations or issue guidance related to the implementation requirements for the revised PM NAAQS at a later date or dates. These may include additional revisions to both the PSD and NNSR regulations, as well as the promulgation of rules or development of guidance related to NAAQS implementation. These actions will be taken on a schedule that provides timely assistance to responsible states. Accordingly, in this section, the EPA solicits comment on several issues that the Agency anticipates will need to be addressed in future guidance or regulatory actions. Because these issues are not relevant to the establishment of the NAAQS, the EPA does not expect to respond, nor is the Agency required to respond, to these comments in the final action on this proposal, but the EPA expects these comments will be helpful as future guidance and regulations are developed.

A. Designation of Areas

After the EPA establishes or revises a NAAQS, the CAA requires the EPA and the 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.[211] 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 boundaries as the EPA may deem necessary. States then have an opportunity to comment on the EPA's tentative decision. 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 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).

Monitoring data are currently available from numerous existing $PM_{2.5}$ mass and $PM_{2.5}$ speciation sites to determine compliance with the proposed revised primary annual $PM_{2.5}$ NAAQS and with the proposed $PM_{2.5}$ visibility index NAAQS. As discussed in sections III and VI above, the EPA is proposing 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); (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 non-visibility-related welfare protection (section VI.F); and (3) establish a distinct secondary $PM_{2.5}$ visibility index standard (section VI.F). The EPA's examination of air quality monitoring data current at the time of this proposal indicates that, for the proposed levels for primary standards and the secondary $PM_{2.5}$ visibility index standard, it is likely that the vast majority of monitors violating this secondary standard would overlap with monitors violating the primary standards. Since the same types of emissions sources contribute to concentrations affecting attainment status for both the proposed primary and secondary NAAQS, the EPA expects that the nonattainment area boundaries in locations with such overlap would be identical. The EPA will, consistent with previous area designations, use area-specific factor analysis[212] to support area boundary decisions for both the primary and secondary standards. The EPA intends to more fully address issues affecting area designations in designations guidance that will be issued around the same time as any revised $PM_{2.5}$ NAAQS are finalized. The EPA solicits comment related to establishing nonattainment area boundaries for the proposed revised primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS, including any relevant technical information that should be considered by the EPA, and any input on the extent to which different considerations may be relevant to establishing boundaries for a secondary $PM_{2.5}$ NAAQS.

For the reasons stated above, upon promulgation of the revised NAAQS, the EPA currently intends to move forward on the same schedule with the initial area designations for both the revised primary annual $PM_{2.5}$ standard and the secondary $PM_{2.5}$ visibility index standard. The EPA notes that promulgating initial area designations for these standards on the same schedule will provide early regulatory certainty for states. The EPA intends to promulgate the revised PM NAAQS in December 2012 and complete initial designations for both the revised primary annual $PM_{2.5}$ NAAQS and the secondary $PM_{2.5}$ visibility index NAAQS by December 2014 using available air quality data from the current $PM_{2.5}$ and speciation monitoring networks. These designations would follow the standard 2-year process described previously and would be based on 3 consecutive years of certified air quality monitoring data from the years 2010 to 2012, or 2011 to 2013. (Note, as discussed in sections IV.F and VI.F above, the EPA is proposing to retain the current primary 24-hour PM_{10} standard and to revise the form of the secondary annual $PM_{2.5}$ standard to

[211] While the CAA says ''designating'' with respect to the Governor's letter, in the full context of the CAA section it is clear that the Governor actually makes a recommendation to which the EPA must respond via a specified process if the EPA does not accept it.

[212] The EPA has used area-specific factor analyses to support boundary determinations by evaluating factors such as air quality data, emissions data, population density and degree of urbanization, traffic and commuting patterns, meteorology, and geography/topography.

remove the option for spatial averaging and to retain all other elements of the current suite of secondary PM standards to address non-visibility welfare effects. A new round of mandatory designations for these standards would occur only if these standards change.[213])

In today's action, as discussed in section VIII.B.3.b.i above, the EPA is proposing to add requirements for establishing near-road $PM_{2.5}$ monitors in certain cities. If these requirements are finalized, the EPA anticipates that it will take up to 3 years to establish new monitoring sites for $PM_{2.5}$ mass, plus an additional 3 years of monitoring thereafter to determine compliance with the mass-based primary and secondary $PM_{2.5}$ NAAQS based on these new monitors. This means that a complete set of air quality data for use in designations from any near-road monitoring sites would not be available until 2018. Also, as discussed in section VIII.B.3.d above, the EPA is proposing that each state with a CBSA over 1 million in population would need to have a 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. This proposal may require the addition of new monitors, or the relocation of existing monitors, in some CBSAs. The EPA is also proposing in today's action to extend the data certification period for speciation measurements by 12 months. Thus, even if EPA were to consider taking an additional year to complete the designations process (i.e., in December 2015 instead of in December 2014), data from new $PM_{2.5}$ near-road monitoring sites would not be available prior to the extended CAA designation deadline; and data from certain CSN (or IMPROVE) monitors also may not be available prior to the extended CAA designation deadline. For these reasons, the EPA does not currently intend to delay designations based on unavailability of data for either the revised primary or distinct secondary standards in order to be able to include data from these new monitors. 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.

The EPA recognizes that the number of $PM_{2.5}$ speciation monitoring sites available to support the state Governors' designation recommendations and EPA's decisions for the proposed secondary $PM_{2.5}$ visibility index NAAQS will be much smaller than the number of $PM_{2.5}$ FRM/FEM/ARM sites available to support designation recommendations and decisions for the revised annual primary $PM_{2.5}$ NAAQS. Therefore, it may well be that more areas of the nation are designated unclassifiable (or unclassifiable/attainment) for the proposed $PM_{2.5}$ visibility index NAAQS than for the proposed revised primary annual $PM_{2.5}$ NAAQS, if finalized. At this time the EPA does not believe that taking an additional year to complete designations for the secondary $PM_{2.5}$ visibility index NAAQS would change this outlook. However, the EPA intends to remain flexible with regard to the designation schedule for the proposed revised $PM_{2.5}$ NAAQS and will reassess the potential need for an extended schedule upon issuance of the final NAAQS rule and thereafter.

In summary, the EPA intends to provide designation guidance to the states at the time of the promulgation of revised NAAQS or very shortly thereafter, to assist them in formulating these recommendations. In accordance with section 107(d)(4) of the CAA, the EPA currently believes that state Governors (and tribes, if they choose) should submit their initial designation recommendations for both the revised primary annual $PM_{2.5}$ NAAQS and the distinct secondary $PM_{2.5}$ visibility index NAAQS to the EPA no later than 1 year following promulgation of any revised NAAQS (e.g., in December 2013 assuming promulgation of the revised PM NAAQS in December 2012). If the Administrator intends to modify any state area recommendation, the EPA would notify the appropriate state Governor no later than 120 days prior to making final designation decisions. A state that believes the Administrator's modification is inappropriate would have an opportunity to demonstrate to EPA why it believes its original recommendation (or a revised recommendation) is more appropriate before designations are promulgated. The Administrator would take any additional input from the state into account in making final designation decisions.

As previously stated, the EPA plans to issue guidance regarding designations for the revised $PM_{2.5}$ NAAQS at or very shortly after the time of their final promulgation. The EPA invites preliminary comment on all aspects of the designation process at this time, which the Agency will consider in developing that guidance.

B. Section 110(a)(2) Infrastructure SIP Requirements

The CAA directs states to address basic SIP requirements to implement, maintain, and enforce the standards. States are to develop and maintain an air quality management infrastructure that includes enforceable emission limitations, a permitting program, an ambient monitoring program, an enforcement program, air quality modeling capabilities, and adequate personnel, resources, and legal authority. Under CAA sections 110(a)(1) and 110(a)(2), states are to submit these SIPs within 3 years after promulgation of a new or revised primary standard. 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. Section 110(b) of the CAA provides that the EPA may extend the deadline for the ''infrastructure'' SIP submission for a new secondary standard by up to 18 months beyond the initial 3 years. If both the revised primary annual $PM_{2.5}$ NAAQS and the distinct secondary $PM_{2.5}$ visibility index NAAQS are finalized, the EPA currently believes it would be more efficient for states and the EPA if each affected state submits a single section 110 infrastructure SIP that addresses both standards at the same time (i.e., within 3 years of promulgation of any revisions to the NAAQS for PM), because the EPA does not at present discern any need for there to be any substantive difference in the infrastructure SIPs for the two standards. However, the EPA also recognizes that states may prefer the flexibility to submit the secondary NAAQS infrastructure SIP at a later date. The EPA solicits comment on these infrastructure SIP submittal timing considerations. The EPA intends to provide guidance regarding the required date(s) for submission of infrastructure SIPs at the same time as or very shortly after promulgation of the revised NAAQS.

Section 110(a)(2) of the CAA includes the following paragraphs describing specific requirements of infrastructure SIPs: (A) Emission limits and other control measures, (B) Ambient air quality monitoring/data system, (C) Programs for enforcement of control measures and for construction or modification of stationary sources, (D)(i) Interstate pollution transport and (D)(ii) Interstate and international pollution abatement, (E) Adequate resources and authority, conflict of interest, and oversight of local governments and

[213] As discussed in section in VII.A.2 above, the EPA is proposing to remove the option for spatial averaging from the form of the secondary annual $PM_{2.5}$ NAAQS consistent with the proposed change in the form of the primary annual $PM_{2.5}$ standard. The EPA does not consider this change to trigger a new round of non-discretionary designations for this standard.

regional agencies, (F) Stationary source monitoring and reporting, (G) Emergency episodes, (H) SIP revisions, (I) Plan revisions for nonattainment areas, (J) Consultation with government officials, public notification, PSD and visibility protection, (K) Air quality modeling and submission of modeling data, (L) Permitting fees, and (M) Consultation and participation by affected local entities.

The EPA interprets the CAA such that for two of the section 110(a)(2) elements, both of which pertain to nonattainment area requirements in part D, title I of the CAA, the required submittal date should not be governed by the 3-year submission deadline of section 110(a)(1). Therefore, for the reasons explained below, the following section 110(a)(2) elements are considered by EPA to be outside the scope of infrastructure SIP actions: (1) Section 110(a)(2)(C) to the extent it refers to permit programs (known as ''nonattainment new source review'') under part D; and (2) section 110(a)(2)(I) (plan revisions for nonattainment areas) in its entirety. The EPA does not expect infrastructure SIP submittals to include regulations or emission limits developed specifically for attaining the relevant standard in areas designated nonattainment for the proposed revised $PM_{2.5}$ NAAQS. Infrastructure SIPs for any final revised $PM_{2.5}$ NAAQS will be due before $PM_{2.5}$ SIPs are due to demonstrate attainment with the same NAAQS. (New emissions limitations and other control measures to attain a revised $PM_{2.5}$ NAAQS will be due 3 years from the effective date of nonattainment area designation as required under CAA section 172(c) and will be reviewed and acted upon through a separate process.) For this reason, the EPA does not expect infrastructure SIP submissions to identify new nonattainment area emissions controls.

It is the responsibility of each state to review its air quality management program's infrastructure SIP provisions in light of each revised NAAQS. Most states have revised and updated their infrastructure SIPs in recent years to address requirements associated with revised NAAQS. It may be the case that for a number of infrastructure elements, the state may believe it has adequate state regulations already adopted and approved into the SIP to address a particular requirement with respect to the revised PM NAAQS. For such portions of the state's infrastructure SIP submittal, the state may provide a ''certification'' specifying that certain existing provisions in the SIP are adequate. Although the term ''certification'' does not appear in the CAA as a type of infrastructure SIP submittal, the EPA sometimes uses the term in the context of infrastructure SIPs, by policy and convention, to refer to a state's minimal SIP submittal (e.g., in the form of a letter to the EPA from the state Governor or her/his designee).

If a state determines that its existing SIP-approved provisions are adequate in light of the revised PM NAAQS with respect to a given infrastructure SIP element (or sub-element), then the state may make a ''certification'' that the existing SIP contains provisions that address those requirements of the specific section 110(a)(2) infrastructure elements. In the case of a certification, the submittal does not have to include a copy of the relevant provision (e.g., rule or statute) itself. Rather, the submittal may provide citations to the SIP-approved state statutes, regulations, or non-regulatory measures, as appropriate, which meet the relevant CAA requirement. Like any other SIP submittal, such certification can be made only after the state has provided reasonable notice and opportunity for public hearing. This ''reasonable notice and opportunity for public hearing'' requirement for infrastructure SIP submittals appears at section 110(a), and it comports with the more general SIP requirement at section 110(l) of the CAA. Under the EPA's regulations at 40 CFR part 51, if a public hearing is held, an infrastructure SIP submittal must include a certification by the state that the public hearing was held in accordance with the EPA's procedural requirements for public hearings. See 40 CFR part 51, appendix V, paragraph 2.1(g), and 40 CFR 51.102.

In consultation with its EPA Regional Office, a state should follow applicable EPA regulations governing infrastructure SIP submittals in 40 CFR part 51—e.g., subpart I (Review of New Sources and Modifications), subpart J (Ambient Air Quality Surveillance), subpart K (Source Surveillance), subpart L (Legal Authority), subpart M (Intergovernmental Consultation), subpart O (Miscellaneous Plan Content Requirements), subpart P (Protection of Visibility), and subpart Q (Reports). For the EPA's general criteria for infrastructure SIP submittals, refer to 40 CFR part 51, appendix V, Criteria for Determining the Completeness of Plan Submissions. A recent EPA guidance memorandum identifies a number of alternatives that are available to states to reduce the administrative burden, cost, and time required to complete the CAA-required steps that are part of submitting infrastructure and other SIP revisions to EPA (McCabe, 2011). The EPA also notes that many of the infrastructure SIP provisions are not NAAQS-specific, and therefore are likely to have been approved as part of SIP actions associated with other recently promulgated NAAQS (e.g., 2006 $PM_{2.5}$ and 2008 lead NAAQS).

The EPA intends to issue a separate guidance document on section 110 infrastructure SIP requirements for any revised PM NAAQS. The target date for issuing such guidance would be no later than 1 year after the revised PM NAAQS are finalized (2 years before state submittals are due). The EPA invites preliminary comment on all aspects of infrastructure SIPs at this time, which the Agency will consider in developing future guidance.

C. Implementing the Proposed Revised Primary Annual $PM_{2.5}$ NAAQS in Nonattainment Areas

Part D of the CAA describes the various program requirements that apply to nonattainment areas for different NAAQS. Section 172 (found in subpart 1 of part D) includes the general SIP requirements that govern the $PM_{2.5}$ program. Under section 172, states are required to submit SIPs within 3 years of the effective date of area designations by the EPA. These plans need to show how the nonattainment area will attain the primary $PM_{2.5}$ standards ''as expeditiously as practicable,'' but presumptively no later than within 5 years from the effective date of designations. However, in certain cases, the EPA can approve attainment dates up to 10 years from the effective date of designations, as appropriate, considering the severity of the air quality concentrations in the area, and the availability and feasibility of emission control measures per section 172(a)(2)(C).

Section 172(a)(1) of the CAA authorizes the EPA to establish classification categories for areas designated nonattainment for the primary or secondary PM NAAQS, but does not require the EPA to do so. The implementation program for the 1997 and 2006 primary and secondary $PM_{2.5}$ standards did not include a tiered classification system. This provided a relatively simple implementation structure and flexibility for states to implement control programs tailored to the specific nature of the problem and source mix in each area. For this same reason, the EPA also does not intend to establish classifications for nonattainment areas for the proposed revised primary annual $PM_{2.5}$ standard (or for a revised primary 24-hour standard if one is promulgated). However, the EPA solicits comment on

whether a classification system would be appropriate and how a classification system could be designed.

In April 2007, the EPA issued a detailed $PM_{2.5}$ implementation rule (72 FR 20586; April 25, 2007) to provide guidance to states regarding development of SIPs to attain the 1997 $PM_{2.5}$ NAAQS. The EPA believes that the overall framework and policy approach of the implementation rule for the 1997 $PM_{2.5}$ NAAQS provides effective and appropriate guidance on the general approach for states to follow in planning for attainment of the revised primary annual $PM_{2.5}$ standard. The EPA intends to develop and propose a revised implementation rule that will address any new implementation requirements as a result of the proposed revised primary annual $PM_{2.5}$ NAAQS and the proposed revised monitoring regulations. The EPA intends to propose this implementation rule within 1 year after the revised PM NAAQS are promulgated, and finalize the implementation rule by no later than the time the area designations process is finalized (approximately 1 year later). The EPA believes that for many issues, regulatory text similar to that of the existing implementation rule for the 1997 $PM_{2.5}$ NAAQS can be included in this new implementation rule. In the implementation rule for the 1997 $PM_{2.5}$ NAAQS, there are a few specific references to the 1997 annual $PM_{2.5}$ NAAQS or associated implementation dates; in a proposed implementation rule for any revised $PM_{2.5}$ NAAQS, such references would be updated as appropriate. In addition, the EPA expects to consider options for potentially updating certain policies in the existing implementation rule based on new information or implementation experience. The EPA solicits preliminary comment on the implementation issues that the Agency should consider for updating.

Under the approach outlined in the implementation rule for the 1997 $PM_{2.5}$ NAAQS, the state begins the development of an attainment demonstration with the evaluation of the air quality improvements the nonattainment area can expect in the future due to ''on the books'' existing federal, state, and local emission reduction measures. The state then must conduct a further assessment of emission sources in the nonattainment area, and the additional reasonably available control measures (RACM) and reasonably available control technology (RACT) that can be implemented by these sources, in determining how soon the area can attain the standard. (Under the current implementation rule, the sources for consideration would be those emitting SO_2, direct $PM_{2.5}$, and presumptively NO_X. Sources of the other $PM_{2.5}$ precursors, VOC and ammonia, presumptively do not need to be evaluated for control measures unless demonstrated by the state or the EPA as significant contributors to $PM_{2.5}$ concentrations in the relevant nonattainment area.) Under section 172 of the CAA as interpreted by the EPA, attainment demonstrations must include a RACM analysis showing that no additional reasonably available measures could be adopted and implemented such that the SIP could specify an attainment date that is 1 or more years earlier.

The evaluation of these potential emission reductions and associated air quality improvement is commonly performed with sophisticated air quality modeling tools. Given that fine particle concentrations are affected both by regionally-transported pollutants (e.g., SO_2 and NO_X emissions from power plants) and emissions of direct $PM_{2.5}$ from local sources in the nonattainment area (e.g., steel mills, rail yards, and highway mobile sources), the EPA recommends the use of regional grid-based models (such as CMAQ and CAMx) in combination with source-oriented dispersion models (such as AERMOD) to develop $PM_{2.5}$ attainment strategies for the revised annual primary NAAQS. Although the EPA projects significant improvements in $PM_{2.5}$ concentrations regionally from a number of recently promulgated rules such as the Cross State Air Pollution Rule (76 FR 48208, August 8, 2011) and the Mercury and Air Toxics Standards rule (77 FR 9304, February 16, 2012) that will result in SO_2 and NO_X reductions from many geographically dispersed sources, local reductions of direct $PM_{2.5}$ emissions also result in important health benefits. On a per ton basis, reductions of direct $PM_{2.5}$ emissions are more effective in reducing $PM_{2.5}$ concentrations than reductions of precursor emissions. Therefore, reductions of direct $PM_{2.5}$ emissions should play a key role in attainment planning as well.

Each nonattainment area needs to ensure that it will make ''reasonable further progress'' (RFP) in accordance with section 172(c)(2) of the CAA from the time of SIP submittal to its attainment date. Under the approach outlined in the implementation rule for the 1997 $PM_{2.5}$ NAAQS, for an area that can demonstrate it will attain the standard within the presumptive 5-year period from designation, its attainment demonstration will be considered to meet the RFP requirement. The EPA believes it is appropriate to apply this same approach for the revised annual primary $PM_{2.5}$ standard. The EPA believes there should be no additional RFP requirements for such an area because the SIP and attainment demonstration would be due 3 years after designations and its attainment date will be only 2 years after that date. An area that cannot demonstrate attainment within the presumptive 5-year period would be required to provide a separate RFP plan showing that the area will achieve emission reductions by certain interim milestone dates which provide for ''generally linear'' progress over the course of the implementation period. All $PM_{2.5}$ attainment plans must also include contingency measures which would apply without significant delay in the event the area fails to attain by its attainment date.

The EPA expects that the same general approach for determining attainment of the 1997 $PM_{2.5}$ primary standard by the attainment deadline would be followed for determining attainment with any primary $PM_{2.5}$ standard. Attainment would be evaluated based on the 3 most recent years of certified, complete, and quality-assured air quality data in the nonattainment area. The EPA also would expect to include similar flexibility provisions for an area to be able to obtain two 1-year attainment date extensions under certain circumstances. In the 1997 $PM_{2.5}$ NAAQS implementation rule, an area whose design value based on the most recent 3 years of data exceeds the standard could receive a 1-year attainment date extension if the air quality concentration for the third year alone does not exceed the level of the standard. Similarly, an area that has received a 1-year extension could receive a second 1-year extension if the average of the area's air quality concentration in the ''extension year'' and the previous year does not exceed the level of the standard.

The EPA notes that in other sections of today's proposal, the EPA describes new requirements for deploying near-road monitors and clarifies certain existing monitoring provisions. As discussed in the designations section, the EPA would not expect that data from any new near-road $PM_{2.5}$ monitors would be available in time to consider during the initial area designations process, and therefore such monitoring data would not be the basis for designating a new nonattainment area at the time of initial designations. The EPA plans to address any potential implications of the proposed monitoring

changes on attainment planning and development of attainment demonstrations by states in the future implementation rule. The EPA requests comment on any specific attainment planning considerations for future SIPs that may be associated with today's proposed changes to monitoring provisions.

With regard to implementation of the pre-existing standards for $PM_{2.5}$, the EPA's current opinion is that the changes in the monitoring regulations, if finalized, should not result in any new requirements with respect to attainment plans or maintenance plans for the 1997 or the 2006 $PM_{2.5}$ NAAQS during some specified transition period.[214] For example, if the proposed PM NAAQS revisions and revised monitoring regulations are finalized in December 2012, many states will have recently submitted, or will be close to submitting their implementation plans to attain the 2006 24-hour $PM_{2.5}$ NAAQS (also due in December 2012). In addition, state and EPA actions are still under way with regard to adopting and approving certain attainment plans and maintenance plans for nonattainment areas under the 1997 $PM_{2.5}$ standards. The EPA does not believe it would be reasonable for requirements applicable to such attainment plans and maintenance plans to change beginning immediately upon any revision of the monitoring regulations. It could be very burdensome on state air quality programs to revise SIPs that have already been submitted to EPA or that have been under development for some time and are about to be submitted. The EPA believes that a more reasonable approach would be to provide for a transition period before the revised monitoring network and data comparability provisions would affect implementation plan and maintenance plan requirements. The EPA believes it would be important for the transition period to provide enough time for the EPA to complete action on attainment and maintenance SIPs for the 1997 or 2006 $PM_{2.5}$ NAAQS that were initiated and completed (or that are close to completion) by states before finalization of the proposed changes to the monitoring regulations. The EPA believes that if a SIP for the 1997 or 2006 $PM_{2.5}$ NAAQS has been approved during the transition period, the state would not be under an obligation to revise it unless the EPA has made a SIP call. The EPA invites preliminary comment on this transition period concept, and on an appropriate date by which the transition period should be concluded.

D. Implementing the Primary and Secondary PM_{10} NAAQS

As summarized in sections IV.F and VI.F above, the EPA is proposing to retain the current primary and secondary 24-hour PM_{10} standards to protect against the health effects associated with short-term exposures to thoracic coarse particles and against welfare effects. If this approach is finalized, the EPA would retain the existing implementation strategy for meeting the CAA requirements for PM_{10}. States and emission sources would continue to follow the existing guidance and regulations for implementing the current standards.

E. Implementing the Proposed Secondary $PM_{2.5}$ Visibility Index NAAQS in Nonattainment Areas

In past actions, the EPA has set the secondary PM standards identical to the primary PM standards. In this action, as summarized in section VI.F above, the EPA is proposing a distinct secondary $PM_{2.5}$ visibility index NAAQS. In addition, as also summarized in section VI.F above, the EPA is proposing to retain the current annual and 24-hour secondary $PM_{2.5}$ standards to provide protection against non-visibility welfare effects. Although the proposed secondary $PM_{2.5}$ visibility index NAAQS would differ from the primary $PM_{2.5}$ NAAQS (and existing secondary $PM_{2.5}$ NAAQS) with respect to indicator/index, statistical form, and level, attainment of this standard would, like the $PM_{2.5}$ mass-based standards, depend on ambient measurements (i.e., specifically speciated $PM_{2.5}$ mass concentrations). The EPA expects that implementation of emission reduction measures that will help to achieve the mass-based 1997 and 2006 primary and secondary $PM_{2.5}$ standards and the proposed revised primary annual $PM_{2.5}$ standard will also provide important improvements in visibility and substantial progress toward meeting the proposed secondary $PM_{2.5}$ visibility index standard because these emission reduction measures will address the same sources and pollutants which also contribute to PM-related visibility impairment. In fact, as discussed below in section IX.F.1, an analysis of the relationships between recent design values for the proposed primary (annual and 24-hour) $PM_{2.5}$ standards and coincident design values for the proposed $PM_{2.5}$ visibility index standard indicates that all or nearly all areas in attainment of the proposed primary $PM_{2.5}$ standards would also likely be in attainment of the proposed secondary $PM_{2.5}$ visibility index standard (Kelly, et al. 2012).[215]

Section 172(a)(1) of the CAA authorizes the EPA to establish classification categories for areas designated nonattainment for the primary or secondary PM NAAQS, but does not require the EPA to do so. The implementation program for the 1997 and 2006 primary and secondary $PM_{2.5}$ standards did not include a tiered classification system. This provided a relatively simple implementation structure and flexibility for states to implement control programs tailored to the specific nature of the problem and source mix in each area. For this same reason, the EPA also does not intend to establish classifications for nonattainment areas for the proposed secondary $PM_{2.5}$ visibility index standard.

Section 172(a)(2) of the CAA provides the same statutory framework for implementing secondary standards in nonattainment areas as it does for primary standards, except that it provides different attainment date requirements for secondary standards. The attainment date for the proposed revised primary annual $PM_{2.5}$ standard is as expeditiously as practicable, but presumptively within 5 years of the date of designation, with the possibility of an attainment date of up to 10 years for certain areas with more severe air quality problems. For secondary NAAQS, however, section 172(a)(2)(B) defines the attainment date for an area designated nonattainment as ''the date by which attainment can be achieved as expeditiously as practicable'' but with no maximum limitation. Thus, it is possible for the EPA to approve an implementation plan that provides for attainment of the secondary standards by a date more than 10 years after the date of designation with an appropriate demonstration.

As noted in the above section on implementing the primary $PM_{2.5}$ standard, the EPA expects that the same general approach for providing two possible 1-year extensions to the

[214] For example, it may be possible that a new near-road monitoring site has collected 3 years of data and shown a violation before final EPA action has been taken on an attainment plan or maintenance plan for the 1997 or 2006 NAAQS.

[215] This analysis was based on 2008 to 2010 air quality data and for illustrative purposes used an alternative standard level of 12 $\mu g/m^3$ for the primary annual $PM_{2.5}$ standard and the proposed level of 35 $\mu g/m^3$ level for the primary 24-hour $PM_{2.5}$ standard together with the proposed levels of 30 and 28 dv in conjunction with a 24-hour averaging time and a 90th percentile form for the secondary $PM_{2.5}$ visibility index standard. The relationships between design values as characterized here are dependent upon the specific level and form of each of the standards.

attainment date would also apply to any revised secondary $PM_{2.5}$ standard. Attainment would be evaluated based on the 3 most recent years of certified, complete, and quality-assured air quality data in the nonattainment area. The EPA also would expect to include similar flexibility provisions for an area to be able to obtain two 1-year attainment date extensions under certain circumstances. An area whose design value based on the most recent 3 years of data exceeds the standard could receive a 1-year attainment date extension if the deciview index for the third year alone does not exceed the level of the standard. Similarly, an area that has received a 1-year extension could receive a second 1-year extension if the average of the area's deciview index in the ''extension year'' and the previous year does not exceed the level of the standard.

As noted previously, the EPA expects that implementation of control measures to achieve the 1997 and 2006 primary annual and 24-hour $PM_{2.5}$ standards and the proposed revised primary annual $PM_{2.5}$ standard will address the same sources and pollutants that contribute to PM-related visibility impairment, and, thus, great progress can be achieved toward attaining the proposed secondary $PM_{2.5}$ visibility index standard as a result of clean air programs designed principally to improve public health by attaining the primary $PM_{2.5}$ standards. However, because the proposed secondary $PM_{2.5}$ standard is based on a visibility index rather than a mass concentration, implementation can be expected to present new challenges when developing part D SIPs. For example, while the proposed revision to the level and form of the primary annual $PM_{2.5}$ standard does not pose any new issues with respect to air quality modeling methods, the speciated nature of the index for the proposed secondary $PM_{2.5}$ visibility index standard does pose new modeling issues. For this reason, the EPA invites commenters to present information concerning air quality modeling and other issues that are expected to be unique to implementing the proposed secondary $PM_{2.5}$ visibility index standard in nonattainment areas and that should be considered by EPA in the development of the future implementation rule and related guidance. The EPA particularly seeks input on how implementation planning for the proposed secondary $PM_{2.5}$ visibility index standard can be integrated as much as possible with implementation planning for the proposed revised primary annual $PM_{2.5}$ standard to increase the efficiency of the process and reduce administrative burden on state agencies and stakeholders. The EPA will consider these comments in developing a proposed implementation rule and related guidance for the revised standards.

F. Prevention of Significant Deterioration and Nonattainment New Source Review Programs for the Proposed Revised Primary Annual $PM_{2.5}$ NAAQS and the Proposed Secondary $PM_{2.5}$ Visibility Index 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 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 NNSR program, respectively. Collectively, those permit requirements are commonly referred to as the ''major NSR program.''

The proposed revised primary annual $PM_{2.5}$ NAAQS and proposed secondary $PM_{2.5}$ visibility index NAAQS, if finalized, would affect certain PSD permitting actions as of the effective date for those NAAQS and would affect certain NNSR permitting actions on and after the effective date of an area designation as ''nonattainment'' for $PM_{2.5}$. In order to minimize the potential for disruption to NSR permitting, the EPA is proposing, in section IX.F.1.a of this preamble, a grandfathering provision for certain PSD permits that are already in process, and is also proposing, in section IX.F.1.c, a surrogacy approach for implementing PSD permitting requirements for the proposed secondary $PM_{2.5}$ visibility index NAAQS. These provisions will assure that NSR permitting will be able to continue using provisions and processes virtually identical to those already in place for the existing $PM_{2.5}$ NAAQS, except that, in evaluating whether a source causes or contributes to a NAAQS violation, an applicant would need to compare the source's impacts to a different level and form of the primary annual standard, if finalized as proposed. As discussed in more detail in the following sections, the EPA is not now proposing to change the $PM_{2.5}$ increments, nor are we proposing to revise screening tools that are now used to implement PSD for $PM_{2.5}$, such as the significant emission rate, 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, 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; or the significant monitoring concentration, 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.

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 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 construction 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 first became applicable to $PM_{2.5}$ in 1997 when EPA established a NAAQS for $PM_{2.5}$ (Seitz, 1997). The EPA's regulations define the term ''regulated NSR pollutant'' to include ''[a]ny pollutant for which a national ambient air quality standard has been promulgated and any pollutant identified [in EPA regulations] as a constituent or precursor to such pollutant'' (40 CFR 51.166(b)(49); 40 CFR 52.21(b)(50)).[216] In addition, on May 16, 2008, the EPA amended its rules 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). States 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 rules at 40 CFR 51.166 and 52.21 to add PSD increments as well as two screening tools for $PM_{2.5}$—significant impact levels (SILs) and a significant monitoring concentration (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, 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 are required to submit the necessary SIP revisions (at least as stringent as the PSD requirements at 40 CFR 51.166) to EPA for approval within 21 months from the date on which the EPA promulgated the new $PM_{2.5}$ increments—by July 20, 2012. This particular schedule is prescribed by the CAA specifically for the adoption of new PSD increments in state PSD programs. Sources for which PSD permits are issued pursuant to the federal PSD program at 40 CFR 52.21 after October 20, 2011, must 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 with the ambient air indicators for PM that the EPA currently uses in 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 themselves, for which proposed and other possible implementation approaches are described further below, the EPA is proposing certain clarifications to the existing monitoring regulations codified at 40 CFR 58.30 (Special considerations for data comparisons to the NAAQS). These proposed 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 used the principles for making these determinations for monitoring sites to also 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. The EPA will continue to use these principles in guiding PSD modeling analysis design. Accordingly, if the proposed PM NAAQS revisions and monitoring regulation clarifications described previously are finalized, the EPA will advise permitting agencies to qualify or disqualify specific receptor locations used in PSD air quality analyses consistent with those final provisions, and we will do so ourselves when we are the permitting authority.

With regard to the specific revisions being proposed to the PM NAAQS, today's action, if finalized as proposed, would affect sources applying for PSD permits in several ways. We first discuss the implications for PSD with respect to the proposed revised primary annual $PM_{2.5}$ standard (some of which also apply to the proposed secondary $PM_{2.5}$ visibility index standard), and then the unique implications for PSD with respect to the proposed secondary $PM_{2.5}$ visibility index standard.

a. Grandfathering Provision

As discussed previously in this preamble, the EPA is proposing to revise the level of the primary annual $PM_{2.5}$ NAAQS and establish a secondary $PM_{2.5}$ visibility index NAAQS.[217] Longstanding EPA policy interprets the CAA and EPA regulations at 40 CFR 52.21(k)(1) and 51.166(k)(1) to generally require that PSD permit applications must include a demonstration that new sources and 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, if the proposed revision to the primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS are promulgated, any proposed new and modified sources with permits pending at the time those $PM_{2.5}$ NAAQS changes take effect would be expected to demonstrate compliance with them, 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 proposed revision of the primary annual NAAQS, the proposed addition of a distinct secondary NAAQS for visibility protection, and the changes to the monitoring requirements discussed earlier, the EPA proposes 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 NAAQS. The EPA proposes that the grandfathering provision would apply specifically to pending PSD permit applications for which the proposed permit (draft permit or preliminary determination) has been noticed for public comment before the effective date of the revised NAAQS.

The proposed grandfathering provision would not be the first such grandfathering provision adopted by the EPA. The Agency 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). As discussed in more detail in these referenced actions, section 165(a)(3) of the CAA requires that a permit applicant demonstrate that its proposed project will not cause or contribute to a violation of any NAAQS. At the same time, section 165(c) of the CAA requires that a PSD permit be

[216] 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.

[217] The EPA is also proposing to revise 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.

granted or denied within 1 year after the permitting authority determines the application for such permit to be complete. In addition, section 301 of the CAA authorizes the Administrator ''to prescribe such regulations as are necessary to carry out his functions under this chapter.'' When read in combination, these three provisions of the CAA provide the EPA with the discretion to promulgate regulations to grandfather pending permit applications from having to address a revised NAAQS where necessary to achieve a balance between the CAA objectives 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 59587 to 59588, Oct. 12, 2005). The reasoning of those prior EPA actions is also applicable to the promulgation of revised PM NAAQS.[218]

The CAA provides the EPA with discretion to establish the appropriate milestone within the permitting process for determining that a permit application is eligible for grandfathering (U.S. EPA, 2011c, p. 81). For example, in 1987, the EPA used the date of submittal of a complete permit application as the milestone upon which to base the grandfathering of a source from new permitting requirements associated with the revisions made to the PM NAAQS at that time (52 FR 24672, July 1, 1987 at 24703). In the context of the implementation of the revisions to the PM NAAQS that are being proposed today, the EPA is proposing to use a different milestone to establish the date before which permits may be grandfathered. Accordingly, to avoid unreasonable delays in permit processing and issuance, and based on basic principles of fairness and equity, we believe that it is appropriate to allow pending permit applications that have reached the notice and comment period on a proposed permit (that is, a notice has been issued for public comment on the proposed permit action) by the effective date of the revised PM NAAQS to continue being processed in accordance with the PM NAAQS requirements in place as the time of the public notice on the proposed permit.[219]

Before a proposed permit is issued for public comment, the applicant still has a reasonable opportunity to amend its permit application to address new or revised NAAQS that become effective while the reviewing authority's preliminary consideration of the application is underway. Furthermore, the reviewing authority has the opportunity to review additional material and revise its fact sheet or statement of basis before beginning the public comment period on such a permit. However, if the EPA and other reviewing authorities were to apply new permitting requirements based on 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 additional work by the reviewing authority at a time when it should be focused on considering public comments and preparing a final permit decision in order to conclude its review of a permit application in a timely manner. Through this proposal, the EPA is providing notice to current and future permit applicants that they may have to provide an analysis showing that their facility will not cause or contribute to a violation of the revised NAAQS for PM if a proposed permit is not issued for public comment before such NAAQS become effective.

Accordingly, the EPA proposes to amend the federal PSD regulations at 40 CFR 52.21 to provide a grandfathering provision to allow for the continued review of permits proposed before a revision to the 2006 p.m. NAAQS under the PM NAAQS that applied at the time of the public notice on the proposed permit. The EPA also proposes that states that issue PSD permits under a 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 proposes to revise section 40 CFR 51.166 to provide a comparable exemption applicable to SIP-approved PSD programs.

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 action would no longer be grandfathered from PSD permitting requirements associated with a revised PM NAAQS. Consistent with past grandfathering actions described above, the EPA is not proposing to include a sunset clause for the proposed grandfathering provision. Permit applicants and reviewing authorities already have strong incentives to process applications and issue draft permits in a timely manner, and the EPA does not believe that the addition of a sunset clause to the proposed grandfathering provision would add meaningful additional incentive for sources or permitting authorities to expedite permitting processes. Furthermore, the EPA believes 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 draft permit issuance and public notice to lapse beyond the sunset date. In such cases, the already delayed permit action would be further delayed to address PSD permitting requirements associated with the revised PM 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. However, the EPA solicits comment on whether a sunset clause would be appropriate under certain circumstances, and if so, what time limits would be placed on the grandfathering period associated with the revised PM NAAQS.

b. Recent Guidance Applicable to the Proposed Revised Primary Annual $PM_{2.5}$ NAAQS

Today's proposal to revise the level of the primary annual $PM_{2.5}$ NAAQS from 15.0 $\mu g/m^3$ to a level within the range of 12.0 and 13 $\mu g/m^3$ and to establish a distinct secondary $PM_{2.5}$ visibility index NAAQS generally will require proposed new major stationary sources and modifications to take these changes into

[218] 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 through adjudication respecting a specific source, 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 EPA generally believes the preferred approach is to enable grandfathering through express regulatory exemptions of the type proposed in this action (U.S. EPA, 2011c, p. 68).

[219] There may be proposed permits 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 grandfathering provision proposed today 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.

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. If the PM NAAQS are revised as proposed, and when effective, proposed sources that are not grandfathered from the new requirements (as described in section IX.F.1.a) would be required to demonstrate compliance with the suite of PM NAAQS, including the revised primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index 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 their impact on the revised primary annual $PM_{2.5}$ NAAQS, if finalized. 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 $PM_{2.5}$. 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 for the existing $PM_{2.5}$ NAAQS, 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. (As discussed in the next section, these recommended approaches may be extended to the proposed secondary NAAQS as well under a surrogacy approach). To this end, the EPA discussed this draft guidance in March 2012 at the EPA's 10th Modeling Conference.[220] Based on its review of public comments received and further technical analyses, the EPA intends to issue final guidance by the end of calendar year 2012.

c. Surrogacy Approach for the Proposed Secondary $PM_{2.5}$ Visibility Index NAAQS

As summarized in section VI.F of this preamble, the EPA is proposing a distinct secondary NAAQS for $PM_{2.5}$ that will provide protection against visibility impairment, measured in terms of a visibility index using a calculated $PM_{2.5}$ light extinction indicator (see section VI.D.1 above). The $PM_{2.5}$ visibility index values are determined using a six-step procedure involving 24-hour speciated $PM_{2.5}$ concentration data together with climatological relative humidity factors. The EPA plans to calculate design values for the proposed secondary $PM_{2.5}$ visibility index NAAQS using the procedures described in section VII.A.5 above, relying upon ambient $PM_{2.5}$ speciation measurement data available through the CSN or IMPROVE methods and spatial interpolation of historical relative humidity data.

As explained above, the PSD program requires individual new or modified stationary sources to carry out an air quality analysis to demonstrate that their proposed emissions increases will not cause or contribute to a violation of any NAAQS. Such a demonstration for the proposed secondary $PM_{2.5}$ visibility index NAAQS could require each PSD applicant to predict, via air quality modeling, the visibility impairment that will result from its proposed emissions in conjunction with an assessment of existing air quality (visibility impairment) conditions. Under 40 CFR 51.166(l)(1) and 40 CFR 52.21(l)(1), all applications of air quality modeling for purposes of determining whether a new or modified source will cause or contribute to a NAAQS violation, including a violation of the proposed secondary visibility index NAAQS for $PM_{2.5}$, must be based upon air quality models specified in appendix W to 40 CFR part 51. Currently there are no air quality models identified in Appendix W that are recommended for regulatory applications (Appendix W to 40 CFR part 51, Section 3.1.1(b)) for addressing the atmospheric chemistry associated with secondary formation of $PM_{2.5}$. Thus, if this demonstration were to be attempted using the six-step procedure that the EPA is proposing to use for calculating $PM_{2.5}$ visibility index design values, significant technical issues with the modeling procedures could arise. Those technical difficulties include the current limitations on speciated source-specific emissions data for model input; the lack of an EPA-approved air quality model with the capability to address the atmospheric chemistry associated with secondary formation of $PM_{2.5}$; and the lack of PSD screening tools for streamlining the air quality analysis process. In addition, due to the limited monitoring network for speciated $PM_{2.5}$, some sources may not be able to rely on existing speciated monitoring data to adequately represent the background air quality and thereby satisfy preconstruction monitoring requirements. Consequently, those prospective PSD sources could be required to collect new data in order to determine the representative background concentrations of $PM_{2.5}$ species (i.e., those required for calculating the $PM_{2.5}$ visibility index values as described in section VII.A.5 above).

Recognizing these difficult technical issues, the EPA believes that there is an essential need to provide alternative approaches to enable prospective PSD sources to demonstrate that they will not cause or contribute to a violation of the secondary $PM_{2.5}$ visibility index NAAQS, if finalized as proposed. To meet this need, the EPA believes that it is reasonable to allow the use of a surrogacy approach, as discussed below, for at least the interim period while technical issues are being resolved, but which could potentially be continued beyond such time if shown to be appropriate. The EPA is providing notice of its intent to follow such an approach and is asking for comments on the approach as discussed in the remainder of this section. The Agency believes that following this approach will facilitate the transition to a workable PSD permitting approach under the proposed secondary $PM_{2.5}$ visibility index NAAQS.

To support consideration of alternative approaches that could be used by prospective PSD sources, the EPA conducted a two-pronged technical analysis of the relationships between the proposed $PM_{2.5}$ visibility index standard and the 24-hour $PM_{2.5}$ standards (Kelly, et al., 2012). 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 $PM_{2.5}$ 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 analysis indicated that small increases in $PM_{2.5}$ concentrations caused by individual

[220] The presentation on this draft guidance was posted on the EPA Web site at: *http://www.epa.gov/ttn/scram/10thmodconf.htm.*

sources produce similarly small changes in visibility impairment for ambient conditions near the proposed standard level of either 30 dv or 28 dv. The second prong of the analysis addressed aspects of a PSD cumulative impact analysis by exploring the relationship between the 3-year design values for the primary and secondary 24-hour $PM_{2.5}$ standards and coincident design values for the proposed $PM_{2.5}$ visibility index standard based on recent air quality data. This analysis showed that visibility generally decreases when daily $PM_{2.5}$ concentrations increase, and vice versa. This analysis further explored the appropriateness of using a demonstration that a source will not cause or contribute to a violation of the 24-hour $PM_{2.5}$ standards as a surrogate for a demonstration that a source will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index standard. The Kelly, et al. (2012) analysis was based on 2008 to 2010 air quality data and on the proposed retention of the 24-hour $PM_{2.5}$ standards with a level of 35 $\mu g/m^3$ in conjunction with a 98th percentile form (sections III.F and IV.F) and the proposed secondary $PM_{2.5}$ visibility index standard with a level of either 30 dv or 28 dv in conjunction with 24-hour averaging time and a 90th percentile form (see section VI.F).[221] This analysis indicated that all or nearly all areas in attainment of the 24-hour $PM_{2.5}$ standards would also likely be in attainment of the proposed secondary $PM_{2.5}$ visibility index standard.

The EPA believes that this technical analysis is robust and will have broad national application. Based on this technical analysis, the EPA currently believes that there is sufficient evidence that, for the purposes of making a demonstration under the PSD program that a new or modified source will not cause or contribute to a violation of the proposed secondary 24-hour $PM_{2.5}$ visibility index NAAQS, a demonstration that the source will not cause or contribute to a violation of the mass-based 24-hour $PM_{2.5}$ NAAQS serves as a suitable surrogate. As such, many or all sources undergoing PSD review for $PM_{2.5}$ would be able to rely upon their analysis demonstrating that they will not cause or contribute to a violation of the mass-based 24-hour $PM_{2.5}$ NAAQS to also demonstrate that they will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index NAAQS, if finalized. The described surrogate approach would thus serve to overcome the technical challenges discussed above and minimize otherwise burdensome and costly air quality analyses associated with individual sources being required to perform separate and distinct analyses with regard to the proposed secondary $PM_{2.5}$ visibility index standard. The EPA believes this surrogacy approach is appropriate to fulfill PSD requirements for individual sources in PSD areas, which, by definition, will not have been designated as nonattainment for the $PM_{2.5}$ visibility index NAAQS. However, our proposed surrogacy approach for PSD should not be construed as a proposal to use a surrogacy approach for designating nonattainment areas or for implementing programs to attain the visibility index NAAQS in those areas.

The surrogacy approach is not intended to replace or otherwise undermine the validity of the analytical techniques employed for air quality related value (AQRV) assessments, including visibility, required under 40 CFR 51.166(p) and 40 CFR 52.21(p). The federal land managers (FLM)—federal officials with direct responsibility for management of Federal Class I parks and wilderness areas—have an affirmative responsibility to protect the AQRVs of such lands, and to provide the appropriate procedures and analysis techniques for assessing AQRVs (Appendix W to 40 CFR part 51, Sections 6.1(b) and 6.2.3(a)). The FLMs have developed specific modeling approaches for AQRV assessments that are not specifically governed under the requirements set forth in 40 CFR 51.166(l)(1) and 40 CFR 52.21(l)(1), thus the surrogacy approach is not applicable to the AQRV assessments under the PSD program.

The surrogate approach could be incorporated into the PSD program in any of three alternative ways. First, the decision as to whether the surrogate approach is adequate could be handled on a case-by-case basis in consultation with the permitting authority, similar to the existing consultation process under the EPA's Guideline on Air Quality Models for ozone and secondary $PM_{2.5}$ impacts (40 CFR part 51, appendix W, section 5.2.1.c), with no presumption regarding its adequacy. Second, the EPA could establish a rebuttable presumption that the surrogate approach is applicable for all permits through either guidance or a notice-and-comment rulemaking. In either the first or second alternative, there would be a possibility that reliance on a surrogate-based demonstration could be subjected to challenge for any particular permit analysis. Third, the EPA could establish that the surrogate approach is applicable for all permits, also through a notice-and-comment rulemaking. The EPA seeks comment on all of the identified issues and proposed alternative implementation mechanisms associated with the proposed surrogate approach. It is the Agency's intention to issue either guidance or new regulatory provisions as just described for a surrogacy approach by the time any final revisions to the PM NAAQS become effective, so that sources seeking permits will not be unnecessarily delayed.

While noting the importance of the surrogacy approach as an essential initial strategy due to limitations on data and analytical tools, the EPA also notes that when a technically robust surrogate relationship exists there may not be a need to apply an end date for the use of a surrogacy approach. Without an end date, PSD applicants would always have the option of relying upon such a demonstration if they would so choose. This would offer long-term benefits in terms of simplification and resource savings for applicants and reviewing authorities. Accordingly, based on the technical analysis for the standards analyzed (Kelly, et al, 2012) which supports the surrogacy approach for demonstrating that a source will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index NAAQS, the EPA may determine that it is not necessary to announce an end date for using it. The EPA invites comment on this aspect of the proposal as well.

For context, the EPA notes that with regard to sources being required to demonstrate that they would not cause or contribute to a violation of the 1997 $PM_{2.5}$ NAAQS, the EPA has previously issued an interim policy (Seitz, 1997). Under the 1997 policy, which is no longer in effect,[222] the EPA stated that demonstrating compliance with the NSR requirements for controlling PM_{10} emissions and for analyzing impacts on PM_{10} air quality could be used to demonstrate compliance with the $PM_{2.5}$ NSR requirements. This approach was designed to control $PM_{2.5}$ emissions and protect $PM_{2.5}$ air quality until certain technical difficulties concerning $PM_{2.5}$ were resolved. At that time, however, we did not support the policy with any technical analysis to show how a demonstration of compliance with the PM_{10} NAAQS would satisfy the $PM_{2.5}$

[221] As identified in section IX.E above, the relationships between design values characterized in the Kelly, et al. (2012) analysis and summarized here are dependent upon the specific level and form of each of these standards.

[222] The 1997 PM_{10} Surrogate Policy formally ended on May 16, 2011. See 76 FR 28646 (May 18, 2011).

requirements and support the issuance of a PSD permit. Consequently, the EPA later concluded that, in keeping with numerous court opinions regarding the use of surrogates, PSD applicants and reviewing authorities seeking to rely specifically on the 1997 PM_{10} Surrogate Policy should consider certain overarching legal principles, including that a surrogate may be used only after it has been shown to be reasonable (such as where the surrogate is a reasonable proxy for the pollutant or has a predictable correlation to the pollutant) and that the relationship between the regulated pollutant and the surrogate pollutant can be shown to apply in the specific instance where an applicant or reviewing authority seeks to rely upon it. In keeping with these principles, the Agency believes that the surrogate approach now being proposed for use in demonstrating that a source will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index NAAQS is supported by a robust technical analysis. The EPA invites comment on this analysis, which is provided in the docket for this action.

The EPA notes that the analysis supporting the surrogacy approach for the PSD program is distinct from and serves a different purpose than the analyses conducted to inform the Administrator's proposed conclusion on the appropriate indicator for a standard intended to protect against PM-related visibility impairment. As discussed in section VI.A above, the EPA has long recognized that the determination of a single, appropriate national level for a secondary standard to address PM-related visibility impairment is complicated by regional differences in several factors that influence visibility, such as background and current $PM_{2.5}$ concentrations, $PM_{2.5}$ composition, 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 the appropriate degree of protection in a different region. Although the analysis upon which the surrogacy approach is based (Kelly, et al., 2012) generally shows that daily $PM_{2.5}$ visibility index values decrease when daily $PM_{2.5}$ mass concentrations decrease, and vice versa, there is nonetheless considerable variability in that relationship across the range of ambient fine particle concentrations. As a result, as discussed in section VI.D.1.d above, the Administrator provisionally concludes that a calculated $PM_{2.5}$ light extinction indicator is an appropriate indicator to replace the current $PM_{2.5}$ mass indicator and that such an indicator 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.

d. PSD Screening Provisions: Significant Emissions Rates, Significant Impact Levels, and Significant Modeling 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 a significant emissions rate (SER), significant impact levels (SILs), and a significant monitoring concentration (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.[223] 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 time of any NAAQS for a particular pollutant. At this time, the EPA is not proposing any change to the existing $PM_{2.5}$ SER as a result of the proposed revisions to the primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS. However, the EPA intends to consider this issue in a subsequent rulemaking that will specifically address various PSD implementation issues that are being described herein. The EPA will solicit comment on any proposed changes to the SERs for $PM_{2.5}$ and its precursors at that time, but also invites preliminary suggestions at this time that we may consider in developing that proposed rulemaking. 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 in existing regulations.

Once it is determined that the proposed new source or modification is significant for $PM_{2.5}$, the permit applicant must complete an air quality analysis. 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 SMC for $PM_{2.5}$ (75 FR 64890 to 64894, October 20, 2010). A separate $PM_{2.5}$ SIL is defined for each averaging period for which $PM_{2.5}$ NAAQS and increments currently exist, as well as for each of the three area classifications, i.e., Class I, II and III, that Congress established in the CAA for PSD purposes.

Historically, sources have been allowed to model their proposed emissions increase to predict ambient impacts associated with that emissions increase, and to compare this predicted 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. At this time, the EPA is not proposing to revise the annual SIL for $PM_{2.5}$ as a result of the proposed revision to the primary annual $PM_{2.5}$ NAAQS. However, the EPA intends to review this issue and will consider any potential need to revise the existing SIL in a separate rulemaking addressing PSD implementation issues. The EPA welcomes preliminary comments concerning this issue, but will also provide an additional opportunity for comments at a later date in the event that a subsequent proposal is made to revise the annual $PM_{2.5}$ SIL.

While the proposed secondary $PM_{2.5}$ visibility index NAAQS is a 24-hour standard for which no $PM_{2.5}$ SIL is currently defined, there is a question as to whether the existing 24-hour $PM_{2.5}$ SIL, expressed on a $PM_{2.5}$ mass basis ($\mu g/m^3$), would be appropriate for this proposed secondary NAAQS, expressed in terms of a $PM_{2.5}$ visibility index. As discussed in section IX.F.1.c above, the EPA conducted an analysis to evaluate whether an individual source's impact resulting in a small increase in $PM_{2.5}$ concentration would produce a comparably small increase in visibility impairment (Kelly et al., 2012). The

[223] 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.

analysis indicates that small increases in $PM_{2.5}$ concentrations caused by individual sources produce similarly small changes in visibility impairment for ambient conditions near the proposed standard level of either 30 dv or 28 dv.

The EPA is not proposing any possible alternatives to the existing 24-hour $PM_{2.5}$ SIL in this proposed rule, but instead intends to issue a separate rulemaking to assess this and other related PSD implementation issues. The EPA also wishes to note 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 existing $PM_{2.5}$ SILs have not been adequately demonstrated to represent *de minimis* values. *Sierra Club* v. *EPA, No. 10–1413* (D.C. Circuit filed December 17, 2010). In the course of this litigation, the EPA has recognized the need to correct the text of two $PM_{2.5}$ SILs provisions in the regulations, and the EPA has asked the court to vacate those provisions so that the EPA may correct them. However, the EPA does not believe this corrective action would preclude use of the $PM_{2.5}$ SILs in the interim, and the EPA intends to provide guidance on continued use of the $PM_{2.5}$ SILs (in a manner consistent with principles articulated by the EPA in the rulemaking and litigation) pending this correction of the regulatory text. The proposed revised primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS do not affect the continued used of the $PM_{2.5}$ SILs in accordance with the forthcoming guidance described above. As a separate matter, the EPA intends to consider the need for a new SIL specifically for implementing any secondary $PM_{2.5}$ visibility index NAAQS under the PSD program. In the event that we do proceed, the EPA now welcomes preliminary comments as to how such a SIL could be developed. The EPA will also provide an additional opportunity for comments at a later date in the event that a subsequent proposal is made to establish a separate SIL for the secondary $PM_{2.5}$ visibility index NAAQS, if such a secondary NAAQS is finalized.

Finally, the SMC, also measured as an ambient pollutant concentration (μg/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. In a future NSR implementation rulemaking that will follow this rulemaking, the EPA intends to evaluate the types of additional ambient data, if any, that may need to be collected by a proposed source concerning the proposed secondary $PM_{2.5}$ visibility index NAAQS, and the feasibility of individual sources being required to gather such additional information. The EPA welcomes preliminary comments concerning this issue, but will provide additional opportunity for comment when a subsequent NSR implementation rulemaking is proposed concerning the proposed revisions to the PM NAAQS.

e. 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 [224] (75 FR 64864, October 20, 2010). The proposed revision to the primary annual $PM_{2.5}$ NAAQS raises the question of whether the EPA should consider revising the annual $PM_{2.5}$ increments. Similarly, the EPA's proposed action to establish a distinct secondary $PM_{2.5}$ visibility index NAAQS raises the question of whether revisions to the $PM_{2.5}$ increments are appropriate to address public welfare considerations protected by the proposed secondary standard.

In this proposal, the EPA is not proposing to revise the $PM_{2.5}$ increments. The EPA will consider whether it is appropriate to propose such an action in the future, and if so, would undertake the necessary rulemaking. The EPA invites preliminary comments at this time on such a need, and on issues we should consider if we undertake a rule 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.

2. Nonattainment New Source Review

The requirements under part D of the CAA pertain 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.'' Thus, the NNSR program applies 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.[225] 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 a precursor of $PM_{2.5}$.

For a major modification, the NNSR rules rely upon SERs described previously in the PSD discussion in section IX.F.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 that results in a significant net emissions increase of that nonattainment 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 the existing values. Any decision to propose

[224] The primary and secondary NAAQS for $PM_{2.5}$ have been the same up until this time where EPA is proposing a distinct secondary NAAQS for PM-related visibility impairment.

[225] 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.''

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. While no formal policy has yet been developed to address this situation, 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.[226] Looking forward, the EPA proposes that areas would be designated for a proposed secondary $PM_{2.5}$ visibility index NAAQS independently of designations for the mass-based annual and 24-hour $PM_{2.5}$ NAAQS. Accordingly, the EPA intends to address this issue in a future NSR rulemaking, but invites comments now 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 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; 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 NNSR requirements as of the effective date of the nonattainment designation; therefore states lacking the appropriate NNSR program requirements at that time will be allowed to issue such permits during the SIP revision period 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 NAAQS upon their effective date. The EPA is not proposing any type of $PM_{2.5}$ grandfathering provision at this time for purposes of NNSR. The timetable for adopting new provisions under the state 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. Further consideration of the need for a grandfathering provision for purposes of NNSR for the revised NAAQS for $PM_{2.5}$ will be made and addressed in the future, as appropriate.

G. 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 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 proposing changes to the transportation conformity rule in this proposed rulemaking. The EPA notes that the transportation conformity rule already addresses the $PM_{2.5}$ and PM_{10} NAAQS. However, in the future, the EPA will review the need to issue or revise guidance describing how the current conformity rule applies in nonattainment and maintenance areas for any revised primary or distinct secondary PM NAAQS, as needed.

As discussed in section VIII above, the EPA is proposing certain clarifying changes to $PM_{2.5}$ air quality monitoring regulations These proposed changes are designed to align different elements of the monitoring regulations for consistency, which will help facilitate the interpretation of modeling results from quantitative $PM_{2.5}$ conformity hot-spot analyses for the annual standards by clarifying which receptors are comparable to the NAAQS.

If the EPA finalizes these changes to the monitoring regulations, the EPA will update its guidance on quantitative $PM_{2.5}$ hot-spot analyses as appropriate to make it consistent with the revised monitoring requirements (U.S. EPA, 2010j). If the proposed revisions to the monitoring requirements are finalized, the EPA intends that the current quantitative $PM_{2.5}$ hot spot guidance would continue to apply to any quantitative $PM_{2.5}$ hot-spot analysis that was begun before the effective date of these proposed revisions to the monitoring regulations. Revised guidance on receptors to be compared to the annual $PM_{2.5}$ standards 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 regarding whether or not a receptor can be compared to the annual $PM_{2.5}$ NAAQS to 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 allows 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.

H. General Conformity Program

General conformity is required by CAA section 176(c). This section requires that federal agencies do not adopt, accept, approve, or fund activities that are not consistent with state air quality goals. General conformity applies to any federal action

[226] However, transportation conformity requirements discussed in section IX.G below are dependent upon the averaging period(s) for which an area is designated nonattainment.

(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 any revised PM NAAQS would 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 any revision to the primary or secondary standards, a federal agency would be expected to continue to estimate emissions for conformity analyses in the same manner as they are estimated for conformity analyses for the current PM NAAQS. 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 emission estimation techniques available (40 CFR 93.159(b)), and EPA would expect that this same principle would be followed for analyses needed with respect to any revised PM NAAQS. When updated and improved emissions estimation techniques become available, EPA would expect the federal agency to use these techniques. The EPA is not proposing changes to the general conformity rule in this proposed rulemaking. The general conformity rule already addresses the $PM_{2.5}$ and PM_{10} NAAQS. 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 and secondary PM 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. 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.

In addition, 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 Proposed 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 alternative levels (in μg/m^3) of the primary annual/24-hour $PM_{2.5}$ standards including: 13/35, 12/35, 11/35, and 11/30. 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 [a] (MILLIONS OF 2006$) [b] FULL ATTAINMENT

Alternate $PM_{2.5}$ Standards (annual/24-hour, in μg/m^3)	Total costs		Monetized benefits [c]		Net benefits [c]	
	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate [d]	7% Discount rate
13/35	$2.9	$2.9	$88 to $220	$79 to $200	$85 to $220	$76 to $200
12/35	69	69	$2,300 to $5,900	$2,100 to $5,400	$2,300 to $5,900	$2,000 to $5,300
11/35	270	270	$9,200 to $23,000	$8,300 to $21,000	$8,900 to $2300	$8,000 to $21,000
11/30	390	390	$14,000 to $36,000	$13,000 to $33,000	$14,000 to $36,000	$13,000 to $33,000

[a] Values are rounded to two significant figures.
[b] Using a 2010$ year increases estimated costs and benefits by approximately 8%.
[c] The reduction in premature death each year accounts for over 90 percent 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.
[d] Due to data limitations, we were unable to discount compliance costs for all sectors at 3%. As a result, the net benefit calculations at 3% were computed by subtracting the monetized benefits at 3% minus the costs at 7%.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.S. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). There are no information collection requirements directly associated with revisions to a NAAQS under section 109 of the CAA.

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 proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed 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. 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 proposed 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. Therefore, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between the EPA and state and local governments, the EPA specifically solicits comment on this proposed rule from state and local officials.

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

The action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). 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. The Tribal Authority Rule gives Tribes the opportunity to develop and implement CAA programs such as the PM NAAQS, but it leaves to the discretion of the Tribe whether to develop these programs and which programs, or appropriate elements of a program, they will adopt. Thus, Executive Order 13175 does not apply to this rule.

Although Executive Order 13175 does not apply to this rule, the EPA consulted with tribal officials or other representatives of tribal governments in developing this action.

The EPA specifically solicits additional comments on this proposed rule from tribal officials.

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 may be especially important for children because childhood represents a lifestage associated with increased susceptibility to PM-related health effects. Because children have been identified as a susceptible 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, IV.B, and IV.C of this preamble. A listing of documents that contain the evaluation of scientific evidence and policy considerations that pertain to children is found in the section on Children's Environmental Health in the Supplementary Information section of this preamble, and a copy of all documents have been placed in the public docket for this action.

The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of early life exposure to PM.

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 proposed 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. The EPA also proposes to add a distinct secondary standard for $PM_{2.5}$ defined in terms of a calculated $PM_{2.5}$ light extinction indicator, which would use $PM_{2.5}$ mass species and relative humidity data to calculate $PM_{2.5}$ light extinction.

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.[227] 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.

For the proposed secondary standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, the EPA proposes to use existing monitoring technologies that are already deployed in the CSN and IMPROVE monitoring programs as well as relative humidity data from sensors already deployed at routine weather stations. The sampling and analysis protocols in use in the CSN program are the result of substantial input and recommendations from CASAC both during their initial deployment about ten years ago, and during the more recent transition to carbon sampling that is consistent with IMPROVE protocols (Henderson 2005c). Monitoring agencies also played a strong role in directing the sampling technologies used in the CSN. During the first few years of implementing the CSN there were up to four different sampling approaches used in the network. Over time as monitoring agencies shared their experiences and data with each other, several agencies shifted their network operations to the sampling technology used today. By 2008, the EPA was working closely with all remaining monitoring agencies to transition to the current CSN sampling for ions and elements. All carbon sampling was fully transitioned to the current method by October of 2009 for consistency with the IMPROVE program. Therefore, while the current CSN sampling methods were not developed or adopted by a voluntary consensus standard body, they are the result of harmonizing the network by monitoring agency users and EPA. The CSN network and methods are described in more detail in the Policy Assessment (U.S. EPA, 2011a, Appendix B, section B.1.3).

The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable voluntary consensus standards for any of the proposed indicators with an explanation as to why such standards should be used in this regulation.

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. The EPA has identified potential disproportionately high and adverse effects on minority and/or low-income populations from this proposed rule.

The EPA has identified persons from lower socioeconomic strata as a susceptible 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. The Agency expects this proposed rule would lead to the establishment of uniform NAAQS for PM. The Integrated Science

[227] A list of designated reference and equivalent methods is available on EPA's Web site at: *http://www.epa.gov/ttn/amtic/criteria.html.*

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.

The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of PM on low-income populations and minority populations.

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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, 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: June 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 proposed to be amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

2. 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.

* * * * *

(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.
$PM_{2.5}$/24-Hour Standard (final level and promulgation date TBD).	2010 to 2011	July 1, 2013	December 12, 2013.
	2012	July 1, 2013[a]	December 12, 2013.
	2013	July 1, 2014[a]	August 1, 2014.
$PM_{2.5}$/Annual Standard (final level and promulgation date TBD).	2010 to 2011	July 1, 2013	December 12, 2013.
	2012	July 1, 2013[a]	December 12, 2013.
	2013	July 1, 2014[a]	August 1, 2014.
$PM_{2.5}$ Visibility Index (final level and promulgation date TBD).	2010 to 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 final initial area designations for new NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment. TBD = to be determined.

* * * * *

3. 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 to 13.0] 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 of 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 to 13.0] 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.

4. Add § 50.19 to read as follows:

§ 50.19 National secondary ambient air quality standard for $PM_{2.5}$

(a) The following national secondary ambient air quality standard for PM is in addition to the national secondary ambient air quality standards for PM_{10} specified in § 50.6 and for $PM_{2.5}$ specified in § 50.13.

(1) [30 or 28] deciviews (dv), 24-hour average concentration, based on a calculated $PM_{2.5}$ visibility index using methods based on appendix C of part 58 of this chapter.

(2) [Reserved].

(b) The 24-hour secondary $PM_{2.5}$ visibility index standard is met when the 90th percentile 24-hour calculated $PM_{2.5}$ visibility index, as determined in accordance with appendix N of this part, is less than or equal to [30 or 28] dv.

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, including the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS specified in § 50.7, 50.13, and 50.18, and the secondary $PM_{2.5}$ visibility index NAAQS specified in § 50.19. $PM_{2.5}$ 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. Chemically speciated $PM_{2.5}$ mass concentrations are derived from ambient air measurements using the methods specified in appendix C of part 58 of this chapter. 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. The data handling and computation procedures to be used to construct the $PM_{2.5}$ visibility index metric from reported speciated $PM_{2.5}$ concentrations (and related climatological relative humidity hygroscopic growth factors), and the associated instructions for comparing these computed metrics to the level of the $PM_{2.5}$ visibility index NAAQS, are specified in sections 2.0, 3.0, and 5.0 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.

The *collocated PM_{10} data substitution test* substitutes reported same-day PM_{10} FRM/FEM daily values from the same site for missing scheduled $PM_{2.5}$ samples in data capture deficient quarters.

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 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 or 90th 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 for the annual and 24-hour $PM_{2.5}$ NAAQS 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. *Daily values* for the $PM_{2.5}$ visibility index NAAQS refer to the 24-hour average $PM_{2.5}$ visibility index values derived from reported speciated $PM_{2.5}$ measurements and corresponding f(RH) factors using the formulae specified in section 5.0 of this appendix.

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 that metric, which is otherwise judged incomplete (via the applicable 75 percent data capture or 11 creditable samples per quarter minimum data completeness options), shall nevertheless be deemed complete and valid for NAAQS comparisons, or alternatively, shall still be considered incomplete and not valid for NAAQS comparisons. There are three data substitution tests, the ''maximum quarterly value'' test, the ''minimum quarterly value'' test, and the ''collocated PM_{10}'' test. Only one of the three tests needs to ''pass'' in order to validate the DV in question. These tests substitute actual same-site extreme daily values for missing data in an incomplete year(s), calculate a revised ''test DV'' using the original plus substituted data, and, if the test DV relays the same NAAQS status (i.e., meets or not meets) as the original (otherwise incomplete) DV, the test is deemed to have ''passed'' and since only one passing test is needed, the original DV (without the diagnostic data substitutions) is then considered complete and valid for NAAQS comparisons. If the test DV relays a different NAAQS status as the original (otherwise incomplete) DV, the test is deemed to have ''failed,'' and if all applicable substitution tests are ''failed'' then the original DV will still be considered incomplete and not valid for NAAQS comparisons.

Deciview is the unit of measure for the level of the secondary $PM_{2.5}$ visibility index NAAQS. This metric describes changes in uniform light extinction that can be perceived by a human observer. One deciview represents the minimal perceptible change in visibility to the human eye. Daily calculated $PM_{2.5}$ light extinction values in units of Mm^{-1} are translated to $PM_{2.5}$ visibility index values in terms of deciviews according to equation 7 in section 5(d)(3) of this appendix.

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 sections 4.0 and 5.0 of this appendix. There are three 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.*''

(3) The 3-year average of annual 90th percentile 24-hour average $PM_{2.5}$ visibility index values calculated for each eligible monitoring site is referred to as the ''*$PM_{2.5}$ visibility index NAAQS DV.*''

Elemental carbon (*EC*) is the reported concentration of $PM_{2.5}$ elemental carbon from the speciation methods identified in appendix C to part 58 of this chapter.

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 and the $PM_{2.5}$ visibility index 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 or 90th percentile value, but are not used to determine which value in the sorted list represents the 98th or 90th percentile.

Fine soil (*FS*) is the calculated measure of $PM_{2.5}$ crustal material. It is derived from the reported speciated $PM_{2.5}$ concentrations of aluminum (Al), silicon (Si), calcium (Ca), iron (Fe), and titanium (Ti) using formula 5d in 5(d)(1) of this appendix. FS data is generated from the speciation methods identified in appendix C to part 58 of this chapter.

f(*RH*) is a unitless water growth factor used to relate a given relative humidity (RH) to its impact on $PM_{2.5}$ light-scattering.

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 values (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 values (year non-specific) contained in the combined site record for the evaluated 3-year period) for missing daily values.

98th percentile [90th percentile] is the smallest daily value out of a year of $PM_{2.5}$ mass monitoring data [$PM_{2.5}$-related visibility indices] below which no more than 98 [90] percent of all daily values fall using the ranking and selection method specified in section 4.5(a) [5.0(d)(4)] of this appendix.

Nitrate is the fully neutralized $PM_{2.5}$ nitrate ion (NO_3^-) concentration. It is the reported concentration of NO_3^- multiplied by a factor (1.29) to account for full neutralization with ammonium. See equation 5b in 5(d)(1) of this appendix. Nitrate data is generated from the speciation methods identified in appendix C to part 58 of this chapter.

Organic mass (OM) is the concentration of $PM_{2.5}$ organic carbon ($PM_{2.5}$ OC) multiplied by a factor (1.4) to adjust the OC for other elements (e.g., hydrogen and oxygen) assumed to be associated with the $PM_{2.5}$ OC. See equation 5c in 5(d)(1) of this appendix. Organic mass data is generated from the speciation methods identified in appendix C to part 58 of this chapter.

$PM_{2.5}$ b_{ext} is a calculated measure of the total fraction of light that is attenuated by $PM_{2.5}$ particles per unit distance (e.g., per inverse megameter, Mm^{-1}). The estimate is derived from daily average speciated $PM_{2.5}$ mass concentrations and climatological monthly average relative humidity data via equation 6 in 5(d)(2) of this appendix.

$PM_{2.5}$ organic carbon ($PM_{2.5}$ OC) refers to the measured organic carbon with an adjustment for adsorbed organic vapors (known as the organic carbon artifact). $PM_{2.5}$ organic carbon data is generated from the speciation methods identified in Appendix C to Part 58.

$PM_{2.5}$ visibility index is the indicator used for the secondary $PM_{2.5}$ visibility index NAAQS. The index is computed on a 24-hour average basis from $PM_{2.5}$ b_{ext} using equation 7 in 5(d)(3) of this appendix.

Primary monitors are suitable monitors designated by a state or local agency in their annual network plan (and in AQS) to be 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 3.0(e).

Seasonal sampling is the practice of collecting data at a reduced frequency during a season of expected low concentrations.

Speciation methods refer to the $PM_{2.5}$ chemical speciation methods identified in section 2.9.2 of appendix C to part 58 of this chapter which include those used by the Chemical Speciation Network (CSN) and the Interagency Monitoring of Protected Visual Environment (IMPROVE) network.

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 per § 58.11 of this chapter. For the $PM_{2.5}$ visibility index NAAQS, suitable monitors include the speciation methods specified in section 2.9.2 of appendix C of part 58 of this chapter which include those used by the CSN and the IMPROVE network.

Sulfate is the fully neutralized $PM_{2.5}$ sulfate ion (SO^{2-}_4) concentration. It is the reported concentration of SO^{2-}_4 multiplied by a factor (1.375) to account for full neutralization with ammonium. See equation 5a in 5(d)(1) of this appendix. Sulfate data are generated from the speciation methods identified in appendix C to part 58 of this chapter.

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 $PM_{2.5}$. All speciation samplers using the speciation methods specified in section 2.9.2 of appendix C of part 58 of this chapter are deemed suitable for comparisons to the $PM_{2.5}$ visibility index NAAQS.

(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 and speciated $PM_{2.5}$ 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 ($\mu g/m^3$) to at least one decimal place, with additional digits to the right being 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 $PM_{2.5}$ mass data are submitted to AQS with less precision than specified above, these data shall nevertheless still be deemed appropriate for NAAQS usage. For the purpose of calculating $PM_{2.5}$ visibility index values, the speciated $PM_{2.5}$ component concentrations of sulfate, nitrate, $PM_{2.5}$ OC, EC, Al, Si, Ca, Fe, and Ti, the AQS will convert (if necessary) reported concentrations into units of $\mu g/m^3$ rounded to four decimal places (0.xxxx5 rounds up), or three significant digits when the concentration value is 0.1 or more. In situations where fewer decimal places or significant digits than specified above are reported to AQS, such data shall nevertheless still be deemed appropriate for NAAQS usage.

(c) Block 24-hour average concentrations will be computed in AQS from submitted hourly $PM_{2.5}$ concentration data (mass or species) 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). For $PM_{2.5}$ mass concentrations, 24-hour periods with seven or more missing hours shall 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 $\mu g/m^3$). 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; twenty-four-hour average $PM_{2.5}$ speciated mass concentrations that are averaged in AQS from hourly values will be rounded to four decimal places (or three significant digits if the average is greater than 0.1), consistent with the data handling procedures 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 and speciated 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 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 for aggregated $PM_{2.5}$ mass. The exception is, if a collocated continuous FEM 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 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. For the $PM_{2.5}$ visibility index NAAQS, creditable samples are based on daily values of $PM_{2.5}$ b_{ext} (which essentially require non-missing values for the nine required input speciated $PM_{2.5}$ parameters, all reported on the same scheduled sampling days). Section 5.0 of this appendix specifies in further detail the procedure for calculating $PM_{2.5}$ visibility index values and the ensuing determination of whether they are creditable or not.

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 to 13.0] $\mu g/m^3$ 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 $\mu g/m^3$ 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 (and complete) if it passes at least one of the three 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 (and complete) if one (or more) of the test conditions specified in 4.1(c)(i), 4.1(c)(ii), and 4.1(c)(iii) is met.

(1) 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 matching 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 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 exceeded in that 3-year period.

(2) 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 are at least 30 days across the three matching quarters of the three years under consideration from which to select the quarter-specific high value. 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 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 months 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 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.

(3) 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 collocated PM_{10} data substitution test. 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 data capture), available collocated FRM/FEM PM_{10} values reported for each $PM_{2.5}$ scheduled day that is missing a valid daily $PM_{2.5}$ value. If there is more than one collocated daily PM_{10} value present for a particular day (that is scheduled for measuring $PM_{2.5}$ but does not have a corresponding valid daily $PM_{2.5}$ value), then the highest of those multiple daily PM_{10} values will be used as the substituted value. If, after substituting the available collocated daily PM_{10} values for as many as possible missing daily $PM_{2.5}$ values in the deficient quarter(s), the procedure yields recalculated data capture rates of 75 percent or more, and a recalculated annual $PM_{2.5}$ NAAQS test DV 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 $\mu g/m^3$.

(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 data capture requirement is not met, the 24-hour $PM_{2.5}$ NAAQS DV shall still be considered valid (and complete) if it passes one (or both) of two applicable data substitution tests (i.e., the maximum quarterly value or collocated PM_{10} data substitution tests).

(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 ''complete and valid'' if either of the test conditions specified in 4.2(c)(i) or 4.2(c)(ii) are met.

(1) 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 are at least 30 days across the three matching quarters of the three years under consideration from which to select the quarter-specific high value.

Procedure: Identify for each deficient quarter (i.e., those with less than 75 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 Administrator, looking across those three months 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 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.

(2) A 24-hour $PM_{2.5}$ NAAQS DV that is equal to or below the level of the NAAQS can be validated if it passes the collocated PM_{10} data substitution test. 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, available collocated FRM/FEM daily PM_{10} values reported for each $PM_{2.5}$ scheduled day that is missing a valid daily $PM_{2.5}$ value. If there is more than one collocated daily PM_{10} value present for a particular day (that is scheduled for measuring $PM_{2.5}$ but doesn't have a corresponding valid daily $PM_{2.5}$ value), then the highest of those daily PM_{10} values will be used as the substituted daily $PM_{2.5}$ value. If, after substituting the available collocated daily PM_{10} values for as many as possible missing daily $PM_{2.5}$ values in the deficient quarter(s), the procedure yields recalculated data capture rates of 75 percent or more, and a recalculated 24-hour $PM_{2.5}$ NAAQS test DV 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 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 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 $\mu g/m^3$ (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 $\mu g/m^3$ (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)	P 0.98, y is the nth maximum 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:

Equation 4

$$\overline{P}_{0.98} = \frac{1}{3}\sum_{y=1}^{3} P_{0.98_y}$$

Where:

$\overline{P}_{0.98}$ = 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.

5.0 Comparisons With the Secondary $PM_{2.5}$ Visibility Index NAAQS

(a) The secondary $PM_{2.5}$ visibility index NAAQS is met when the $PM_{2.5}$ visibility index NAAQS DV at each eligible monitoring site is less than or equal to [30 or 28] deciviews.

(b) Three years of valid annual 90th percentile concentrations of 24-hour average $PM_{2.5}$ visibility index values are required to produce a valid $PM_{2.5}$ visibility index NAAQS DV. A year meets data completeness requirements when there are at least 11 creditable daily values of $PM_{2.5}$ visibility indices in each quarter (all four of the year); a daily value is defined as one that contains valid estimates for all five major speciation $PM_{2.5}$ components: Sulfate, nitrate, OM, EC, and FS. In order to derive these five major components, 24-hour average concentrations are needed for the following nine parameters:

$$SO_4^{2-},\ NO_3^-,$$

EC, Al, Si, Ca, Fe, and Ti, and $PM_{2.5}$ OC. Years with less than 11 creditable samples in each quarter shall still be considered complete and the corresponding identified 90th percentile deemed valid, if the 90th percentile value for that year or a resulting 3-year average 90th percentile value (i.e., a $PM_{2.5}$ visibility index NAAQS DV) encompassing that annual value exceeds the NAAQS level (i.e., [30 or 28] deciviews). The use of less than complete data (i.e., data not meeting the criteria stated in this subsection) is subject to the approval of the EPA Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

(c) Rounding Conventions: For the purposes of calculating $PM_{2.5}$ visibility index NAAQS DVs to compare to the level of the standard, it is necessary to round the final results of the calculations described in sections 5(d) of this appendix as noted below. Results for all intermediate calculations shall not be rounded unless otherwise specified.

(1) Daily deciview values shall be rounded to the nearest 0.1 deciview (decimals 0.x5 and greater are rounded up to the next tenth, and any decimal lower than 0.x5 is rounded down to the stated tenth).

(2) The $PM_{2.5}$ visibility index NAAQS DV shall be rounded to the nearest 1 deciview (decimal values x.5 and greater are rounded up to the nearest whole number, and any decimal values lower than x.5 are rounded down to the nearest whole number).

(d) Procedures and Equations for the Secondary $PM_{2.5}$ Visibility Index NAAQS

(1) The five major speciation components (Sulfate, Nitrate, OM, EC, and FS) are derived from reported concentrations of

$$SO_4^{2-},\ NO_3^-,$$

EC, Al, Si, Ca, Fe, and Ti, and reported/adjusted concentrations of $PM_{2.5}$ OC, according to the equations below:

Equation 5a

$$Sulfate_i = SO_{4\ i_i}^{2-} \times 1.375$$

Where:

$Sulfate_i$ = ammonium sulfate for day *i*; and

$SO_{4\ i}^{2-}$ = the reported sulfate ion concentration (SO_4^{2-}) for day *i*

Equation 5b

$$Nitrate_i = NO_{3\ i}^{-} \times 1.29$$

Where:

$Nitrate_i$ = ammonium nitrate for day *i*; and

$NO_{3\ i}^{-}$ = the reported nitrate ion concentration (NO_3^-) for day *i*

Equation 5c

$$OM_i = (PM_{2.5}OC_i) \times 1.4$$

Where:

OM_i = organic mass for day *i;* and

$PM_{2.5}$ OC_i = measured organic carbon with an adjustment for adsorbed organic vapors

Equation 5d

$$FS_i = (Al_i \times 2.20) + (Si_i \times 2.49) + (Ca_i \times 1.63) + (Fe_i \times 2.42) + (Ti_i \times 1.94)$$

Where:

FS_i = fine soil for day i; and

Al_i = the reported aluminum concentration for day i; and

Si_i = the reported silicon concentration for day i; and

Ca_i = the reported calcium concentration for day i; and

Fe_i = the reported iron concentration for day i; and

Ti_i = the reported titanium concentration for day i

(2) Daily estimates of $PM_{2.5}$-related calculated light-extinction, $PM_{2.5}$ b_{ext} (expressed in units of inverse megameters (Mm^{-1})), are derived by equation 6. The components sulfate, nitrate, OM, and FS are derived using formulae, 5a, 5b, 5c, and 5d. The component EC is the reported concentration of $PM_{2.5}$ elemental carbon. The *f*(RH) value corresponding to each site-day shall be identified from the most recent 10-year average climatological database. This database contains spatially gridded monthly values of *f*(RH). The database record for the grid-point closest in distance to the monitoring site shall be selected for utilization in calculating $PM_{2.5}$ b_{ext}. The monthly value identified from the database record for the selected grid location will be the one corresponding to the sample month of the reported input speciation concentrations.

Equation 6:

$$PM_{2.5}\ b_{ext:\,i} = (3 \times Sulfate_i \times f(RH)_{m,gp}) + (3 \times Nitrate_i \times f(RH)_{m,gp}) + (4 \times OM_i) + (10 \times EC_i) + (FS_i)$$

Where:

$PM_{2.5}$ $b_{ext:\,i}$ = $PM_{2.5}$-related light extinction in Mm^{-1} for day i; and

$Sulfate_i$ = ammonium sulfate for day i; and

$Nitrate_i$ = ammonium nitrate for day; and

OM_i = organic mass for day; and

EC_i = the reported concentration of elemental carbon for day i; and

FS_i = fine soil for day i; and

$f(RH)_{m,gp}$ = the RH hygroscopic growth factor determined from the EPA "climatological *f*(RH) database" corresponding to month m for day i for the grid point gp closest in distance to the monitoring site

(3) Daily estimates of $PM_{2.5}$ $b_{ext,}$ in units of Mm^{-1}, are converted to $PM_{2.5}$ visibility index values, in units of deciviews, according to equation 7.

Equation 7:

$$PM_{2.5}\_visibility\_index_i = 10 \times \ln\left(\frac{(PM_{2.5}\_b_{ext_i} + 10)}{10}\right)$$

Where:

$PM_{2.5}$ _ visibility _ $index_i$ = $PM_{2.5}$ visibility index value (in deciview units) for day *i;* and

$PM_{2.5}$ _ $B_{ext\,i}$ = $PM_{2.5}$-related light extinction (in Mm^{-1} units) for day *i*

(4) Identification of annual 90th percentile $PM_{2.5}$ visibility index values is accomplished by the steps provided in this subsection. Table 2 of this appendix shall be used to identify annual 90th percentile values according to the creditable number of 24-hour $PM_{2.5}$ visibility index values calculated for the year.

Procedure: Sort all the daily $PM_{2.5}$ visibility index 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 90th percentile is determined from this sorted series of values which is ordered from the highest to the lowest number. Using the left column of Table 2, determine the appropriate range for the annual creditable number of samples for year y (n_y) (e.g., for 35 creditable samples in a year, the appropriate range would be 31 to 40). The corresponding ''nth'' value in the right column identifies the rank of the annual 90th percentile value in the descending sorted list of $PM_{2.5}$ visibility index values for year y (*e.g.,* for the range of 31 to 40, n is equal to 4). Thus, $P_{0.90, y}$ = the nth largest value (e.g., for the range of 31 to 40, the 90th percentile value would be the fourth highest value in the sorted series of $PM_{2.5}$ visibility index values).

(5) The $PM_{2.5}$ visibility index NAAQS DV is then calculated by averaging the annual 90th percentile $PM_{2.5}$ visibility index values for three consecutive years using equation 8 of this appendix:

Equation 8

$$\overline{P}_{0.90} = \frac{1}{3}\sum_{y=1}^{3} P_{0.90;y}$$

Where:

$\overline{P}_{0.90}$ = the $PM_{2.5}$ visibility index NAAQS DV; and

$P_{0.90,y}$ = the annual 90th percentile $PM_{2.5}$ visibility index value for year y

TABLE 2

Annual number of creditable samples for year ''y'' (cn_y)	P 0.90, y is the nth maximum for the year where n is the listed number
1 to 10	1
11 to 20	2
21 to 30	3
31 to 40	4
41 to 50	5
51 to 60	6
61 to 70	7
71 to 80	8
81 to 90	9
91 to 100	10
101 to 110	11
111 to 120	12
121 to 130	13
131 to 140	14
141 to 150	15
151 to 160	16
161 to 170	17
171 to 180	18
181 to 190	19
191 to 200	20
201 to 210	21
211 to 220	22
221 to 230	23
231 to 240	24
241 to 250	25
251 to 260	26
261 to 270	27
271 to 280	28
281 to 290	29
291 to 300	30
301 to 310	31
311 to 320	32
321 to 330	33
331 to 340	34
341 to 350	35
351 to 360	36
361 to 366	37

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) *Exemptions.* * * *

(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 $PM_{2.5}$ as in effect on [EFFECTIVE DATE OF FINAL RULE] if the reviewing authority has first published before that date public notice that a preliminary determination for the permit subject to this section has been issued. Instead, the requirements in paragraph (k)(1) shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ as in effect at the time of the public notice on the proposed permit.

* * * * *

PART 52—APPROVAL AND PROMULGATIONS 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 $PM_{2.5}$ as in effect on [EFFECTIVE DATE OF FINAL RULE] if the Administrator has first published before that date a public notice that a draft permit subject to this section has been prepared. Instead, the requirements in paragraph (k)(1) shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ as 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 Clean Air Act (42 U.S.C. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

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)''.

The addition reads 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 adding paragraph (a)(8).
b. By adding paragraph (b)(13).
c. By revising paragraph (c).
d. By revising paragraph (d).

The additions and revisions read as follows:

§ 58.10 Annual monitoring network plan and periodic network assessment.

(a) * * *

(8) A plan for establishing near-road $PM_{2.5}$ monitoring sites in accordance with the requirements of appendix D to this part shall be submitted to the Regional Administrator by July 1, 2014. The plan shall provide for all required monitoring stations to be operational by January 1, 2015.

(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 collected for the period of time that the plan covers (i.e., the next 18 months or until a new plan is submitted addressing this issue) 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 § 58.10 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, for any case where the data are identified as not of sufficient comparability to a collocated FRM, such that the FEM or ARM 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)(13) for any case where the FEM or ARM is identified as not of sufficient comparability to a collocated FRM. The performance criteria apply with the following provisions to accommodate how monitoring agencies operate their collocated $PM_{2.5}$ methods:

(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 apply; the precision statistic requirement does not apply, even if precision data are available.

(5) All seasons must be covered with no more than three years in total aggregated together.

16. Section 58.12 is amended by revising paragraph (d)(1)(iii) and by removing and reserving paragraph (f)(2).

The revision reads as follows:

§ 58.12 Operating schedules.

* * * * *

(d) * * *

(1) * * *

(iii) Required SLAMS stations whose measurements determine the design value for their area and that are within plus or minus 5 percent of the 24-hour $PM_{2.5}$ NAAQS must have an FRM or FEM operate on a daily schedule if the 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.

* * * * *

17. Section 58.13 is amended by adding paragraphs (f) and (g) 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 no later than January 1, 2015, and at that time, must be operating under all of the requirements of this part, including the requirements of appendices A, C, D, and E to this part.

(g) CSN (or IMPROVE) monitoring stations required as described in appendix D to this part not already operational, must be physically established no later than January 1, 2015, and at that time must be operating under all of the requirements of this part, including the requirements of appendices A, C, D, and E to this part.

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; $PM_{10-2.5}$ 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 $PM_{10-2.5}$ 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 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.

* * * * *

Subpart C—Special Purpose Monitors

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.

* * * * *

Subpart D—Comparability of Ambient Data to the NAAQS

20. The heading for Subpart D is revised to read as set forth above.

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.

(1) $PM_{2.5}$ measurement data from all eligible monitors are compared to the 24-hour $PM_{2.5}$ NAAQS.

(2) $PM_{2.5}$ measurement data from all eligible monitors that are representative of area-wide air quality are compared to the annual $PM_{2.5}$ NAAQS. 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. As specified in appendix D to this part, section 4.7.1, when micro- or middle-scale $PM_{2.5}$ monitoring sites are presumed to collectively identify a larger region of localized high ambient $PM_{2.5}$ concentrations; for example, a $PM_{2.5}$ monitoring site located in a near-road environment where there are many other similar locations in the same CBSA, these 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 relatively unique middle-scale impact sites are not eligible for comparison to the annual $PM_{2.5}$ NAAQS. As specified in § 58.30(a)(1), $PM_{2.5}$ 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 (c) in section 1 and revising it.

b. By adding paragraph (a) to section 1.

c. By adding paragraph (b) to section 1.

d. By revising paragraph 1.1.3.

e. By revising paragraphs 3.2.3, 3.2.4, 3.2.5.6, and 3.2.6.3.

f. By adding paragraph 3.2.9.

g. By revising paragraphs 3.3.2 and 3.3.3.

h. By adding paragraph 3.3.9.

i. By revising paragraphs (b) and (c) in section 4.

j. By adding paragraph (c)(6) in section 4.

k. By revising paragraph 4.3 and 4.3.1.

l. By revising Tables A–1 and A–2.

The revisions and additions read as follows:

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *

1. * * *

(a) For this Appendix, the term ''$PM_{2.5}$'' refers to $PM_{2.5}$ mass measurements used in determining whether areas meet the primary and secondary $PM_{2.5}$ standards and ''$PM_{2.5}$ CSN'' refers to the chemically speciated $PM_{2.5}$ mass measurements used to calculate $PM_{2.5}$ light extinction to determine if areas meet the secondary PM standard to address visibility impairment.

(b) 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, the checks and procedures required in this appendix shall be used in combination with other data quality information, reports, and similar documents showing overall compliance with part 58 by the monitoring agencies and by EPA, and using 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.

(c) 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, $PM_{2.5}$, $PM_{2.5}$ CSN, PM_{10} and $PM_{10-2.5}$ 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, part 1 (see reference 10 of this appendix) and at a national level in references 1, 2, and 3 of this appendix.

* * * * *

1.1.3 The requirements for precision assessment for the automated methods are the same for both SLAMS and PSD. However, for manual methods, only one collocated site is required for PSD. $PM_{2.5}$ CSN collocation is not required for PSD sites.

* * * * *

3. * * *

3.2 * * *

3.2.3 Flow Rate Verification for Particulate Matter. A one-point flow rate verification check must be performed at least once every month on each automated analyzer used to measure PM_{10}, $PM_{10-2.5}$, $PM_{2.5}$, and $PM_{2.5}$ CSN. The verification is made by checking the operational flow rate of the analyzer. If the verification is made in conjunction with a flow rate adjustment, it must be made prior to such flow rate adjustment. Randomization of the flow rate verification with respect to time of day, day of week, and routine service and adjustments is encouraged where possible. For the standard procedure, use a flow rate transfer standard certified in accordance with section 2.6 of this appendix to check the analyzer's normal flow rate. Care should be used in selecting and using the flow rate measurement device such that it does not alter the normal operating flow rate of the analyzer. Report the flow rate of the transfer standard and the corresponding flow rate measured by the analyzer. The percent differences between the audit and measured flow rates are used to assess the bias of the monitoring data as described in section 4.2.2 of this appendix (using flow rates in lieu of concentrations).

3.2.4 Semi-Annual Flow Rate Audit for Particulate Matter. Every 6 months, audit the flow rate of the PM_{10}, $PM_{10-2.5}$, $PM_{2.5}$, and $PM_{2.5}$ CSN particulate analyzers. Where possible, EPA strongly encourages more frequent auditing. The audit should (preferably) be conducted by a trained experienced technician other than the routine site operator. The audit is made by measuring the analyzer's normal operating flow rate using a flow rate transfer standard certified in accordance with section 2.6 of this appendix. The flow rate standard used for auditing must not be the same flow rate standard used to calibrate the analyzer. However, both the calibration standard and the audit standard may be referenced to the same primary flow rate or volume standard. Great care must be used in auditing the flow rate to be certain that the flow measurement device does not alter the normal operating flow rate of the analyzer. Report the audit flow rate of the transfer standard and the corresponding flow rate measured (indicated) by the analyzer. The percent differences between these flow rates described in section 4.2.3 of this appendix are used to validate the one-point flow rate verification checks described in section 4.2.2 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 of up to 10 meters between a primary and collocated sampler may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation. 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 of up to 10 meters 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. Calibration, sampling, and analysis must be the same for all the collocated samplers in each agency's network.

* * * * *

3.2.9 Collocated Sampling Procedures for $PM_{2.5}$ CSN. $PM_{2.5}$ CSN Collocation is not required for PSD sites. A minimum of six collocated sites are required nationally for the CSN monitoring network. Sites selected for collocation should reflect spatial, temporal, and constituent variability of the chemical speciation network. Collocated sites may be rotated within the network at 3 year intervals. Decisions on rotations will be made by the Regional Administrator taking into consideration geographic coverage, chemical species, and capabilities of the monitoring agency. Data from the collocated sites will be used to estimate precision of the secondary PM standard to address visibility impairment. For each pair of collocated monitors, designate one sampler as the primary monitor whose concentrations will be used to report air quality for the site, and designate the other as the audit monitor.

3.2.9.1 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. Calibration, sampling, and analysis must be the same for all the collocated samplers in each agency's network.

3.2.9.2 Sample the collocated audit monitor on a 12-day schedule. Report the measurements from both primary and collocated audit monitors at each collocated sampling site. The calculations for evaluating precision between the two collocated monitors are described in section 4.3.1 of this appendix.

3.3 * * *

3.3.2 Flow Rate Verification for Particulate Matter. Follow the same procedure as described in section 3.2.3 of this appendix for $PM_{2.5}$, $PM_{2.5}$ CSN, PM_{10} (low-volume instruments), and $PM_{10-2.5}$. High-volume PM_{10} and TSP instruments can also follow the procedure in section 3.2.3 but the audits are required to be conducted quarterly. The percent differences between the audit and measured flow rates are used to assess the bias of the monitoring data as described in section 4.2.2 of this appendix.

3.3.3 Semi-Annual Flow Rate Audit for Particulate Matter. Follow the same procedure as described in section 3.2.4 of this appendix for $PM_{2.5}$, $PM_{2.5}$ CSN, PM_{10}, $PM_{10-2.5}$ and TSP instruments. The percent differences between these flow rates described in section 4.2.3 of this appendix are used to validate the one-point flow rate verification checks described in section 4.2.2 of this appendix.

Great care must be used in auditing high-volume particulate matter samplers having flow regulators because the introduction of resistance plates in the audit flow standard device can cause abnormal flow patterns at the point of flow sensing. For this reason, the flow audit standard should be used with a normal filter in place and without resistance plates in auditing flow-regulated high-volume samplers, or other steps should be taken to assure that flow patterns are not perturbed at the point of flow sensing.

* * * * *

3.3.9 Collocated Sampling Procedures for $PM_{2.5}$ CSN. $PM_{2.5}$ CSN Collocation is not required for PSD sites. Follow the same procedure as described in Section 3.2.9

4. * * *

(b) The EPA will provide annual assessments of data quality aggregated by site and primary quality assurance organization for SO_2, NO_2, O_3 and CO; by primary quality assurance organization for PM_{10}, $PM_{2.5}$, and Pb; and by primary quality assurance organization and nationally for $PM_{10-2.5}$, Pb at NCore, and $PM_{2.5}$ CSN.

(c) At low concentrations, agreement between values (measurements or calculations) of collocated samplers, expressed as relative percent difference or percent difference, may be relatively poor. For this reason, collocated pairs are selected for use in the precision and bias calculations only when both values are equal to or above the following limits:

* * * * *

(6) $PM_{2.5}$ CSN: 5 deciviews

* * * * *

4.3 Statistics for the Assessment of $PM_{2.5}$, $PM_{2.5}$ CSN, and $PM_{10-2.5}$

4.3.1 Precision Estimate. Precision for collocated instruments for $PM_{2.5}$, $PM_{2.5}$ CSN, and $PM_{10-2.5}$ may be estimated where both the primary and collocated instruments are the same method designation and when the

method designations are not similar. Follow the procedure described in section 4.2.1 of this appendix. In addition, one may want to perform an estimate of bias when the primary monitor is an FEM and the collocated monitor is an FRM. Follow the procedure described in section 4.1.3 of this appendix in order to provide an estimate of bias using the collocated data.

* * * * *

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.
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.

TABLE A–2 OF APPENDIX A TO PART 58—MINIMUM DATA ASSESSMENT REQUIREMENTS FOR SLAMS SITES

Method	Assessment method	Coverage	Minimum frequency	Parameters reported
Automated Methods				
1-Point QC for SO_2, NO_2, O_3, CO.	Response check at concentration 0.01–0.1 ppm SO_2, NO_2, O_3, and 1–10 ppm CO.	Each analyzer	Once per 2 weeks	Audit concentration [1] and measured concentration [2].
Annual performance evaluation for SO_2, NO_2, O_3, CO.	See section 3.2.2 of this appendix.	Each analyzer	Once per year	Audit concentration [1] and measured concentration [2] for each level.
Flow rate verification PM_{10}, $PM_{2.5}$, $PM_{2.5}$ CSN $PM_{10\text{-}2.5}$.	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM_{10}, $PM_{2.5}$, $PM_{2.5}$ CSN $PM_{10\text{-}2.5}$.	Check of sampler flow rate using independent standard.	Each sampler	Once every 6 months	Audit flow rate and measured flow rate indicated by the sampler.
Collocated sampling $PM_{2.5}$, $PM_{10\text{-}2.5}$.	Collocated samplers	15%	Every 12 days	Primary sampler concentration and duplicate sampler concentration.
$PM_{2.5}$ CSN	Collocated samplers	6 per national network	Every 12 days	Primary sampler concentration and duplicate sampler concentration.
Performance evaluation program $PM_{2.5}$, $PM_{10\text{-}2.5}$.	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites. 2. 8 valid audits for primary QA orgs, with >5 sites. 3. All samplers in 6 years.	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Manual Methods				
Collocated sampling PM_{10}, TSP, $PM_{10\text{-}2.5}$, $PM_{2.5}$, Pb-TSP, Pb-PM_{10}.	Collocated samplers	15%	Every 12 days PSD—every 6 days.	Primary sampler concentration and duplicate sampler concentration.
$PM_{2.5}$ CSN	Collocated samplers	6 per network	Every 12 days	Primary sampler concentration and duplicate sampler concentration.
Flow rate verification PM_{10} (low-vol), $PM_{10\text{-}2.5}$, $PM_{2.5}$, $PM_{2.5}$ CSN, Pb-PM_{10}.	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.

TABLE A–2 OF APPENDIX A TO PART 58—MINIMUM DATA ASSESSMENT REQUIREMENTS FOR SLAMS SITES—Continued

Method	Assessment method	Coverage	Minimum frequency	Parameters reported
Flow rate verification PM_{10} (high-vol), TSP, Pb-TSP.	Check of sampler flow rate	Each sampler	Once every quarter	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM_{10}, TSP, $PM_{10-2.5}$, $PM_{2.5}$, $PM_{2.5}$ CSN, Pb-TSP, Pb-PM_{10}.	Check of sampler flow rate using independent standard.	Each sampler, all locations	Once every 6 months	Audit flow rate and measured flow rate indicated by the sampler.
Pb audit strips Pb-TSP, Pb-PM_{10}.	Check of analytical system with Pb audit strips.	Analytical	Each quarter	Actual concentration and audit concentration.
Performance evaluation program $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites. 2. 8 valid audits for primary QA orgs, with >5 sites. 3. All samplers in 6 years.	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Performance evaluation program Pb-TSP, Pb-PM_{10}.	Collocated samplers	1. 1 valid audit and 4 collocated samples for primary QA orgs, with >5 sites. 2. 2 valid audits and 6 collocated samples for primary QA orgs, with >5 sites.	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration. Primary sampler concentration and duplicate sampler concentration.

[1] Effective concentration for open path analyzers.
[2] Corrected concentration, if applicable, for open path analyzers.

* * * * *

23. Appendix C to part 58 is amended as follows:

a. By revising paragraph 2.9.

b. In section 6.0 by adding references 8 through 13.

Appendix C to Part 58—Ambient Air Quality Monitoring Methodology

* * * * *

2.9 Use of Chemical Speciation Methods at SLAMS

$PM_{2.5}$ chemical speciation network (CSN) stations include analysis for elements, selected anions and cations, and carbon. Descriptions of the CSN standard operating procedures and QAPP are available in references 10 and 11. Interagency Monitoring of Protected Visual Environments (IMPROVE) station methods also provide analysis for elements, selected anions and cations, and carbon, and in addition include a PM_{10} mass channel. Descriptions of the IMPROVE samplers and the data they collect are available in references 4, 5, and 6 of this appendix. The CSN Quality Assurance Project Plan (QAPP) (which include field SOPs), and laboratory SOPs are available in references 8 through 13.

2.9.1 Use of IMPROVE Samplers at a SLAMS Site. IMPROVE samplers may be used in SLAMS for monitoring of regional background and regional transport concentrations of fine particulate matter. The IMPROVE samplers were developed for use in the IMPROVE network to characterize all of the major components and many trace constituents of the particulate matter that impair visibility in Federal Class I Areas.

2.9.2 Use of CSN or IMPROVE sampling methods at a SLAMS site to provide chemical species data used in the $PM_{2.5}$ light extinction calculation. Chemical species data resulting from CSN or IMPROVE sampling methods used at SLAMS are eligible for use in the $PM_{2.5}$ light extinction calculation defined in Appendix N to 40 CFR Part 50.

* * * * *

6.0 References

* * * * *

8. Quality Assurance Project Plan: $PM_{2.5}$ Chemical Speciation Sampling at Trends, NCore, Supplemental and Tribal Sites. Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711. EPA–454/B–12–003. June 2012.

9. Standard Operating Procedure for the X-Ray Fluorescence Analysis of Particulate Matter Deposits on Teflon Filters, RTI International, Research Triangle Park, NC. August 19, 2009.

10. Standard Operating Procedure for $PM_{2.5}$ Cation Analysis, RTI International, Research Triangle Park, NC. August 25, 2009.

11. Standard Operating Procedure for $PM_{2.5}$ Anion Analysis, RTI International, Research Triangle Park, NC. August 26, 2009.

12. Standard Operating Procedure for Cleaning Nylon Filters Used for the Collection of $PM_{2.5}$ Material, RTI International, Research Triangle Park, NC. August 25, 2009.

13. DRI Standard Operating Procedure #2–216r2—DRI Model 2001 Thermal/Optical Carbon Analysis (TOR/TOT) of Aerosol Filter Samples—Method IMPROVE_A, Reno, NC, Revised July 2008.

24. Appendix D to part 58 is amended as follows:

a. By revising paragraphs 4.7.1(b), 4.7.1(c)(1), and 4.7.4

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. * * *

4.7 * * *

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 in an area of expected maximum concentration.

(2) For MSAs with a population over 1,000,000, at least one $PM_{2.5}$ FRM, FEM, or ARM is to be collocated at a near-road NO_2 station described 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.

* * * * *

4.7.4 $PM_{2.5}$ Chemical Speciation Site Requirements.

(a) Each state shall continue to conduct chemical speciation monitoring and analysis at sites designated to be part of the $PM_{2.5}$ Speciation Trends Network (STN). The selection and modification of these STN sites must be approved by the Administrator. The $PM_{2.5}$ chemical speciation urban trends sites shall include analysis for elements, selected anions and cations, and carbon. Samples must be collected using the monitoring methods and the sampling schedules approved by the Administrator. Chemical speciation is encouraged at additional sites where the chemically resolved data would be useful in developing state implementation plans and supporting atmospheric or health effects related studies.

(b) For purposes of supplying chemical species data for use in the calculated $PM_{2.5}$ light extinction indicator, states shall be required to operate CSN or IMPROVE monitoring stations at SLAMS under the following provisions:

(1) Operation of CSN or IMPROVE measurements is only required in states having at least one CBSA with a population of 1,000,000 or more people; however, multiple CBSAs with a population of 1,000,000 or more people in the same state are not each required to have CSN or IMPROVE methods operating at SLAMS unless specified below.

(2) The requirement to operate at least one CSN or IMPROVE monitoring station in a CBSA at a SLAMS shall be considered met by any approved NCore or STN station operating in a CBSA within the state.

(3) All CBSAs with a population of 2,500,000 or more people shall be required to have at least one CSN or IMPROVE monitoring station at a SLAMS within the CBSA; alternatively, the CSN or IMPROVE monitoring station may be sited in another CBSA adjacent to or downwind of the CBSA with a population of 2,500,000 or more people, when the alternative CBSA is expected to have a higher design value for the secondary PM NAAQS for visibility impairment.

(4) When siting additional CSN or IMPROVE monitoring equipment at SLAMS, the location of the monitoring site can be either a representative area-wide location for the CBSA or in an area-wide location of expected maximum concentration.

* * * * *

25. Appendix E to part 58 is amended as follows:

a. By adding paragraph (d) to section 1.

b. By adding table E–1 to section 6 after paragraph (c) introductory text.

c. By revising table E–4 in section 11.

Appendix E to Part 58—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

* * * * *

1. * * *

(d) $PM_{2.5}$ CSN measurement equipment sited at SLAMS to provide data for use in the calculation for comparison to the secondary PM standard to address visibility impairment follow the same probe and siting criteria as prescribed for PM samplers in this appendix.

* * * * *

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, middle (300 m), Neighborhood (1 km).	3½: 2–15	>1	>10	2–10; *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 meters for near-road micro-scale.
	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.

26. Appendix G to Part 58 is amended:

a. By revising sections 9 and 10.

b. By revising paragraph 12.i.a and table 2 in 12.i.d.

c. By revising section 13.

The revisions read as follows:

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 of this appendix.

* * * * *

12. * * *

i. * * *

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

d. * * *

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—(12.0–13.0)	0–54	0.0–4.4	0–35	0–53	0–50	Good.
0.060–0.075		(12.1–13.1)—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	55.5—150.4	255–354	12.5–15.4	186–304	361–649	151–200	Unhealthy.
0.116–0.374	0.205–0.404	150.5—250.4	355–424	15.5–30.4	305–604	650–1249	201–300	Very Unhealthy.
([2])	0.405–0.504	250.5—350.4	425–504	30.5–40.4	605–804	1250–1649	301–400	Hazardous.
([2])	0.505–0.604	350.5—500.4	505–604	40.5–50.4	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.

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

Bureau of Consumer Financial Protection

12 CFR Part 1071, 1080, 1081, *et al.*
Rules of Practice for Adjudication Proceedings

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1081

[Docket No. CFPB–2011–0006]

RIN 3170–AA05

Rules of Practice for Adjudication Proceedings

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule.

SUMMARY: The Dodd-Frank Wall Street Reform and Consumer Protection Act requires the Bureau of Consumer Financial Protection (Bureau) to prescribe rules establishing procedures for the conduct of adjudication proceedings. On July 28, 2011, the Bureau published an interim final rule establishing these procedures with a request for comment. This final rule responds to the comments received by the Bureau and amends the Bureau's regulations accordingly.

DATES: This final rule is effective on June 29, 2012.

FOR FURTHER INFORMATION CONTACT: John R. Coleman, Office of the General Counsel, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552, (202) 435–5724.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) was signed into law on July 21, 2010. Title X of the Dodd-Frank Act established the Bureau to regulate the offering and provision of consumer financial products or services under the Federal consumer financial laws. On July 28, 2011, the Bureau promulgated its Rules of Practice Governing Adjudication Proceedings (Interim Final Rule), pursuant to section 1053(e) of the Dodd-Frank Act, 12 U.S.C. 5563(e). The Bureau promulgated the Interim Final Rule with a request for comment at 76 FR 45338. The comment period on the Interim Final Rule ended on September 26, 2011. After reviewing and considering the issues raised by the comments, the Bureau is now promulgating, in final form, its Rules of Practice Governing Adjudication Proceedings (Final Rule) establishing procedures for the conduct of adjudication proceedings conducted pursuant to section 1053 of the Dodd-Frank Act. 12 U.S.C. 5563.

Section 1053 of the Dodd-Frank Act authorizes the Bureau to conduct administrative adjudications to ensure or enforce compliance with (a) the provisions of Title X of the Dodd-Frank Act, (b) the rules prescribed by the Bureau under Title X of the Dodd-Frank Act, and (c) any other Federal law or regulation that the Bureau is authorized to enforce. 12 U.S.C. 5563(a). The Final Rule does not apply to proceedings governing the issuance of a temporary order to cease and desist pursuant to section 1053(c) of the Dodd-Frank Act. 12 U.S.C. 5563(c). As discussed in greater detail below, the Bureau currently intends to address such proceedings in a future rulemaking.

II. Summary of the Final Rule

Like the Interim Final Rule, the Final Rule is modeled on the uniform rules and procedures for administrative hearings adopted by the prudential regulators pursuant to section 916 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, 56 FR 38024 (Aug. 9, 1991) (Uniform Rules); [1] the Rules of Practice for Adjudicative Proceedings adopted by the Federal Trade Commission, 16 CFR part 3 (FTC Rules); and the Rules of Practice adopted by the Securities and Exchange Commission (SEC), 17 CFR part 201 (SEC Rules). The Bureau also considered the Model Adjudication Rules (MARs) prepared by the Administrative Conference of the United States. *See* Michael P. Cox, The Model Adjudication Rules (MARs), 11 T.M. Cooley L. Rev. 75 (1994).

In drafting the Final Rule, the Bureau endeavored to create an adjudicatory process that provides for the expeditious resolution of claims while ensuring that parties who appear before the Bureau receive a fair hearing. Notably, in the last several decades, both the SEC and the FTC revised their rules of practice relating to administrative proceedings to make the adjudicatory process more efficient. In 1990, the SEC created a task force ''to review the rules and procedures relating to [SEC] administrative proceedings, to identify sources of delay in those proceedings and to recommend steps to make the adjudicatory process more efficient and effective.'' 60 FR 32738 (June 23, 1995). The result was a comprehensive revision of the SEC Rules in 1995. *See id.* Similarly, when the FTC proposed revisions to the FTC Rules in 2008, the FTC's Notice of Proposed Rulemaking stated: ''In particular, the [FTC's] Part 3 adjudicatory process has long been criticized as being too protracted * * *. The [FTC] believes that these comprehensive proposed rule revisions would strike an appropriate balance between the need for fair process and quality decision-making, the desire for efficient and speedy resolution of matters, and the potential costs imposed on the Commission and the parties.'' 73 FR 58832–58833 (Oct. 7, 2008).

In drafting the Final Rule, the Bureau considered and attempted to improve upon these and other agencies' efforts to streamline their processes while protecting parties' rights to fair and impartial proceedings. The following discussion outlines some significant aspects of the Final Rule.

Like the Interim Final Rule, the Final Rule adopts a decision-making procedure that incorporates elements of the SEC Rules, the FTC Rules, and the Uniform Rules. The Final Rule implements a procedure, like that in the Uniform Rules, whereby a hearing officer will issue a recommended decision in each administrative adjudication. Like the FTC Rules, the Final Rule provides any party the right to contest the recommended decision by filing a notice of appeal and perfecting the appeal by later filing an opening brief. In the event a party fails to timely file a notice of appeal or perfect an appeal, the Director may either adopt the recommended decision as the Bureau's final decision or order further briefing with respect to any findings of fact or conclusions of law contained in the recommended decision. The Bureau believes this approach best balances the need for expeditious decision-making with the parties' right to ultimate consideration of a matter by the Director.

In keeping with this approach, the Final Rule also provides that the hearing officer will decide dispositive motions in the first instance, subject to the same right of review provided for recommended decisions in the event that the ruling upon such a motion disposes of the case. Again, the Bureau has adopted this model because it provides for the most expeditious resolution of matters while preserving all parties' rights to review by the Director.

The Final Rule sets deadlines for both the recommended decision of the hearing officer and the final decision of the Director. The Bureau has adopted an approach, similar to that used by the SEC, wherein the hearing officer is

[1] The ''prudential regulators'' are defined by section 1002(24) of the Dodd-Frank Act as the Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (Board), the Federal Deposit Insurance Corporation (FDIC), the former Office of Thrift Supervision (OTS), and the National Credit Union Administration (NCUA). 12 U.S.C. 5481(24). For ease of reference, citations to the Uniform Rules herein are to the Uniform Rules as adopted by the OCC, which are codified at 12 CFR part 19, subpart A.

permitted a specified period of time—300 days from service of the notice of charges or 90 days after briefing is complete—to issue a recommended decision. The Final Rule also requires the hearing officer to convene a scheduling conference soon after the respondent files its answer to craft a schedule appropriate to the particular proceeding. This construct gives the hearing officer considerable discretion in conducting proceedings and flexibility to respond to the nuances of individual matters while ensuring that each case concludes within a fixed number of days. The Final Rule permits the hearing officer to request an extension of the 300-day deadline, but the Bureau's intent is that such extensions will be requested by hearing officers and granted by the Director only in rare circumstances.

The section of the Final Rule governing the timing of the Director's decision on appeal or review is consistent with the language of section 1053 of the Dodd-Frank Act. If a recommended decision is appealed to the Director, or the Director orders additional briefing regarding the recommended decision, the Final Rule provides that the Office of Administrative Adjudication must notify the parties that the case has been submitted for final Bureau decision at the expiration of the time permitted for filing reply briefs with the Director. The Director then must issue his or her final decision within 90 days. *See* 12 U.S.C. 5563(b)(3). To further the goal of providing for the expeditious resolution of claims, the Final Rule also adopts the SEC's standard governing extensions of time, which makes clear that such extensions are generally disfavored.

The Bureau has adopted the SEC's affirmative disclosure approach to fact discovery in administrative adjudications. *See* 17 CFR 201.230. Thus, the Final Rule provides that the Office of Enforcement will provide any party in an adjudication proceeding an opportunity to inspect and copy certain categories of documents obtained by the Office of Enforcement from persons not employed by the Bureau, as that term is defined in the Final Rule, in connection with the investigation leading to the institution of the proceedings, and certain categories of documents created by the Bureau, provided such material is not privileged or otherwise protected from disclosure. The Office of Enforcement's obligation under the Final Rule relates only to documents obtained by the Office of Enforcement; documents located only in the files of other divisions or offices of the Bureau are beyond the scope of the affirmative disclosure obligation. As set forth in greater detail in the section-by-section analysis below, the Bureau has modified the SEC Rules slightly by eliminating any reference to *Brady* v. *Maryland* while retaining a general obligation to turn over material exculpatory information in the Office of Enforcement's possession, by providing that nothing in paragraph (a) of § 1081.206 shall require the Office of Enforcement to provide reports of examination to parties if they are not the subject of the report, and by providing an exception for information provided by another government agency upon condition that it not be disclosed.

The goal in adopting the SEC's basic approach is to ensure that respondents have prompt access to the non-privileged documents underlying enforcement counsel's decision to commence enforcement proceedings, while eliminating much of the expense and delay often associated with pre-trial discovery in civil matters. Recognizing that administrative adjudications will take place after a Bureau investigation intended to gather relevant evidence, and in light of the affirmative obligation that the Final Rule places on enforcement counsel to provide access to materials gathered in the course of the investigation, the Final Rule does not provide for certain other traditional forms of pre-trial discovery, such as interrogatories and discovery depositions. The Final Rule does provide for the deposition of witnesses unavailable for trial, the use of subpoenas to compel the production of documentary or tangible evidence, and in appropriate cases, expert discovery, thus ensuring that respondents have an adequate opportunity to marshal evidence in support of their defense. The Bureau believes this approach will promote the fair and speedy resolution of claims while ensuring that parties have access to the information necessary to prepare a defense.

III. Public Comment on the Interim Final Rule

In response to the Interim Final Rule, the Bureau received seven comment letters. Four letters were received from trade associations representing sectors of the financial industry, one letter was received from a mortgage company, and two letters were received from individual consumers.

Trade associations' comments generally fell into several categories. Several comments suggested that the Bureau revisit the deadlines contained in the Interim Final Rule. Two trade association comment letters objected to the affirmative disclosure approach to discovery, and requested that the Bureau allow respondents to conduct additional forms of traditional civil discovery. Two trade associations requested that the Bureau adopt a process to notify potential respondents that the Bureau is contemplating an enforcement action, similar to the Wells Notice process used by the SEC. One trade association commenter expressed concern about the confidentiality of adjudication proceedings and filings. Trade associations made other specific comments as well, all of which are addressed in part V below in connection with the section of the Interim Final Rule to which they pertain.

The comment letter received from the mortgage company related to the Rules Relating to Investigations, *see* 12 CFR part 1080, not the Interim Final Rule. The comment letter is addressed in the Final Rule establishing part 1080.

The comment letters from consumers did not contain any specific comments or suggestions pertaining to the Interim Final Rule.

In part IV of this preamble, the Bureau addresses general comments that were not directly related to particular sections of the Interim Final Rule. In part V, the Bureau describes each section of the Interim Final Rule, responds to significant issues raised by the comments pertaining to each section, and explains any changes made to the Interim Final Rule that are reflected in the Final Rule. Many sections of the Interim Final Rule received no comment and, as noted, are being finalized without change.

IV. General Comments

The Bureau received several comments that were not directed at specific sections of the Interim Final Rule. Those comments are addressed here.

Two commenters suggested that the Bureau adopt a process for a prospective respondent to be given the opportunity to respond to the Bureau's allegations before an action is filed or a notice of charges is issued, similar to the Wells Process adopted by the SEC.

The Bureau announced on November 7, 2011 that it has adopted a process similar to the Wells Process.[2] The process will allow the subject of an investigation, in most cases, to respond to any potential legal violations that Bureau enforcement counsel believe have been committed before the Bureau decides whether to initiate an

[2] See *www.consumerfinance.gov/pressrelease/consumer-financial-protection-bureau-plans-to-provide-early-warning-of-possible-enforcement-actions.*

enforcement proceeding. The Bureau's process for providing advance notice of a possible legal action is not required by law, but the Bureau believes it will promote even-handed enforcement of Federal consumer financial law.

The Bureau received several comments raising concern about the disclosure of confidential material contained in administrative filings.

The Final Rule provides that filings containing confidential information subject to a protective order or a pending motion for a protective order may not be published or otherwise disclosed. In addition, the Bureau will adopt a policy providing for a ten-day delay before publishing filings, in order to allow any party an opportunity to object to the disclosure of allegedly confidential information contained within such filings. This policy is intended to protect confidential information from inadvertent disclosure in public documents. The comments regarding the Bureau's treatment of confidential information are addressed in more detail below in connection with the specific rules to which they were directed.

One commenter asked the Bureau to identify the official authorized to initiate enforcement proceedings in the absence of a Bureau Director. This commenter also suggested that once a Director is in place, only the Director should be authorized to initiate enforcement proceedings.

The President appointed a Director to the Bureau on January 4, 2012. The Director, or any official to whom the Director has delegated his authority pursuant to section 1012 of the Dodd-Frank Act, 12 U.S.C. 5492(b), will authorize the initiation of enforcement proceedings through the issuance of a notice of charges.

One commenter asserted that section 1052(c)(1) of the Dodd-Frank Act prohibits the Bureau from issuing civil investigative demands after the institution of any proceedings under a Federal consumer financial law, including proceedings initiated by a State or a private party. 12 U.S.C. 5562(c)(1). The commenter argued that a civil investigative demand should be accompanied by a certification that the demand will have no bearing on any proceeding then in process.

Section 1052(c)(1) provides, in relevant part, that ''the Bureau may, before the institution of any proceedings under the Federal consumer financial law, issue in writing, and cause to be served upon such person, a civil investigative demand.'' The language ''before the institution of any proceeding under Federal consumer financial law'' refers to the institution of proceedings by the Bureau related to the investigation that results in the proceeding. It does not limit the Bureau's authority to issue civil investigative demands based upon the commencement of a proceeding by other parties, such as a State or a private party. Nor does it limit the Bureau's authority to issue civil investigative demands to investigate potential violations of Federal consumer law not at issue in a pending proceeding.

In addition, the Bureau notes that any limitations placed upon it by section 1052(c)(1) of the Dodd-Frank Act are incorporated in 12 CFR 1080.6, which provides that civil investigative demands will be issued in accordance with section 1052(c) of the Dodd-Frank Act, 12 U.S.C. 5562(c).

One commenter argued the Right to Financial Privacy Act (RFPA), 12 U.S.C. 3401 *et seq.,* limits the Bureau's ability to bring administrative enforcement proceedings without a Director. The commenter contended RFPA restricts the Bureau's authority to share information protected under RFPA with the Secretary of the Treasury. The commenter therefore recommended that the Bureau revise the Interim Final Rule to provide that, until the Bureau has a Director, the Bureau will not commence or continue adjudication proceedings in cases where material information includes information that RFPA purportedly does not permit to be disclosed to the Secretary of the Treasury.

As noted above, the President appointed a Director to the Bureau on January 4, 2012. The Bureau will comply with RFPA, but the commenters' particular concern about the sharing of information with the Secretary of the Treasury is moot.

V. Section-by-Section Analysis

Subpart A—General Rules

Section 1081.100 Scope of the Rules of Practice

This section of the Interim Final Rule sets forth the scope of the Interim Final Rule and states that it applies to adjudication proceedings brought under section 1053 of the Dodd-Frank Act. The Interim Final Rule does not apply to Bureau investigations, rulemakings, or other proceedings. As drafted and pursuant to the definition of the term ''*adjudication proceeding''* in § 1081.103, the Interim Final Rule does not apply to the issuance, pursuant to section 1053(c) of the Dodd-Frank Act, of a temporary order to cease-and-desist pending completion of the underlying cease-and-desist proceedings.

The Bureau invited comments as to whether special rules governing such proceedings are necessary and, if so, what the rules should provide. One commenter recommended that the Bureau undertake a new rulemaking to promulgate rules governing temporary cease-and-desist proceedings initiated pursuant to section 1053(c) of the Dodd-Frank Act and suggested that such proceedings should be based on findings made on specific criteria. The commenter pointed to the Federal Deposit Insurance Corporation's rules governing temporary cease-and-desist proceedings, 12 CFR 308.131, as an example of such rules.

The Bureau agrees that there should be specific rules governing temporary cease-and-desist proceedings initiated pursuant to section 1053(c) of the Dodd-Frank Act, and currently intends to issue separate rules governing such proceedings.

One commenter also sought clarification as to whether the Interim Final Rule was intended to apply to proceedings in which the Bureau is seeking civil money penalties available under section 1055(c) of the Dodd-Frank Act. 12 U.S.C. 5565(c). The commenter noted that in many instances, the Bureau is likely to seek both an order to cease-and-desist and a civil money penalty based on the same facts. The commenter stated it would be more efficient to have both hearings combined into one hearing on the record.

To provide further guidance to covered persons, the Bureau clarifies that it will rely on the Final Rule when seeking civil money penalties in adjudication proceedings. The Bureau agrees with the commenter that there will be many instances where the Bureau will simultaneously seek civil money penalties, a cease-and-desist order, and potentially other available remedies. The Bureau will periodically be reviewing its experience under the Final Rule to consider whether additional changes may be warranted, including whether additional rules governing the imposition of civil money penalties pursuant to section 1055(c) of the Dodd-Frank Act would be beneficial.

With the exception of a technical change in the citation to the Dodd-Frank Act, the Bureau adopts § 1081.100 of the Interim Final Rule without change in the Final Rule.

Section 1081.101 Expedition and Fairness of Proceedings

This section of the Interim Final Rule, which is modeled on the FTC Rules, 16 CFR 3.1, sets forth the Bureau's policy

to avoid delays in any stage of an adjudication proceeding while still ensuring fairness to all parties. It permits the hearing officer or the Director to shorten time periods established by the Interim Final Rule with the parties' consent. This authority could be used in proceedings where expedited hearings would serve the public interest or where the issues do not require expert discovery or extended evidentiary hearings.

One commenter noted its strong support for fair and impartial adjudication proceedings, but indicated that whether such proceedings should also be ''expeditious'' depends on the meaning of that term, and on the facts and circumstances of individual cases. The Bureau notes that expeditious proceedings are contemplated under section 1053(b) of the Dodd-Frank Act, 12 U.S.C. 5563(b), which requires that the hearing be held no earlier than 30 days nor later than 60 days after the date of service of the notice of charges, unless an earlier or later date is set by the Bureau at the request of any party so served. The Bureau believes that, in drafting the Interim Final Rule, it created a process that simultaneously provides for the prompt and efficient resolution of claims and ensures that parties who appear before the Bureau receive a fair hearing.

The Bureau adopts § 1081.101 of the Interim Final Rule without change in the Final Rule.

Section 1081.102 Rules of Construction

This section of the Interim Final Rule, drawn from the Uniform Rules, 12 CFR 19.2, makes clear that the use of any term in the Interim Final Rule includes either its singular or plural form, as appropriate, and that the use of the masculine, feminine, or neuter gender shall, if appropriate, be read to encompass all three. This section also explicitly states that, unless otherwise indicated, any action required to be taken by a party to a proceeding may be taken by the party's counsel. Finally, this section to the Final Rule provides that terms not otherwise defined by § 1081.103 should be defined in accordance with section 1002 of the Dodd-Frank Act, 12 U.S.C. 5481; the Interim Final Rule did not specifically reference section 1002.

The Bureau adopts § 1081.102 of the Interim Final Rule with the changes discussed above.

Section 1081.103 Definitions

This section of the Interim Final Rule sets forth definitions of certain terms used in the Interim Final Rule.

This section defines ''*adjudication proceeding*'' to include any proceeding conducted pursuant to section 1053 of the Dodd-Frank Act, except for proceedings related to the issuance of a temporary order to cease and desist pursuant to section 1053(c) of the Dodd-Frank Act. As previously noted, the Bureau currently intends to issue rules governing the issuance of temporary orders to cease and desist in the future.

The Bureau intends for the term ''*counsel*'' to include any individual representing a party, including, as appropriate, an individual representing himself or herself. The term ''*Director*'' has been defined to include the Director, as well as any person authorized to perform the functions of the Director in accordance with the law. This is intended to allow the Deputy Director, or a delegee of the Director, as appropriate, to perform the functions of the Director. The term ''*person employed by the Bureau*'' is defined to include Bureau employees and contractors as well as others working under the direction of Bureau personnel, and is intended to encompass, among other things, consulting experts.

On its own initiative, the Bureau replaced the defined term ''*Act,*'' which had been defined as the Consumer Financial Protection Act of 2010, with the defined term ''*Dodd-Frank Act*'' and defined ''*Dodd-Frank Act*'' to mean the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010.

On its own initiative, the Bureau has included a new definition in the Final Rule for the ''*Office of Administrative Adjudication.*'' The Interim Final Rule provided that the receipt of filings and certain other administrative tasks related to the Director's review of recommended decisions would be performed by the Bureau's Executive Secretary. After publication of the Interim Final Rule, the Bureau formed an Office of Administrative Adjudication to perform these functions. The Final Rule has been amended to reflect the creation of the Office of Administrative Adjudication and the transfer of the Executive Secretary's duties in adjudication proceedings to this Office. The defined term ''*Executive Secretary*'' has been removed from § 1081.103 as unnecessary.

On its own initiative, the Bureau also amended the definitions of ''*party*'' and ''*respondent*'' to account for persons that intervene in a proceeding for the limited purpose of seeking a protective order pursuant to amended § 1081.119(a).

Finally, the Bureau changed the term ''*Division of Enforcement*'' to ''*Office of Enforcement*'' to accurately reflect the Bureau's organizational nomenclature.

The Bureau adopts § 1081.103 of the Interim Final Rule with the changes discussed above.

Section 1081.104 Authority of the Hearing Officer

This section of the Interim Final Rule enumerates powers granted to the hearing officer subsequent to appointment. The hearing officer has the powers specifically enumerated in paragraph (b) of this section, as well as the power to take any other action necessary and appropriate to discharge the duties of a presiding officer. All powers granted by this provision are intended to further the Bureau's goal of an expeditious, fair, and impartial hearing process. The powers set forth in this section are generally drawn from the Administrative Procedure Act (APA), 5 U.S.C. 556, 557, and are similar to the powers granted to hearing officers and administrative law judges under the Uniform Rules, the SEC Rules, and the FTC Rules.

This section provides the hearing officer with the explicit authority to issue sanctions against parties or their counsel as may be necessary to deter sanctionable conduct, provided that any person to be sanctioned first has an opportunity to show cause as to why no sanction should issue. The Bureau believes such authority is included within the hearing officer's authority to regulate the course of the hearing, 5 U.S.C. 556(c)(5), but considers it appropriate to explicitly authorize the exercise of such authority in the Final Rule. The Bureau notes that the MARs provide adjudicators with the authority ''to impose appropriate sanctions against any party or person failing to obey her/his order, refusing to adhere to reasonable standards of orderly and ethical conduct, or refusing to act in good faith.'' *See* MARs, 11 T. M. Cooley L. Rev. at 83.

One commenter recommended that this section be revised to make clear that the hearing officer has the authority to provide a person requesting confidential treatment of information the time to come into compliance with applicable requirements before making a determination regarding confidentiality. The commenter expressed concern that the section as drafted authorized the hearing officer to immediately make public purportedly confidential material if the applicable requirements were not met.

The Bureau believes that the section as drafted adequately addresses this

circumstance. The hearing officer is authorized to ''deny confidential status to documents and testimony *without prejudice* until a party complies with all relevant rules'' (emphasis added). The inclusion of the ''without prejudice'' language authorizes the hearing officer to treat material as confidential while the party attempts to comply with the relevant rules. It also provides the hearing officer the authority to deny confidential status to documents when appropriate; for example, if a party repeatedly and/or willfully fails to comply with the requirements of the Final Rule.

The section permits the hearing officer to deny confidential status without prejudice until a party complies with ''all relevant rules.'' The commenter stated that the reference to ''all relevant rules'' is vague because the adjudication proceeding could be based on a respondent's alleged noncompliance with other rules. The commenter questioned whether the respondent would have to comply with those other rules before the hearing officer will treat material as confidential for the purposes of the adjudication proceeding.

The Bureau does not anticipate that the hearing officer will confuse the substantive rules the respondent is alleged to have violated with the procedural rules governing the treatment of purportedly confidential material. In light of this comment, however, and in the interest of providing covered persons additional guidance, the Bureau directs parties to §§ 1081.111, 1081.112, and 1081.119, as well as any applicable orders of the Director or hearing officer and any guidance issued by the Office of Administrative Adjudication, as the relevant rules with which persons seeking confidential treatment of material must comply.

Finally, the commenter stated that the hearing officer's authority to ''reject written submissions that fail to comply with the requirements of this part, and to deny confidential status to documents and testimony without prejudice until a party complies with all relevant rules'' was unclear. The commenter suggested that the hearing officer should only be permitted to reject filings that ''materially'' fail to comply with applicable requirements, so as not to elevate form over substance.

The Bureau has revised the Interim Final Rule to address this comment. Rejection of submissions merely because they fail to comply with this part in an immaterial fashion would be inconsistent with the Bureau's policy of encouraging fair and expeditious proceedings. Accordingly, the Bureau has revised § 1081.104(b)(6). The Final Rule provides that the hearing officer has the authority to ''reject written submissions that materially fail to comply with the requirements of this part.'' The Bureau adopts § 1081.104 of the Interim Final Rule with the changes discussed above.

Section 1081.105 Assignment, Substitution, Performance, Disqualification of Hearing Officer

This section of the Interim Final Rule is modeled on the FTC and the SEC Rules setting forth the process for assigning hearing officers in the event that more than one hearing officer is available to the Bureau. *See* 16 CFR 3.42(b), (e); 17 CFR 201.110, 201.112, 201.120. Consistent with 5 U.S.C. 3105, hearing officers will be ''assigned to cases in rotation so far as practicable.'' This section also sets forth the process by which hearing officers may be disqualified from presiding over an adjudication proceeding. The APA, 5 U.S.C. 556(b), provides that a hearing officer may disqualify himself or herself at any time. The standard for making a motion to disqualify requires that the movant have a reasonable, good faith basis for the motion. This standard is intended to emphasize that there must be an objective reason to seek a disqualification, not just a subjective, though sincerely held, belief. If a hearing officer does not withdraw in response to a motion for withdrawal, the motion is certified to the Director for his or her review in accordance with the Interim Final Rule's interlocutory review provision. Finally, this section provides the procedure for reassignment of a proceeding in the event a hearing officer becomes unavailable.

No comments were received specifically relating to this section, but commenters strongly supported a policy that adjudications should be fair and impartial. To that end, the Bureau has amended § 1081.201 of the Interim Final Rule by adding a new paragraph (e), which will require respondents, nongovernmental amici, and nongovernmental intervenors under § 1081.119(a) to file a disclosure statement and notification of financial interest. This disclosure statement and notification, discussed in more detail below, will provide the hearing officer and the parties with information to determine actual or potential bases for financial disqualification of the hearing officer early in the proceeding.

The Bureau adopts § 1081.105 of the Interim Final Rule without change in the Final Rule.

Section 1081.106 Deadlines

This section of the Interim Final Rule provides that deadlines for action by the hearing officer established by the Interim Final Rule do not confer any substantive rights on respondents. The SEC Rules, 17 CFR 201.360(a)(2), contain similar language regarding the timelines set out for certain hearing officer actions in SEC proceedings.

The Bureau received no comment on § 1081.106 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.107 Appearance and Practice in Adjudication Proceedings

This section of the Interim Final Rule is largely based on the Uniform Rules, 12 CFR 19.6, and prescribes who may act in a representative capacity for parties in adjudication proceedings. A notice of appearance is required to be filed by an individual representing any party, including an individual representing the Bureau, simultaneously with or before the submission of papers or other act of representation on behalf of a party. Any counsel filing a notice of appearance is deemed to represent that he or she agrees and is authorized to accept service on behalf of the represented party. The section also sets forth the standards of conduct expected of attorneys and others practicing before the Bureau. It provides that counsel may be excluded or suspended from proceedings, or disbarred from practicing before the Bureau, for engaging in sanctionable conduct during any phase of the adjudication proceeding.

The Bureau received no comments on § 1081.107, and the Final Rule is substantially similar to the Interim Final Rule. On the Bureau's own initiative, however, the Bureau amended § 1081.107(a)(1) to clarify that an attorney who is currently suspended or debarred from practicing in any jurisdiction may not appear before the Bureau or a hearing officer. This clarification is consistent with the SEC Rules, 17 CFR 201.102(e)(2), which provide for the suspension of any attorney who has been suspended or debarred by a court of the United States or of any State, and is designed to prohibit the appearance before the Bureau by a person who is authorized to practice in one State, but has been debarred or suspended in another jurisdiction.

The Bureau adopts § 1081.107 of the Interim Final Rule with the changes discussed above.

Section 1081.108 Good Faith Certification

This section of the Interim Final Rule is based on the Uniform Rules, 12 CFR 19.7, and requires that all filings and submissions be signed by at least one counsel of record, or the party if appearing on his or her own behalf. This section provides that, by signing a filing or submission, the counsel or party certifies and attests that the document has been read by the signer, and, to the best of his or her knowledge, is well grounded in fact and is supported by existing law or a good faith argument for the extension or modification of the existing law. In addition, the certification attests that the filing or submission is not for purposes of unnecessary delay or any improper purpose. Oral motions or arguments are also subject to the good faith certification: The act of making the oral motion or argument constitutes the required certification. Finally, this section makes clear that a violation of the good faith certification requirement would be grounds for sanctions under § 1081.104(b)(13). This section, which also mirrors the requirements of Federal Rule of Civil Procedure 11, is intended to ensure that parties and their counsel do not abuse the administrative process by making filings that are factually or legally unfounded or intended simply to delay or obstruct the proceeding.

The Bureau received no comment on § 1081.108 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.109 Conflict of Interest

This section of the Interim Final Rule provides that, in general, conflicts of interest in representing parties to adjudication proceedings are prohibited. The hearing officer is empowered to take corrective steps to eliminate such conflicts. If counsel represents more than one party to a proceeding, counsel is required to file at the time he or she files his or her notice of appearance a certification that: (1) The potential for possible conflicts of interest has been fully discussed with each such party; and (2) the parties individually waive any right to assert any conflicts of interest during the proceeding. This approach is modeled after the Uniform Rules, 12 CFR 19.8, which were based upon the Model Code of Conduct for attorneys and the District of Columbia Ethics Rule. *See* 56 FR 27790, 27793 (June 17, 1991).

The Bureau received no comment on § 1081.109 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.110 Ex Parte Communication

This section of the Interim Final Rule implements the APA's prohibition on ex parte communications. *See* 5 U.S.C. 554(d)(1), 557(d)(1). Paragraphs (a)(1), (a)(2), and (b) are based on the Uniform Rules, 12 CFR 19.9(a), (b), and prohibit an ex parte communication relevant to the merits of an adjudication proceeding between a person not employed by the Bureau and the Director, hearing officer, or any decisional employee during the pendency of an adjudication proceeding. Paragraph (a)(3) defines the term ''*pendency of an adjudication proceeding,*'' and provides that if the person responsible for the communication has knowledge that a notice of charges will or is likely to be issued, the pendency of an adjudication shall be deemed to have commenced at the time of his or her acquisition of such knowledge. This provision implements 5 U.S.C. 557(d)(1)(E).

Consistent with the MARs and the practice of other agencies, communications regarding the status of the proceeding are expressly excluded from the definition of ex parte communications. *See* MARs, 11 T.M. Cooley L. Rev. at 87; 12 CFR 19.9(a)(2); 16 CFR 4.7(a). If an ex parte communication does occur, the document itself, or if oral, a memorandum describing the substance of the communication must be placed in the record. All other parties to the proceeding may have the opportunity to respond to the prohibited communication, and such response may include a recommendation for sanctions. The hearing officer or the Director, as appropriate, may determine whether sanctions are appropriate.

Finally, paragraph (e) of this section provides that the hearing officer is not permitted to consult an interested person or a party on any matter relevant to the merits of the adjudication, except to the extent required for the disposition of ex parte matters. Consistent with 5 U.S.C. 554(d), this paragraph also provides that Bureau employees engaged in an investigational or prosecutorial function, other than the Director, may not participate in the decision-making function in the same or a factually related matter.

The Bureau received several comments regarding this section. One commenter expressed the concern that it may be difficult to determine whether a notice of charges ''will be'' or is ''likely to be'' issued for the purpose of determining when the prohibition on ex parte communications begins. The commentator stated that, because an individual makes the final decision to issue a notice of charges and the individual's thinking could change unexpectedly, anything short of respondent's actual knowledge that a notice of charges has actually been issued should be insufficient to begin the prohibition on ex parte communications. The commentator stated that it would not be appropriate to sanction someone for an ex parte communication when the person does not know whether a notice of charges has been issued. The commenter proposed that the Bureau revise this section of the Interim Final Rule to begin the ban on ex parte communications upon notice of actual issuance and service of a notice of charges, regardless of whether the person has knowledge that a notice of charges will be issued. Similarly, in cases in which a court has vacated a final decision and order and remanded a matter for further adjudication proceedings, the commenter proposed that this section of the Interim Final Rule be revised to prohibit ex parte communications after remand beginning when the party actually knows the Bureau will not file an appeal because the time for filing an appeal has lapsed and the party has not been served with a notice of appeal.

The Bureau has revised the section after considering these comments. The APA provides that the prohibition on ex parte communications ''shall apply beginning at such time as the agency may designate, but in no case shall they begin to apply later than the time at which a proceeding is noticed for hearing unless the person responsible for the communication has knowledge that it will be noticed, in which case the prohibitions shall apply beginning at the time of his acquisition of such knowledge.'' 5 U.S.C. 557(d)(1)(E). The APA does not, however, prohibit ex parte communications from the time a party knows a proceeding ''is likely to be'' issued. Accordingly, the Bureau has struck the phrase ''is likely to be'' from § 1081.110(a)(3).

The Bureau has also revised § 1081.110(a)(3) with respect to the timing of the respondent's knowledge of whether the Bureau will file an appeal. The Final Rule removes that provision of the Interim Final Rule stating that ''an order of remand by a court of competent jurisdiction shall be deemed to become effective when the Bureau determines not to file an appeal or a petition for a writ of certiorari,'' and slightly revises the rest of the section to reflect the fact that review of an appellate court's decision may only be had upon the grant of a petition for rehearing by the

panel or an en banc panel, or the grant of a petition for a writ of certiorari. This amendment responds to the commenter's concern that a respondent will not know whether the Bureau intends to appeal until the Bureau provides notice of its intention.

Finally, paragraph (e) provides that Bureau employees engaged in an investigational or prosecutorial function, other than the Director, may not participate in the decision-making function in the same or a factually related matter. The commenter expressed concern that this section would permit the Director to engage in ex parte communications with Bureau enforcement counsel regarding the decision, recommended decision, or agency review of the recommended decision in the same or factually related case. The commenter therefore recommended that this section be revised to prohibit enforcement counsel from communicating with the Director under these circumstances.

The Bureau notes that, while this section of the Interim Final Rule does not bar enforcement counsel from communicating with the Director regarding matters unrelated to the Director's adjudicatory functions, this section expressly prohibits enforcement counsel from participating or advising in the decision, recommended decision, or agency review of the recommended decision, except as witness or counsel in a public proceeding. The Bureau believes that these prohibitions are consistent with the separation of functions provision of the APA, 5 U.S.C. 554(d), and address the commenter's concern. Accordingly, the Bureau declines to revise paragraph (e).

The Bureau adopts § 1081.110 of the Interim Final Rule with the changes discussed above.

Section 1081.111 Filing of Papers

This section of the Interim Final Rule requires the filing of papers in an adjudication proceeding. It specifies the papers that must be filed and addresses the time and manner of filing. The Bureau received no comments regarding this section. In the interest of clarity and to provide further guidance to parties, however, the Bureau has amended the Interim Final Rule in several respects.

First, the Final Rule makes technical revisions to paragraph (a) to require the filing of the disclosure statement and notification of financial interest required under the new § 1081.201(e). The Final Rule also includes a slight revision to paragraph (a) intended to clarify that the Bureau must file the proof of service of the notice of charges. Among other things, the filing of the proof of service will provide notice of the beginning of the ten-day period after which the Bureau will publish the notice of charges under § 1081.200(c).

The Final Rule makes non-substantive changes to paragraph (b) of the Interim Final Rule to make uniform the references to the United States Postal Service and the different mail services. The Bureau also revised paragraph (b) to reflect the transfer of certain authorities to the newly-created Office of Administrative Adjudication. As a result, the section provides for filing by electronic transmission upon the conditions specified by the Office of Administrative Adjudication, recognizing that while the Bureau anticipates the development of an electronic filing system, it may adopt other means of electronic filing in the interim (*e.g.,* email transmission). The section authorizes other methods of filing if a respondent demonstrates, in accordance with guidance issued by the Office of Administrative Adjudication, that filing via electronic transmission is not practical.

Finally, the Bureau added a new paragraph (c), providing that unless otherwise ordered by the Bureau or the hearing officer, or in the absence of a pending motion seeking such an order, all papers filed in connection with an adjudication proceeding are presumed to be open to the public. This paragraph is consistent with the Bureau's commitment to making adjudication proceedings as transparent as reasonably possible, as reflected in §§ 1081.119(c) and 1081.300, which both recognize a presumption that documents and testimony in adjudication hearings are public.

The Bureau adopts § 1081.111 of the Interim Final Rule with the changes discussed above.

Section 1081.112 Formal Requirements as to Papers Filed

This section of the Interim Final Rule sets forth the formal requirements for papers filed in adjudication proceedings. It sets forth formatting requirements, requires that all documents be signed in accordance with § 1081.108, and requires the redaction of sensitive personal information from filings where the filing party determines that such information is not relevant or otherwise necessary for the conduct of the proceeding. This section also sets forth the method of filing documents containing information for which confidential treatment has been granted or is sought, and requires that in addition to filing the confidential information under seal, an expurgated copy of the filing be made on the public record. Section 1081.119 governs the filing of motions seeking confidential treatment of information and sets forth the standard to be applied by the hearing officer in determining whether to grant such treatment.

One commenter suggested that the Bureau remove the requirement in paragraph (e) that sensitive personal information be redacted from filings. The commenter believed that this requirement was not workable because the Interim Final Rule did not define ''sensitive personal information'' and only provided examples of such information. The commenter also pointed out that the Uniform Rules and the SEC Rules do not require the redaction of sensitive personal information.

The Bureau declines to omit the requirement that sensitive personal information be redacted from filings. The Bureau continues to believe that it is improper to file Social Security numbers, financial account numbers, and other sensitive personal information in an adjudication proceeding where the information is not relevant or otherwise necessary for the conduct of the proceeding. The Bureau notes that this section is modeled on the FTC Rules, 16 CFR 3.45(b), and is also similar to Federal Rule of Civil Procedure 5.2, which require filers to redact certain personal information, including Social Security numbers and financial account numbers, from filings. The Bureau agrees, however, that the term ''sensitive personal information'' should be defined and has therefore revised paragraph (e) to define that term.

The commenter also recommended the removal of paragraph (f)(2), which requires a party seeking confidential treatment of information in a filing to file an expurgated copy of the filing with the allegedly confidential material redacted. Specifically, the commenter stated that paragraph (f)(2)'s requirement that the redacted version show the size and location of the redactions could, in effect, disclose what was redacted and may be impractical when redactions are made electronically. The commenter stated that the SEC Rules and Uniform Rules do not include this requirement. The Bureau notes that paragraph (f)(2) is modeled on the FTC Rules, 16 CFR 3.45(e), and that the commenter did not identify how this redaction requirement could disclose confidential information or would be impractical. Accordingly, the Bureau declines to omit this requirement.

Section 1081.112(e) has been revised to include a definition of sensitive personal information, and to clarify the

obligations of a party filing a document containing sensitive personal information. Section 1081.112(f) has been revised to clarify the obligation of parties to comply with any applicable order of the hearing officer or the Director when seeking confidential treatment of information in a filing.

The Bureau adopts § 1081.112 of the Interim Final Rule with the changes discussed above.

Section 1081.113 Service of Papers

This section of the Interim Final Rule requires that every paper filed in a proceeding be served on all other parties to the proceeding in the manner set forth in this section. Service by electronic transmission is encouraged, but is conditioned upon the consent of the parties. The section also sets forth specific methods for the Bureau to serve notices of charges, as well as recommended decisions and final orders. In this regard, the section provides that such service cannot be made by First Class mail, but also provides that service may be made on authorized agents for service of process.

The section also provides that the Bureau may serve persons at the most recent business address provided to the Bureau in connection with a person's registration with the Bureau. Although no such registration requirements currently exist, the Bureau has included this provision to account for any such requirements in the future. In the event that a party is required to register with the Bureau and maintain the accuracy of such registration information, the Bureau should be entitled to rely upon such information for service of process. This provision is modeled on the SEC Rules, 17 CFR 201.141(a)(2)(iii).

The Bureau did not receive comments specifically related to § 1081.113. However, the Bureau made technical revisions to clarify and make this section of the Final Rule consistent with other sections of the Final Rule. The Bureau revised paragraph (d)(1)(v), which requires the Bureau to maintain a record of service of the notice of charges on parties, to also require the Bureau to file the certificate of service consistent with revised § 1081.111(a) to give notice of the beginning of the ten-day period after which the Bureau will publish the notice of charges under § 1081.200(c).

In addition, the Bureau revised paragraph (a) of this section to make it clear that the parties must comply with any applicable order of the hearing officer or the Director governing the service of papers.

Finally, as it did with § 1081.111(b), the Bureau made non-substantive changes to paragraphs (c) and (d) to make uniform the references to the United States Postal Service and the different mail services.

The Bureau adopts § 1081.113 of the Interim Final Rule with the changes discussed above.

Section 1081.114 Construction of Time Limits

This section of the Interim Final Rule provides for the manner of computing time limits, taking into account the effect of weekends and holidays on time periods that are ten days or less. This section also sets forth when filing or service is effective. With regard to time limits for responsive pleadings or papers, this section incorporates a three-day extension for mail service, similar to the Federal Rules of Civil Procedure, and a one-day extension for overnight delivery, as contained in some agencies' existing rules. A one-day extension for service by electronic transmission is consistent with the Uniform Rules and reflects that electronic transmission may result in delays in actual receipt by the person served.

Although the Bureau did not receive comments specifically related to § 1081.114, the Bureau made technical, non-substantive revisions to this section. As it did with §§ 1081.111 and 1081.113, the Bureau made non-substantive changes to make uniform the references to the United States Postal Service and the different mail services.

The Bureau adopts § 1081.114 of the Interim Final Rule with the changes discussed above.

Section 1081.115 Change of Time Limits

This section of the Interim Final Rule is modeled on the SEC Rules, 17 CFR 201.161, and is intended to limit extensions of time to those necessary to prevent substantial prejudice. The section is intended to further the Bureau's goal of ensuring the timely conclusion of adjudication proceedings. The section generally provides the hearing officer and the Director the authority to extend the time limits prescribed by the Interim Final Rule in certain defined circumstances. In keeping with the goal of expeditious resolution of proceedings, this section provides that motions for extension of time are strongly disfavored and may only be granted after consideration of various enumerated factors, provided that the requesting party makes a strong showing that denial of the motion would substantially prejudice its case. The section also provides that any extension of time shall not exceed 21 days unless the hearing officer or Director, as appropriate, states on the record or in a written order the reasons why a longer extension of time is necessary. Finally, the section provides that the granting of a motion for an extension of time does not affect the deadline for the recommended decision of the hearing officer, which must be filed no later than the earlier of 300 days after the filing of the notice or charges or 90 days after the end of post-hearing briefing (unless separately extended by the Director as provided for in § 1081.400).

Commenters expressed concern over paragraph (b) of this section, which sets forth a policy strongly disfavoring motions for extensions of time. The commenters recommended that the Bureau delete paragraph (b).

The Bureau believes the policy reflected in paragraph (b) ensures fairness to both the parties and the hearing officer by allowing an administrative matter to proceed within the timeframes provided by the Interim Final Rule, which were designed to provide sufficient time to both the litigants and the hearing officer. The Bureau believes that mandatory deadlines for the completion of certain stages of administrative proceedings, and a policy strongly disfavoring extensions, postponements or adjournments, is necessary to ensure that these proceedings are expeditious and fair.

The Bureau notes that the SEC amended its rules in 2003 to improve the timeliness of its administrative proceedings. The SEC Rules, 17 CFR 201.161, on which this section is modeled, were revised in 2003 to incorporate a policy strongly disfavoring extensions, postponements or adjournments except in circumstances where the requesting party makes a strong showing that the denial of the request or motion would substantially prejudice its case. The SEC stated that this provision was necessary in light of another amendment to the SEC Rules that changed the suggested guidelines for completion of administrative matters to mandatory deadlines. *See* 68 FR 35787 (June 17, 2003). The Bureau finds the SEC's experience instructive, and declines to delete paragraph (b) of this section.

The Bureau adopts § 1081.115 of the Interim Final Rule without change in the Final Rule.

Section 1081.116 Witness Fees and Expenses

This section of the Interim Final Rule provides that fees and expenses for non-party witnesses subpoenaed pursuant to

the Interim Final Rule shall be the same as for witnesses in United States district courts.

The Bureau received no comment on § 1081.116 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.117 Bureau's Right To Conduct Examination, Collect Information

This section of the Interim Final Rule, which is modeled on the Uniform Rules, 12 CFR 19.16, states that nothing contained in the Interim Final Rule shall be construed to limit the right of the Bureau to conduct examinations or visitations of any person, or the right of the Bureau to conduct any form of investigation authorized by law, or to take other actions the Bureau is authorized to take outside the context of conducting adjudication proceedings. This section is intended to clarify that the pendency of an adjudication proceeding with respect to a person shall not affect the Bureau's authority to exercise any of its powers with respect to that person.

One commenter asserted that section 1052(c)(1) of the Dodd-Frank Act prohibits the Bureau from issuing civil investigative demands after the institution of any proceedings under Federal consumer financial law, including proceedings initiated by a State law enforcement agency or a private party. The commenter asked the Bureau to amend the Interim Final Rule to require every civil investigative demand to be accompanied by a certification that the demand will have no bearing on any proceeding then in process.

This comment arguably should have been directed to the Rules of Investigation, 12 CFR part 1080, but the Bureau addresses it here. The Bureau notes that this section of the Interim Final Rule did not purport to implement or interpret section 1052(c)(1) of the Dodd-Frank Act. Rather, it states that nothing within ''this part'' (*i.e.,* the Interim Final Rule) should be construed as limiting the Bureau's supervisory, investigatory, or other authority to gather information in accordance with law. The Bureau does not agree with the commenter's interpretation of section 1052(c)(1) of the Dodd-Frank Act, but notes that any limitations placed upon it by that section are incorporated in 12 CFR 1080.6, which provides that civil investigative demands will be issued in accordance with section 1052(c) of the Dodd-Frank Act.

The Bureau adopts § 1081.117 of the Interim Final Rule without change in the Final Rule.

Section 1081.118 Collateral Attacks on Adjudication Proceedings

This section of the Interim Final Rule, which is modeled on the Uniform Rules, 12 CFR 19.17, is intended to preclude the use of collateral attacks to circumvent or delay the administrative process.

The Bureau received no comment on § 1081.118 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.119 Confidential Information; Protective Orders

This section of the Interim Final Rule sets forth the means by which a party or another person may seek a protective order shielding confidential information. While generally modeled on the SEC Rules, 17 CFR 201.322, this section of the Interim Final Rule adopts the substantive standard set forth in the FTC Rules, 16 CFR 3.45(b), which provides that the hearing officer may grant a protective order only upon a finding that public disclosure will likely result in a clearly defined, serious injury to the person requesting confidential treatment, or after finding that the material constitutes sensitive personal information. The Bureau adopted the FTC's standard in order to provide as much transparency in the adjudicative process as possible, while also protecting confidential business information or other sensitive information of parties appearing before the Bureau or third parties whose information may be introduced into evidence. The Bureau expects that the standard set forth in this section will be met in cases where the disclosure of trade secrets or other information to the public or to parties is likely to result in harm, but that the standard will not be met simply because the information at issue is deemed ''confidential'' or ''proprietary'' by the movant. To the extent that a movant can identify a clearly defined, serious injury likely to result from the disclosure of such particular information, it will be protected; generalized claims of competitive or other injury generally will not suffice. This section provides that documents subject to a motion for confidential treatment will be maintained under seal until the motion is decided.

One commenter expressed concern that the Interim Final Rule may not accommodate a situation where the person seeking confidential treatment is not the same as the person who would be harmed by the disclosure of the material. In order to clarify the rights of third parties whose confidential information may be disclosed during the adjudicative process, the Bureau added a new paragraph (a), providing that a party may not disclose confidential information obtained from a third party without providing the third party at least ten days notice prior to the disclosure. In response to this notice, the third party has the option to consent to the disclosure of such information, which may be conditioned on the entry of a protective order, or may intervene in the proceeding for the limited purpose of moving for a protective order pursuant to this section. The new paragraph (a) further provides that a party must certify that proper notice was provided for any written filing or oral motion or argument that contains confidential information obtained from a third party.

In order to streamline the process for disclosing confidential information obtained from third parties, the Bureau revised paragraph (b) of the Interim Final Rule (paragraph (c) of the Final Rule) to provide for the mandatory entry of a stipulated protective order that has been agreed to by all parties, including third parties to the extent their information is at issue. However, the Office of Enforcement reserves the right to refuse to stipulate to a protective order that does not meet the substantive standards set forth in this section.

One commenter recommended that the Bureau adopt the SEC's standard for granting a protective order and revise paragraph (b) of the Interim Final Rule to provide that a ''motion for a protective order shall be granted only upon a finding that the harm resulting from disclosure would outweigh the benefits of disclosure.''

As noted above, the Bureau considered the SEC's standard, but ultimately decided to adopt the FTC's standard because it comports with the Bureau's goals of providing transparency in the adjudicative process while also protecting confidential business information or other sensitive information. The Bureau believes the standard it adopts in this section serves the public interest by balancing the need for a public understanding of the Bureau's adjudication proceedings with the interests of respondents in avoiding competitive injury from public disclosure of information. *See In re Gen. Foods Corp.,* 95 F.T.C. 352 (1980).

The commenter raised a number of specific concerns regarding the Bureau's adoption of the FTC's standard. First, the commenter stated that the standard prevents a financial institution from seeking confidential treatment of its customers' personal information. However, the Interim Final Rule

provides that a protective order shall be issued after finding that the material constitutes sensitive personal information. There is no prohibition on persons seeking confidential treatment of sensitive personal information of other persons. On the contrary, the Bureau contemplates that the sensitive personal information of consumers will regularly be protected under §§ 1081.112(e) and 1081.119(b), whether because of a motion for a protective order filed by a person other than the consumer or stipulated to by the parties, or because of the requirement that sensitive personal information generally be redacted under § 1081.112(e).

The commenter also objected to this standard because it does not define the terms ''serious injury,'' ''likely,'' or ''clearly defined.'' The commenter identified the unpredictable possibility of identity theft as a possibility of injury that may not be ''likely.'' The Bureau believes that the commenter's concerns regarding potential identity theft should be addressed by § 1081.112(e), which generally requires the redaction of sensitive personal information. The Bureau reiterates that it anticipates that sensitive personal information of consumers will regularly be protected from public disclosure. The Bureau again notes that § 1081.112(e) is based on the FTC Rules, 16 CFR 3.45(b), and that the FTC has significant experience applying these standards in many types of cases. The Bureau believes leaving these terms undefined provides the hearing officer with the necessary flexibility to address confidentiality concerns on a case-by-case basis based on the relevant facts and circumstances. At the same time, this standard is consistent with the Bureau's goal of transparency and avoids granting confidential status based on unsupported and generalized claims of competitive or other injury.

The commenter also stated that the Interim Final Rule does not accommodate the possibility that the public disclosure of information may be illegal under laws unrelated to the adjudication proceeding. The Bureau agrees and has therefore revised paragraph (b) of this section (now paragraph (c)) to break up the bases for issuance of protective orders into subsections and to include a new subsection making clear that the hearing officer shall grant a protective order where public disclosure is prohibited by law.

Finally, consistent with the Bureau's commitment to transparency and open government, the Bureau clarified paragraph (b) of the Interim Rule (paragraph (c) of the Final Rule) to recognize that documents and testimony filed in connection with an adjudication proceeding are presumed to be public. This clarification is consistent with § 1081.300 and the revised § 1081.111(c), both of which recognize a presumption that documents, testimony, and hearings are public.

The Bureau adopts § 1081.119 of the Interim Final Rule with the changes discussed above.

Section 1081.120 Settlement

This section of the Interim Final Rule is based on the SEC Rules, 17 CFR 201.240. The Bureau on its own initiative revised this section to make it consistent with § 1081.100 of this part regarding the scope of the Interim Final Rule. Section 1081.100 makes clear that the Interim Final Rule applies only to adjudication proceedings authorized by section 1053 of the Dodd-Frank Act and not to Bureau investigations, investigational hearings or other proceedings that do not arise from proceedings after the issuance of a notice of charges. As revised, this section governs only offers of settlement made after the institution of adjudication proceedings under this part. Under this section, any respondent in a proceeding may make an offer of settlement in writing at any time. Any settlement offer shall be presented to the Director with a recommendation, except that, if the recommendation is unfavorable, the offer shall not be presented to the Director unless the person making the offer so requests.

The section requires that each offer of settlement recite or incorporate as part of the offer the provisions of paragraphs (c)(3) and (4). Because certain facts necessary for the Director to make a reasoned judgment as to whether a particular settlement offer is in the public interest will often be available only to the Bureau employee that negotiated the proposed settlement, paragraph (c)(4)(i) requires waiver of any provisions, under the Interim Final Rule or otherwise, that may be construed to prohibit ex parte communications regarding the settlement offer between the Director and Bureau employee involved in litigating the proceeding. Paragraph (c)(4)(ii) requires waiver of any right to claim bias or prejudgment by the Director arising from the Director's consideration or discussions concerning settlement of all or any part of the proceeding. If the Director rejects the offer of settlement, the person making the offer shall be notified of the Director's action. The rejection of the offer of settlement shall not affect the continued validity of the waivers pursuant to paragraph (c)(4).

The Bureau also revised this section to include a new paragraph (d) governing the content of stipulations and consent orders and providing a process for resolving an adjudication proceeding through a consent order. This process requires the respondent and the Bureau to reduce the terms of any settlement into a written stipulation and consent order memorializing the terms of the settlement and including certain required provisions. The Bureau will then issue an order with the consent of the respondent.

The Bureau adopts § 1081.120 of the Interim Final Rule with the changes discussed above.

Section 1081.121 Cooperation With Other Agencies

This section of the Interim Final Rule sets forth the Bureau's policy to cooperate with other governmental agencies to avoid unnecessary overlapping or duplication of regulatory functions.

The Bureau received no comment on § 1081.121 of the Interim Final Rule and adopts it without change in the Final Rule.

Subpart B—Initiation of Proceedings and Prehearing Rules

Section 1081.200 Commencement of Proceedings and Contents of Notice of Charges

This section of the Interim Final Rule, similar to the comparable section of the Uniform Rules, 12 CFR 19.18, contains the requirements relating to the initiation of adjudication proceedings, including the required content of a notice of charges initiating a hearing. In provisions modeled on the MARs and the Federal Rules of Civil Procedure, *see* MARs, 11 T.M. Cooley L. Rev. at 96; Fed. R. Civ. P. 41(a), this section also sets forth the circumstances under which the Bureau may voluntarily dismiss an adjudication proceeding, either on its own motion before the respondent(s) serve an answer, or by filing a stipulation of dismissal signed by all parties who have appeared. Unless the notice or stipulation of dismissal states otherwise, a dismissal pursuant to this section is without prejudice. In keeping with the principle that Bureau proceedings are presumed to be public, this section also provides that a notice of charges shall be released to the public after affording the respondent or others an opportunity to seek a protective order to shield confidential information.

On its own initiative, the Bureau amended this section to include a new

paragraph (d) to conform with the revisions made to § 1081.120 and to provide a procedural mechanism to commence an adjudication proceeding to effectuate a settlement agreed to before the filing of a notice of charges. As noted above, § 1081.120 has been revised to clarify that the settlement procedure laid out in that section applies only after a notice of charges has been issued. The Bureau recognizes, however, that settlement negotiations may commence prior to the filing of a notice of charges. In those circumstances, the Bureau may determine that an adjudication proceeding—rather than litigation elsewhere—is the most appropriate forum in which to enter a consent order. New paragraph (d) therefore provides that, where the parties agree to settlement before the filing of a notice of charges, a proceeding may be commenced by filing a stipulation and a consent order concluding the proceeding. Paragraph (d) also requires that certain information be included in the stipulation, tracking the information required under § 1081.120(d). Finally, in the interest of transparency, paragraph (d) requires that the consent order set forth the legal authority for the proceeding and for the Bureau's jurisdiction over the proceeding, and a statement of the matters of fact and law showing that the Bureau is entitled to relief. *See* § 1081.200(b)(1) and (2).

The Bureau adopts § 1081.200 of the Interim Final Rule with the changes discussed above.

Section 1081.201 Answer and Disclosure Statement and Notification of Financial Interest

This section of the Interim Final Rule requires a respondent to file an answer in all cases. The Bureau considered, but rejected, the approach set forth in the SEC Rules, 17 CFR 201.220(a), whereby an answer is required only if specified in the notice of charges. The Bureau believes that an answer can help focus and narrow the matters at issue.

Pursuant to paragraph (a) of this section, respondents must file an answer within 14 days of service of the notice of charges. The 14-day time period is adopted from the FTC Rules, 16 CFR 3.12. Two commenters requested that paragraph (a) of this section be amended to provide 20 days from service of the notice of charges, rather than 14 days, to file an answer. One commenter stated that it takes a considerable amount of time to review the notice of charges, investigate the factual and legal allegations, determine the appropriate response, and draft an answer. That commenter also stated that more than 14 days will be necessary to prepare an answer because the Bureau is not required to provide affirmative disclosures pursuant to § 1081.206(d) until seven days after service of the notice of charges. Both commenters note that the Federal banking agencies and the SEC allow 20 days to file an answer. Finally, one commentator stated that the 14-day requirement may cause respondents to answer with repeated assertions that they lack information, leading to fewer stipulations, and undercutting the Bureau's goal of timely adjudications.

The Bureau declines to amend the Interim Final Rule as requested. The statutory requirement that a hearing be held between 30 to 60 days after the service of the notice of charges, unless an earlier date is set at the request of any party so served, necessitates a compressed timeline for litigating adjudication proceedings. The Bureau is not alone in setting a 14-day deadline for an answer. As noted above, the FTC requires respondents in administrative proceedings to file an answer within 14 days of service of the complaint.

Further, as noted above, the Bureau has adopted a policy pursuant to which it will generally provide advance notice of a possible enforcement action to prospective respondents before filing a notice of charges. Recipients of such notices will have an opportunity to submit a response in writing. As a result, many respondents will have considered and responded to most or all of the Bureau's allegations before receiving the notice of charges. The advance notice will also give respondents a prior opportunity to identify facts to which they may stipulate, addressing the expressed concern that a 14-day deadline to answer may lead to fewer factual stipulations.

Likewise, the Bureau is not persuaded that respondents need additional time to answer after receiving the Bureau's affirmative disclosure documents. In typical civil litigation, and in administrative proceedings before the prudential regulators and the FTC, respondents file an answer before conducting any discovery. The Bureau's affirmative disclosure obligation will be triggered before a respondent's answer is due. Thus, respondents will have access to more information prior to filing an answer than is available to most respondents in other civil and administrative proceedings.

Finally, pursuant to § 1081.115, a respondent may ask for an extension of time to file an answer. While such extensions are strongly disfavored, they may be granted if the respondent makes a strong showing that the denial of its motion for an extension of time would substantially prejudice its case. For all of these reasons, the Bureau declines to amend the deadline for filing an answer contained in paragraph (a) of § 1081.201 of the Interim Final Rule.

As in the Uniform Rules, 12 CFR 19.19(c), paragraph (d) of this section provides that failure to file a timely answer is deemed to be a waiver of the right to appear and a consent to the entry of an order granting the relief sought by the Bureau in the notice of charges. This section provides that in the case of default, the hearing officer is authorized, without further proceedings, to find the facts to be as alleged in the notice of charges and to enter a recommended decision containing appropriate findings and conclusions.

Paragraph (d)(2) of this section adopts the procedure from the SEC Rules for a motion to set aside a default, 17 CFR 201.155. It also provides that the hearing officer, prior to the filing of the recommended decision, or the Director, at any time, may set aside a default for good cause shown.

In the discussion of § 1081.105 above, the Bureau noted the addition of a new § 1081.201(e) requiring the filing of a disclosure statement and notification of financial interest. Consistent with the Bureau's goal of an expeditious, fair, and impartial hearing process, the Bureau seeks to provide the parties and the hearing officer with information to identify potential or actual bases for disqualification early in the process. Section 1081.201(e) is modeled on the disclosure statements required under Federal Rule of Civil Procedure 7.1, Federal Rule of Appellate Procedure 26.1, Third Circuit Local Appellate Rule 26.1.1, and Sixth Circuit Rule 26.1. This disclosure is calculated to reach a majority of the circumstances that are likely to call for disqualification on the basis of financial information that a hearing officer may not know or recollect; however, the disclosure does not cover all of the circumstances that may call for disqualification. In addition to requiring a respondent, a nongovernmental amicus, or a nongovernmental intervenor to identify any parent corporation or any publicly owned corporation owning 10% or more of its stock, § 1081.201(e) also requires the identification of ''any publicly owned corporation not a party to the proceeding that has a financial interest in the outcome of the proceeding and the nature of that interest.'' The types of financial interests that must be disclosed under this section include, for example, insurance, franchise, or indemnity agreements giving a publicly

owned corporation a financial interest in the outcome of the proceeding. *See, e.g.,* Sixth Circuit Rule 26.1(b)(2).

The Bureau adopts § 1081.201 of the Interim Final Rule with the changes discussed above.

Section 1081.202 Amended Pleadings

This section of the Interim Final Rule provides that a notice of charges or an answer may be amended or supplemented as a matter of course at any stage of the proceeding.

The Bureau did not receive comment on § 1081.202, but the Bureau has amended paragraph (a) of this section on its own initiative to require a party who wishes to amend a pleading to obtain the consent of the other party or leave of the hearing officer. By requiring written consent or leave of the hearing officer to amend pleadings, the revised section encourages parties to plead their case fully, as opposed to reserving claims and defenses for last minute amendments. This section continues to reflect a liberal standard of permitting amendments of pleadings, but implements an appropriate limit for amendments that are unduly prejudicial.

The Bureau adopts paragraph (b) of § 1081.202 of the Interim Final Rule without change. As a result, when a party seeks to introduce evidence at a hearing that is outside the scope of matters raised in the notice of charges or answer, the hearing officer may admit the evidence when admission is likely to assist in adjudicating the merits of the action unless the objecting party demonstrates that admission of such evidence would unfairly prejudice that party's action or defense upon the merits.

The Bureau adopts § 1081.202 of the Interim Final Rule with the changes discussed above.

Section 1081.203 Scheduling Conference

Section 1081.203 of the Interim Final Rule sets forth the requirements related to scheduling conferences. Paragraph (a) of this section requires the parties to meet before the initial scheduling conference to discuss the nature and basis of their claims and defenses, the possibilities for a prompt settlement or resolution of the case, and other matters to be determined at the scheduling conference.

Paragraph (b) of § 1081.203 of the Interim Final Rule provides that within 20 days of the service of the notice of charges, or at another time if the parties agree, the hearing officer and the parties are to have a scheduling conference. The Bureau revised paragraph (b) to clarify that a scheduling conference is to be held, not just scheduled, within 20 days of service of the notice of charges. This clarification is intended to reflect the Bureau's original intent with respect to the timing of the scheduling conference.

Paragraph (b) of this section also sets forth the issues to be discussed at the scheduling conference. These issues are drawn from those the parties are required to discuss at scheduling and prehearing conferences under the Uniform Rules, 12 CFR 19.31, the SEC Rules, 17 CFR 201.221, and the FTC Rules, 16 CFR 3.21. Paragraph (b)(1) provides that the parties shall be prepared to address the determination of hearing dates and location, and whether, in proceedings under section 1053(b) of the Dodd-Frank Act, the hearing should commence later than 60 days after service of the notice of charges. This provision is intended to account for the requirement in section 1053(b) of the Dodd-Frank Act that the hearing be held no earlier than 30 days nor later than 60 days after the date of service of the notice of charges, unless an earlier or later date is set by the Bureau at the request of any party so served. It is expected that the parties will discuss a hearing date at the scheduling conference, and that this would afford respondents the opportunity to request a hearing date outside the 30-to-60 day timeframe.

It is also expected that at or before the scheduling conference, the parties will discuss any issues related to the production of documents pursuant to § 1081.206, any anticipated motions for witness statements pursuant to § 1081.207, whether either party intends to issue documentary subpoenas, and whether either party believes that depositions will be necessary to preserve the testimony of witnesses who will be unavailable for the hearing. The parties are also expected to discuss the need and a schedule for any expert discovery.

Pursuant to paragraph (d) of § 1081.203, the hearing officer is required to issue a scheduling order at or within five days of the conclusion of the scheduling hearing, setting forth the date and location of the hearing, as well as other procedural determinations made. It is expected that the hearing officer will establish any dates for expert discovery in the scheduling order, or else expressly find that such discovery is not necessary or reasonable in a particular case. This scheduling order will govern the course of the proceedings, unless later modified by the hearing officer.

Provision for a prompt scheduling conference followed by prompt issuance of a scheduling order is necessary in order to allow for the orderly course of proceedings on the timeline set forth elsewhere in the Interim Final Rule. Particularly in cases brought pursuant to section 1053(b) of the Dodd-Frank Act in which the respondent does not request a hearing date outside the 30-to-60 day timeframe set forth in the statute, it is essential that the hearing officer and the parties have a clear understanding of the applicable schedule at the earliest possible date.

As provided for in the SEC Rules, 17 CFR 201.221(f), paragraph (e) of this section provides that any person named as a respondent in a notice of charges who fails to appear at a scheduling conference may be deemed in default pursuant to § 1081.201(d)(1). Finally, like the FTC Rules, 16 CFR 3.21(g), this section provides that scheduling conferences are presumptively public unless the hearing officer determines otherwise based on the standard set forth in § 1081.119(c).

The Bureau received no comment on § 1081.203 of the Interim Final Rule and adopts it with the single clarification discussed above in the Final Rule.

Section 1081.204 Consolidation and Severance of Actions

This section of the Interim Final Rule, modeled after the Uniform Rules, 12 CFR 19.22, allows the consolidation of actions if the proceedings arise out of the same transaction, occurrence, or series of transactions or occurrences or if the proceedings involve at least one common respondent or a material common question of law or fact. Proceedings are not to be consolidated if doing so would unreasonably delay the proceeding or cause injustice.

Severance, on the other hand, may be granted by the hearing officer only if he or she determines that undue prejudice or injustice would result from a consolidated proceeding and if such prejudice or injustice would outweigh the interests of judicial economy and speed in the adjudication of actions. This is a higher standard than is required for the consolidation of actions.

The Bureau received no comments on § 1081.204 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.205 Non-Dispositive Motions

This section of the Interim Final Rule governs all motions other than motions to dismiss or motions for summary disposition, which are governed by

§ 1081.212. The section generally sets forth the requirements for filing a non-dispositive motion, and requires that all such motions must be in writing, state with particularity the relief sought, and include a proposed order. This section also makes clear that motions filed pursuant to sections that impose different requirements should follow those requirements, and the requirements of § 1081.205 to the extent they are not inconsistent. For example, § 1081.208(g) of the Interim Final Rule (paragraph (h) of the Final Rule), which relates to motions to quash subpoenas, provides for a shorter time period for the filing of a responsive brief and prohibits the filing of a reply unless requested by the hearing officer. These conditions govern motions to quash, but such motions are still subject to other provisions of § 1081.205, including, *inter alia,* the need to meet and confer, deadlines for the hearing officer's ruling, and length limitations of the briefs.

Like the Uniform Rules and the FTC Rules, 12 CFR 19.23(d)(1); 16 CFR 3.22(d), this section gives a party ten days after service of a non-dispositive motion to respond to such a motion in writing. It also provides for reply briefs, which must be filed within three days after service of the response. A party's failure to respond to a motion shall waive that party's right to oppose such motion and constitutes consent to the entry of an order substantially in the form of the order accompanying that motion. This section adopts the SEC's 15-page length limitation for non-dispositive motions and oppositions, 17 CFR 201.154(c), and a six page length limitation for reply briefs. The Bureau has adopted these time and length limitations because they provide parties ample opportunity to express their views on matters that do not concern the ultimate disposition of the action.

This section also requires parties to make a good faith effort to meet and confer prior to the filing of a non-dispositive motion in an effort to resolve the controversy by agreement. The Bureau has included the meet-and-confer requirement because it believes such conferences can help obviate the need for, or narrow the scope of, disputed motions, thus saving both the parties and the hearing officer time and resources.

This section provides that the hearing officer shall rule on a non-dispositive motion within 14 days after the expiration of the time for filing of all motions papers authorized by this section, and that the pendency of a motion shall not stay proceedings. This time limitation is based on the FTC Rules, 16 CFR 3.22(e), and is intended to ensure the timely resolution of disputes so that the proceeding as a whole can conclude in a fair and expeditious manner. As noted above, both the FTC and the SEC have revised their rules of practice to provide for the more expeditious resolution of administrative adjudications, and the incorporation of a time period in which the hearing officer must rule on a non-dispositive motion is, in the view of the Bureau, a critical part of that effort. *See* 73 FR 58832, 58836 (Oct. 7, 2008) (FTC expects that provision requiring ALJs to decide motions within 14 days will expedite cases).

The Bureau received no comment on § 1081.205 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.206 Availability of Documents for Inspection and Copying

Modeled primarily after the SEC Rules, 17 CFR 201.230, this section of the Interim Final Rule adopts the SEC's affirmative disclosure approach to fact discovery in administrative adjudications. Generally, this section requires that the Office of Enforcement make available for inspection and copying certain categories of documents obtained by the Office of Enforcement prior to the institution of proceedings from persons not employed by the Bureau, in connection with the investigation leading to the institution of proceedings, and certain categories of documents produced by persons employed by the Bureau.

The Bureau received several comments requesting amendment to this section. Before addressing each specific comment, the Bureau sets forth its understanding of this provision in order to provide guidance to both the public and future respondents regarding how it intends to comply with the affirmative disclosure obligations of § 1081.206.

As the Bureau stated when it issued the Interim Final Rule, this section is intended to promote the fair and efficient resolution of adjudicatory proceedings. A respondent has an automatic right to inspect and copy documents under this section at the outset of the proceeding. The respondent is not required to make a formal request or wait until after the scheduling conference to gain access to documents underlying the Bureau's decision to initiate proceedings. Instead, the Bureau will provide the respondent with access to, in effect, the documents they would likely seek and obtain in the course of a protracted discovery period soon after service of the notice of charges.

This approach has several advantages. By automatically providing respondents with the factual information gathered by the Office of Enforcement in the course of the investigation leading to the institution of proceedings, this provision helps ensure that respondents have a complete understanding of the factual basis for the Bureau's action and can more accurately and efficiently determine the nature of their defenses or whether they wish to seek settlement. Because this approach renders traditional document discovery largely unnecessary, it will lead to a faster and more efficient resolution of Bureau administrative proceedings, saving both the Bureau and respondents the resources typically expended in the civil discovery process.

Section 1081.206 adopts most of the procedures and conditions set forth in the SEC Rules, as discussed below.

Pursuant to paragraph (a)(1), the Office of Enforcement's obligation under this section relates to documents obtained by the Office of Enforcement. Documents located only in the files of other divisions or offices of the Bureau are beyond the scope of paragraph (a). The term ''*documents*'' has been defined in the same manner as the term ''*documentary material*'' in section 1051(4) of the Dodd-Frank Act, 12 U.S.C. 5561(4), and encompasses, among other things, electronic files or other data or data compilations stored in any medium.

Paragraph (a)(1) also provides that the Office of Enforcement will make the documents available for inspection and copying. This provision is modeled after the SEC Rules and the Federal Rules of Civil Procedure. The Bureau anticipates that in most cases it will simply provide either paper or electronic copies of the material at issue to respondents, but has adopted the formulation in this section to preserve flexibility and the Office of Enforcement's right to require inspection and copying in appropriate cases.

Paragraphs (a)(1)(i), (ii), and (iii) describe the types of documents that are subject to the disclosure requirement of paragraph (a)(1). The Bureau interprets its obligation under paragraph (a)(1)(iii) to include both records obtained by the Office of Enforcement directly from persons not employed by the Bureau, as well as documents obtained by the Office of Enforcement indirectly from persons not employed by the Bureau. For example, if the Office of Enforcement obtains information from the Bureau's supervisory staff in connection with an investigation that the supervisory staff obtained from persons not employed by the Bureau,

the Office of Enforcement will disclose such information, provided it is not privileged or otherwise protected from disclosure.

Paragraph (a)(2) provides that the Office of Enforcement shall also make available each civil investigative demand or other written request to provide documents or to be interviewed issued by the Office of Enforcement in connection with the investigation leading to the institution of proceedings. The Office of Enforcement shall also make available any final examination or inspection reports prepared by any other office of the Bureau if the Office of Enforcement either intends to introduce any such report into evidence or to use any such report to refresh the recollection of, or impeach, any witness. The provisions of paragraph (a)(2) are included in the SEC Rules, but have been broken out into a separate paragraph of this section because they do not comprise documents that the Office of Enforcement obtained from persons not employed by the Bureau, and thus do not technically fall within the scope of paragraph (a)(1).

Pursuant to § 1081.208, a respondent may seek production of other documents pursuant to subpoena. Paragraph (a)(3) is intended to make clear that the affirmative disclosure obligation set forth in paragraphs (a)(1) and (a)(2) does not preclude the availability of subpoenas as separately provided by § 1081.208.

Paragraph (a)(4) provides that this section does not require the Office of Enforcement to produce a final examination or inspection report prepared by any other Office of the Bureau to a respondent who is not the subject of that report. The Bureau has included this provision, which does not appear in the SEC Rules, out of concern for the privileged and confidential nature of examination and inspection reports and to make clear that respondents cannot rely upon the Bureau's affirmative disclosure obligation to require the production of supervision or examination reports concerning other persons. Although the disclosure obligation as drafted would not require the production of such reports, the Bureau included this provision to remove any question regarding the issue.

Paragraph (a)(4) of the Interim Final Rule did not explicitly apply to final inspection or examination reports obtained from other government agencies. The Final Rule has been amended to clarify that such reports, to which the confidentiality and privilege concerns discussed above apply equally, are also excluded from the Bureau's disclosure obligation.

Paragraph (b)(1) of the Interim Final Rule permitted the Office of Enforcement to withhold documents that would otherwise be produced under paragraph (a) under five exceptions. The Final Rule retains these exceptions and adds an additional exception, paragraph (b)(1)(iii), as described below.

The first exception, in paragraph (b)(1)(i) shields information subject to a claim of privilege. The second exception, in paragraph (b)(1)(ii), protects as work product internal documents prepared by persons employed by the Bureau, including consulting experts, which will not be offered in evidence. Work product includes any notes, working papers, memoranda or other similar materials, prepared by an attorney or under an attorney's direction in anticipation of litigation. *See Hickman* v. *Taylor,* 329 U.S. 495 (1947); *see also* Fed. R. Civ. P. 26(b)(3) and (b)(5). Accountants, paralegals, investigators, and consulting experts who work on an investigation do so at the direction of the Director, an associate director, or another supervisory attorney, and their work product is therefore not subject to the affirmative disclosure obligation. Although such material would not fall within the purview of paragraphs (a)(1) and (a)(2), the Bureau has retained this provision of the SEC Rules to make clear that such work product is not subject to the affirmative disclosure obligation. An examination or inspection report prepared by one of the Bureau's supervision offices, which the Office of Enforcement intends to introduce into evidence or to use to refresh the recollection of, or impeach, a witness, is explicitly excluded from the materials that may be withheld pursuant to this exception.

The third exception, contained in paragraph (b)(1)(iii), is added to the Final Rule. Modeled upon a similar provision in the Rules of Practice of the Commodity Futures Trading Commission, 17 CFR 10.42, this paragraph protects documents obtained from other governmental entities that are either not relevant to the proceeding or were provided to the Bureau on the condition that the information not be disclosed. The Bureau has added this provision to accommodate any agreements limiting the disclosure of documents received from other governmental entities. To the extent the Bureau withholds documents pursuant to this exception, it will not rely upon those documents at the hearing.

The fourth exception, contained in paragraph (b)(1)(iv) of the Final Rule, protects the identity of a confidential source. *See* 5 U.S.C. 552(b)(7)(C) and (D). The fifth exception, contained in paragraph (b)(1)(v) of the Final Rule, provides that documents need not be produced where applicable law prohibits their production. The final exception protects any other document or category of documents that the hearing officer determines may be withheld as not relevant to the subject matter of the proceeding, or otherwise for good cause shown. This exception is intended to provide the hearing officer with the flexibility to adjust the Bureau's affirmative disclosure obligation to the particular contours of a proceeding. For example, this exception could be used in a situation where a single investigation involves other industry participants that are related only indirectly, or not at all, to the recommendations ultimately made to the Director with respect to the particular respondents in a specific proceeding. To require that documents not relevant to the proceeding be made available, simply because they were obtained as part of a broad investigation, burdens the respondent as well as the Office of Enforcement with unnecessary costs and delay.

Paragraph (b)(2) of this section provides that paragraph (b) does not authorize the Office of Enforcement to withhold material exculpatory evidence in the possession of the Office of Enforcement that would otherwise be subject to disclosure pursuant to paragraph (a). Pursuant to this section, the Office of Enforcement will provide respondents with material exculpatory evidence it has obtained from persons not employed by the Bureau even if such evidence is contained in documents that the Office of Enforcement is otherwise permitted to withhold pursuant to paragraph (b)(1).

The Bureau declines to adopt the SEC Rules' explicit reference to *Brady* v. *Maryland,* 373 U.S. 83 (1963) in this context. Proceedings under this part are civil in nature, not criminal, and the requirements of *Brady* are therefore inapplicable. The Office of Enforcement will turn over information from its investigatory file obtained from persons not employed by the Bureau as part of the investigation resulting in the Bureau's decision to institute proceedings, including any material exculpatory evidence so obtained. The Bureau understands this approach to be consistent with that provided for in the SEC Rules.

The Bureau also adds the clause ''that would otherwise be required to be

produced pursuant to paragraph (a) of this section'' to paragraph (b) to make clear that the material exculpatory evidence provision works in concert with paragraph (a). Paragraph (b) does not impose a separate, free-standing obligation to disclose exculpatory evidence that is not otherwise within the scope of paragraph (a).

Paragraph (c) provides that the hearing officer may require the Office of Enforcement to submit a withheld document list, and may order that a withheld document be made available for inspection and copying. Paragraph (c) has been amended to incorporate a provision from the Rules of Practice of the Commodity Futures Trading Commission, 17 CFR 10.42. This provision limits the disclosures that the Bureau will make with respect to documents withheld pursuant to paragraph (b)(1)(iii). The Bureau will inform the other parties of the fact that such documents are being withheld, but will not make further disclosures regarding those documents. Like paragraph (b)(1)(iii), this provision was added to enable the Bureau to comply with agreements limiting the disclosure of documents received from other governmental entities.

Pursuant to paragraph (d), the Office of Enforcement is required to make the material governed by this section available for inspection and copying no later than seven days after service of the notice of charges unless otherwise ordered by the hearing officer. The Bureau has considered requiring production of the covered material at the time the notice of charges is served, but has decided against such an approach. A provision for a delay of no more than seven days will allow parties to move for any appropriate protective orders and is consistent with the SEC's approach in this regard. *See* 17 CFR 201.230(d). The Bureau notes that, if seven days after the service of a notice of charges a motion for a protective order is pending but has not yet been ruled upon, production of the documents that are the subject of the motion could be delayed. The hearing officer could order temporary remedies where appropriate, such as the production of redacted copies pending a decision on the motion for a protective order. It is the Bureau's expectation that the Office of Enforcement will make the material available as soon as possible in every case.

Paragraphs (e) and (f) set forth the procedure to obtain copies of documents and the costs of such copies. As noted above, the Bureau anticipates providing electronic copies of the documents to respondents in most cases, and paragraph (f) accounts for such a provision of electronic documents. In order to preserve the discretion of the Office of Enforcement, however, this paragraph includes provisions governing the inspection and copying of documents. In order to provide for the safekeeping of documents subject to inspection, and to control costs associated with the implementation of this section, paragraph (e) provides that documents shall be made available for inspection and copying at the Bureau office where they are ordinarily maintained, or at such other place as the parties may agree. In cases in which electronic production is unwarranted, this process appears more likely to result in prompt access to documents obtained by the Office of Enforcement that are the basis of the allegations contained in the notice of charges.

Paragraph (g) of this section imposes upon the Office of Enforcement a duty to supplement its disclosures under paragraph (a)(1) of this section if it acquires information after making its disclosures that it intends to rely upon at a hearing. Although the SEC Rules do not include an analogous provision, the Bureau believes that imposing a duty to supplement will reduce the need for unnecessary discovery requests.

Like the SEC Rules, 17 CFR 201.230(h), paragraph (h) provides for a ''harmless error'' standard in the event the Office of Enforcement fails to make available to a respondent a document required to be made available by this section.

Finally, paragraph (i) is modeled on the FTC Rules, 16 CFR 3.31(g), and provides a ''claw back'' mechanism whereby inadvertent disclosure of privileged or protected information or communications shall not constitute a waiver of the privilege or protection, provided that the party took reasonable steps to prevent disclosure and promptly took reasonable steps to rectify the error. Furthermore, paragraph (i) provides that disclosure of privileged or protected information or communications shall waive the privilege only if the waiver was intentional and that the scope of such waiver is limited to the undisclosed information or communications concerning the same subject matter, which in fairness ought to be considered together with the disclosed information or communications. Paragraph (i) expressly applies to disclosures made by any party during an adjudication proceeding.

The Bureau received several comments to this section, and will address them in turn.

Comment: One commenter asserted that the ''affirmative disclosure'' approach puts respondents at a significant disadvantage to the Bureau, because the Bureau, unlike the respondent, will have already gathered all of the information it needs to prepare for the hearing through examinations and investigation proceedings as well as through its ability to collect consumer complaints and collect information from covered persons.

Response: While the Bureau will have already conducted an investigation prior to filing its notice of charges, the ''affirmative disclosure'' approach will give a respondent automatic access to the vast majority of the documents gathered as part of that investigation. Production to respondents will include any consumer complaints or documents from covered persons that enforcement counsel obtained in connection with the investigation, provided that production of those documents would not reveal the identity of a confidential source or otherwise fall within the scope of one of the relevant exceptions.

This approach will provide respondents automatic access to the factual information gathered by the Office of Enforcement in the course of the investigation leading to the institution of proceedings. As a result, the process will help ensure that respondents have a complete understanding of the basis for the Bureau's action, and can assess their defenses accordingly. If necessary, respondents may seek to obtain additional information through subpoena.

Furthermore, the exceptions to the Bureau's affirmative disclosure obligation do not disadvantage respondents as compared to traditional civil discovery because the exceptions protect documents that often would be protected in traditional civil discovery. When producing documents in traditional discovery, litigants routinely seek protection for documents that (i) are privileged; (ii) constitute work product; (iii) are irrelevant or required to be kept confidential; (iv) would reveal the identity of a confidential source; [3] (v) are prohibited from production by applicable law; or (vi) are deemed by the hearing officer or judge to be not relevant to the subject matter or otherwise not subject to production for good cause shown.

[3] As discussed below, information provided by a confidential source, and in some cases even that source's identity, will be made available to the extent the Bureau plans to call that source as a witness, rely upon information he or she provided, or to the extent the information is exculpatory.

In short, the Bureau believes the affirmative disclosure process will promote a fair and efficient resolution of administrative proceedings without placing the respondent at an unfair disadvantage.

Comment: Respondents should be permitted to (a) depose third parties who have direct knowledge of relevant matters; (b) issue and enforce subpoenas for documents and testimony, and (c) serve third parties with interrogatories.

Response: The Bureau declines to make these changes. The Bureau considered allowing third-party depositions or interrogatories but declined to do so because the need for these third-party discovery tools will likely be met through the discovery mechanisms that are available under the Final Rule, and because of the potential for third-party depositions and interrogatories to delay the proceedings.

Even without third-party discovery depositions, respondents will be able to present testimony of third-parties with knowledge of relevant matters at the hearing to support their defense. Pursuant to § 1081.208, respondents may request the issuance of a subpoena for the attendance and testimony of a witness at the hearing. If a witness is unavailable for the hearing, a respondent may take that witness's deposition and introduce that testimony on the record at a hearing.

The Bureau believes that the marginal benefit of permitting third-party interrogatories is not justified in light of the likelihood that disputes over interrogatories may delay the proceedings. The Bureau notes that neither the SEC's Rules nor the Uniform Rules permit prehearing discovery depositions or interrogatories.

As drafted, § 1081.208 requires a party to request the issuance of a subpoena from the hearing officer, and generally requires the Bureau to seek judicial enforcement of subpoenas. The Bureau considered whether to permit parties to issue subpoenas. The Bureau declined to do so because a hearing officer can help ensure that subpoenas are not ''unreasonable, oppressive, excessive in scope, or unduly burdensome.'' The commenter requested that respondents be permitted to enforce subpoenas, but the Dodd-Frank Act requires the Bureau to do so. 12 U.S.C. 5562(b)(2). The Bureau's General Counsel will enforce subpoenas on relation of a respondent, provided such enforcement is consistent with the law and the policies of the Dodd-Frank Act.

The third-party discovery permitted by the Interim Final Rule is consistent with the practice of the SEC, which shares a common approach to discovery with the Bureau. *See* 17 CFR 201.230–234. It is also consistent with the Uniform Rules, which, like the Interim Final Rule, allow third-party depositions only when a witness is unavailable for hearing, *see* 12 CFR 19.27, and require parties to apply to the administrative law judge for a third-party document subpoena, which may be granted only if the administrative law judge determines the subpoena is not ''unreasonable, oppressive, excessive in scope, or unduly burdensome.'' *See* 12 CFR 19.26. Like the SEC, the Bureau will make documents available to respondents through the affirmative disclosure process. As a result, traditional discovery is limited, and it is appropriate to require parties to request issuance of a subpoena in order to ensure that the Bureau's subpoena power is exercised appropriately and not for purposes of delay or obstruction.

This practice is also appropriate considering that respondents must demonstrate that a witness is unavailable for the hearing in order to obtain a deposition subpoena. This standard is more easily enforced if a party has to request, and a hearing officer has to issue, those subpoenas. The SEC and the Uniform Rules both restrict depositions to circumstances when a witness will not be available for the hearing, and both require parties to request or apply for a deposition subpoena.

Comment: It is unclear whether the affirmative disclosure process limits the right of respondents to seek other documents from the Bureau through subpoena. Respondents may be prevented from seeking certain documents through subpoena on the grounds that it could physically inspect and copy those same documents through the affirmative disclosure process.

Response: Section 1081.208 permits a respondent to seek other documents from the Bureau through subpoena. Such a subpoena would presumably not be necessary if the documents sought by the respondent were included in the affirmative disclosure production, but the existence of that process does not negate a respondent's right to request a subpoena for other relevant documents in the possession of the Bureau, as the Interim Final Rule makes clear in paragraph (a)(3) of § 1081.206.

Comment: The affirmative disclosure process covers documents that are ''obtained by the Office of Enforcement.'' Whether documents are relevant and should be discoverable is unrelated to who at the Bureau ''obtained'' the documents. This could lead to protracted litigation over who ''obtained'' a document that a Bureau employee sees and reads but does not touch.

Response: The affirmative disclosure process outlined in § 1081.206 is based upon the SEC's affirmative disclosure approach to fact discovery in administrative adjudications. The ''obtained by'' the Office of Enforcement language is taken directly from the SEC Rules. Section 1081.206 is intended to give respondents access to the material facts underlying enforcement counsel's decision to recommend the commencement of enforcement proceedings. It is not intended to create an obligation for enforcement counsel to search the files of other divisions or offices in the Bureau. As explained above, the Bureau will include in its affirmative disclosure documents obtained by other elements of the Bureau from persons not employed by the Bureau and later provided to the Office of Enforcement for its use ''in connection with the investigation leading to the institution of proceedings.'' § 1081.206(a)(1).

Comment: Disclosure should not be limited to documents obtained ''in connection with the investigation.'' The Bureau might have come across relevant, discoverable information without an investigation. For example, a State may conduct an investigation and turn its findings over to the Bureau and the Bureau could bring charges based on the State's findings. Or the Bureau may issue a notice of charges based upon examination findings without an investigation.

Response: The Office of Enforcement will not interpret the phrase ''in connection with the investigation'' in the manner contemplated by this commenter. Through the affirmative disclosure process, the Office of Enforcement will turn over the documents that informed its decision to recommend the institution of proceedings, except to the extent those documents meet an exception outlined in § 1081.206. In the first example offered by this commenter, the Office of Enforcement would consider documents turned over by a State that formed the basis for the Office's recommendation to bring charges against a respondent to have been obtained ''in connection with the investigation.'' The Bureau would disclose those documents to the respondent unless they were provided to the Bureau on the condition that they not be disclosed, *see* § 1081.206(b)(1)(iii), or unless the State obtained a protective order to prevent their disclosure, *see* § 1081.119(a). If documents were withheld from the respondent for either of these reasons,

the Bureau would not rely upon those documents in the proceeding.

Likewise, the Bureau would consider information obtained by the Office of Enforcement through the Bureau's supervisory channels to be obtained ''in connection with the investigation'' if such information formed the factual basis of an enforcement action.

Comment: The section excludes from discovery, in all cases, final examination ''or inspection'' reports to respondents who are not the subject of the report. Such an absolute limit on discovery, regardless of the significance of the information, is not appropriate. Further, the term ''inspection'' could mean almost anything, such as notes a Bureau employee takes when asking anyone a question about a covered person.

Response: Paragraph (a)(4) is intended to make clear that respondents have no automatic right to examination or inspection reports related to other entities. Nothing in the Interim Final Rule prevents a respondent from seeking a final examination or inspection report regarding another entity through subpoena, although given the confidential nature of such reports the Bureau would anticipate that such subpoena requests would generally be denied. Finally, the Bureau does not intend for the term ''inspection report'' to cover interview notes, for purposes of this section.

Comment: The Interim Final Rule requires the Bureau to turn over documents ''obtained'' by the Bureau's Office of Enforcement before the notice of charges issued. When the Bureau obtained documents is not relevant to whether they should be discoverable.

Response: The Bureau agrees that relevant documents upon which the Bureau intends to rely should be made available to the respondent even if they are obtained after the issuance of a notice of charges. Paragraph (g) obligates the Bureau to supplement its disclosures with any additional information that it intends to rely upon at the hearing.

Comment: The Interim Final Rule creates an incentive for Bureau employees to withhold material exculpatory evidence from the Office of Enforcement because delivering it could make it discoverable.

Response: The Bureau has no independent legal obligation to produce material exculpatory evidence *sua sponte.* Section 1081.206 of the Interim Final Rule provides for such production, but does so in a manner that is workable and practical. It is intended to ensure that respondents are in possession of material exculpatory information obtained from persons not employed by the Bureau that enforcement counsel has considered in its determination to recommend enforcement action. Extending the scope of the Interim Final Rule to cover exculpatory evidence that is not in the Office of Enforcement's possession would impose an unworkable and legally unfounded obligation on enforcement counsel and the rest of the Bureau. Furthermore, § 1081.208 enables respondents to subpoena additional documents that they believe are relevant to their defense.

Comment: This section is based upon the SEC Rules, but the SEC does not examine all of the institutions it regulates so does not necessarily have relevant, nonpublic materials outside of the Office of Enforcement. The Bureau should not be able to declare all of these materials to be per se beyond the scope of discovery without allowing respondent to seek a determination as to whether any of the materials are relevant.

Response: The Bureau does not believe that its supervisory powers require further amendment of this section. Aside from privileged internal notes and working papers generated by Bureau employees, the documents obtained by the Bureau through the exercise of its supervisory authority will come almost exclusively from the institution itself. The institution will have provided the documents to the Bureau, and cannot claim to be deprived of access to such documents in discovery. The purpose of affirmative disclosure is to give the respondent access to all of the material evidence underlying enforcement counsel's decision to commence enforcement proceedings. Rather than provide the respondent with access to all of the documents that in any way relate to it or its business—including many completely unrelated to the proceeding—enforcement counsel will turn over those documents that enforcement counsel obtained or considered in its decision to proceed in the particular action.

In addition, respondents will have the ability to conduct some limited discovery, including document subpoenas, depositions of third-parties who are unavailable for the hearing, and, in some circumstances, limited expert discovery.

Comment: This section permits the Bureau to withhold documents that ''would disclose the identity of a confidential source,'' which is inappropriate and not based upon the Uniform Rules or the SEC Rules. The respondent should be permitted to impeach the credibility of all witnesses. This section should be deleted, and in its place the Bureau should be required to produce ''a list identifying all persons or entities that have made allegations or accusations relevant to any matters being heard.'' If the person or entity is not sufficiently identified to be called as a witness, all evidence relating to or derived from the allegations or accusations is inadmissible.

Response: The commenter is incorrect in asserting that this exception to the affirmative disclosure obligation is not based upon the SEC Rules—the language is identical to the SEC Rules. *See* 17 CFR 201.230(b)(1)(iii). A respondent's ability to impeach the credibility of a witness will not be impacted by this exception to the affirmative disclosure obligation. The Bureau will identify any individual on whose testimony the Bureau intends to rely at the hearing, whether or not that individual came to the Bureau as a confidential source. The Bureau must prove all of its assertions at the hearing, and the respondent will have the ability to challenge all evidence offered.

Comment: The Office of Enforcement should be required to produce relevant materials without the hearing officer ordering production, and the Interim Final Rule should be revised to require the Office of Enforcement to produce a detailed log of the bases for withholding any privileged materials.

Response: The Office of Enforcement is required by § 1081.206 to disclose the documents described in the section without a separate order from the hearing officer. The Bureau does not believe that the affirmative disclosure obligation, which is based upon and substantively the same as that found in the SEC Rules, should be broadened further. The material subject to affirmative disclosure will provide respondents with access to all, or nearly all, of the information obtained by enforcement counsel in the investigation leading to the institution of proceedings. With respect to privilege logs, the Bureau adopts language from the SEC Rules, 17 CFR 201. 230(c). The hearing officer may require that the Office of Enforcement submit a list of documents or categories of documents withheld pursuant to paragraphs (b)(1)(i) and (ii) and (iv) through (vi), and the hearing officer may so order when appropriate. (As discussed above, with respect to documents withheld pursuant to paragraph (b)(1)(iii), the Bureau must inform respondent that such documents are being withheld, but no further disclosure is required.) To require the Bureau to produce a withheld document list in all cases,

even when not deemed appropriate by the hearing officer, would be unnecessary and unduly burdensome.

Comment: The Bureau should complete, rather than commence, production of the affirmative disclosure documents within seven days.

Response: The Bureau fully intends to supply all affirmative disclosure documents to respondents within seven days except in extraordinary circumstances (such as when a motion for protective order is pending on the seventh day). The Bureau adopted the language of this section from the SEC Rules, and has decided to retain the language in order to allow flexibility in those rare circumstances where a full production within seven days is not feasible, such as when a motion for a protective order is pending with respect to some of the documents. The Bureau expects these situations to arise very infrequently if at all, and expects to complete production within seven days in most cases.

Comment: The Bureau should be required to produce all documents electronically. Photocopying should not be required.

Response: The Bureau adopted the language regarding photocopying from the SEC Rules, but as indicated in the preamble to § 1081.206, the Bureau anticipates providing electronic copies of documents to respondents in most cases. The Bureau is retaining the language regarding photocopying in order to retain its discretion, particularly in cases where the safekeeping of documents subject to inspection and the cost of production may be of particular concern. The Bureau expects these cases to be rare.

The Bureau adopts § 1081.206 of the Interim Final Rule with the changes discussed above.

Section 1081.207 Production of Witness Statements

Modeled after the SEC Rules, 17 CFR 201.231, this section of the Interim Final Rule provides that a respondent may request for inspection and copying any statement of a witness to be called by the Office of Enforcement that (1) pertains to or is expected to pertain to his or her direct testimony; and (2) would be required to be produced pursuant to the Jencks Act, 18 U.S.C. 3500, if the adjudication proceeding were a criminal proceeding. This section is intended to promote the principles of transparency and efficiency discussed with respect to § 1081.206. Note, however, that the respondent is required to move for the production of these statements. The Bureau notes that the requirements set forth in paragraph (a) of this section do not overcome the limitations on discovery related to expert communications set forth in § 1081.210(e).

The Jencks Act does not require production of a witness's prior statement until the witness takes the stand. The Bureau expects that in most cases, the Office of Enforcement will provide prehearing production voluntarily. Submission of a witness's prior statement, however, may provide a motive for intimidation of that witness or improper contact by a respondent with the witness. This section provides, therefore, that the time for delivery of witness statements is to be determined by the hearing officer, so that a case-specific determination of such risks can be made if necessary. Upon a showing that there is substantial risk of improper use of a witness's prior statement, the hearing officer may take appropriate steps. For example, a hearing officer may delay production of a prior statement, or prohibit parties from communicating with particular witnesses.

Like § 1081.206 and the SEC Rules, this section provides for a ''harmless error'' standard in the event the Office of Enforcement fails to make available a statement required to be made available by this section.

The Bureau received no comment on § 1081.207 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.208 Subpoenas

This section of the Interim Final Rule is modeled after the SEC Rules, 17 CFR 201.232, and provides that, in connection with a hearing, a party may request the issuance of a subpoena for the attendance and testimony of a witness or the production of documents. The availability of subpoenas for witnesses and documents ensures that respondents have available to them the necessary tools to adduce evidence in support of their defenses. A subpoena may only be issued by the hearing officer (as opposed to counsel) and the section sets forth procedures to prevent the issuance of subpoenas that may be unreasonable, oppressive, excessive in scope, or unduly burdensome. The section also sets forth procedures and standards applicable to a motion to quash or modify a subpoena.

Paragraph (i) (which was paragraph (h) in the Interim Final Rule) of this section also provides that, if a subpoenaed person fails to comply, the Bureau, on its own motion or on the motion of the party at whose request the subpoena was issued, may seek a judicial order requiring compliance. In accordance with section 1052(b)(2) of the Dodd-Frank Act, which authorizes the Bureau or a Bureau investigator to seek enforcement of a subpoena, paragraph (i) only authorizes the Bureau—and not the party at whose request the subpoena was issued—to seek judicial enforcement of the subpoena. *Compare* 12 U.S.C. 1818(n) (authorizing any party to proceedings brought pursuant to 1818 to bring an action to enforce a subpoena issued in connection with the proceeding); 12 CFR 19.26(c) (authorizing the ''subpoenaing party or any other aggrieved party'' to seek judicial enforcement). In a provision added by the Bureau, this section also sets forth that failure to request that the Bureau seek enforcement of a subpoena constitutes waiver of any claim of prejudice predicated upon the unavailability of the testimony or evidence sought. This provision was added to prevent a respondent from declining to request that the Bureau seek to enforce the subpoena of a witness who fails to comply, and later claiming that his or her defense was prejudiced based upon the unavailability of that witness. The Bureau amended § 1081.208(h) of the Interim Final Rule (which is paragraph (i) in the Final Rule) to clarify that the General Counsel will initiate actions to enforce subpoenas on behalf of respondents, with the expectation that respondents will intervene to litigate on their own behalf. This will prevent conflicts that could arise were enforcement counsel required to enforce a subpoena sought by respondents in a proceeding.

One commenter asserted that respondents should be permitted to issue and enforce subpoenas. The Bureau's substantive response to this comment is discussed above in the context of a similar comment addressing § 1081.206.

Another commenter stated that the hearing officer should not be permitted to delegate the manual signing of deposition subpoenas, as there needs to be a basic check on the issuance of subpoenas, such as review by the hearing officer. This section provides that a hearing officer must issue a subpoena only upon the request of a party, which includes either respondents or the Bureau, and only if the hearing officer determines that the subpoena is not ''unreasonable, oppressive, excessive in scope, or unduly burdensome.''

Paragraph (c) of the Interim Final Rule permitted the hearing officer to delegate the manual signing of the subpoena to

''any other person authorized to issue subpoenas,'' which includes enforcement counsel. The Bureau has revised paragraph (c) to provide that the hearing officer may delegate the manual signing of the subpoena ''to any other person.'' This will give the hearing officer, in the interests of efficiency, the option of allowing counsel for either party to manually sign subpoenas after they have been issued by the hearing officer. But this delegation, should it occur, does not permit the issuance of subpoenas without the hearing officer's independent review and consent.

The Bureau on its own initiative added new paragraph (g) to § 1081.208. This paragraph requires a person responding to a subpoena for documentary material to file a sworn certificate of compliance with the subpoena response. This is intended to confirm that all of the documentary material required by the subpoena and in the possession, custody, or control of the person to whom the subpoena is directed has been produced and made available to the custodian.

The Bureau adopts § 1081.208 of the Interim Final Rule with the changes discussed above.

Section 1081.209 Deposition of Witness Unavailable for Hearing

This section of the Interim Final Rule, generally modeled after the Uniform Rules, 12 CFR 19.27, and the SEC Rules, 17 CFR 201.233, provides that parties may seek to depose material witnesses unavailable for the hearing upon application to the hearing officer for a deposition subpoena. The application must state that the witness is expected to be unavailable due to age, illness, infirmity or other reason and that the petitioning party was not the cause of the witness's unavailability. The Bureau has adopted the Uniform Rules' formulation of this standard, which provides for such depositions when the witness is ''otherwise unavailable,'' to account for the possible unavailability of witnesses for reasons other than those specified in the SEC Rules.

Paragraph (a)(2) requires a party seeking to record a deposition by audio-visual means to so note in the request for a deposition subpoena. This provision is modeled on Federal Rule of Civil Procedure 30(b)(3). Paragraph (a)(4) also provides that a deposition cannot be taken on less than 14 days' notice to the witness and all parties, absent an order to the contrary from the hearing officer.

Paragraph (g) incorporates several provisions from the SEC Rules. It provides that the witness being deposed may have an attorney present during the deposition; that objections to questions of evidence shall be noted by the deposition officer, but that only the hearing officer shall have the power to decide on the competency, materiality, or relevance of evidence; and that transcripts shall be available to the deponent and each party for purchase. Paragraph (g) of the Final Rule was amended slightly to provide that the deposition shall be filed with the Office of Administrative Adjudication (as opposed to the Executive Secretary as set forth in the Interim Final Rule).

Paragraph (h) of this section also incorporates certain procedures from § 1081.208 of the Interim Final Rule pertaining to subpoenas. Those procedures are intended to protect against deposition requests that may be unreasonable, oppressive, excessive in scope, or unduly burdensome, and to provide a mechanism for signing and service of a deposition subpoena, the filing of a motion to quash, and for enforcing subpoenas. This paragraph was amended slightly to conform to the amendments to § 1081.208.

One commenter suggested that respondents should be permitted to conduct pre-hearing depositions of third parties with relevant information, even if such witnesses will be available for the hearing. In promulgating the Interim Final Rule, the Bureau considered whether respondents should be allowed to issue subpoenas for the purpose of compelling prehearing discovery depositions as is allowed in actions under the Federal Rules of Civil Procedure. The Bureau believes expanding the scope of prehearing discovery to permit discovery depositions is not warranted for several reasons.

First, the Bureau believes that even if limitations were placed on the availability of discovery depositions, there remains a significant potential for extensive collateral litigation over their use. Second, use of discovery depositions is in tension with the statutory timetable for hearings in cease-and-desist proceedings under section 1053(b) of the Dodd-Frank Act. Indeed, in part for these reasons, the Final Rule, like the Interim Final Rule, allows the hearing officer to decide whether and to what extent to permit expert discovery in adjudication proceedings. Allowing prehearing depositions would present extreme scheduling difficulties in those cases in which respondents did not request hearing dates outside the 30-to-60 day timeframe set forth in the Dodd-Frank Act.

Finally, the Final Rule includes three provisions that address in significant part a respondent's interest in obtaining discovery prior to the start of the hearing. Section 1081.206 mandates that the Office of Enforcement generally make available not only transcripts of testimony, but documents obtained from persons not employed by the Bureau during the investigation leading to the initiation of the proceeding, as well as certain documents of the Bureau. Section 1081.208 authorizes the issuance of subpoenas *duces tecum* for the production of documents returnable at any designated time or place. In addition, § 1081.210 provides for expert discovery in appropriate cases. Given these discovery mechanisms, the ability to subpoena witnesses to testify at the hearing, the ability to take the deposition of material witnesses unavailable for hearing, and the ability of respondents to conduct informal discovery, the Bureau continues to believe that the marginal benefits of prehearing depositions are not justified by their likely cost in time, expense, collateral disputes and scheduling complexities.

The Bureau adopts § 1081.209 of the Interim Final Rule with the changes discussed above.

Section 1081.210 Expert Discovery

This section of the Interim Final Rule is modeled after the FTC Rules, 16 CFR 3.31A. Neither the Uniform Rules nor the SEC Rules provide for expert discovery. The Bureau has provided for expert discovery in appropriate cases so that the parties may fully understand the other side's position prior to the hearing, which will enable a clearer and more efficient airing of the issues at the hearing, and which may also clarify the issues for a possible prehearing settlement. It will also enable the parties to identify rebuttal expert witnesses, if needed, prior to the hearing.

Paragraph (a) provides that the hearing officer shall establish a date for the exchange of expert reports in the scheduling order. This provision is intended to allow flexibility in scheduling expert discovery depending on the complexity of the case and the date of the hearing.

Like the FTC Rules, 16 CFR 3.31A, paragraph (b) limits parties to five expert witnesses, including any rebuttal or surrebuttal experts, except in extraordinary circumstances. The Bureau believes this limitation will provide the parties with a sufficient opportunity to present expert testimony without unduly delaying the proceedings. Paragraph (b) also provides that no party may call an expert witness unless that witness has been identified and has provided a report in accordance with this section, unless the hearing

officer provides otherwise at a scheduling conference. The last clause is intended to reflect a hearing officer's discretion, at a scheduling conference, to dispense with or otherwise limit expert discovery in a particular case (as expressly provided for in paragraph (e) of this section).

Paragraph (c) sets forth the required contents of an expert report. This section is based upon the corresponding provisions of the FTC Rules.

Paragraph (d) provides for expert depositions, which are not to exceed eight hours absent agreement of the parties or an order by the hearing officer. These limitations are intended to provide adequate time to prepare for expert testimony without unduly delaying the proceedings. Paragraph (d) also provides that expert depositions shall be conducted pursuant to the procedures set forth in § 1081.209. Finally, paragraph (d) provides that an expert's deposition shall be conducted after submission of the expert's report but no later than seven days prior to the deadline for submission of rebuttal expert reports. This provision is intended to allow parties to rely upon the deposition of an opposing party's expert in the preparation of a rebuttal expert report. Because, pursuant to paragraph (a), rebuttal reports are due 28 days after the exchange of expert reports, expert depositions will need to take place within that 28-day period.

Finally, paragraph (e) (paragraph (f) of the Final Rule) authorizes the hearing officer to dispense with expert discovery in appropriate cases. For example, the Bureau envisions hearing officers relying on this provision in cease-and-desist proceedings brought pursuant to section 1053(b) of the Dodd-Frank Act, where the respondent has not requested a hearing date outside the statutory 30-to-60 day timeframe. In such cases, it may be appropriate to dispense with expert discovery for timing reasons, while allowing the parties to call expert witnesses.

After the Bureau promulgated the Interim Final Rule, the FTC amended its rule governing expert discovery. *See* 76 FR 52249 (Aug. 22, 2011). The FTC added a new paragraph to its expert discovery rule regarding materials that the parties cannot discover, including language nearly identical to language recently added to Federal Rule of Civil Procedure 26(b)(4)(B) and (C). The Bureau has similarly revised § 1081.210 to adopt these recent enhancements to the FTC Rules and the Federal Rules of Civil Procedure. The Bureau is therefore adding a new paragraph (e) to § 1081.210 and renumbering former paragraph (e) as paragraph (f). Under new paragraph (e), parties may not discover drafts of any report required by this section, regardless of the form in which the draft is recorded. In addition, the new language prohibits parties from discovering any communications, regardless of form, between another party's attorney and any of its expert witnesses, unless the communication: (1) Relates to the testifying expert's compensation for the study or testimony; (2) identifies facts or data provided by the party's attorney and considered by the testifying expert in forming the opinions to be expressed; or (3) identifies assumptions provided by the party's attorney and relied on by the testifying expert in forming the opinions to be expressed. The Bureau has also adopted the portion of the FTC Rules providing that a party may not discover facts known or opinions held by an expert who has been retained or specifically employed by another party in anticipation of litigation or preparation for the hearing and who is not listed as a witness for the hearing. The Bureau believes this section, which is consistent with Federal Rule of Civil Procedure 26(b)(4)(D), appropriately limits the ability of parties to discover opinions held by experts who will not offer opinions at the hearing.

The Bureau did not receive comments on § 1081.210 of the Interim Final Rule, and with exception to the changes discussed above, adopts it without change in the Final Rule.

Section 1081.211 Interlocutory Review

This section of the Interim Final Rule sets forth the procedure and standards applicable to interlocutory review by the Director of a ruling or order of the hearing officer.

Paragraph (a) of this section provides that the Director may take up a matter on his or her own motion at any time, even if a hearing officer does not certify it for interlocutory review, and that this section is the exclusive means for reviewing a hearing officer's ruling prior to the issuance of a recommended decision by the hearing officer.

Paragraph (b) provides that any party may file a motion for certification of a ruling or order for interlocutory review within five days of service of the order or ruling. Responses to such motions are due within three days, and the hearing officer is required to rule upon such a motion within five days thereafter.

Paragraph (c) sets forth the permissible bases for certifying a ruling or order. Certification is appropriate if the hearing officer's ruling would compel testimony or production of documents from Bureau officers or employees, or officers or employees from another governmental agency. This is consistent with the SEC Rules, 17 CFR 201.400. Like the FTC Rules, 16 CFR 3.23(a)(1), however, this provision includes officers and employees from other governmental agencies, and not just the Bureau, in order to afford the same treatment to other government agencies. Paragraph (c) also provides for certification of rulings or orders where there is a substantial ground for difference of opinion and an immediate review may materially advance the completion of the proceeding or subsequent review will be an inadequate remedy. The hearing officer may also certify a ruling or order where the ruling or order involves a motion for disqualification of the hearing officer or the suspension of an individual from appearing before the Bureau.

Paragraph (d) provides that a party whose motion for certification is denied by the hearing officer may petition the Director directly for interlocutory review. This provision is intended to guard against a hearing officer's unwillingness to certify a ruling that appears to meet the standards set forth in the section. The Bureau expects such direct petitions to the Director to be used sparingly.

Paragraph (e) governs the Director's review of matters certified pursuant to paragraph (c) or for which review is sought pursuant to paragraph (d). It sets forth the policy of the Bureau that interlocutory review is disfavored and provides that the Director will grant such review only in extraordinary circumstances.

Paragraph (f) provides that proceedings will not be stayed by the filing of a motion for certification for interlocutory review or a grant of such review unless the hearing officer or the Director shall so order. This is intended to promote the expeditious resolution of proceedings and to deter frivolous motions for certification or review.

The Bureau did not receive comment on § 1081.211 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.212 Dispositive Motions

This section of the Interim Final Rule establishes the procedures and standards for motions to dismiss and motions for summary disposition. Section 1081.212 expressly provides for the filing of motions to dismiss, but makes clear that filing such a motion does not affect a party's obligation to file an answer or take any other action. This is intended to ensure that motions to dismiss do not delay the proceedings unnecessarily. The timelines for decisions on dispositive motions,

discussed below, should help ensure that a party ultimately determined to be entitled to dismissal is not required to engage in the adjudicative process for a lengthy period of time.

Paragraph (b) provides that a respondent may file a motion to dismiss asserting that, even assuming the truth of the facts alleged in the notice of charges, it is entitled to dismissal as a matter of law. Neither the SEC Rules, the FTC Rules, nor the Uniform Rules specifically set forth procedures or a standard applicable to motions to dismiss, although the FTC Rules and Uniform Rules appear to contemplate such motions. *See* 16 CFR 3.22(a) (referencing motions to dismiss); 12 CFR 19.5(b)(7) (same). The Bureau has determined that such motions are appropriate and should be provided for in the Rules, but should not serve to delay the proceedings.

Paragraphs (c) and (d) govern the filing of motions for summary disposition. They adopt standards similar to those set forth in the Uniform Rules, the SEC Rules, and the FTC Rules for such motions. Any party to a proceeding may file a motion for summary disposition of a proceeding or for partial summary disposition of a proceeding if: (1) There is no genuine issue as to any material fact; and (2) the moving party is entitled to a favorable decision as a matter of law. The motion, which may be filed after a respondent's answer has been filed and documents have been made available for inspection and copying pursuant to § 1081.206, must be accompanied by a statement of the uncontested material facts, a brief, and any documentary evidence in support of the motion.

Any party opposing such a motion must file a statement setting forth those material facts as to which he or she contends a genuine dispute exists, supported by the same type of evidence permitted with a motion for summary disposition, and a brief in support of the contention that summary disposition would be inappropriate. These paragraphs are modeled after the Uniform Rules, 12 CFR 19.29.

Pursuant to paragraphs (e), (f), and (g), motions to dismiss and for summary disposition are subject to a 35-page limit (modeled on the SEC Rules, 17 CFR 201.250(c)), responses to such motions are due within 20 days and are subject to a 35-page limit (modeled on the Uniform Rules, 12 CFR 19.29(b)(1)), and reply briefs are due within five days of the response and shall not exceed ten pages. Oral argument is permitted at the request of any party or by motion of the hearing officer.

Paragraph (h) provides that the hearing officer must decide a dispositive motion within 30 days of the expiration of the time for filing all oppositions and replies. The Uniform Rules do not set a deadline for a decision on dispositive motions. The FTC Rules provide for the Commission to decide substantive motions within 45 days, 16 CFR 3.22(a), and the SEC Rules state that motions for summary disposition are to be decided ''promptly'' by the hearing officer, 17 CFR 201.250(b). The Bureau has adopted the 30-day timeframe for decisions on dispositive motions in keeping with its emphasis on expeditious decision-making in administrative proceedings. The Bureau believes that 30 days affords sufficient time for the hearing officer to properly assess the merits of the motion and draft either a ruling denying the motion or a recommended decision granting it.

If the hearing officer finds that a party is not entitled to dismissal or summary disposition, he or she shall make a ruling denying that motion. This ruling would not be subject to interlocutory appeal unless such an appeal was granted pursuant to the procedures and standards set forth in § 1081.211. If the hearing officer determines that dismissal or summary adjudication is appropriate, he or she will issue a recommended decision to that effect. If a party, for good cause shown, cannot yet present facts essential to justify opposition to the motion, the hearing officer is to deny or defer the motion.

The Bureau received no comments on § 1081.212 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.213 Partial Summary Disposition

Section 1081.213 is modeled on the FTC Rules, 16 CFR 3.24(a)(5). It permits a hearing officer who denies summary adjudication of the whole case nevertheless to issue an order specifying the facts that appear without substantial controversy. Those facts will be deemed established in the proceeding. This section enables the hearing officer to narrow the dispute between the parties so that the hearing can proceed as efficiently as possible.

The Bureau received no comment on § 1081.213 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.214 Prehearing Conferences

This section of the Interim Final Rule sets forth the procedures for a prehearing conference, which the hearing officer may convene on his own motion or at the request of a party. It sets forth matters that may be discussed at a prehearing conference. As with a scheduling conference pursuant to § 1081.203, the conference is presumptively public unless the hearing officer determines otherwise under the standard set forth in § 1081.119.

The Bureau received no comment on § 1081.214 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.215 Prehearing Submissions

This section of the Interim Final Rule was modeled primarily after the Uniform Rules, 12 CFR 19.32, which provide for mandatory prehearing submissions by the parties. Section 1081.215 requires that the following documents be served upon the other parties no later than ten days prior to the start of the hearing: a prehearing statement; a final list of witnesses to be called to testify that includes a description of the expected testimony of each witness; any prior sworn statements that a party intends to admit into evidence pursuant to § 1081.303; a list of exhibits along with a copy of each exhibit; and any stipulations of fact or liability. The failure of a party to comply with this provision will preclude the party from presenting any witnesses or exhibits not listed in its prehearing submission at the hearing, except for good cause shown. To account for cases in which the hearing officer has dispensed with expert discovery, this section also requires that a statement of any expert's qualifications and other information concerning the expert be turned over if it has not been provided pursuant to § 1081.210.

The FTC Rules do not provide for a prehearing submission, and the SEC Rules, 17 CFR 201.222, do not make such a submission mandatory. The Bureau has followed the Uniform Rules' model as it believes that prehearing submissions will assist the parties in clarifying and narrowing the issues to be adjudicated at the hearing, which is especially important under the expedited hearing schedule provided for by section 1053(b) of the Dodd-Frank Act and this Final Rule.

The Bureau received no comment on § 1081.215 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.216 Amicus Participation

This section of the Interim Final Rule, based upon the SEC Rules, 17 CFR 201.210, allows for amicus briefs in proceedings under this part, but only

under certain circumstances. Specifically, under paragraph (a) of this section, an amicus brief may be allowed when a motion for leave to file the brief has been granted; the brief is accompanied by written consent of all parties; the brief is filed at the request of the Director or the hearing officer, as appropriate; or the brief is presented by the United States or an officer or agency thereof, or by a State, or a political subdivision thereof.

One commenter expressed concern that the authorization for governmental agencies to file amicus briefs without receiving prior permission will result in the filing of numerous amicus briefs. The Bureau believes that amicus briefs from governmental entities are likely to make a valuable contribution to the adjudicative process, and are unlikely to become overwhelming or detrimental. The Bureau will consider revisiting this section if this belief proves incorrect, but the Final Rule adopts paragraph (a) of the Interim Final Rule without change.

A motion to file an amicus brief is subject to the procedural requirements set forth in § 1081.205. An amicus will be granted oral argument only for extraordinary reasons. In order to provide additional guidance to parties seeking to file amicus briefs, § 1081.216(d) provides that amicus briefs shall be filed pursuant to § 1081.111 and shall comply with the requirements of § 1081.112. Amicus briefs shall also be subject to the length limitations set forth in § 1081.212(e). The Bureau received no comments regarding the rest of § 1081.216 of the Interim Final Rule, and adopts the remaining paragraphs without change in the Final Rule.

Subpart C—Hearings

Section 1081.300 Public Hearings

This section of the Interim Final Rule provides that hearings before the Bureau will be presumptively public, a practice that is consistent with the provisions of the FTC Rules, 16 CFR 3.41(a), the SEC Rules, 17 CFR 201.301, and the Uniform Rules, 12 CFR 19.33(a). Specifically, the Interim Final Rule provides that hearings will be public unless a confidentiality order is entered by the hearing officer according to the standard set forth in § 1081.119, or unless the Director otherwise orders a non-public hearing on the ground that holding an open hearing would be contrary to the public interest.

One commenter stated that the hearing officer needs greater flexibility in limiting the public nature of adjudication hearings. This commenter argued that allowing the hearing officer to limit the public nature of the proceeding in accordance with the standard set forth in § 1081.119 was problematic and advocated for the hearing officer to be permitted to establish time, place and manner limitations on the attendance of the public and the media for any public hearing. This commenter also recommended that the Director be permitted to close a hearing.

The Bureau has considered this comment but determined to retain its articulated standard and presumption of public hearings. Incorporating the standard set forth in § 1081.119 into the standard for limiting the public nature of a hearing provides meaningful guidance to the hearing officer as to the types of hearings that should not be public, and promotes consistency in adjudication proceedings. With respect to the commenter's recommendation that the Director have the authority to close a public hearing, this section as previously promulgated allows the Director to limit the public nature of an adjudication proceeding on the grounds that holding an open hearing would be contrary to the public interest.

The Bureau adopts § 1081.300 of the Interim Final Rule without change in the Final Rule.

Section 1081.301 Failure To Appear

This section of the Interim Final Rule is modeled after the Uniform Rules, 12 CFR 19.21. It provides that the failure of a respondent to appear in person or by duly authorized counsel at the hearing may constitute a waiver of the respondent's right to a hearing and may be deemed an admission of the facts alleged and a consent to the relief sought in the notice of charges. This section directs the hearing officer to file a recommended decision addressing the relief sought in the notice of charges, without further notice to the respondent, when respondents fail to appear at the hearing.

The Bureau received no comments on § 1081.301 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.302 Conduct of Hearings

This section of the Interim Final Rule provides general principles for the conduct of hearings and the order in which the parties are to present their cases. The first sentence emphasizing the goals of fairness, impartiality, expediency, and orderliness is drawn from the SEC Rules, 17 CFR 201.300. The remainder of the section, which governs the order in which the parties are to present their cases, is modeled after the Uniform Rules, 12 CFR 19.35.

The Bureau received no comment on § 1081.302 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.303 Evidence

This section of the Interim Final Rule sets forth the provisions governing the offering and admissibility of evidence at hearings, and adopts evidentiary standards similar to those set forth in the FTC Rules, the SEC Rules, and the Uniform Rules.

Paragraph (a) of this section provides that enforcement counsel shall bear the burden of proving the ultimate issue(s) of the Bureau's claims at the hearing. Consistent with general administrative practice, paragraph (b) of § 1081.303 provides that evidence that is relevant, material, reliable, and not unduly repetitive shall be admissible to the fullest extent authorized by the APA and other applicable law, and that evidence shall not be excluded solely on the basis of its being hearsay if it is otherwise admissible and bears satisfactory indicia of reliability. Paragraph (c) of this section provides that official notice may be taken of any material fact that is not subject to reasonable dispute in that it is either generally known or capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

Paragraph (d)(1) provides that duplicate copies of documents are admissible to the same extent as originals unless a genuine issue is raised about the veracity or legibility of a document. Paragraph (d)(2) of this section provides that, subject to paragraph (b), any document prepared by a prudential regulator or by a State regulatory agency is presumptively admissible either with or without a sponsoring witness. On its own initiative, the Bureau is revising paragraph (d)(2) of this section to add the Bureau to the list of regulators whose documents are presumptively admissible with or without a sponsoring witness. The Uniform Rules, 12 CFR 19.36(c)(2), on which this paragraph is modeled, is promulgated by each of the prudential regulators, and therefore the intent of this paragraph is, in part, for each regulator to have its own documents be deemed presumptively admissible. Consistent with the intended purpose of this paragraph, the Bureau adds itself as a regulator under paragraph (d)(2). Finally, paragraph (d)(4) of this section provides that documents generated by respondents that come from their own files are

presumed authentic and kept in the regular course of business. Respondents bear the burden of proof to introduce evidence to rebut this presumption.

Paragraph (e) of this section of the Interim Final Rule provides that objections to the admissibility of evidence must be timely made and that a failure to object to the admission of evidence shall constitute a waiver of the objection.

Pursuant to paragraph (f) of this section of the Interim Final Rule, parties may, at any stage of the proceeding, stipulate as to any relevant matters of fact or the authentication of any relevant documents. Such stipulations may be received in evidence at the hearing and are binding on the parties.

Paragraph (g) of this section of the Interim Final Rule provides that witnesses at a hearing are required to testify under oath or affirmation. Parties are entitled to present their cases or defenses by sworn oral testimony and documentary evidence, including through the testimony of a witness appearing via videoconference or teleconference.

Paragraph (h) of this section, which relates to the admissibility of prior sworn statements of witnesses, is modeled after the SEC Rules, 17 CFR 201.235. Under paragraph (h) prior sworn statements may be admitted if a witness is dead, outside of the United States, unable to attend because of age, sickness, infirmity, imprisonment or other disability, or if the party offering the sworn statement is unable to procure the attendance of the witness by subpoena. Even if these conditions are not met, a prior sworn statement may be introduced into the record at the discretion of the hearing officer.

The Bureau adopts § 1081.303 of the Interim Final Rule with the changes discussed above.

Section 1081.304 Record of the Hearing

Modeled on the FTC Rules, 16 CFR 3.44, this section of the Interim Final Rule provides that hearings will be stenographically reported and transcribed and that the original transcript shall be part of the record. It outlines the procedure by which a party may request correction of the transcript. Finally, it states that upon completion of the hearing, the hearing officer will issue an order closing the record after giving the parties three days to determine whether the record is complete or requires supplementation.

The Bureau received no comment on § 1081.304 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.305 Post-Hearing Filings

This section of the Interim Final Rule is drawn largely from the Uniform Rules, 12 CFR 19.37, and provides that the parties may file proposed findings of fact, proposed conclusions of law, and a proposed order within 30 days following service of a notice on the parties that the transcript has been properly filed or within such longer period as the hearing officer may order. Proposed findings and conclusions must be supported by citation to any relevant authorities, and by page references to any relevant portions of the record. Responsive briefs may be filed to these proposed findings and conclusions within 15 days after the deadline for the proposed findings and conclusions, provided that the party responding has filed its own proposed findings and conclusions. The hearing officer shall not order the filing by any party of any post-hearing brief or responsive brief in advance of the other party's filing of its post-hearing brief.

The Bureau received no comment on § 1081.305 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.306 Record in Proceedings Before Hearing Officer; Retention of Documents; Copies

This section of the Interim Final Rule, drawn from the SEC Rules, 17 CFR 201.350, lists the documents that comprise the record of a proceeding before the hearing officer. It provides that those documents excluded from evidence should be excluded from the record but retained until either a decision of the Bureau has become final, or the conclusion of any judicial review of the Director's final order. This section also states that a copy of a document in the record may be substituted for an original.

The Bureau has amended this section to reflect the transfer of certain functions to the Office of Administrative Adjudications.

The Bureau adopts § 1081.306 of the Interim Final Rule with the changes discussed above.

Subpart D—Decision and Appeal

Section 1081.400 Recommended Decision of the Hearing Officer

This section of the Interim Final Rule adopts the general framework of the SEC Rules, 17 CFR 201.360, governing decisions by the hearing officer. Section 1081.400 provides that the hearing officer will file a recommended decision in each case within a specified time frame. Unlike the SEC Rules, which provide that the hearing officer will issue an ''initial decision,'' this section provides that the hearing officer's decision will be a ''recommended decision'' to the Director.

This section also deviates from the analogous SEC Rules in that it provides for only one timeline, rather than multiple ''tracks'' or timelines. Paragraph (a) of this section provides that the hearing officer will file a recommended decision in each case no later than 90 days after the deadline for filing post-hearing responsive briefs and in no event later than 300 days after service of the notice of charges. The 300-day timeframe is taken from the SEC Rules, 17 CFR 201.360(a)(2), and the 90-day timeframe is modeled on the FTC Rules, 16 CFR 3.51(a).

Paragraph (b) of this section provides that requests by the hearing officer for extensions of this time frame must be made to the Director and will be granted only if the Director determines that additional time is necessary or appropriate in the public interest. The Bureau anticipates such requests and extensions to be rare. As noted above, this provision was adopted to ensure the timely resolution of adjudication proceedings in light of the experience of other agencies. The Bureau believes that the 90-day and 300-day timelines set forth in this section provide sufficient time for the hearing officer to conduct appropriate proceedings and issue an informed recommended decision.

Paragraph (c) of this section is modeled on the SEC Rules, 17 CFR 201.360(b), and sets forth the contents of the recommended decision, providing that the recommended decision shall include a statement of findings of fact and conclusions of law, as well as the reasons or basis therefore, and an appropriate order, sanction, relief or denial thereof. The recommended decision shall also state that a notice of appeal may be filed within ten days after service of the recommended decision, and shall include a statement that the Director may issue a final decision and order adopting the recommended decision, unless a party timely files and perfects a notice of appeal. The recommended decision shall be filed with the Office of Administrative Adjudication (as opposed to the Executive Secretary as set forth in the Interim Final Rule), which will promptly serve the recommended decision on the parties.

Drawing from the FTC Rules, 16 CFR 3.51(d), paragraph (d) of this section provides that the recommended decision shall be made by the hearing officer who presided over the hearing, except when he or she has become unavailable to the Bureau. In such

instances, the Bureau expects the matter to be reassigned pursuant to § 1081.105(d). Paragraph (e) of this section provides that the hearing officer may reopen proceedings for receipt of further evidence upon a showing of good cause until the close of the hearing record. With the exception of correcting clerical errors or addressing a remand from the Director, the hearing officer's jurisdiction terminates upon the filing of the recommended decision.

The Bureau received no comment on § 1081.400 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.401 Transmission of Documents to Director; Record Index; Certification

This section of the Interim Final Rule is modeled on the Uniform Rules, 12 CFR 19.38(b), and the SEC Rules, 17 CFR 201.351(c). It directs the hearing officer to furnish to the Director a certified index for the case at the same time that the hearing officer files the recommended decision. It also establishes the process by which the record is transmitted to the Director for review.

The Bureau received no comment relating to this section of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.402 Notice of Appeal; Review by the Director

This section of the Interim Final Rule sets forth the process for review of a recommended decision by the Director.

Paragraph (a) of this section is drawn from the FTC Rules, 16 CFR 3.52(b), and states that any party may object to the recommended decision of the hearing officer by filing a notice of appeal to the Director within ten days of the recommended decision and perfecting that notice of appeal by filing an opening brief within 30 days of the recommended decision. Any party may respond to the opening brief by filing an answering brief within 30 days of service of the opening brief, and reply briefs may be filed within seven days after that. Appeals to the Director are available as of right in all cases where the hearing officer has issued a recommended decision.

A commenter noted that the ten-day deadline by which a party must file a notice of appeal is shorter than the 30-day deadline required by the prudential regulators, and urged the Bureau to extend its deadline to 30 days. The Bureau has considered this suggestion but has decided to keep the ten-day deadline. The burden on a party to file a proper notice of appeal is minimal. A party need only specify the party or parties against whom the appeal is taken, and designate the recommended decision or part thereof appealed from. The ten-day timeline provides adequate time to make these initial determinations. The more comprehensive document in the appeals process, the opening brief, is not due until 30 days from the service of the recommended decision. Moreover, an extension of the deadline for a notice of appeal would require extension of other deadlines in the appeal process, such as the Director's review in the absence of a notice of appeal.

This section also provides that within 40 days after the date of service of the recommended decision, the Director, on his or her own initiative, may order further briefing or argument with respect to any recommended decision or portion of any recommended decision or may issue a final decision and order adopting the recommended decision. The 40-day time period is intended to provide the Director with the benefit of knowing whether any party has filed and perfected an appeal before determining whether further briefing and argument regarding a recommended decision is necessary. Any such order shall set forth the scope of further review and the issues that will be considered and will provide for the filing of briefs if the Director deems briefing appropriate.

Finally, this section provides that, pursuant to 5 U.S.C. 704, a perfected appeal to the Director of a recommended decision is a prerequisite to the seeking of judicial review of a final decision and order, unless the Director issues a final decision and order that does not incorporate the recommended decision, in which case judicial review shall be limited to that portion of the Director's final decision and order that does not adopt the recommended decision.

The Bureau adopts § 1081.402 of the Interim Final Rule without change in the Final Rule.

Section 1081.403 Briefs Filed With the Director

This section of the Interim Final Rule outlines the requirements for briefs filed with the Director. Paragraph (a) of this section is modeled on the SEC Rules, 17 CFR 201.450(b), and governs the content of briefs. Paragraph (b) is also drawn from the SEC Rules, 17 CFR 201.450(c), and sets forth length limitations for briefs. Unlike the SEC and the FTC, the Bureau has placed page limits—rather than word limits—on briefs. This change is intended to simplify practice before the Director.

The Bureau received no comment on § 1081.403 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.404 Oral Argument Before the Director

This section of the Interim Final Rule adopts the SEC's policy for oral argument on appeal wherein the Director will consider appeals, motions, and other matters on the basis of the papers filed without oral argument unless the Director determines that the presentation of facts and legal arguments in the briefs and record and the decisional process would be significantly aided by oral argument. A party who seeks oral argument is directed to indicate such a request on the first page of its opening or answering brief. Oral argument shall be public unless otherwise ordered by the Director.

The Bureau received no comment on § 1081.404 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.405 Decision of the Director

This section of the Interim Final Rule sets forth the provisions regarding the final decision and order of the Director. Paragraph (a) provides for the scope of the Director's review and defines the record before the Director as consisting of all items that were part of the record below in accordance with § 1081.306; any notices of appeal or order directing review; all briefs, motions, submissions, and other papers filed on appeal or review; and the transcript of any oral argument held.

Paragraph (b) provides that the Director may have the advice and assistance of decisional employees in considering and disposing of a case. Paragraph (c) provides that the Director's final decision will affirm, adopt, modify, set aside, or remand for further proceedings the hearing officer's recommended decision and will include a statement of the reasons or basis for the Director's actions and the findings of fact relied upon.

In accordance with section 1053 of the Dodd-Frank Act, paragraph (d) of this section provides that, at the expiration of the time permitted for the filing of reply briefs with the Director, the Office of Administrative Adjudication will notify the parties that the case has been submitted for final Bureau decision by the Director. The Director will then issue a final decision and order within 90 days of such notification to the parties. This policy

ensures a timely final resolution to all administrative adjudications.

Paragraph (e) provides that copies of final decisions and orders by the Director will be served upon each party, upon other persons required by statute, and, if directed by the Director or required by statute, upon any appropriate State or Federal supervisory authority. The final decision and order will also be published on the Bureau's Web site or as otherwise deemed appropriate by the Bureau.

The Bureau received no comments on § 1081.405 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.406 Reconsideration

This section of the Interim Final Rule permits parties to file petitions for reconsideration of a final decision and order within 14 days after service of the decision and order. The Bureau adopts the practice set forth in the SEC Rules, 17 CFR 201.470, pursuant to which no response to a petition for reconsideration will be filed unless requested by the Director, and the Bureau adds a provision providing that the Director will request such a response before granting any motion for reconsideration. This is intended to lessen the burden on prevailing parties while preserving their opportunity to be heard if the Director is considering granting a motion for reconsideration.

The Bureau received no comments on § 1081.406 of the Interim Final Rule and adopts it without change in the Final Rule.

Section 1081.407 Effective Date; Stays Pending Judicial Review

Paragraph (a) of this section of the Interim Final Rule governs the effective date of the Director's final orders, other than consent orders. Consistent with section 1053(b) of the Dodd-Frank Act, orders to cease and desist and for other affirmative relief shall become effective 30 days after the date of service of the Director's final decision and order, unless stayed by the Director under paragraph (b) of this section.

Paragraph (b) of this section contains the procedures regarding stays of Bureau orders. Any party subject to a final order, other than a consent order, may apply to the Director for a stay of all or part of that order pending judicial review. Such a motion must be made within 30 days of service of the Director's final decision and order. A motion for a stay shall address the likelihood of the movant's success on appeal, whether the movant will suffer irreparable harm if a stay is not granted, the degree of injury to other parties if a stay is granted, and why the stay is in the public interest.

Finally, paragraph (d) of this section adopts the provision from the Uniform Rules, 12 CFR 19.41, providing that the commencement of proceedings for judicial review of a final decision and order of the Director does not, unless specifically ordered by the Director or a reviewing court, operate as a stay of any order issued by the Director.

The Bureau received no comments on § 1081.407 of the Interim Final Rule and adopts it in the Final Rule without change.

VI. Legal Authority

The Bureau promulgates the Final Rule pursuant to its authority to implement section 1053 of the Dodd-Frank Act, 12 U.S.C. 5563(e), as well as its general rulemaking authority to promulgate rules necessary or appropriate to carry out the Federal consumer financial laws, 12 U.S.C. 5512(b)(1).

VII. Section 1022(b)(2) Provisions

In developing the Final Rule, the Bureau has considered the potential benefits, costs, and impacts and has consulted or offered to consult with the prudential regulators, the Department of Housing and Urban Development, the SEC, the Department of Justice, and the FTC before and after issuing the Interim Final Rule, including with regard to consistency with any prudential, market, or systemic objectives administered by such agencies.[4]

The Dodd-Frank Act requires the Bureau to prescribe rules necessary to conduct hearings and adjudicatory proceedings. The Final Rule neither imposes obligations on consumers, nor is it expected to affect their access to consumer financial products or services.

The Final Rule is intended to provide an expeditious decision-making process, which will benefit both consumers and covered persons. The Final Rule adopts an affirmative disclosure approach to fact discovery, pursuant to which the Bureau will make available to respondents the information obtained by the Office of Enforcement from persons not employed by the Bureau prior to the institution of proceedings, in connection with the investigation leading to the institution of proceedings that is not otherwise privileged or protected from disclosure. This affirmative disclosure obligation substitutes for the traditional civil discovery process, which can be both time-consuming and expensive. This clear and efficient process for the conduct of adjudication proceedings benefits consumers by providing a systematic process for protecting them from unlawful behavior. At the same time, this process will afford covered persons with a cost-effective way to have their cases heard. The Final Rule is based upon, and drawn from, existing rules of the prudential regulators, the FTC, and the SEC. The Final Rule's similarity to existing rules should further reduce the expense of administrative adjudication for covered persons.

Further, the Final Rule has no unique impact on insured depository institutions or insured credit unions with less than $10 billion in assets described in section 1026(a) of the Dodd-Frank Act. Finally, the Final Rule does not have a unique impact on rural consumers.

A commenter stated that the four interim final rules that the Bureau promulgated together on July 28, 2011 failed to satisfy the rulemaking requirements under section 1022 of the Dodd-Frank Act. Specifically, the commenter stated that ''the CFPB's analysis of the costs and benefits of its rules does not recognize the significant costs the CFPB imposes on covered persons.'' The Bureau believes that it appropriately considered the benefits, costs, and impacts of the Interim Final Rule pursuant to section 1022 of the Dodd-Frank Act. Notably, the commenter did not identify any specific costs to covered persons imposed by the Rules of Practice for Adjudication Proceedings that are not discussed in Part C of the **SUPPLEMENTARY INFORMATION** to the Interim Final Rule.

VIII. Procedural Requirements

As noted in publishing the Interim Final Rule, under the Administrative Procedure Act, 5 U.S.C. 553(b), notice and comment is not required for rules of agency organization, procedure, or practice. As discussed in the preamble to the Interim Final Rule, the Bureau confirms its finding that this is a procedural rule for which notice and comment is not required. In addition,

[4] Section 1022(b)(2)(A) of the Dodd-Frank Act addresses the consideration of the potential benefits and costs of regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act; and the impact on consumers in rural areas. Section 1022(b)(2)(B) addresses consultation between the Bureau and other Federal agencies during the rulemaking process. The manner and extent to which these provisions apply to procedural rules and benefits, costs and impacts that are compelled by statutory changes rather than discretionary Bureau action is unclear. Nevertheless, to inform this rulemaking more fully, the Bureau performed the described analyses and consultations.

because the Final Rule relates solely to agency procedure and practice, it is not subject to the 30-day delayed effective date for substantive rules under section 553(d) of the Administrative Procedure Act, 5 U.S.C. 551 *et seq.*

Because no notice of proposed rulemaking is required, the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601(2) do not apply. Finally, the Bureau has determined that this Final Rule does not impose any new recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval under 44 U.S.C. 3501 *et seq.*

List of Subjects in 12 CFR Part 1081

Administrative practice and procedure, Banking, Banks, Consumer protection, Credit, Credit unions, Law enforcement, National banks, Savings associations, Trade practices.

Authority and Issuance

For the reasons set forth above, the Bureau of Consumer Financial Protection revises part 1081 to 12 CFR chapter X to read as follows:

PART 1081—RULES OF PRACTICE FOR ADJUDICATION PROCEEDINGS

Subpart A—General Rules

Subpart B—Initiation of Proceedings and Prehearing Rules

Subpart C—Hearings

Subpart D—Decision and Appeals

Authority: Pub. L. 111–203, Title X.

Subpart A—General Rules

§ 1081.100 Scope of the rules of practice.

This part prescribes rules of practice and procedure applicable to adjudication proceedings authorized by section 1053 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) to ensure or enforce compliance with the provisions of Title X of the Dodd-Frank Act, rules prescribed by the Bureau under Title X of the Dodd-Frank Act, and any other Federal law or regulation that the Bureau is authorized to enforce. These rules of practice do not govern the conduct of Bureau investigations, investigational hearings or other proceedings that do not arise from proceedings after a notice of charges.

§ 1081.101 Expedition and fairness of proceedings.

To the extent practicable, consistent with requirements of law, the Bureau's policy is to conduct such adjudication proceedings fairly and expeditiously. In the conduct of such proceedings, the hearing officer and counsel for all parties shall make every effort at each stage of a proceeding to avoid delay. With the consent of the parties, the Director, at any time, or the hearing officer at any time prior to the filing of his or her recommended decision, may shorten any time limit prescribed by this part.

§ 1081.102 Rules of construction.

For the purposes of this part:

(a) Any term in the singular includes the plural, and the plural includes the singular, if such use would be appropriate;

(b) Any use of a masculine, feminine, or neutral gender encompasses all three, if such use would be appropriate;

(c) Unless context requires otherwise, a party's counsel of record, if any, may, on behalf of that party, take any action required to be taken by the party; and

(d) To the extent this part uses terms defined by section 1002 of the Dodd-Frank Act, such terms shall have the same meaning as set forth therein, unless defined differently by § 1081.103.

§ 1081.103 Definitions.

For the purposes of this part, unless explicitly stated to the contrary:

Dodd-Frank Act means the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Public Law 111–203 (July 21, 2010).

Adjudication proceeding means a proceeding conducted pursuant to section 1053 of the Dodd-Frank Act and intended to lead to the formulation of a final order other than a temporary order to cease and desist issued pursuant to section 1053(c) of the Dodd-Frank Act.

Bureau means the Bureau of Consumer Financial Protection.

Chief hearing officer means the hearing officer charged with assigning hearing officers to specific proceedings, in the event there is more than one hearing officer available to the Bureau.

Counsel means any person representing a party pursuant to § 1081.107.

Decisional employee means any employee of the Bureau who has not engaged in an investigative or prosecutorial role in a proceeding and who may assist the Director or the hearing officer, respectively, in preparing orders, recommended decisions, decisions, and other documents under this part.

Director means the Director of the Bureau or a person authorized to perform the functions of the Director in accordance with the law.

Enforcement counsel means any individual who files a notice of appearance as counsel on behalf of the Bureau in an adjudication proceeding.

Final order means an order issued by the Bureau with or without the consent of the respondent, which has become final, without regard to the pendency of any petition for reconsideration or review.

General Counsel means the General Counsel of the Bureau or any Bureau employee to whom the General Counsel has delegated authority to act under this part.

Hearing officer means an administrative law judge or any other person duly authorized to preside at a hearing.

Notice of charges means the pleading that commences an adjudication proceeding, as described in § 1081.200, except that it does not include a stipulation and consent order under § 1081.200(d).

Office of Administrative Adjudication means the office of the Bureau responsible for conducting adjudication proceedings.

Office of Enforcement means the office of the Bureau responsible for enforcement of Federal consumer financial law.

Party means the Bureau, any person named as a party in any notice of charges issued pursuant to this part, and, to the extent applicable, any person who intervenes in the proceeding pursuant to § 1081.119(a) to seek a protective order.

Person means an individual, partnership, company, corporation, association (incorporated or unincorporated), trust, estate, cooperative organization, or other entity.

Person employed by the Bureau means Bureau employees, contractors, agents, and others acting for or on behalf of the Bureau, or at its direction, including consulting experts.

Respondent means the party named in the notice of charges.

State means any State, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, or the United States Virgin Islands or any federally recognized Indian tribe, as defined by the Secretary of the Interior under section 104(a) of the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a–1(a).

§ 1081.104 Authority of the hearing officer.

(a) *General Rule.* The hearing officer shall have all powers necessary to conduct a proceeding in a fair and impartial manner and to avoid unnecessary delay. No provision of this part shall be construed to limit the powers of the hearing officers provided by the Administrative Procedure Act, 5 U.S.C. 556, 557.

(b) *Powers.* The powers of the hearing officer include but are not limited to the power:

(1) To administer oaths and affirmations;

(2) To issue subpoenas, subpoenas *duces tecum,* and protective orders, as authorized by this part, and to quash or modify any such subpoenas or orders;

(3) To take depositions or cause depositions to be taken;

(4) To receive relevant evidence and to rule upon the admission of evidence and offers of proof;

(5) To regulate the course of a proceeding and the conduct of parties and their counsel;

(6) To reject written submissions that materially fail to comply with the requirements of this part, and to deny confidential status to documents and testimony without prejudice until a party complies with all relevant rules;

(7) To hold conferences for settlement, simplification of the issues, or any other proper purpose and require the attendance at any such conference of at least one representative of each party who has authority to negotiate concerning the resolution of issues in controversy;

(8) To inform the parties as to the availability of one or more alternative means of dispute resolution, and to encourage the use of such methods;

(9) To certify questions to the Director for his or her determination in accordance with the rules of this part;

(10) To consider and rule upon, as justice may require, all procedural and other motions appropriate in adjudication proceedings;

(11) To issue and file recommended decisions;

(12) To recuse himself or herself by motion made by a party or on his or her own motion;

(13) To issue such sanctions against parties or their counsel as may be necessary to deter repetition of sanctionable conduct or comparable conduct by others similarly situated, as provided for in this part or as otherwise necessary to the appropriate conduct of hearings and related proceedings, provided that no sanction shall be imposed before providing the sanctioned person an opportunity to show cause why no such sanction should issue; and

(14) To do all other things necessary and appropriate to discharge the duties of a presiding officer.

§ 1081.105 Assignment, substitution, performance, disqualification of hearing officer.

(a) *How assigned.* In the event that more than one hearing officer is available to the Bureau for the conduct of proceedings under this part, the presiding hearing officer shall be designated by the chief hearing officer, who shall notify the parties of the hearing officer designated.

(b) *Interference.* Hearing officers shall not be subject to the supervision or direction of, or responsible to, any officer, employee, or agent engaged in the performance of investigative or prosecuting functions for the Bureau, and all direction by the Bureau to the hearing officer concerning any adjudication proceedings shall appear in and be made part of the record.

(c) *Disqualification of hearing officers.* (1) When a hearing officer deems himself or herself disqualified to preside in a particular proceeding, he or she shall issue a notice stating that he or she is withdrawing from the matter and setting forth the reasons therefore.

(2) Any party who has a reasonable, good faith basis to believe that a hearing officer has a personal bias, or is otherwise disqualified from hearing a case, may make a motion to the hearing officer that the hearing officer withdraw. The motion shall be accompanied by an affidavit setting forth the facts alleged to constitute grounds for disqualification. Such motion shall be filed at the earliest practicable time after the party learns, or could reasonably have learned, of the alleged grounds for disqualification. If the hearing officer does not disqualify himself or herself within ten days, he or she shall certify the motion to the Director pursuant to § 1081.211, together with any statement he or she may wish to have considered by the Director. The Director shall promptly determine the validity of the grounds alleged, either directly or on the report of another hearing officer appointed to conduct a hearing for that purpose, and shall either direct the reassignment of the matter or confirm the hearing officer's continued role in the matter.

(d) *Unavailability of hearing officer.* In the event that the hearing officer withdraws or is otherwise unable to perform the duties of the hearing officer, the chief hearing officer or the Director shall designate another hearing officer to serve.

§ 1081.106 Deadlines.

The deadlines for action by the hearing officer established by §§ 1081.203, 1081.205, 1081.211, 1081.212, and 1081.400, or elsewhere in this part, confer no substantive rights on respondents.

§ 1081.107 Appearance and practice in adjudication proceedings.

(a) *Appearance before the Bureau or a hearing officer.* (1) *By attorneys.* Any member in good standing of the bar of the highest court of any State may represent others before the Bureau if such attorney is not currently suspended or debarred from practice before the Bureau or by a court of the United States or of any State.

(2) *By non-attorneys.* So long as such individual is not currently suspended or debarred from practice before the Bureau:

(i) An individual may appear on his or her own behalf;

(ii) A member of a partnership may represent the partnership;

(iii) A duly authorized officer of a corporation, trust or association may represent the corporation, trust or association; and

(iv) A duly authorized officer or employee of any government unit, agency, or authority may represent that unit, agency, or authority.

(3) *Notice of appearance.* Any individual acting as counsel on behalf of a party, including the Bureau, shall file a notice of appearance at or before the time that the individual submits papers or otherwise appears on behalf of a party in the adjudication proceeding. The notice of appearance must include a written declaration that the individual is currently qualified as provided in paragraph (a)(1) or (a)(2) of this section and is authorized to represent the particular party, and if applicable, must include the attorney's jurisdiction of admission or qualification, attorney identification number, and a statement by the appearing attorney attesting to his or her good standing within the legal profession. By filing a notice of appearance on behalf of a party in an adjudication proceeding, the counsel agrees and represents that he or she is authorized to accept service on behalf of the represented party and that, in the event of withdrawal from representation, he or she will, if required by the hearing officer, continue to accept service until a new counsel has filed a notice of appearance or until the represented party indicates that he or she will proceed on a pro se basis. The notice of appearance shall provide the representative's email address, telephone number and business address and, if different from the representative's addresses, electronic or other address at which the represented party may be served.

(b) *Sanctions.* Dilatory, obstructionist, egregious, contemptuous or contumacious conduct at any phase of any adjudication proceeding may be grounds for exclusion or suspension of counsel from the proceeding. An order imposing a sanction must describe the sanctioned conduct and explain the basis for the sanction.

(c) *Standards of conduct; disbarment.* (1) All attorneys practicing before the Bureau shall conform to the standards of ethical conduct required by the bars of which the attorneys are members.

(2) If for good cause shown, the Director believes that any attorney is not conforming to such standards, or that an attorney or counsel to a party has otherwise engaged in conduct warranting disciplinary action, the Director may issue an order requiring such person to show cause why he should not be suspended or disbarred from practice before the Bureau. The alleged offender shall be granted due opportunity to be heard in his or her own defense and may be represented by counsel. Thereafter, if warranted by the facts, the Director may issue against the attorney or counsel an order of reprimand, suspension, or disbarment.

§ 1081.108 Good faith certification.

(a) *General requirement.* Every filing or submission of record following the issuance of a notice of charges shall be signed by at least one counsel of record in his or her individual name and shall state counsel's address, email address, and telephone number. A party who acts as his or her own counsel shall sign his or her individual name and state his or her address, email address, and telephone number on every filing or submission of record. Papers filed by electronic transmission may be signed with an ''/s/'' notation, which shall be deemed the signature of the party or representative whose name appears below the signature line.

(b) *Effect of signature.* (1) The signature of counsel or a party shall constitute a certification that: the counsel or party has read the filing or submission of record; to the best of his or her knowledge, information, and belief formed after reasonable inquiry, the filing or submission of record is well-grounded in fact and is warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law; and the filing or submission of record is not made for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

(2) If a filing or submission of record is not signed, the hearing officer shall strike the filing or submission of record, unless it is signed promptly after the omission is called to the attention of the filer.

(c) *Effect of making oral motion or argument.* The act of making any oral motion or oral argument by any counsel or party constitutes a certification that to the best of his or her knowledge, information, and belief formed after reasonable inquiry, his or her statements are well-grounded in fact and are warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law, and are not made for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

(d) *Sanctions.* Counsel or a party that fails to abide by the requirements of this section may be subject to sanctions pursuant to § 1081.104(b)(13).

§ 1081.109 Conflict of interest.

(a) *Conflict of interest in representation.* No person shall appear as counsel for another person in an adjudication proceeding if it reasonably appears that such representation may be materially limited by that counsel's responsibilities to a third person or by the counsel's own interests. The hearing officer may take corrective measures at any stage of a proceeding to cure a conflict of interest in representation, including the issuance of an order limiting the scope of representation or disqualifying an individual from appearing in a representative capacity for the duration of the proceeding.

(b) *Certification and waiver.* If any person appearing as counsel represents two or more parties to an adjudication proceeding or also represents a non-party on a matter relevant to an issue in the proceeding, counsel must certify in writing at the time of filing the notice of appearance required by § 1081.107(a)(3):

(1) That the counsel has personally and fully discussed the possibility of conflicts of interest with each such party and non-party; and

(2) That each such party and/or non-party waives any right it might otherwise have had to assert any known conflicts of interest or to assert any conflicts of interest during the course of the proceeding.

§ 1081.110 Ex parte communication.

(a) *Definitions.* (1) For purposes of this section, *ex parte communication* means any material oral or written

communication relevant to the merits of an adjudication proceeding that was neither on the record nor on reasonable prior notice to all parties that takes place between:

(i) An interested person not employed by the Bureau (including such person's counsel); and

(ii) The hearing officer handling the proceeding, the Director, or a decisional employee.

(2) *Exception.* A request for status of the proceeding does not constitute an ex parte communication.

(3) *Pendency of an adjudication proceeding* means the time from when the Bureau issues a notice of charges, unless the person responsible for the communication has knowledge that a notice of charges will be issued, in which case the pendency of an adjudication shall commence at the time of his or her acquisition of such knowledge, or from when an order by a court of competent jurisdiction remanding a Bureau decision and order for further proceedings becomes effective, until the time the Director enters his or her final decision and order in the proceeding and the time permitted to seek reconsideration of that decision and order has elapsed. For purposes of this section, an order of remand by a court of competent jurisdiction shall be deemed to become effective when the Bureau's right to petition for review or for a writ of certiorari has lapsed without a petition having been filed, or when such a petition has been denied. If a petition for reconsideration of a Bureau decision is filed pursuant to § 1081.406, the matter shall be considered to be a pending adjudication proceeding until the time the Bureau enters an order disposing of the petition.

(b) *Prohibited ex parte communications.* During the pendency of an adjudication proceeding, except to the extent required for the disposition of ex parte matters as authorized by law or as otherwise authorized by this part:

(1) No interested person not employed by the Bureau shall make or knowingly cause to be made to the Director, or to the hearing officer, or to any decisional employee, an ex parte communication; and

(2) The Director, the hearing officer, or any decisional employee shall not make or knowingly cause to be made to any interested person not employed by the Bureau any ex parte communication.

(c) *Procedure upon occurrence of ex parte communication.* If an ex parte communication prohibited by paragraph (b) of this section is received by the hearing officer, the Director, or any decisional employee, that person shall cause all such written communications (or, if the communication is oral, a memorandum stating the substance of the communication) to be placed on the record of the proceeding and served on all parties. All other parties to the proceeding shall have an opportunity, within ten days of receipt of service of the ex parte communication, to file responses thereto and to recommend any sanctions, in accordance with paragraph (d) of this section, that they believe to be appropriate under the circumstances.

(d) *Sanctions.* (1) *Adverse action on claim.* Upon receipt of an ex parte communication knowingly made or knowingly caused to be made by a party and prohibited by paragraph (b) of this section, the Director or hearing officer, as appropriate, may, to the extent consistent with the interests of justice and the policy of the underlying statutes, require the party to show cause why his claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation.

(2) *Discipline of persons practicing before the Bureau.* The Director may, to the extent not prohibited by law, censure, suspend, or revoke the privilege to practice before the Bureau of any person who makes, or solicits the making of, an unauthorized ex parte communication.

(e) *Separation of functions.* Except to the extent required for the disposition of ex parte matters as authorized by law, the hearing officer may not consult a person or party on any matter relevant to the merits of the adjudication, unless upon notice and opportunity for all parties to participate. An employee or agent engaged in the performance of investigative or prosecuting functions for the Bureau in a case, other than the Director, may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review of the recommended decision, except as witness or counsel in public proceedings.

§ 1081.111 Filing of papers.

(a) *Filing.* The following papers must be filed by parties in an adjudication proceeding: the notice of charges, proof of service of the notice of charges, notices of appearance, answer, the disclosure statement required under § 1081.201(e), motion, brief, request for issuance or enforcement of a subpoena, response, opposition, reply, notice of appeal, or petition for reconsideration. The hearing officer shall file all written orders, rulings, notices, or requests. Any papers required to be filed shall be filed with the Office of Administrative Adjudication, except as otherwise provided herein.

(b) *Manner of filing.* Unless otherwise specified by the Director or the hearing officer, filing may be accomplished by:

(1) Electronic transmission in accordance with guidance issued by the Office of Administrative Adjudication; or

(2) Any of the following methods if respondent demonstrates, in accordance with guidance issued by the Office of Administrative Adjudication, that electronic filing is not practicable:

(i) Personal delivery;

(ii) Delivery to a reliable commercial courier service or overnight delivery service; or

(iii) Mailing the papers through the U.S. Postal Service by First Class Mail, Registered Mail, Certified Mail or Express Mail.

(c) *Papers filed in an adjudication proceeding are presumed to be public.* Unless otherwise ordered by the Bureau or the hearing officer, all papers filed in connection with an adjudication proceeding are presumed to be open to the public. The Bureau may provide public access to and publish any papers filed in an adjudication proceeding except if there is a pending motion for a protective order filed pursuant to § 1081.119, or if there is an order from the Director, hearing officer, or a Federal court authorizing the confidential treatment of the papers filed.

§ 1081.112 Formal requirements as to papers filed.

(a) *Form.* All papers filed by parties must:

(1) Set forth the name, address, telephone number, and email address of the counsel or party making the filing;

(2) Be double-spaced (except for single-spaced footnotes and single-spaced indented quotations) and printed or typewritten on 8½ x 11 inch paper in 12-point or larger font;

(3) Include at the head of the paper, or on a title page, a caption setting forth the title of the case, the docket number of the proceeding, and a brief descriptive title indicating the purpose of the paper;

(4) Be paginated with margins at least one inch wide; and

(5) If filed by other than electronic means, be stapled, clipped or otherwise fastened in a manner that lies flat when opened.

(b) *Signature.* All papers must be dated and signed as provided in § 1081.108.

(c) *Number of copies.* Unless otherwise specified by the Director or the hearing officer, one copy of all

documents and papers shall be filed if filing is by electronic transmission. If filing is accomplished by any other means, an original and one copy of all documents and papers shall be filed, except that only one copy of transcripts of testimony and exhibits must be filed.

(d) *Authority to reject document for filing.* The Office of Administrative Adjudication or the hearing officer may reject a document for filing that materially fails to comply with these rules.

(e) *Sensitive personal information.* Sensitive personal information means an individual's Social Security number, taxpayer identification number, financial account number, credit card or debit card number, driver's license number, State-issued identification number, passport number, date of birth (other than year), and any sensitive health information identifiable by individual, such as an individual's medical records. Sensitive personal information shall not be included in, and must be redacted or omitted from, filings unless the person filing the paper determines that such information is relevant or otherwise necessary for the conduct of the proceeding. If the person filing a paper determines the sensitive personal information contained in the paper is relevant or necessary to the proceeding, the person shall file the paper in accordance with paragraph (f) of this section, including filing an expurgated copy of the paper with the sensitive personal information redacted.

(f) *Confidential treatment of information in certain filings.* A party seeking confidential treatment of information contained in a filing must contemporaneously file either a motion requesting such treatment in accordance with § 1081.119 or a copy of the order from the Director, hearing officer, or Federal court authorizing such confidential treatment. The filing must comply with any applicable order of the Director or hearing officer and must be accompanied by:

(1) A complete, sealed copy of the documents containing the materials as to which confidential treatment is sought, with the allegedly confidential material clearly marked as such, and with the first page of the document labeled ''Under Seal.'' If the movant seeks or has obtained a protective order against disclosure to other parties as well as the public, copies of the documents shall not be served on other parties; and

(2) An expurgated copy of the materials as to which confidential treatment is sought, with the allegedly confidential materials redacted. The redacted version shall indicate any omissions with brackets or ellipses, and its pagination and depiction of text on each page shall be identical to that of the sealed version.

(g) *Certificate of service.* Any papers filed in an adjudication proceeding shall contain proof of service on all other parties or their counsel in the form of a statement of the date and manner of service and of the names of the persons served, certified by the person who made service. The certificate of service must be affixed to the papers filed and signed in accordance with § 1081.108.

§ 1081.113 Service of papers.

(a) *When required.* In every adjudication proceeding, each paper required to be filed by § 1081.111 shall be served upon each party in the proceeding in accordance with the provisions of this section; provided, however, that absent an order to the contrary, no service shall be required for motions which are to be heard ex parte.

(b) *Upon a person represented by counsel.* Whenever service is required to be made upon a person represented by counsel who has filed a notice of appearance pursuant to § 1081.107(a)(3), service shall be made pursuant to paragraph (c) of this section upon counsel, unless service upon the person represented is ordered by the Director or the hearing officer, as appropriate.

(c) *Method of service.* Except as provided in paragraph (d) of this section or as otherwise ordered by the hearing officer or the Director, service shall be made by delivering a copy of the filing by one of the following methods:

(1) Transmitting the papers by electronic transmission where the persons so serving each other have consented to service by specified electronic transmission and provided the Bureau and the parties with notice of the means for service by electronic transmission (e.g., email address or facsimile number);

(2) Handing a copy to the person required to be served; or leaving a copy at the person's office with a clerk or other person in charge thereof, or, if there is no one in charge, leaving it in a conspicuous place therein; or, if the office is closed or the person to be served has no office, leaving it at the person's dwelling or usual place of abode with some person of suitable age and discretion then residing therein;

(3) Mailing the papers through the U.S. Postal Service by First Cass Mail, Registered Mail, Certified Mail or Express Mail delivery addressed to the person; or

(4) Sending the papers through a third-party commercial courier service or express delivery service.

(d) *Service of certain papers by the Bureau.* Service of the notice of charges, recommended decisions and final orders of the Bureau shall be effected as follows:

(1) *Service of a notice of charges.* (i) *To individuals.* Notice of a proceeding shall be made to an individual by delivering a copy of the notice of charges to the individual or to an agent authorized by appointment or by law to receive such notice. Delivery, for purposes of this paragraph, means handing a copy of the notice to the individual; or leaving a copy at the individual's office with a clerk or other person in charge thereof; or leaving a copy at the individual's dwelling house or usual place of abode with some person of suitable age and discretion then residing therein; or sending a copy of the notice addressed to the individual through the U.S. Postal Service by Registered Mail, Certified Mail or Express Mail delivery, or by third-party commercial carrier, for overnight delivery and obtaining a confirmation of receipt.

(ii) *To corporations or entities.* Notice of a proceeding shall be made to a person other than a natural person by delivering a copy of the notice of charges to an officer, managing or general agent, or any other agent authorized by appointment or law to receive such notice, by any method specified in paragraph (d)(1)(i) of this section.

(iii) *Upon persons registered with the Bureau.* In addition to any other method of service specified in paragraph (d)(1)(i) or (ii) of this section, notice may be made to a person currently registered with the Bureau by sending a copy of the notice of charges addressed to the most recent business address shown on the person's registration form by U.S. Postal Service certified, registered or Express Mail and obtaining a confirmation of receipt or attempted delivery.

(iv) *Upon persons in a foreign country.* Notice of a proceeding to a person in a foreign country may be made by any method specified in paragraph (d)(1) of this section, or by any other method reasonably calculated to give notice, provided that the method of service used is not prohibited by the law of the foreign country.

(v) *Record of service.* The Bureau shall maintain and file a record of service of the notice of charges on parties, identifying the party given notice, the method of service, the date of service, the address to which service was made, and the person who made service. If service is made in person, the certificate of service shall state, if

available, the name of the individual to whom the notice of charges was given. If service is made by U.S. Postal Service Registered Mail, Certified Mail or Express Mail, the Bureau shall maintain the confirmation of receipt or attempted delivery. If service is made to an agent authorized by appointment to receive service, the certificate of service shall be accompanied by evidence of the appointment.

(vi) *Waiver of service.* In lieu of service as set forth in paragraph (d)(1)(i) or (d)(1)(ii) of this section, the party may be provided a copy of the notice of charges by First Class Mail or other reliable means if a waiver of service is obtained from the party and placed in the record.

(2) *Service of recommended decisions and final orders.* Recommended decisions issued by the hearing officer and final orders issued by the Bureau shall be served promptly on each party pursuant to any method of service authorized under paragraph (d)(1) of this section. Such decisions and orders may also be served by electronic transmission if the party to be served has agreed to accept such service in writing, signed by the party or its counsel, and has provided the Bureau with information concerning the manner of electronic transmission.

§ 1081.114 Construction of time limits.

(a) *General rule.* In computing any period of time prescribed by this part, by order of the Director or a hearing officer, or by any applicable statute, the date of the act or event that commences the designated period of time is not included. The last day so computed is included unless it is a Saturday, Sunday, or Federal holiday as set forth in 5 U.S.C. 6103(a). When the last day is a Saturday, Sunday, or Federal holiday, the period runs until the end of the next day that is not a Saturday, Sunday, or Federal holiday. Intermediate Saturdays, Sundays, and Federal holidays are included in the computation of time, except when the time period within which an act is to be performed is ten days or less, not including any additional time allowed for in paragraph (c) of this section.

(b) *When papers are deemed to be filed or served.* Filing and service are deemed to be effective:

(1) In the case of personal service or same day commercial courier delivery, upon actual receipt by person served;

(2) In the case of overnight commercial delivery service, Express Mail delivery, First Class Mail, Registered Mail, or Certified Mail, upon deposit in or delivery to an appropriate point of collection; or

(3) In the case of electronic transmission, upon transmission.

(c) *Calculation of time for service and filing of responsive papers.* Whenever a time limit is measured by a prescribed period from the service of any notice or paper, the applicable time limits are calculated as follows:

(1) If service is made by First Class Mail, Registered Mail, or Certified Mail, add three calendar days to the prescribed period;

(2) If service is made by Express Mail or overnight delivery service, add one calendar day to the prescribed period; or

(3) If service is made by electronic transmission, add one calendar day to the prescribed period.

§ 1081.115 Change of time limits.

(a) Except as otherwise provided by law, the hearing officer may, in any proceeding before him or her, for good cause shown, extend the time limits prescribed by this part or by any notice or order issued in the proceedings. After appeal to the Director pursuant to § 1081.402, the Director may grant extensions of the time limits for good cause shown. Extensions may be granted on the motion of a party after notice and opportunity to respond is afforded all non-moving parties or on the Director's or the hearing officer's own motion, as appropriate.

(b) *Considerations in determining whether to extend time limits or grant postponements, adjournments and extensions.* In considering all motions for extensions of time filed pursuant to paragraph (a) of this section, the Director or the hearing officer should adhere to a policy of strongly disfavoring granting such motions, except in circumstances where the moving party makes a strong showing that the denial of the motion would substantially prejudice its case. In determining whether to grant any motions, the Director or hearing officer, as appropriate, shall consider, in addition to any other relevant factors:

(1) The length of the proceeding to date;

(2) The number of postponements, adjournments or extensions already granted;

(3) The stage of the proceedings at the time of the motion;

(4) The impact of the motion on the hearing officer's ability to complete the proceeding in the time specified by § 1081.400(a); and

(5) Any other matters as justice may require.

(c) *Time limit.* Postponements, adjournments, or extensions of time for filing papers shall not exceed 21 days unless the Director or the hearing officer, as appropriate, states on the record or sets forth in a written order the reasons why a longer period of time is necessary.

(d) *No effect on deadline for recommended decision.* The granting of any extension of time pursuant to this section shall not affect any deadlines set pursuant to § 1081.400(a).

§ 1081.116 Witness fees and expenses.

Respondents shall pay to witnesses subpoenaed for testimony or depositions on their behalf the same fees for attendance and mileage as are paid in the United States district courts in proceedings in which the United States is a party, provided that, in the case of a deposition subpoena addressed to a party, no witness fees or mileage need be paid. Fees for witnesses shall be tendered in advance by any respondent requesting the issuance of a subpoena, except that fees and mileage need not be tendered in advance where the Bureau is the party requesting the subpoena. The Bureau shall pay to witnesses subpoenaed for testimony or depositions on behalf of the Office of Enforcement the same fees for attendance and mileage as are paid in the United States district courts in proceedings in which the United States is a party, but the Bureau need not tender such fees in advance.

§ 1081.117 Bureau's right to conduct examination, collect information.

Nothing contained in this part limits in any manner the right of the Bureau to conduct any examination, inspection, or visitation of any person, to conduct or continue any form of investigation authorized by law, to collect information in order to monitor the market for risks to consumers in the offering or provision of consumer financial products or services, or to otherwise gather information in accordance with law.

§ 1081.118 Collateral attacks on adjudication proceedings.

Unless a court of competent jurisdiction, or the Director for good cause, so directs, if an interlocutory appeal or collateral attack is brought in any court concerning all or any part of an adjudication proceeding, the challenged adjudication proceeding shall continue without regard to the pendency of that court proceeding. No default or other failure to act as directed in the adjudication proceeding within the times prescribed in this part shall be excused based on the pendency before any court of any interlocutory appeal or collateral attack.

§ 1081.119 Confidential information; protective orders.

(a) Rights of third parties. Any party that intends to disclose information obtained from a third party that is subject to a claim of confidentiality must provide notice to the third party at least ten days prior to the proposed disclosure of such information. In response to such notice, the third party may consent to the disclosure of such information, which may be conditioned on the entry of an appropriate protective order, or may intervene in the proceeding for the limited purpose of moving for a protective order pursuant to this section. Any written filing by a party that contains such confidential information must be accompanied by a certification that proper notice was provided. The act of making any oral motion or oral argument by any counsel or party which contains such confidential information constitutes a certification that proper notice was provided. A third party wishing to intervene for purposes of protecting its confidential information may file a single motion, in conformity with all applicable rules, setting forth the basis of both the third party's right to intervene and the basis for the protective order, in conformity with paragraph (b).

(b) *Procedure.* In any adjudication proceeding, a party, including a third party who has intervened pursuant to paragraph (a) of this section, may file a motion requesting a protective order to limit from disclosure to other parties or to the public documents or testimony that contain confidential information. The motion should include a general summary or extract of the documents or testimony without revealing confidential details, and a copy of the proposed protective order. A motion for confidential treatment of documents should be filed in accordance with § 1081.112(f), and all other applicable rules.

(c) *Basis for issuance.* Documents and testimony introduced in a public hearing, or filed in connection with an adjudication proceeding, are presumed to be public. A motion for a protective order shall be granted:

(1) Upon a finding that public disclosure will likely result in a clearly defined, serious injury to the party or third party requesting confidential treatment;

(2) After finding that the material constitutes sensitive personal information, as defined in § 1081.112(e);

(3) If all parties, including third parties to the extent their information is at issue, stipulate to the entry of a protective order; or

(4) Where public disclosure is prohibited by law.

(d) *Requests for additional information supporting confidentiality.* The hearing officer may require a movant under paragraph (b) of this section to furnish in writing additional information with respect to the grounds for confidentiality. Failure to supply the information so requested within five days from the date of receipt by the movant of a notice of the information required shall be deemed a waiver of the objection to public disclosure of that portion of the documents to which the additional information relates, unless the hearing officer shall otherwise order for good cause shown at or before the expiration of such five-day period.

(e) *Confidentiality of documents pending decision.* Pending a determination of a motion under this section, the documents as to which confidential treatment is sought and any other documents that would reveal the confidential information in those documents shall be maintained under seal and shall be disclosed only in accordance with orders of the hearing officer. Any order issued in connection with a motion under this section shall be public unless the order would disclose information as to which a protective order has been granted, in which case that portion of the order that would reveal the protected information shall be nonpublic.

§ 1081.120 Settlement.

(a) *Availability.* Any respondent in an adjudication proceeding instituted under this part, may, at any time, propose in writing an offer of settlement.

(b) *Procedure.* An offer of settlement shall state that it is made pursuant to this section; shall recite or incorporate as a part of the offer the provisions of paragraphs (c)(3) and (4) of this section; shall be signed by the person making the offer, not by counsel; and shall be submitted to enforcement counsel.

(c) *Consideration of offers of settlement.* (1) Offers of settlement shall be considered when time, the nature of the proceedings, and the public interest permit.

(2) Any settlement offer shall be presented to the Director with a recommendation, except that, if the recommendation is unfavorable, the offer shall not be presented to the Director unless the person making the offer so requests.

(3) By submitting an offer of settlement, the person making the offer waives, subject to acceptance of the offer:

(i) All hearings pursuant to the statutory provisions under which the proceeding has been instituted;

(ii) The filing of proposed findings of fact and conclusions of law;

(iii) Proceedings before, and a recommended decision by, a hearing officer;

(iv) All post-hearing procedures;

(v) Judicial review by any court; and

(vi) Any objection to the jurisdiction of the Bureau under section 1053 of the Dodd-Frank Act.

(4) By submitting an offer of settlement the person further waives:

(i) Such provisions of this part or other requirements of law as may be construed to prevent any Bureau employee from participating in the preparation of, or advising the Director as to, any order, opinion, finding of fact, or conclusion of law to be entered pursuant to the offer; and

(ii) Any right to claim bias or prejudgment by the Director based on the consideration of or discussions concerning settlement of all or any part of the proceeding.

(5) If the Director rejects the offer of settlement, the person making the offer shall be notified of the Director's action and the offer of settlement shall be deemed withdrawn. The rejected offer shall not constitute a part of the record in any proceeding against the person making the offer, provided, however, that rejection of an offer of settlement does not affect the continued validity of waivers pursuant to paragraph (c)(4) of this section with respect to any discussions concerning the rejected offer of settlement.

(d) *Consent orders.* If the Director accepts the offer of settlement, all terms and conditions of a settlement entered into under this section shall be recorded in a written stipulation signed by all settling parties, and a consent order concluding the proceeding. The stipulation and consent order shall be filed pursuant to § 1081.111, and shall recite or incorporate as a part of the stipulation the provisions of paragraphs (c)(3) and (4) of this section. The Director will then issue a consent order, which shall be a final order concluding the proceeding.

§ 1081.121 Cooperation with other agencies.

It is the policy of the Bureau to cooperate with other governmental agencies to avoid unnecessary overlap or duplication of regulatory functions.

Subpart B—Initiation of Proceedings and Prehearing Rules

§ 1081.200 Commencement of proceeding and contents of notice of charges.

(a) *Commencement of proceeding.* A proceeding governed by this part is commenced by filing of a notice of charges by the Bureau in accordance with § 1081.111. The notice of charges must be served by the Bureau upon the respondent in accordance with § 1081.113(d)(1).

(b) *Contents of a notice of charges.* The notice of charges must set forth:

(1) The legal authority for the proceeding and for the Bureau's jurisdiction over the proceeding;

(2) A statement of the matters of fact and law showing that the Bureau is entitled to relief;

(3) A proposed order or prayer for an order granting the requested relief;

(4) The time and place of the hearing as required by law or regulation;

(5) The time within which to file an answer as required by law or regulation;

(6) That the answer shall be filed and served in accordance with subpart A of this part; and

(7) The docket number for the adjudication proceeding.

(c) *Publication of notice of charges.* Unless otherwise ordered by the Bureau, the notice of charges shall be given general circulation by release to the public, by publication on the Bureau's Web site and, where directed by the hearing officer or the Director, by publication in the **Federal Register**. The Bureau may publish any notice of charges after ten days from the date of service except if there is a pending motion for a protective order filed pursuant to § 1081.119.

(d) *Commencement of proceeding through a consent order.* Notwithstanding paragraph (a) of this section, where the parties agree to settlement before the filing of a notice of charges, a proceeding may be commenced by filing a stipulation and consent order. The stipulation and consent order shall be filed pursuant to § 1081.111. The stipulation shall contain the information required under § 1081.120(d), and the consent order shall contain the information required under paragraphs (b)(1) through (b)(2) of this section. The proceeding shall be concluded upon issuance of the consent order by the Director.

(e) *Voluntary dismissal.* (1) *Without an order.* The Bureau may voluntarily dismiss an adjudication proceeding without an order entered by a hearing officer by filing either:

(i) A notice of dismissal before the respondent(s) serves an answer; or

(ii) A stipulation of dismissal signed by all parties who have appeared.

(2) *Effect.* Unless the notice or stipulation states otherwise, the dismissal is without prejudice, and does not operate as an adjudication on the merits.

§ 1081.201. Answer and disclosure statement and notification of financial interest.

(a) *Time to file answer.* Within 14 days of service of the notice of charges, respondent shall file an answer as designated in the notice of charges.

(b) *Content of answer.* An answer must specifically respond to each paragraph or allegation of fact contained in the notice of charges and must admit, deny, or state that the party lacks sufficient information to admit or deny each allegation of fact. A statement of lack of information has the effect of a denial. Denials must fairly meet the substance of each allegation of fact denied; general denials are not permitted. When a respondent denies part of an allegation, that part must be denied and the remainder specifically admitted. Any allegation of fact in the notice of charges which is not denied in the answer shall be deemed admitted for purposes of the proceeding. A respondent is not required to respond to the portion of a notice of charges that constitutes the prayer for relief or proposed order. The answer must set forth affirmative defenses, if any, asserted by the respondent.

(c) *If the allegations of the complaint are admitted.* If the respondent elects not to contest the allegations of fact set forth in the notice of charges, the answer shall consist of a statement that the respondent admits all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the notice of charges, and together with the notice of charges will provide a record basis on which the hearing officer shall issue a recommended decision containing appropriate findings and conclusions and a proposed order disposing of the proceeding. In such an answer, the respondent may, however, reserve the right to submit proposed findings of fact and conclusions of law under § 1081.305.

(d) *Default.* (1) Failure of a respondent to file an answer within the time provided shall be deemed to constitute a waiver of the respondent's right to appear and contest the allegations of the notice of charges and to authorize the hearing officer, without further notice to the respondent, to find the facts to be as alleged in the notice of charges and to enter a recommended decision containing appropriate findings and conclusions. In such cases, respondent shall have no right to appeal pursuant to § 1081.402, but must instead proceed pursuant to paragraph (d)(2) of this section.

(2) A motion to set aside a default shall be made within a reasonable time, state the reasons for the failure to appear or defend, and specify the nature of the proposed defense in the proceeding. In order to prevent injustice and on such conditions as may be appropriate, the hearing officer, at any time prior to the filing of the recommended decision, or the Director, at any time, may for good cause shown set aside a default.

(e) *Disclosure statement and notification of financial interest.* (1) *Who must file; contents.* A respondent, nongovernmental intervenor, or nongovernmental amicus must file a disclosure statement and notification of financial interest that:

(i) Identifies any parent corporation, any publicly owned corporation owning ten percent or more of its stock, and any publicly owned corporation not a party to the proceeding that has a financial interest in the outcome of the proceeding and the nature of that interest; or

(ii) States that there are no such corporations.

(2) *Time for filing; supplemental filing.* A respondent, nongovernmental intervenor, or nongovernmental amicus must:

(i) File the disclosure statement with its first appearance, pleading, motion, response, or other request addressed to the hearing officer or the Bureau; and

(ii) Promptly file a supplemental statement if any required information changes.

§ 1081.202 Amended pleadings.

(a) *Amendments before the hearing.* The notice of charges, answer, or any other pleading may be amended or supplemented only with the opposing party's written consent or leave of the hearing officer. The respondent must answer an amended notice of charges within the time remaining for the respondent's answer to the original notice of charges, or within ten days after service of the amended notice of charges, whichever is later, unless the hearing officer orders otherwise for good cause.

(b) *Amendments to conform to the evidence.* When issues not raised in the notice of charges or answer are tried at the hearing by express or implied consent of the parties, they will be treated in all respects as if they had been raised in the notice of charges or answer, and no formal amendments are

required. If evidence is objected to at the hearing on the ground that it is not within the issues raised by the notice of charges or answer, the hearing officer may admit the evidence when admission is likely to assist in adjudicating the merits of the action and the objecting party fails to satisfy the hearing officer that the admission of such evidence would unfairly prejudice that party's action or defense upon the merits. The hearing officer may grant a continuance to enable the objecting party to meet such evidence.

§ 1081.203 Scheduling conference.

(a) *Meeting of the parties before scheduling conference.* As early as practicable before the scheduling conference described in paragraph (b) of this section, counsel for the parties shall meet to discuss the nature and basis of their claims and defenses and the possibilities for a prompt settlement or resolution of the case. The parties shall also discuss and agree, if possible, on the matters set forth in paragraph (b) of this section.

(b) *Scheduling conference.* Within 20 days of service of the notice of charges or such other time as the parties and hearing officer may agree, counsel for all parties shall appear before the hearing officer in person at a specified time and place or by telephone for the purpose of scheduling the course and conduct of the proceeding. This meeting or telephone conference is called a *scheduling conference.* At the scheduling conference, counsel for the parties shall be prepared to address:

(1) Determination of the dates and location of the hearing, including, in proceedings under section 1053(b) of the Dodd-Frank Act, whether the hearing should commence later than 60 days after service of the notice of charges;

(2) Simplification and clarification of the issues;

(3) Amendments to pleadings;

(4) Settlement of any or all issues;

(5) Production of documents as set forth in § 1081.206 and of witness statements as set forth in § 1081.207, and prehearing production of documents in response to subpoenas *duces tecum* as set forth in § 1081.208;

(6) Whether or not the parties intend to move for summary disposition of any or all issues;

(7) Whether the parties intend to seek the deposition of witnesses pursuant to § 1081.209;

(8) A schedule for the exchange of expert reports and the taking of expert depositions, if any; and

(9) Such other matters as may aid in the orderly disposition of the proceeding.

(c) *Transcript.* The hearing officer, in his or her discretion, may require that a scheduling conference be recorded by a court reporter. A transcript of the conference and any materials filed, including orders, becomes part of the record of the proceeding. A party may obtain a copy of the transcript at his or her expense.

(d) *Scheduling order.* At or within five days following the conclusion of the scheduling conference, the hearing officer shall serve on each party an order setting forth the date and location of the hearing and any agreements reached and any procedural determinations made.

(e) *Failure to appear; default.* Any person who is named in a notice of charges as a person against whom findings may be made or sanctions imposed and who fails to appear, in person or through counsel, at a scheduling conference of which he or she has been duly notified may be deemed in default pursuant to § 1081.201(d)(1). A party may make a motion to set aside a default pursuant to § 1081.201(d)(2).

(f) *Public access.* The scheduling conference shall be public unless the hearing officer determines, based on the standard set forth in § 1081.119(c), that the conference (or any part thereof) shall be closed to the public.

§ 1081.204 Consolidation and severance of actions.

(a) *Consolidation.* (1) On the motion of any party, or on the hearing officer's own motion, the hearing officer may consolidate, for some or all purposes, any two or more proceedings, if each such proceeding involves or arises out of the same transaction, occurrence or series of transactions or occurrences, or involves at least one common respondent or a material common question of law or fact, unless such consolidation would cause unreasonable delay or injustice.

(2) In the event of consolidation under paragraph (a)(1) of this section, appropriate adjustment to the prehearing schedule may be made to avoid unnecessary expense, inconvenience, or delay.

(b) *Severance.* The hearing officer may, upon the motion of any party, sever the proceeding for separate resolution of the matter as to any respondent only if the hearing officer finds that:

(1) Undue prejudice or injustice to the moving party would result from not severing the proceeding; and

(2) Such undue prejudice or injustice would outweigh the interests of judicial economy and expedition in the complete and final resolution of the proceeding.

§ 1081.205 Non-dispositive motions.

(a) *Scope.* This section applies to all motions except motions to dismiss and motions for summary disposition. A non-dispositive motion filed pursuant to another section of this part shall comply with any specific requirements of that section and this section to the extent these requirements are not inconsistent.

(b) *In writing.* (1) Unless made during a hearing or conference, an application or request for an order or ruling must be made by written motion.

(2) All written motions must state with particularity the relief sought and must be accompanied by a proposed order.

(3) No oral argument may be held on written motions except as otherwise directed by the hearing officer. Written memoranda, briefs, affidavits or other relevant material or documents may be filed in support of or in opposition to a motion.

(c) *Oral motions.* The Director or the hearing officer, as appropriate, may order that an oral motion be submitted in writing.

(d) *Responses and replies.* (1) Except as otherwise provided herein, within ten days after service of any written motion, or within such other period of time as may be established by the hearing officer or the Director, as appropriate, any party may file a written response to a motion. The hearing officer shall not rule on any oral or written motion before each party has had an opportunity to file a response.

(2) Reply briefs, if any, may be filed within three days after service of the response.

(3) The failure of a party to oppose a written motion or an oral motion made on the record is deemed consent by that party to the entry of an order substantially in the form of the order accompanying the motion.

(e) *Length limitations.* No motion subject to this section (together with the brief in support of the motion) or brief in response to the motion shall exceed 15 pages in length, exclusive of pages containing the table of contents, table of authorities, and any addendum that consists solely of copies of applicable cases, pertinent legislative provisions or rules, and exhibits. No reply brief shall exceed six pages in length, exclusive of pages containing the table of contents, table of authorities, and any addendum that consists solely of copies of applicable cases, pertinent legislative

provisions or rules, and exhibits. Motions for leave to file motions and briefs in excess of these limitations are disfavored.

(f) *Meet and confer requirements.* Each motion filed under this section shall be accompanied by a signed statement representing that counsel for the moving party has conferred or made a good faith effort to confer with opposing counsel in a good faith effort to resolve by agreement the issues raised by the motion and has been unable to reach such an agreement. If some of the matters in controversy have been resolved by agreement, the statement shall specify the matters so resolved and the matters remaining unresolved.

(g) *Ruling on non-dispositive motions.* Unless otherwise provided by a relevant section of this part, a hearing officer shall rule on non-dispositive motions. Such ruling shall be issued within 14 days after the expiration of the time period allowed for the filing of all motion papers authorized by this section. The Director, for good cause, may extend the time allowed for a ruling.

(h) *Proceedings not stayed.* A motion under consideration by the Director or the hearing officer shall not stay proceedings before the hearing officer unless the Director or the hearing officer, as appropriate, so orders.

(i) *Dilatory motions.* Frivolous, dilatory, or repetitive motions are prohibited. The filing of such motions may form the basis for sanctions.

§ 1081.206 Availability of documents for inspection and copying.

For purposes of this section, the term *documents* shall include any book, document, record, report, memorandum, paper, communication, tabulation, chart, logs, electronic files, or other data or data compilations stored in any medium.

(a) *Documents to be available for inspection and copying.* (1) Unless otherwise provided by this section, or by order of the hearing officer, the Office of Enforcement shall make available for inspection and copying by any respondent documents obtained by the Office of Enforcement prior to the institution of proceedings, from persons not employed by the Bureau, in connection with the investigation leading to the institution of proceedings. Such documents shall include:

(i) Any documents turned over in response to civil investigative demands or other written requests to provide documents or to be interviewed issued by the Office of Enforcement;

(ii) All transcripts and transcript exhibits; and

(iii) Any other documents obtained from persons not employed by the Bureau.

(2) In addition, the Office of Enforcement shall make available for inspection and copying by any respondent:

(i) Each civil investigative demand or other written request to provide documents or to be interviewed issued by the Office of Enforcement in connection with the investigation leading to the institution of proceedings; and

(ii) Any final examination or inspection reports prepared by any other Office of the Bureau if the Office of Enforcement either intends to introduce any such report into evidence or to use any such report to refresh the recollection of, or impeach, any witness.

(3) Nothing in paragraph (a) of this section shall limit the right of the Office of Enforcement to make available any other document, or shall limit the right of a respondent to seek access to or production pursuant to subpoena of any other document, or shall limit the authority of the hearing officer to order the production of any document pursuant to subpoena.

(4) Nothing in paragraph (a) of this section shall require the Office of Enforcement to produce a final examination or inspection report prepared by any other Office of the Bureau or any other government agency to a respondent who is not the subject of that report.

(b) *Documents that may be withheld.* (1) The Office of Enforcement may withhold a document if:

(i) The document is privileged;

(ii) The document is an internal memorandum, note or writing prepared by a person employed by the Bureau or another government agency, other than an examination or supervision report as specified in paragraph (a)(2)(ii) of this section, or would otherwise be subject to the work product doctrine and will not be offered in evidence;

(iii) The document was obtained from a domestic or foreign governmental entity and is either not relevant to the resolution of the proceeding or was provided on condition that the information not be disclosed;

(iv) The document would disclose the identity of a confidential source;

(v) Applicable law prohibits the disclosure of the document; or

(vi) The hearing officer grants leave to withhold a document or category of documents as not relevant to the subject matter of the proceeding or otherwise, for good cause shown.

(2) Nothing in paragraph (b)(1) of this section authorizes the Office of Enforcement in connection with an adjudication proceeding to withhold material exculpatory evidence in the possession of the Office that would otherwise be required to be produced pursuant to paragraph (a) of this section.

(c) *Withheld document list.* The hearing officer may require the Office of Enforcement to produce a list of documents or categories of documents withheld pursuant to paragraphs (b)(1)(i) through (v) of this section or to submit to the hearing officer any document withheld, except for any documents that are being withheld pursuant to section (b)(1)(iii), in which case the Office of Enforcement shall inform the other parties of the fact that such documents are being withheld, but no further disclosures regarding those documents shall be required. The hearing officer may determine whether any withheld document should be made available for inspection and copying. When similar documents are withheld pursuant to paragraphs (b)(1)(i) through (v) of this section, those documents may be identified by category instead of by individual document. The hearing officer retains discretion to determine when an identification by category is insufficient.

(d) *Timing of inspection and copying.* Unless otherwise ordered by the hearing officer, the Office of Enforcement shall commence making documents available to a respondent for inspection and copying pursuant to this section no later than seven days after service of the notice of charges.

(e) *Place of inspection and copying.* Documents subject to inspection and copying pursuant to this section shall be made available to the respondent for inspection and copying at the Bureau office where they are ordinarily maintained, or at such other place as the parties, in writing, may agree. A respondent shall not be given custody of the documents or leave to remove the documents from the Bureau's offices pursuant to the requirements of this section other than by written agreement of the Office of Enforcement. Such agreement shall specify the documents subject to the agreement, the date they shall be returned and such other terms or conditions as are appropriate to provide for the safekeeping of the documents.

(f) *Copying costs and procedures.* The respondent may obtain a photocopy of any documents made available for inspection or, at the discretion of the Office of Enforcement, electronic copies of such documents. The respondent shall be responsible for the cost of photocopying. Unless otherwise ordered, charges for copies made by the

Office of Enforcement at the request of the respondent will be at the rate charged pursuant to part 1070. The respondent shall be given access to the documents at the Bureau's offices or such other place as the parties may agree during normal business hours for copying of documents at the respondent's expense.

(g) *Duty to supplement.* If the Office of Enforcement acquires information that it intends to rely upon at a hearing after making its disclosures under paragraph (a)(1) of this section, the Office of Enforcement shall supplement its disclosures to include such information.

(h) *Failure to make documents available—harmless error.* In the event that a document required to be made available to a respondent pursuant to this section is not made available by the Office of Enforcement, no rehearing or redecision of a proceeding already heard or decided shall be required unless the respondent establishes that the failure to make the document available was not harmless error.

(i) *Disclosure of privileged or protected information or communications; scope of waiver; obligations of receiving party.* (1) The disclosure of privileged or protected information or communications by any party during an adjudication proceeding shall not operate as a waiver if:

(i) The disclosure was inadvertent;

(ii) The holder of the privilege or protection took reasonable steps to prevent disclosure; and

(iii) The holder promptly took reasonable steps to rectify the error, including notifying any party that received the information or communication of the claim and the basis for it.

(2) After being notified, the receiving party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the hearing officer under seal for a determination of the claim. The producing party must preserve the information until the claim is resolved.

(3) The disclosure of privileged or protected information or communications by any party during an adjudication proceeding shall waive the privilege or protection, with respect to other parties to the proceeding, as to undisclosed information or communications only if:

(i) The waiver is intentional;

(ii) The disclosed and undisclosed information or communications concern the same subject matter; and

(iii) They ought in fairness to be considered together.

§ 1081.207 Production of witness statements.

(a) *Availability.* Any respondent may move that the Office of Enforcement produce for inspection and copying any statement of any person called or to be called as a witness by the Office of Enforcement that pertains, or is expected to pertain, to his or her direct testimony and that would be required to be produced pursuant to the Jencks Act, 18 U.S.C. 3500, if the adjudication proceeding were a criminal proceeding. For purposes of this section, the term ''statement'' shall have the meaning set forth in 18 U.S.C. 3500(e). Such production shall be made at a time and place fixed by the hearing officer and shall be made available to any party, provided, however, that the production shall be made under conditions intended to preserve the items to be inspected or copied.

(b) *Failure to produce—harmless error.* In the event that a statement required to be made available to a respondent pursuant to this section is not made available by the Office of Enforcement, no rehearing or redecision of a proceeding already heard or decided shall be required unless the respondent establishes that the failure to make the statement available was not harmless error.

§ 1081.208 Subpoenas.

(a) *Availability.* In connection with any hearing ordered by the hearing officer, a party may request the issuance of one or more subpoenas requiring the attendance and testimony of witnesses at the designated time and place of the hearing, or the production of documentary or other tangible evidence returnable at any designated time or place.

(b) *Procedure.* Unless made on the record at a hearing, requests for issuance of a subpoena shall be made in writing, and filed and served on each party pursuant to subpart A of this part. The request must contain a proposed subpoena and a brief statement showing the general relevance and reasonableness of the scope of testimony or documents sought.

(c) *Signing may be delegated.* A hearing officer may authorize issuance of a subpoena, and may delegate the manual signing of the subpoena to any other person.

(d) *Standards for issuance.* The hearing officer shall promptly issue any subpoena requested pursuant to this section. However, where it appears to the hearing officer that the subpoena sought may be unreasonable, oppressive, excessive in scope, or unduly burdensome, he or she may, in his or her discretion, as a condition precedent to the issuance of the subpoena, require the person seeking the subpoena to show further the general relevance and reasonable scope of the testimony or other evidence sought. If after consideration of all the circumstances, the hearing officer determines that the subpoena or any of its terms is unreasonable, oppressive, excessive in scope, or unduly burdensome, he or she may refuse to issue the subpoena, or issue it only upon such conditions as fairness requires. In making the foregoing determination, the hearing officer may inquire of the other participants whether they will stipulate to the facts sought to be proved.

(e) *Service.* Upon issuance by the hearing officer, the party making the request shall serve the subpoena on the person named in the subpoena and on each party in accordance with § 1081.113(c). Subpoenas may be served in any State, territory, possession of the United States, or the District of Columbia, on any person or company doing business in any State, territory, possession of the United States, or the District of Columbia, or as otherwise permitted by law.

(f) *Tender of fees required.* When a subpoena compelling the attendance of a person at a hearing is issued at the request of anyone other than an officer or agency of the United States, service is valid only if the subpoena is accompanied by a tender to the subpoenaed person of the fees for one day's attendance and mileage specified by § 1081.116.

(g) *Production of documentary material.* Production of documentary material in response to a subpoena shall be made under a sworn certificate, in such form as the subpoena designates, by the person to whom the subpoena is directed or, if not a natural person, by any person having knowledge of the facts and circumstances relating to such production, to the effect that all of the documentary material required by the subpoena and in the possession, custody, or control of the person to whom the subpoena is directed has been produced and made available to the custodian.

(h) *Motion to quash or modify.* (1) *Procedure.* Any person to whom a subpoena is directed, or who is an owner, creator, or the subject of the documents that are to be produced

pursuant to a subpoena, or any party may, prior to the time specified therein for compliance, but in no event more than ten days after the date of service of such subpoena, move that the subpoena be quashed or modified. Such motion shall be filed and served on all parties pursuant to subpart A of this part. Notwithstanding § 1081.205, the party on whose behalf the subpoena was issued or enforcement counsel may, within five days of service of the motion, file a response to the motion. Reply briefs are not permitted unless requested by the hearing officer. Filing a motion to modify a subpoena does not stay the movant's obligation to comply with those portions of the subpoena that the person has not sought to modify.

(2) *Standards governing motion to quash or modify.* If compliance with the subpoena would be unreasonable, oppressive, or unduly burdensome, the hearing officer shall quash or modify the subpoena, or may order return of the subpoena only upon specified conditions. These conditions may include but are not limited to a requirement that the party on whose behalf the subpoena was issued shall make reasonable compensation to the person to whom the subpoena was addressed for the cost of copying or transporting evidence to the place for return of the subpoena.

(i) *Enforcing subpoenas.* If a subpoenaed person fails to comply with any subpoena issued pursuant to this section or any order of the hearing officer which directs compliance with all or any portion of a subpoena, the Bureau's General Counsel may, on its own motion or at the request of the party on whose behalf the subpoena was issued, apply to an appropriate United States district court, in the name of the Bureau but on relation of such party, for an order requiring compliance with so much of the subpoena as the hearing officer has not quashed or modified, unless, in the judgment of the General Counsel, the enforcement of such subpoena would be inconsistent with law and the policies of Title X of the Dodd-Frank Act. Failure to request that the Bureau's General Counsel seek enforcement of a subpoena constitutes a waiver of any claim of prejudice predicated upon the unavailability of the testimony or evidence sought.

§ 1081.209 Deposition of witness unavailable for hearing.

(a) *General rules.* (1) If a witness will not be available for the hearing, a party desiring to preserve that witness's testimony for the record may request in accordance with the procedures set forth in this section that the hearing officer issue a subpoena, including a subpoena *duces tecum,* requiring the attendance of the witness at a deposition. The hearing officer may issue a deposition subpoena under this section upon a showing that:

(i) The witness will be unable to attend or may be prevented from attending the hearing because of age, sickness, or infirmity, or will otherwise be unavailable;

(ii) The witness's unavailability was not procured or caused by the subpoenaing party;

(iii) The testimony is reasonably expected to be material; and

(iv) Taking the deposition will not result in any undue burden to any other party and will not cause undue delay of the proceeding.

(2) In addition to making a showing as required by paragraph (a)(1) of this section, the request for a deposition subpoena must contain a proposed deposition subpoena and a brief statement showing the general relevance and reasonableness of the scope of testimony and documents sought, and the time and place for taking the deposition. Any request to record the deposition by audio-visual means must be made in the request for a deposition subpoena.

(3) Any requested deposition subpoena that sets forth a valid basis for its issuance must be promptly issued, unless the hearing officer on his or her own motion requires a written response or requires attendance at a conference concerning whether the requested subpoena should be issued. However, where it appears to the hearing officer that the deposition subpoena sought may be unreasonable, oppressive, excessive in scope, or unduly burdensome, he or she may, in his or her discretion, as a condition precedent to the issuance of the deposition subpoena, require the person seeking the deposition subpoena to show further the general relevance and reasonable scope of the testimony or other evidence sought. If after consideration of all the circumstances, the hearing officer determines that the deposition subpoena or any of its terms is unreasonable, oppressive, excessive in scope, or unduly burdensome, he or she may refuse to issue the deposition subpoena, or issue it only upon such conditions as fairness requires. In making the foregoing determination, the hearing officer may inquire of the other participants whether they will stipulate to the facts sought to be proved.

(4) Unless the hearing officer orders otherwise, no deposition under this section shall be taken on fewer than 14 days' notice to the witness and all parties.

(b) *Procedure.* Unless made on the record at a hearing, requests for issuance of a deposition subpoena shall be made in writing, and filed and served on each party pursuant to subpart A of this part.

(c) *Signing may be delegated.* A hearing officer may authorize issuance of a deposition subpoena, and may delegate the manual signing of the deposition subpoena to any other person.

(d) *Service.* Upon issuance by the hearing officer, the party making the request shall serve the subpoena on the person named in the subpoena and on each party in accordance with § 1081.113(c). Deposition subpoenas may be served in any State, territory, possession of the United States, or the District of Columbia, on any person or company doing business in any State, territory, possession of the United States, or the District of Columbia, or as otherwise permitted by law.

(e) *Tender of fees required.* When a subpoena compelling the attendance of a person at a deposition is issued at the request of anyone other than an officer or agency of the United States, service is valid only if the subpoena is accompanied by a tender to the subpoenaed person of the fees for one day's attendance and mileage specified by § 1081.116.

(f) *Motion to quash or modify.* (1) *Procedure.* Any person to whom a deposition subpoena is directed, or who is an owner, creator, or the subject of the documents that are to be produced pursuant to a deposition subpoena, or any party may, prior to the time specified therein for compliance, but in no event more than ten days after the date of service of such subpoena, move that the deposition subpoena be quashed or modified. Such motion must include a statement of the basis for the motion to quash or modify the deposition subpoena, and shall be filed and served on all parties pursuant to subpart A of this part. Notwithstanding § 1081.205, the party on whose behalf the deposition subpoena was issued or enforcement counsel may, within five days of service of the motion, file a response to the motion. Reply briefs are not permitted unless requested by the hearing officer.

(2) *Standards governing motion to quash or modify.* If compliance with the deposition subpoena would be unreasonable, oppressive or unduly burdensome, or the deposition subpoena does not meet the requirements set forth in paragraph (a)(1) of this section, the hearing officer shall quash or modify the deposition

subpoena, or may order return of the deposition subpoena only upon specified conditions. These conditions may include but are not limited to a requirement that the party on whose behalf the deposition subpoena was issued shall make reasonable compensation to the person to whom the deposition subpoena was addressed for the cost of copying or transporting evidence to the place for return of the deposition subpoena.

(g) *Procedure upon deposition.* (1) Depositions shall be taken before any person before whom a deposition may be taken pursuant to the Federal Rules of Civil Procedure (the ''deposition officer'').

(2) The witness being deposed may have an attorney present during the deposition.

(3) Each witness testifying pursuant to a deposition subpoena must be duly sworn, and each party shall have the right to examine the witness. Objections to questions or documents must be in short form, stating the grounds for the objection. Objections to questions of evidence shall be noted by the deposition officer upon the deposition, but a deposition officer other than the hearing officer shall not have the power to decide on the competency, materiality, or relevance of evidence. Failure to object to questions or documents is not deemed a waiver except where the ground for the objection might have been avoided if the objection had been timely presented. All questions, answers, and objections must be recorded.

(4) The deposition must be subscribed by the witness, unless the parties and the witness, by stipulation, have waived the signing, or the witness is ill, cannot be found, or has refused to sign. If the deposition is not subscribed by the witness, the court reporter taking the deposition shall certify that the transcript is a true and complete transcript of the deposition.

(5) The original deposition transcript and exhibits shall be filed with the Office of Administrative Adjudication. The cost of the transcript shall be paid by the party requesting the deposition. A copy of the deposition shall be available to the deponent and each party for purchase at prescribed rates.

(h) *Enforcing subpoenas.* Any party may move before the hearing officer for an order compelling the witness to answer any questions the witness has refused to answer or submit any evidence the witness has refused to submit during the deposition. If a subpoenaed person fails to comply with any order of the hearing officer which directs compliance with all or any portion of a deposition subpoena under this section, the Bureau's General Counsel may, on its own motion or at the request of the party on whose behalf the subpoena was issued, apply to an appropriate United States district court, in the name of the Bureau but on relation of such party, for an order requiring compliance with so much of the subpoena as the hearing officer has not quashed or modified, unless, in the judgment of the General Counsel, the enforcement of such subpoena would be inconsistent with law and the policies of Title X of the Dodd-Frank Act. Failure to request that the Bureau seek enforcement of a subpoena constitutes a waiver of any claim of prejudice predicated upon the unavailability of the testimony or evidence sought.

§ 1081.210 Expert discovery.

(a) At a date set by the hearing officer at the scheduling conference, each party shall serve the other with a report prepared by each of its expert witnesses. Each party shall serve the other parties with a list of any rebuttal expert witnesses and a rebuttal report prepared by each such witness not later than 28 days after the deadline for service of expert reports, unless another date is set by the hearing officer. A rebuttal report shall be limited to rebuttal of matters set forth in the expert report for which it is offered in rebuttal. If material outside the scope of fair rebuttal is presented, a party may file a motion not later than five days after the deadline for service of rebuttal reports, seeking appropriate relief with the hearing officer, including striking all or part of the report, leave to submit a surrebuttal report by the party's own experts, or leave to call a surrebuttal witness and to submit a surrebuttal report by that witness.

(b) No party may call an expert witness at the hearing unless he or she has been listed and has provided reports as required by this section, unless otherwise directed by the hearing officer at a scheduling conference. Each side will be limited to calling at the hearing five expert witnesses, including any rebuttal or surrebuttal expert witnesses. A party may file a motion seeking leave to call additional expert witnesses due to extraordinary circumstances.

(c) Each report shall be signed by the expert and contain a complete statement of all opinions to be expressed and the basis and reasons therefore; the data, materials, or other information considered by the witness in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the witness, including a list of all publications authored or co-authored by the witness within the preceding ten years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified or sought to testify as an expert at trial or hearing, or by deposition within the preceding four years. A rebuttal or surrebuttal report need not include any information already included in the initial report of the witness.

(d) A party may depose any person who has been identified as an expert whose opinions may be presented at trial. Unless otherwise ordered by the hearing officer, a deposition of any expert witness shall be conducted after the disclosure of a report prepared by the witness in accordance with paragraph (a) of this section, and at least seven days prior to the deadline for submission of rebuttal expert reports. A deposition of an expert witness shall be completed no later than 14 days before the hearing unless otherwise ordered by the hearing officer. No expert deposition shall exceed eight hours on the record, absent agreement of the parties or an order of the hearing officer for good cause shown. Expert depositions shall be conducted pursuant to the procedures set forth in § 1081.209(g).

(e) A party may not discover facts known or opinions held by an expert who has been retained or specifically employed by another party in anticipation of litigation or preparation for the hearing and who is not listed as a witness for the hearing. A party may not discover drafts of any report required by this section, regardless of the form in which the draft is recorded, or any communications between another party's attorney and any of that other party's experts, regardless of the form of the communications, except to the extent that the communications:

(1) Relate to compensation for the testifying expert's study or testimony;

(2) Identify facts or data that the other party's attorney provided and that the testifying expert considered in forming the opinions to be expressed; or

(3) Identify assumptions that the other party's attorney provided and that the testifying expert relied on in forming the opinions to be expressed.

(f) The hearing officer shall have the discretion to dispense with the requirement of expert discovery in appropriate cases.

§ 1081.211 Interlocutory review.

(a) *Availability.* The Director may, at any time, direct that any matter be submitted to him or her for review. Subject to paragraph (c) of this section, the hearing officer may, on his or her own motion or on the motion of any

party, certify any matter for interlocutory review by the Director. This section is the exclusive remedy for review of a hearing officer's ruling or order prior to the Director's consideration of the entire proceeding.

(b) *Procedure.* Any party's motion for certification of a ruling or order for interlocutory review shall be filed with the hearing officer within five days of service of the ruling or order, shall specify the ruling or order or parts thereof for which interlocutory review is sought, shall attach any other portions of the record on which the moving party relies, and shall otherwise comply with § 1081.205. Notwithstanding § 1081.205, any response to such a motion must be filed within three days of service of the motion. The hearing officer shall issue a ruling on the motion within five days of the deadline for filing a response.

(c) *Certification process.* Unless the Director directs otherwise, a ruling or order may not be submitted to the Director for interlocutory review unless the hearing officer, upon the hearing officer's motion or upon the motion of a party, certifies the ruling or order in writing. The hearing officer shall not certify a ruling or order unless:

(1) The ruling or order would compel testimony of Bureau officers or employees, or those from another governmental agency, or the production of documentary evidence in the custody of the Bureau or another governmental agency;

(2) The ruling or order involves a motion for disqualification of the hearing officer pursuant to § 1081.105(c)(2);

(3) The ruling or order suspended or barred an individual from appearing before the Bureau pursuant to § 1081.107(c); or

(4) Upon motion by a party, the hearing officer is of the opinion that:

(i) The ruling or order involves a controlling question of law as to which there is substantial ground for difference of opinion; and

(ii) An immediate review of the ruling or order is likely to materially advance the completion of the proceeding or subsequent review will be an inadequate remedy.

(d) *Interlocutory review.* A party whose motion for certification has been denied by the hearing officer may petition the Director for interlocutory review.

(e) *Director review.* The Director shall determine whether or not to review a ruling or order certified under this section or the subject of a petition for interlocutory review. Interlocutory review is disfavored, and the Director will grant a petition to review a hearing officer's ruling or order prior to his or her consideration of a recommended decision only in extraordinary circumstances. The Director may decline to review a ruling or order certified by a hearing officer pursuant to paragraph (c) of this section or the petition of a party who has been denied certification if he or she determines that interlocutory review is not warranted or appropriate under the circumstances, in which case he or she may summarily deny the petition. If the Director determines to grant the review, he or she will review the matter and issue his or her ruling and order in an expeditious fashion, consistent with the Bureau's other responsibilities.

(f) *Proceedings not stayed.* The filing of a motion requesting that the hearing officer certify any of his or her prior rulings or orders for interlocutory review or a petition for interlocutory review filed with the Director, and the grant of any such review, shall not stay proceedings before the hearing officer unless he or she, or the Director, shall so order. The Director will not consider a motion for a stay unless the motion shall have first been made to the hearing officer.

§ 1081.212 Dispositive motions.

(a) *Dispositive motions.* This section governs the filing of motions to dismiss and motions for summary disposition. The filing of any such motion does not obviate a party's obligation to file an answer or take any other action required by this part or by an order of the hearing officer, unless expressly so provided by the hearing officer.

(b) *Motions to dismiss.* A respondent may file a motion to dismiss asserting that, even assuming the truth of the facts alleged in the notice of charges, it is entitled to dismissal as a matter of law.

(c) *Motion for summary disposition.* A party may make a motion for summary disposition asserting that the undisputed pleaded facts, admissions, affidavits, stipulations, documentary evidence, matters as to which official notice may be taken, and any other evidentiary materials properly submitted in connection with a motion for summary disposition show that:

(1) There is no genuine issue as to any material fact; and

(2) The moving party is entitled to a decision in its favor as a matter of law.

(d) *Filing of motions for summary disposition and responses.* (1) After a respondent's answer has been filed and documents have been made available to the respondent for inspection and copying pursuant to § 1081.206, any party may move for summary disposition in its favor of all or any part of the proceeding.

(2) A motion for summary disposition must be accompanied by a statement of the material facts as to which the moving party contends there is no genuine issue. Such motion must be supported by documentary evidence, which may take the form of admissions in pleadings, stipulations, depositions, investigatory depositions, transcripts, affidavits and any other evidentiary materials that the moving party contends support his or her position. The motion must also be accompanied by a brief containing the points and authorities in support of the contention of the moving party. Any party opposing a motion for summary disposition must file a statement setting forth those material facts as to which he or she contends a genuine dispute exists. Such opposition must be supported by evidence of the same type as may be submitted in support of a motion for summary disposition and a brief containing the points and authorities in support of the contention that summary disposition would be inappropriate.

(3) Any affidavit or declaration submitted in support of or in opposition to a motion for summary disposition shall set forth such facts as would be admissible in evidence, shall show affirmatively that the affiant is competent to testify to the matters stated therein, and must be signed under oath and penalty of perjury.

(e) *Page limitations for dispositive motions.* A motion to dismiss or for summary disposition, together with any brief in support of the motion (exclusive of any declarations, affidavits, or attachments) shall not exceed 35 pages in length. Motions for extensions of this length limitation are disfavored.

(f) *Opposition and reply response time and page limitation.* Any party, within 20 days after service of a dispositive motion, or within such time period as allowed by the hearing officer, may file a response to such motion. The length limitations set forth in paragraph (e) of this section shall also apply to such responses. Any reply brief filed in response to an opposition to a dispositive motion shall be filed within five days after service of the opposition. Reply briefs shall not exceed ten pages.

(g) *Oral argument.* At the request of any party or on his or her own motion, the hearing officer may hear oral argument on a dispositive motion.

(h) *Decision on motion.* Within 30 days following the expiration of the time for filing all responses and replies to any dispositive motion, the hearing officer shall determine whether the motion shall be granted. If the hearing

officer determines that dismissal or summary disposition is warranted, he or she shall issue a recommended decision granting the motion. If the hearing officer finds that no party is entitled to dismissal or summary disposition, he or she shall make a ruling denying the motion. If it appears that a party, for good cause shown, cannot present by affidavit, prior to hearing, facts essential to justify opposition to the motion, the hearing officer shall deny or defer the motion.

§ 1081.213 Partial summary disposition.

If on a motion for summary disposition under § 1081.212 a decision is not rendered upon the whole case or for all the relief asked and a hearing is necessary, the hearing officer shall issue an order specifying the facts that appear without substantial controversy and directing further proceedings in the action. The facts so specified shall be deemed established.

§ 1081.214 Prehearing conferences.

(a) *Prehearing conferences.* The hearing officer may, in addition to the scheduling conference, on his or her own motion or at the request of any party, direct counsel for the parties to meet with him or her (in person or by telephone) at a prehearing conference for further discussion of the issues outlined in § 1081.203, or for discussion of any additional matters that in the view of the hearing officer will aid in an orderly disposition of the proceeding, including but not limited to:

(1) Identification of potential witnesses and limitation on the number of witnesses;

(2) The exchange of any prehearing materials including witness lists, statements of issues, exhibits, and any other materials;

(3) Stipulations, admissions of fact, and the contents, authenticity, and admissibility into evidence of documents;

(4) Matters of which official notice may be taken; and

(5) Whether the parties intend to introduce prior sworn statements of witnesses as set forth in § 1081.303(h).

(b) *Transcript.* The hearing officer, in his or her discretion, may require that a prehearing conference be recorded by a court reporter. A transcript of the conference and any materials filed, including orders, becomes part of the record of the proceeding. A party may obtain a copy of the transcript at his or her expense.

(c) *Public access.* Any prehearing conferences shall be public unless the hearing officer determines, based on the standard set forth in § 1081.119(c), that the conference (or any part thereof) shall be closed to the public.

§ 1081.215 Prehearing submissions.

(a) Within the time set by the hearing officer, but in no case later than ten days before the start of the hearing, each party shall serve on every other party:

(1) A prehearing statement, which shall include an outline or narrative summary of its case or defense, and the legal theories upon which it will rely;

(2) A final list of witnesses to be called to testify at the hearing, including the name and address of each witness and a short summary of the expected testimony of each witness;

(3) Any prior sworn statements that a party intends to admit into evidence pursuant to § 1081.303(h);

(4) A list of the exhibits to be introduced at the hearing along with a copy of each exhibit; and

(5) Any stipulations of fact or liability.

(b) *Expert witnesses.* Each party who intends to call an expert witness shall also serve, in addition to the information required by paragraph (a)(2) of this section, a statement of the expert's qualifications, a listing of other proceedings in which the expert has given or sought to give expert testimony at trial or hearing or by deposition within the preceding four years, and a list of publications authored or co-authored by the expert within the preceding ten years, to the extent such information has not already been provided pursuant to § 1081.210.

(c) *Effect of failure to comply.* No witness may testify and no exhibits may be introduced at the hearing if such witness or exhibit is not listed in the prehearing submissions pursuant to paragraph (a) of this section, except for good cause shown.

§ 1081.216 Amicus participation.

(a) *Availability.* An amicus brief may be filed only if:

(1) A motion for leave to file the brief has been granted;

(2) The brief is accompanied by written consent of all parties;

(3) The brief is filed at the request of the Director or the hearing officer, as appropriate; or

(4) The brief is presented by the United States or an officer or agency thereof, or by a State or a political subdivision thereof.

(b) *Procedure.* An amicus brief may be filed conditionally with the motion for leave. The motion for leave shall identify the interest of the movant and shall state the reasons why a brief of an amicus curiae is desirable. Except as all parties otherwise consent, any amicus curiae shall file its brief within the time allowed the party whose position the amicus will support, unless the Director or hearing officer, as appropriate, for good cause shown, grants leave for a later filing. In the event that a later filing is allowed, the order granting leave to file shall specify when an opposing party may reply to the brief.

(c) *Motions.* A motion for leave to file an amicus brief shall be subject to § 1081.205.

(d) *Formal requirements as to amicus briefs.* Amicus briefs shall be filed pursuant to § 1081.111 and shall comply with the requirements of § 1081.112 and shall be subject to the length limitation set forth in § 1081.212(e).

(e) *Oral argument.* An amicus curiae may move to present oral argument at any hearing before the hearing officer, but such motions will be granted only for extraordinary reasons.

Subpart C—Hearings

§ 1081.300 Public hearings.

All hearings in adjudication proceedings shall be public unless a confidentiality order is entered by the hearing officer pursuant to § 1081.119 or unless otherwise ordered by the Director on the grounds that holding an open hearing would be contrary to the public interest.

§ 1081.301 Failure to appear.

Failure of a respondent to appear in person or by a duly authorized counsel at the hearing constitutes a waiver of respondent's right to a hearing and may be deemed an admission of the facts as alleged and consent to the relief sought in the notice of charges. Without further proceedings or notice to the respondent, the hearing officer shall file a recommended decision containing findings of fact and addressing the relief sought in the notice of charges.

§ 1081.302 Conduct of hearings.

All hearings shall be conducted in a fair, impartial, expeditious, and orderly manner. Enforcement counsel shall present its case-in-chief first, unless otherwise ordered by the hearing officer, or unless otherwise expressly specified by law or regulation. Enforcement counsel shall be the first party to present an opening statement and a closing statement, and may make a rebuttal statement after the respondent's closing statement. If there are multiple respondents, respondents may agree among themselves as to their order of presentation of their cases, but if they do not agree, the hearing officer shall fix the order.

§ 1081.303 Evidence.

(a) *Burden of proof.* Enforcement counsel shall have the burden of proof of the ultimate issue(s) of the Bureau's claims at the hearing.

(b) *Admissibility.* (1) Except as is otherwise set forth in this section, relevant, material, and reliable evidence that is not unduly repetitive is admissible to the fullest extent authorized by the Administrative Procedure Act and other applicable law. Irrelevant, immaterial, and unreliable evidence shall be excluded.

(2) Evidence, even if relevant, may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice or confusion of the issues; if the evidence would be misleading; or based on considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

(3) Evidence that constitutes hearsay may be admitted if it is relevant, material, and bears satisfactory indicia of reliability so that its use is fair. Hearsay is a statement, other than one made by the declarant while testifying at the hearing, offered in evidence to prove the truth of the matter asserted. If otherwise meeting the standards for admissibility described in this section, transcripts of depositions, investigational hearings, prior testimony in Bureau or other proceedings, and any other form of hearsay shall be admissible and shall not be excluded solely on the ground that they are or contain hearsay.

(4) Evidence that would be admissible under the Federal Rules of Evidence is admissible in a proceeding conducted pursuant to this part. Evidence that would be inadmissible under the Federal Rules of Evidence may not be deemed or ruled to be inadmissible in a proceeding conducted pursuant to this part solely on that basis.

(c) *Official notice.* Official notice may be taken of any material fact that is not subject to reasonable dispute in that it is either generally known or capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. If official notice is requested or is taken of a material fact not appearing in the evidence in the record, the parties, upon timely request, shall be afforded an opportunity to disprove such noticed fact.

(d) *Documents.* (1) A duplicate copy of a document is admissible to the same extent as the original, unless a genuine issue is raised as to whether the copy is in some material respect not a true and legible copy of the original.

(2) Subject to the requirements of paragraph (b) of this section, any document, including a report of examination, supervisory activity, inspection or visitation, prepared by the Bureau, a prudential regulator, as that term is defined in section 1002(24) of the Dodd-Frank Act, or by a State regulatory agency, is presumptively admissible either with or without a sponsoring witness.

(3) Witnesses may use existing or newly created charts, exhibits, calendars, calculations, outlines or other graphic material to summarize, illustrate, or simplify the presentation of testimony. Such materials may, subject to the hearing officer's discretion, be used with or without being admitted into evidence.

(4) As respondents are in the best position to determine the nature of documents generated by such respondents and which come from their own files, the burden of proof is on the respondent to introduce evidence to rebut a presumption that such documents are authentic and kept in the regular course of business.

(e) *Objections.* (1) Objections to the admissibility of evidence must be timely made and rulings on all objections must appear on the record.

(2) Whenever evidence is excluded from the record, the party offering such evidence may make an offer of proof, which shall be included in the record. Rejected exhibits, adequately marked for identification, shall be retained pursuant to § 1081.306(b) so as to be available for consideration by any reviewing authority.

(3) Failure to object to admission of evidence or to any ruling constitutes a waiver of the objection.

(f) *Stipulations.* (1) The parties may, at any stage of the proceeding, stipulate as to any relevant matters of fact or the authentication of any relevant documents. Such stipulations must be received in evidence at a hearing and are binding on the parties with respect to the matters therein stipulated.

(2) Unless the hearing officer directs otherwise, all stipulations of fact and law previously agreed upon by the parties, and all documents, the admissibility of which have been previously stipulated, will be admitted into evidence upon commencement of the hearing.

(g) *Presentation of evidence.* (1) A witness at a hearing for the purpose of taking evidence shall testify under oath or affirmation.

(2) A party is entitled to present its case or defense by sworn oral testimony and documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as, in the discretion of the hearing officer, may be required for a full and true disclosure of the facts.

(3) An adverse party, or an officer, agent, or employee thereof, and any witness who appears to be hostile, unwilling, or evasive, may be interrogated by leading questions and may also be contradicted and impeached by the party calling him or her.

(4) The hearing officer shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(i) Make the interrogation and presentation effective for the ascertainment of the truth;

(ii) Avoid needless consumption of time; and

(iii) Protect witnesses from harassment or undue embarrassment.

(5) The hearing officer may permit a witness to appear at a hearing via video conference or telephone for good cause shown.

(h) *Introducing prior sworn statements of witnesses into the record.* At a hearing, any party wishing to introduce a prior, sworn statement of a witness, not a party, otherwise admissible in the proceeding, may make a motion setting forth the reasons therefore. If only part of a statement is offered in evidence, the hearing officer may require that all relevant portions of the statement be introduced. If all of a statement is offered in evidence, the hearing officer may require that portions not relevant to the proceeding be excluded. A motion to introduce a prior sworn statement may be granted if:

(1) The witness is dead;

(2) The witness is out of the United States, unless it appears that the absence of the witness was procured by the party offering the prior sworn statement;

(3) The witness is unable to attend or testify because of age, sickness, infirmity, imprisonment or other disability;

(4) The party offering the prior sworn statement has been unable to procure the attendance of the witness by subpoena; or

(5) In the discretion of the hearing officer, it would be desirable, in the interests of justice, to allow the prior sworn statement to be used. In making this determination, due regard shall be given to the presumption that witnesses will testify orally in an open hearing. If the parties have stipulated to accept a prior sworn statement in lieu of live testimony, consideration shall also be given to the convenience of the parties in avoiding unnecessary expense.

§ 1081.304 Record of the hearing.

(a) *Reporting and transcription.* Hearings shall be stenographically reported and transcribed under the supervision of the hearing officer, and the original transcript shall be a part of the record and the sole official transcript. The live oral testimony of each witness may be video recorded digitally, in which case the video recording and the written transcript of the testimony shall be made part of the record. Copies of transcripts shall be available from the reporter at prescribed rates.

(b) *Corrections.* Corrections of the official transcript may be made only when they involve errors affecting substance and then only in the manner herein provided. Corrections ordered by the hearing officer or agreed to in a written stipulation signed by all counsel and parties not represented by counsel, and approved by the hearing officer, shall be included in the record, and such stipulations, except to the extent they are capricious or without substance, shall be approved by the hearing officer. Corrections shall not be ordered by the hearing officer except upon notice and opportunity for the hearing of objections. Such corrections shall be made by the official reporter by furnishing substitute type pages, under the usual certificate of the reporter, for insertion in the official record. The original uncorrected pages shall be retained in the files of the Bureau.

(c) *Closing of the hearing record.* Upon completion of the hearing, the hearing officer shall issue an order closing the hearing record after giving the parties three days to determine if the record is complete or needs to be supplemented. The hearing officer shall retain the discretion to permit or order correction of the record as provided in paragraph (b) of this section.

§ 1081.305 Post-hearing filings.

(a) *Proposed findings and conclusions and supporting briefs.* (1) Using the same method of service for each party, the hearing officer shall serve notice upon each party that the certified transcript, together with all hearing exhibits and exhibits introduced but not admitted into evidence at the hearing, has been filed promptly after that filing. Any party may file with the hearing officer proposed findings of fact, proposed conclusions of law, and a proposed order within 30 days following service of this notice by the hearing officer or within such longer period as may be ordered by the hearing officer.

(2) Proposed findings and conclusions must be supported by citation to any relevant authorities and by page references to any relevant portions of the record. A post-hearing brief may be filed in support of proposed findings and conclusions, either as part of the same document or in a separate document.

(b) *Responsive briefs.* Responsive briefs may be filed within 15 days after the date on which the parties' proposed findings, conclusions, and order are due. Responsive briefs must be strictly limited to responding to matters, issues, or arguments raised in another party's papers. A party who has not filed proposed findings of fact and conclusions of law or a post-hearing brief may not file a responsive brief. Unless directed by the hearing officer, reply briefs are not permitted.

(c) *Order of filing.* The hearing officer shall not order the filing by any party of any post-hearing brief or responsive brief in advance of the other party's filing of its post-hearing brief or responsive brief.

§ 1081.306 Record in proceedings before hearing officer; retention of documents; copies.

(a) *Contents of the record.* The record of the proceeding shall consist of:

(1) The notice of charges, the answer, and any amendments thereto;

(2) Each motion, submission, or other paper filed in the proceedings, and any amendments and exceptions to or regarding them;

(3) Each stipulation, transcript of testimony, and any document or other item admitted into evidence;

(4) Any transcript of a conference or hearing before the hearing officer;

(5) Any amicus briefs filed pursuant to § 1081.216;

(6) With respect to a request to disqualify a hearing officer or to allow the hearing officer's withdrawal under § 1081.105(c), each affidavit or transcript of testimony taken and the decision made in connection with the request;

(7) All motions, briefs, and other papers filed on interlocutory appeal;

(8) All proposed findings and conclusions;

(9) Each written order issued by the hearing officer or Director; and

(10) Any other document or item accepted into the record by the hearing officer.

(b) *Retention of documents not admitted.* Any document offered into evidence but excluded shall not be considered part of the record. The Office of Administrative Adjudication shall retain any such document until the later of the date upon which an order by the Director ending the proceeding becomes final and not appealable, or upon the conclusion of any judicial review of the Director's order.

(c) *Substitution of copies.* A true copy of a document may be substituted for any document in the record or any document retained pursuant to paragraph (b) of this section.

Subpart D—Decision and Appeals

§ 1081.400 Recommended decision of the hearing officer.

(a) *Time period for filing recommended decision.* Subject to paragraph (b) of this section, the hearing officer shall file a recommended decision no later than 90 days after the deadline for filing post-hearing responsive briefs pursuant to § 1081.305(b) and in no event later than 300 days after filing of the notice of charges.

(b) *Extension of deadlines.* In the event the hearing officer presiding over the proceeding determines that it will not be possible to issue the recommended decision within the time periods specified in paragraph (a) of this section, the hearing officer shall submit a written request to the Director for an extension of the time period for filing the recommended decision. This request must be filed no later than 30 days prior to the expiration of the time for issuance of a recommended decision. The request will be served on all parties in the proceeding, who may file with the Director briefs in support of or in opposition to the request. Any such briefs must be filed within three days of service of the hearing officer's request and shall not exceed five pages. If the Director determines that additional time is necessary or appropriate in the public interest, the Director shall issue an order extending the time period for filing the recommended decision.

(c) *Content.* (1) A recommended decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable, probative, and substantial evidence. The recommended decision shall include a statement of findings of fact (with specific page references to principal supporting items of evidence in the record) and conclusions of law, as well as the reasons or basis therefore, as to all the material issues of fact, law, or discretion presented on the record and the appropriate order, sanction, relief or denial thereof. The recommended decision shall also state that a notice of appeal may be filed within ten days after service of the recommended decision and include a statement that, unless a party timely files and perfects

a notice of appeal of the recommended decision, the Director may adopt the recommended decision as the final decision and order of the Bureau without further opportunity for briefing or argument.

(2) Consistent with paragraph (a) of this section, when more than one claim for relief is presented in an adjudication proceeding, or when multiple parties are involved, the hearing officer may direct the entry of a recommended decision as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just reason for delay and upon an express direction for the entry of a recommended decision.

(d) *By whom made.* The recommended decision shall be made and filed by the hearing officer who presided over the hearings, except when he or she shall have become unavailable to the Bureau.

(e) *Reopening of proceeding by hearing officer; termination of jurisdiction.* (1) At any time from the close of the hearing record pursuant to § 1081.304(c) until the filing of his or her recommended decision, a hearing officer may reopen the proceeding for the receipt of further evidence for good cause shown.

(2) Except for the correction of clerical errors or pursuant to an order of remand from the Director, the jurisdiction of the hearing officer is terminated upon the filing of his or her recommended decision with respect to those issues decided pursuant to paragraph (c) of this section.

(f) *Filing, service, and publication.* Upon filing by the hearing officer of the recommended decision, the Office of Administrative Adjudication shall promptly transmit the recommended decision to the Director and serve the recommended decision upon the parties.

§ 1081.401 Transmission of documents to Director; record index; certification.

(a) *Filing of index.* At the same time the Office of Administrative Adjudication transmits the recommended decision to the Director, the hearing officer shall furnish to the Director a certified index of the entire record of the proceedings. The certified index shall include, at a minimum, an entry for each paper, document or motion filed in the proceeding, the date of the filing, and the identity of the filer. The certified index shall also include an exhibit index containing, at a minimum, an entry consisting of exhibit number and title or description for each exhibit introduced and admitted into evidence and each exhibit introduced but not admitted into evidence.

(b) *Retention of record items by the Office of Administrative Adjudication.* After the close of the hearing, the Office of Administrative Adjudication shall retain originals of any motions, exhibits or any other documents filed with, or accepted into evidence by, the hearing officer, or any other portions of the record that have not already been filed with the Office of Administrative Adjudication.

§ 1081.402 Notice of appeal; review by the Director.

(a) *Notice of appeal.* (1) *Filing.* Any party may file exceptions to the recommended decision of the hearing officer by filing a notice of appeal with the Office of Administrative Adjudication within ten days after service of the recommended decision. The notice shall specify the party or parties against whom the appeal is taken and shall designate the recommended decision or part thereof appealed from. If a timely notice of appeal is filed by a party, any other party may thereafter file a notice of appeal within five days after service of the first notice, or within ten days after service of the recommended decision, whichever period expires last.

(2) *Perfecting a notice of appeal.* Any party filing a notice of appeal must perfect its appeal by filing its opening appeal brief within 30 days of service of the recommended decision. Any party may respond to the opening appeal brief by filing an answering brief within 30 days of service of the opening brief. Any party may file a reply to an answering brief within seven days of service of the answering brief. These briefs must conform to the requirements of § 1081.403.

(b) *Director review other than pursuant to an appeal.* In the event no party perfects an appeal of the recommended decision, the Director shall, within 40 days after the date of service of the recommended decision, either issue a final decision and order adopting the recommended decision, or order further briefing regarding any portion of the recommended decision. The Director's order for further briefing shall set forth the scope of review and the issues that will be considered and will make provision for the filing of briefs in accordance with the timelines set forth in paragraph (a)(2) of this section (except that that opening briefs shall be due within 30 days of service of the order of review) if deemed appropriate by the Director.

(c) *Exhaustion of administrative remedies.* Pursuant to 5 U.S.C. 704, a perfected appeal to the Director of a recommended decision pursuant to paragraph (a) of this section is a prerequisite to the seeking of judicial review of a final decision and order, or portion of the final decision and order, adopting the recommended decision.

§ 1081.403 Briefs filed with the Director.

(a) *Contents of briefs.* Briefs shall be confined to the particular matters at issue. Each exception to the findings or conclusions being reviewed shall be stated succinctly. Exceptions shall be supported by citation to the relevant portions of the record, including references to the specific pages relied upon, and by concise argument including citation of such statutes, decisions, and other authorities as may be relevant. If the exception relates to the admission or exclusion of evidence, the substance of the evidence admitted or excluded shall be set forth in the brief, in an appendix thereto, or by citation to the record. Reply briefs shall be confined to matters in answering briefs of other parties.

(b) *Length limitation.* Except with leave of the Director, opening and answering briefs shall not exceed 30 pages, and reply briefs shall not exceed 15 pages, exclusive of pages containing the table of contents, table of authorities, and any addendum that consists solely of copies of applicable cases, pertinent legislative provisions or rules, and exhibits. Motions to file briefs in excess of these limitations are disfavored.

§ 1081.404 Oral argument before the Director.

(a) *Availability.* The Director will consider appeals, motions, and other matters properly before him or her on the basis of the papers filed by the parties without oral argument unless the Director determines that the presentation of facts and legal arguments in the briefs and record and decisional process would be significantly aided by oral argument, in which case the Director shall issue an order setting the date on which argument shall be held. A party seeking oral argument shall so indicate on the first page of its opening or answering brief.

(b) *Public arguments; transcription.* All oral arguments shall be public unless otherwise ordered by the Director. Oral arguments before the Director shall be reported stenographically, unless otherwise ordered by the Director. Motions to correct the transcript of oral argument shall be made according to the same procedure provided in § 1081.304(b).

§ 1081.405 Decision of the Director.

(a) Upon appeal from or upon further review of a recommended decision, the Director will consider such parts of the record as are cited or as may be necessary to resolve the issues presented and, in addition, will, to the extent necessary or desirable, exercise all powers which he or she could have exercised if he or she had made the recommended decision. In proceedings before the Director, the record shall consist of all items part of the record below in accordance with § 1081.306; any notices of appeal or order directing review; all briefs, motions, submissions, and other papers filed on appeal or review; and the transcript of any oral argument held. Review by the Director of a recommended decision may be limited to the issues specified in the notice(s) of appeal or the issues, if any, specified in the order directing further briefing. On notice to all parties, however, the Director may, at any time prior to issuance of his or her decision, raise and determine any other matters that he or she deems material, with opportunity for oral or written argument thereon by the parties.

(b) Decisional employees may advise and assist the Director in the consideration and disposition of the case.

(c) In rendering his or her decision, the Director will affirm, adopt, reverse, modify, set aside, or remand for further proceedings the recommended decision and will include in the decision a statement of the reasons or basis for his or her actions and the findings of fact upon which the decision is predicated.

(d) At the expiration of the time permitted for the filing of reply briefs with the Director, the Office of Administrative Adjudication will notify the parties that the case has been submitted for final Bureau decision. The Director will issue and the Office of Administrative Adjudication will serve the Director's final decision and order within 90 days after such notice, unless within that time the Director orders that the adjudication proceeding or any aspect thereof be remanded to the hearing officer for further proceedings.

(e) Copies of the final decision and order of the Director shall be served upon each party to the proceeding, upon other persons required by statute, and, if directed by the Director or required by statute, upon any appropriate State or Federal supervisory authority. The final decision and order will also be published on the Bureau's Web site or as otherwise deemed appropriate by the Bureau.

§ 1081.406 Reconsideration.

Within 14 days after service of the Director's final decision and order, any party may file with the Director a petition for reconsideration, briefly and specifically setting forth the relief desired and the grounds in support thereof. Any petition filed under this section must be confined to new questions raised by the final decision or final order and upon which the petitioner had no opportunity to argue, in writing or orally, before the Director. No response to a petition for reconsideration shall be filed unless requested by the Director, who will request such response before granting any petition for reconsideration. The filing of a petition for reconsideration shall not operate to stay the effective date of the final decision or order or to toll the running of any statutory period affecting such decision or order unless specifically so ordered by the Director.

§ 1081.407 Effective date; stays pending judicial review.

(a) Other than consent orders, which shall become effective at the time specified therein, an order to cease and desist or for other affirmative action under section 1053(b) of the Dodd-Frank Act becomes effective at the expiration of 30 days after the date of service pursuant to § 1081.113(d)(2), unless the Director agrees to stay the effectiveness of the order pursuant to this section.

(b) Any party subject to a final decision and order, other than a consent order, may apply to the Director for a stay of all or part of that order pending judicial review.

(c) A motion for stay shall state the reasons a stay is warranted and the facts relied upon, and shall include supporting affidavits or other sworn statements, and a copy of the relevant portions of the record. The motion shall address the likelihood of the movant's success on appeal, whether the movant will suffer irreparable harm if a stay is not granted, the degree of injury to other parties if a stay is granted, and why the stay is in the public interest.

(d) A motion for stay shall be filed within 30 days of service of the order on the party. Any party opposing the motion may file a response within five days after receipt of the motion. The movant may file a reply brief, limited to new matters raised by the response, within three days after receipt of the response.

(e) The commencement of proceedings for judicial review of a final decision and order of the Director does not, unless specifically ordered by the Director or a reviewing court, operate as a stay of any order issued by the Director. The Director may, in his or her discretion, and on such terms as he or she finds just, stay the effectiveness of all or any part of an order pending a final decision on a petition for judicial review of that order.

Dated: June 4, 2012.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2012–14061 Filed 6–28–12; 8:45 am]

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BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1080

[Docket No.: CFPB–2011–0007]

RIN 3170–AA03

Rules Relating to Investigations

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule.

SUMMARY: After considering the public comments on its interim final rule for the Rules Relating to Investigations, the Bureau of Consumer Financial Protection (Bureau), pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act), is making revisions to its procedures for investigations under section 1052 of the Dodd-Frank Act.

DATES: The final rule is effective June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Peter G. Wilson, Office of the General Counsel, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552, (202) 435–7585.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) was signed into law on July 21, 2010. Title X of the Dodd-Frank Act established the Bureau of Consumer Financial Protection (Bureau) to regulate the offering and provision of consumer financial products or services under the Federal consumer financial laws. The Dodd-Frank Act transferred to the Bureau the consumer financial protection functions formerly carried out by the Federal banking agencies, as well as certain authorities formerly carried out by the Department of Housing and Urban Development (HUD) and the Federal Trade Commission (FTC). As required by section 1062 of the Dodd-Frank Act, 12 U.S.C. 5582, the Secretary of the Treasury selected a

designated transfer date and the Federal banking agencies' functions and authorities transferred to the Bureau on July 21, 2011.

The Dodd-Frank Act authorizes the Bureau to conduct investigations to ascertain whether any person is or has been engaged in conduct that, if proved, would constitute a violation of any provision of Federal consumer financial law. Section 1052 of the Dodd-Frank Act sets forth the parameters that govern these investigations. 12 U.S.C. 5562. Section 1052 became effective immediately upon transfer on July 21, 2011 and did not require rules to implement its provisions. On July 28, 2011, the Bureau issued the interim final rule for the Rules Relating to Investigations (Interim Final Rule) to provide parties involved in Bureau investigations with clarification on how to comply with the statutory requirements relating to Bureau investigations.

II. Summary of the Final Rule

Consistent with section 1052 of the Dodd-Frank Act, the final rule for the Rules Relating to Investigations (Final Rule) describes a number of Bureau policies and procedures that apply in an investigational, nonadjudicative setting. Among other things, the Final Rule sets forth (1) the Bureau's authority to conduct investigations, and (2) the rights of persons from whom the Bureau seeks to compel information in investigations.

Like the Interim Final Rule, the Final Rule is modeled on investigative procedures of other law enforcement agencies. For guidance, the Bureau reviewed the procedures currently used by the FTC, the Securities and Exchange Commission (SEC), and the prudential regulators, as well as the FTC's recently proposed amendments to its nonadjudicative procedures. In light of the similarities between section 1052 of the Dodd-Frank Act and section 20 of the Federal Trade Commission Act (FTC Act), 15 U.S.C. 41 *et seq.,* the Bureau drew most heavily from the FTC's nonadjudicative procedures in constructing the rules.

The Final Rule lays out the Bureau's authority to conduct investigations before instituting judicial or administrative adjudicatory proceedings under Federal consumer financial law. The Final Rule authorizes the Director, the Assistant Director of the Office of Enforcement, and the Deputy Assistant Directors of the Office of Enforcement to issue civil investigative demands (CIDs) for documentary material, tangible things, written reports, answers to questions, or oral testimony. The demands may be enforced in district court by the Director, the General Counsel, or the Assistant Director of the Office of Enforcement. The Final Rule also details the authority of the Bureau's investigators to conduct investigations and hold investigational hearings pursuant to civil investigative demands for oral testimony.

Furthermore, the Final Rule sets forth the rights of persons from whom the Bureau seeks to compel information in an investigation. Specifically, the Final Rule describes how such persons should be notified of the purpose of the Bureau's investigation. It also details the procedures for filing a petition for an order modifying or setting aside a CID, which the Director is authorized to rule upon. And it describes the process by which persons may obtain copies of or access to documents or testimony they have provided in response to a civil investigative demand. In addition, the Final Rule describes a person's right to counsel at investigational hearings.

III. Legal Authority

As noted above, section 1052 of the Dodd-Frank Act outlines how the Bureau will conduct investigations and describes the rights of persons from whom the Bureau seeks information in investigations. This section became effective immediately upon the designated transfer date, July 21, 2011, without any requirement that the Bureau first issue procedural rules. Nevertheless, the Bureau believes that the legislative purpose of section 1052 will be furthered by the issuance of rules that specify the manner in which persons can comply with its provisions.

Section 1022 of the Dodd-Frank Act authorizes the Director to prescribe rules as may be necessary or appropriate for the Bureau to administer and carry out the purposes and objectives of Federal consumer financial laws and to prevent evasion of those laws. 12 U.S.C. 5512. The Bureau believes that the Final Rule will effectuate the purpose of section 1052 and facilitate compliance with Bureau investigations.

IV. Overview of Public Comments on the Interim Final Rule

After publication of the Interim Final Rule on July 28, 2011, the Bureau accepted public comments until September 26, 2011. During the comment period, the Bureau received seven comments. Two of the comments were submitted by individual consumers. Four trade associations and a mortgage company also submitted comments. The trade associations represent credit unions, banks, consumer credit companies, members of the real estate finance industry, and other financial institutions.

The commenters generally support the Interim Final Rule. Most sections of the Interim Final Rule received no comment and are being finalized without change. The comments did, however, contain questions and recommendations for the Bureau.

Several of the commenters expressed concern that the Interim Final Rule appeared to provide staff-level Bureau employees with unchecked authority to initiate investigations and issue CIDs, or that the Interim Final Rule otherwise did not provide sufficient oversight for particular actions.

A number of commenters expressed concern about sections of the Interim Final Rule that relate to CIDs. One trade association recommended that a statement of ''the purpose and scope'' of a Bureau investigation—in addition to a notification of the nature of the conduct constituting the alleged violation under investigation and the applicable provisions of law—be included in CIDs. A commenter suggested that the Bureau require a conference between CID recipients and the Assistant Director of the Office of Enforcement to negotiate the terms of compliance with the demand. Three of the trade associations noted concern with the statement that extensions of time are disfavored for petitions to modify or set aside CIDs. Two commenters questioned who would rule on such petitions without a confirmed Director. One trade association commented that witnesses should be permitted to object to questions demanding information outside of the scope of the investigation during an investigational hearing pursuant to a CID for oral testimony.

A number of commenters expressed concern about maintaining the confidentiality of demand material, sharing information with other State and Federal agencies, and the duties of the custodians of those materials. For example, one trade association and the mortgage company recommended that investigations should remain confidential in all circumstances. Another trade association asserted that the Bureau is not permitted to engage in joint investigations with State attorneys general.

The Bureau reviewed all of the comments on its Interim Final Rule thoroughly and addresses the significant issues they raise herein. Although most sections of the Interim Final Rule received no comment and are being finalized without change, the Bureau has made several changes to the Interim Final Rule based on the comments it received. The comments and these

changes are discussed in more detail in parts V and VI of the **SUPPLEMENTARY INFORMATION**.

V. General Comments

Some comments on the Interim Final Rule were not directed at a specific section but rather concerned issues of general applicability. The Bureau addresses those comments in this section and addresses comments related to specific sections of the Interim Final Rule in part VI.

One commenter asked the Bureau to specify who would rule on petitions to set aside or modify CIDs while the Bureau lacked a Director. This commenter also asked who would review requests to the Attorney General under § 1080.12 for authority to immunize witnesses and to order them to testify or provide other information. The President appointed a Director of the Bureau on January 4, 2012. Therefore, both questions posed by this commenter are moot. The Director or any official to whom the Director has delegated his authority pursuant to 12 U.S.C. 5492(b) will rule on petitions to set aside or modify CIDs. Furthermore, the Bureau has revised § 1080.12 to clarify that only the Director has the authority to request approval from the Attorney General for the issuance of an order immunizing witnesses.

A commenter asserted that section 1052(c)(1) of the Dodd-Frank Act prohibits the Bureau from issuing CIDs after the institution of any proceedings under Federal consumer financial laws, including proceedings initiated by a State or a private party. The commenter argued that a CID should be accompanied by a certification that the demand will have no bearing on any ongoing proceeding. Section 1052(c)(1) provides, in relevant part, that ''the Bureau may, before the institution of any proceedings under the Federal consumer financial law, issue in writing, and cause to be served upon such person, a civil investigative demand.'' The language ''before the institution of any proceeding under Federal consumer financial law'' refers to the institution of proceedings by the Bureau. It does not limit the Bureau's authority to issue CIDs based upon the commencement of a proceeding by other parties.

Another commenter requested that the Bureau exempt all credit unions from Bureau investigations. The Bureau believes that granting an exemption from the Bureau's enforcement authority through the Final Rule would be inappropriate and that there is an insufficient record to support such an exemption.

A commenter recommended that covered persons be allowed to recover attorneys' fees and costs incurred by defending against an investigation that is shown to be without merit. The Dodd-Frank Act does not provide the right to recover fees and costs by defending against an investigation. Further, as explained below, the Bureau believes that the procedures for petitioning to modify or set aside a CID set forth in § 1080.6(d) of the Interim Final Rule (now 1080.6(e) of the Final Rule) provide sufficient protections to a recipient of a demand it believes lacks merit.

VI. Section-by-Section Summary

Section 1080.1 Scope

This section describes the scope of the Interim Final Rule. It makes clear that these rules only apply to investigations under section 1052 of the Dodd-Frank Act. The Bureau received no comment on § 1080.1 of the Interim Final Rule and is adopting it as the Final Rule without change.

Section 1080.2 Definitions

This section of the Interim Final Rule defines several terms used throughout the rules. Many of these definitions also may be found in section 1051 of the Dodd-Frank Act.

A commenter questioned the breadth of the definition of the term ''Assistant Director of the Division of Enforcement.'' The commenter argued that because that term was defined to include ''any Bureau employee to whom the Assistant Director of the Division of Enforcement has delegated authority to act under this part,'' the Interim Final Rule could give Bureau employees inappropriately broad authority to take certain actions, such as issuing CIDs.

The Bureau has revised the Final Rule in response to these comments. The Final Rule identifies those with authority to take particular actions under each section of the Final Rule. Sections 1080.4 (initiating and conducting investigations) and 1080.6 (civil investigative demands) of the Final Rule clarify that the authority to initiate investigations and issue CIDs cannot be delegated by the identified officials. The Final Rule also changes the defined term ''Division of Enforcement'' to ''Office of Enforcement'' to reflect the Bureau's current organizational structure.

Section 1080.3 Policy as to Private Controversies

This section of the Interim Final Rule states the Bureau's policy of pursuing investigations that are in the public interest. Section 1080.3 is consistent with the Bureau's mission to protect consumers by investigating potential violations of Federal consumer financial law. The Bureau received no comments on § 1080.3 of the Interim Final Rule and is adopting it as the Final Rule without change.

Section 1080.4 Initiating and Conducting Investigations

This section of the Interim Final Rule explains that Bureau investigators are authorized to conduct investigations pursuant to section 1052 of the Dodd-Frank Act.

A commenter observed that this section of the Interim Final Rule did not explicitly provide a procedure for senior agency officials to authorize the opening of an investigation. The commenter argued that only senior agency officials should decide whether to initiate investigations. The commenter questioned whether staff-level employees could open investigations and issue CIDs without sufficient supervision, and noted that the FTC's analogous rule specifically lists the senior officials to whom the Commission has delegated, without power of redelegation, the authority to initiate investigations.

A commenter also expressed concern that the FTC's analogous rule explicitly provides that FTC investigators must comply with the laws of the United States and FTC regulations. According to the commenter, such language is necessary to ensure that the Bureau complies with the Right to Financial Privacy Act (RFPA) to the extent that statute applies to the Bureau. The commenter also believes that this language is needed to guard against investigations undertaken for what the commenter characterized as the impermissible purpose of aiding State attorneys general or State regulators. The commenter suggested that the Bureau add a statement to this section of the Interim Final Rule similar to the FTC's rule requiring compliance with Federal law and agency regulations.

The Final Rule clarifies that only the Assistant Director or any Deputy Assistant Director of the Office of Enforcement has the authority to initiate investigations. The Bureau has significant discretion to determine whether and when to open an investigation, and the public benefits from a process whereby the Bureau can open and close investigations efficiently. But the Bureau did not intend its rules to be interpreted so broadly as to suggest that any staff-level employee could unilaterally open an investigation or issue a CID. The Final

Rule also provides that Bureau investigators will perform their duties in accordance with Federal law and Bureau regulations.

Section 1080.5 Notification of Purpose

This section of the Interim Final Rule specifies that a person compelled to provide information to the Bureau or to testify in an investigational hearing must be advised of the nature of the conduct constituting the alleged violation under investigation and the applicable provisions of law. This section of the Interim Final Rule implements the requirements for CIDs described in section 1052(c)(2) of the Dodd-Frank Act.

Commenters noted that although the Dodd-Frank Act and the FTC Act both require CIDs to state ''the nature of the conduct constituting the alleged violation which is under investigation and the provision of law applicable to such violation,'' the two agencies' implementing regulations on this topic differ. Both agencies' regulations require a statement of the nature of the conduct at issue and the relevant provisions of law, but the FTC rule also requires that the recipient of the CID be advised of ''the purpose and scope'' of the investigation. Commenters argued that the Bureau should add this phrase to its rule because excluding it would lead to requests for materials outside the scope of an investigation. One commenter argued that only senior agency officials should authorize investigations to ensure that CIDs are relevant to the purpose and scope of the Bureau's investigations.

The language in § 1080.5 of the Interim Final Rule mirrors the language of the Dodd-Frank Act, which provides that ''[e]ach civil investigative demand shall state the nature of the conduct constituting the alleged violation which is under investigation and the provision of law applicable to such violation.'' The Bureau believes that the information covered by this statutory language provides sufficient notice to recipients of CIDs. As discussed above, § 1080.4 (initiating and conducting investigations) of the Final Rule limits the authority to open investigations to the Assistant Director or any Deputy Assistant Director of the Office of Enforcement. Similarly, § 1080.6 of the Final Rule (civil investigative demands) limits the authority to issue CIDs to the Director of the Bureau, the Assistant Director of the Office of Enforcement, and the Deputy Assistant Directors of the Office of Enforcement. Thus, one of these identified officials will review and approve the initiation of all investigations and the issuance of all CIDs. In addition, to the extent recipients of CIDs consider the demands to be for an unauthorized purpose or outside the scope of the investigation, they will have an opportunity to negotiate the terms of compliance pursuant to § 1080.6(c) of the Interim Final Rule (now § 1080.6(d) of the Final Rule) or to petition to set aside or modify the demand pursuant to § 1080.6(d) of the Interim Final Rule (now § 1080.6(e) of the Final Rule).

The Bureau therefore adopts this section of the Interim Final Rule as the Final Rule without change.

Section 1080.6 Civil Investigative Demands

This section of the Interim Final Rule lays out the Bureau's procedures for issuing CIDs. It authorizes the Assistant Director of the Office of Enforcement to issue CIDs for documentary material, tangible things, written reports, answers to questions, and oral testimony. This section of the Interim Final Rule details the information that must be included in CIDs and the requirement that responses be made under a sworn certificate. Section 1080.6 of the Interim Final Rule also authorizes the Assistant Director of the Office of Enforcement to negotiate and approve the terms of compliance with CIDs and grant extensions for good cause. Finally, this section of the Interim Final Rule describes the procedures for seeking an order to modify or set aside a CID, which the Director is authorized to rule upon.

One commenter argued that § 1080.6(a) permits almost any Bureau employee to issue CIDs without sufficient supervision. The commenter stated that this lack of oversight is problematic and does not reflect Congress' intent when it enacted the Act.

Section 1080.6(a) of the Final Rule limits the authority to issue CIDs to the Director, the Assistant Director of the Office of Enforcement, and the Deputy Assistant Directors of the Office of Enforcement. This change to the Final Rule balances the efficiency of the Bureau's investigative process with appropriate supervision and oversight.

A commenter suggested that the Bureau require a conference between the CID recipient and the Assistant Director of the Office of Enforcement within ten days of service of the CID to negotiate and approve the terms of compliance. The commenter envisioned a conference analogous to a discovery planning conference under the Federal Rules of Civil Procedure, during which the parties could discuss requests for information, appropriate limitations on the scope of requests, issues related to electronically stored information (ESI), issues related to privilege and confidential information, and a reasonable time for compliance. The commenter stated that this type of conference would better ensure prompt and efficient production of material and information related to the investigation.

The Bureau agrees that a conference between the parties within ten calendar days of serving a CID is likely to improve the efficiency of investigations, and § 1080.6(c) of the Final Rule provides for such a conference. The Final Rule does not, however, adopt the suggestion that the Assistant Director of the Office of Enforcement preside over all such conferences.

Several commenters also noted concern with the statement in § 1080.6(d) of the Interim Final Rule disfavoring extensions of time for petitioning for an order modifying or setting aside CIDs. One commenter argued that the 20-day period to file petitions, for which extensions of time are disfavored, is inconsistent with the ''reasonable'' period of time for compliance with the CID set forth in § 1080.6(a). The commenter also argued that this timeframe leaves a short period for the CID recipient to decide which documents are privileged or otherwise protected and to file a petition articulating privilege and scope objections. Another commenter noted that the analogous FTC rules do not include a provision disfavoring extensions for petitions to modify or set aside a CID. These commenters recommended that the Bureau delete the sentence related to disfavoring extensions. One commenter recommended that the rules be corrected to provide an independent review if a covered person believes a CID is without merit.

Like the Interim Final Rule, the Final Rule includes a provision disfavoring extensions of time for petitions to modify or set aside a CID. The Bureau believes its policy of disfavoring extensions is appropriate in light of its significant interest in promoting an efficient process for seeking materials through CIDs. By disfavoring extensions, the Bureau means to prompt recipients to decide within 20 days whether they intend to comply with the CID. The Final Rule also clarifies that this 20-day period should be computed with calendar days.

The Bureau notes that § 1080.6(d) of the Interim Final Rule (now § 1080.6(e) of the Final Rule) only provides the due date for a petition for an order modifying or setting aside a CID. It does not require recipients to comply fully

with CIDs within 20 days. In addition, the Final Rule provides several options to recipients of CIDs that need additional time to respond. For example, the recipient may negotiate for a reasonable extension of time for compliance or a rolling document production schedule pursuant to § 1080.6(c) of the Interim Final Rule (now § 1080.6(d) of the Final Rule).

Section 1080.6(e) of the Final Rule clarifies that recipients of CIDs should not assert claims of privilege through a petition for an order modifying or setting aside a CID. Instead, when privilege is the only basis for withholding particular materials, they should utilize the procedures set forth in § 1080.8 (withholding requested material) of the Final Rule. Section 1080.6(e) of the Final Rule also lays out the authority of Bureau investigators to provide to the Director a reply to a petition seeking an order modifying or setting aside a CID. Specifically, the Final Rule states that Bureau investigators may provide the Director with a statement setting forth any factual and legal responses to a petition. The Bureau will not make these statements or any other internal deliberations part of the Bureau's public records. Section 1080.6(g) of the Final Rule clarifies that the Bureau, however, will make publicly available both the petition and the Director's order in response. Section 1080.6(g) of the Final Rule also clarifies that if a CID recipient wants to prevent the Director from making the petition public, any showing of good cause must be made no later than the time the petition is filed. The Final Rule also adds a provision clarifying how the Bureau will serve the petitioner with the Director's order.

Finally, the Bureau believes the procedures for petitions to modify or set aside a CID set forth in the Final Rule adequately protect a covered person who believes a CID is without merit, and that an additional independent review is unnecessary.

Section 1080.7 Investigational Hearings

This section of the Interim Final Rule describes the procedures for investigational hearings initiated pursuant to a CID for oral testimony. It also lays out the roles and responsibilities of the Bureau investigator conducting the investigational hearing, which include excluding unauthorized persons from the hearing room and ensuring that the investigational hearing is transcribed, the witness is duly sworn, the transcript is a true record of the testimony, and the transcript is provided to the designated custodian.

A commenter argued that the Bureau is not authorized to conduct joint investigations with State attorneys general under the Dodd-Frank Act and, correspondingly, State attorneys general cannot attend an investigational hearing as a representative of an agency with whom the Bureau is conducting a joint investigation. The commenter argued that Congress distinguished between State attorneys general and State regulatory agencies in section 1042 of the Dodd-Frank Act and that State attorneys general are therefore not ''agencies'' with whom the Bureau can partner. The commenter also asserted that the Bureau cannot share a copy of the transcript of an investigational hearing with another agency without the consent of the witness.

Another commenter argued that representatives of agencies with which the Bureau is conducting a joint investigation may be present at an investigational hearing only with the witness's consent. This commenter stated that the Bureau should recognize in the rules that a witness who does not consent to the presence of a representative of another agency at an investigational hearing should not be presumed guilty.

The Dodd-Frank Act states that the Bureau ''may engage in joint investigations and requests for information, as authorized under this title.'' This statutory language permits the Bureau to engage in joint investigations with State or Federal law enforcement agencies, including State attorneys general, with jurisdiction that overlaps with the Bureau's. The Bureau's disclosure rules also permit the Bureau to share certain confidential information, including investigational hearing transcripts, with Federal or State agencies to the extent the disclosure is relevant to the exercise of an agency's statutory or regulatory authority. *See* 12 CFR 1070.43(b). In addition, neither the Dodd-Frank Act nor the rules require the consent of the witness to permit a representative of an agency with which the Bureau is conducting a joint investigation to be present at the hearing. Consent is required only when people other than those listed in the rule are included.

Thus, the Bureau adopts § 1080.7 of the Interim Final Rule as the Final Rule without change.

Section 1080.8 Withholding Requested Material

This section of the Interim Final Rule describes the procedures that apply when persons withhold material responsive to a CID. It requires the recipient of the CID to assert a privilege by the production date and, if so directed in the CID, also to submit a detailed schedule of the items withheld. Section 1080.8 also sets forth the procedures for handling the disclosure of privileged or protected information or communications.

The Bureau received no comment on § 1080.8 of the Interim Final Rule and is adopting it as the Final Rule without substantive change.

Section 1080.9 Rights of Witnesses in Investigations

This section of the Interim Final Rule describes the rights of persons compelled to submit information or provide testimony in an investigation. It details the procedures for obtaining a copy of submitted documents or a copy of or access to a transcript of the person's testimony. This section of the Interim Final Rule also describes a witness's right to make changes to his or her transcript and the rules for signing the transcript.

Section 1080.9 of the Interim Final Rule lays out a person's right to counsel at an investigational hearing and describes his or her counsel's right to advise the witness as to any question posed for which an objection may properly be made. It also describes the witness's or counsel's rights to object to questions or requests that the witness is privileged to refuse to answer. This section of the Interim Final Rule states that counsel for the witness may not otherwise object to questions or interrupt the examination to make statements on the record but may request that the witness have an opportunity to clarify any of his or her answers. Finally, this section of the Interim Final Rule authorizes the Bureau investigator to take all necessary action during the course of the hearing to avoid delay and to prevent or restrain disorderly, dilatory, obstructionist, or contumacious conduct, or contemptuous language.

A commenter noted that under the Interim Final Rule witnesses could not object during an investigational hearing on the ground that a question was outside the scope of the investigation. The commenter argued that a covered person's inability to raise such objections might allow ''a fishing expedition.'' The commenter recommended amending § 1080.9(b) to allow objections based on scope.

Section 1052(c)(13)(D)(iii) of the Dodd-Frank Act states, in relevant part:

> [a]n objection may properly be made, received, and entered upon the record when it is claimed that such person is entitled to

refuse to answer the question on grounds of any constitutional or other legal right or privilege, including the privilege against self-incrimination, but the person shall not otherwise object to or refuse to answer any question, and such person or attorney shall not otherwise interrupt the oral examination.

Thus, to the extent the scope objection was grounded in a witness's constitutional or other legal right, it would be a proper objection.

The Final Rule clarifies that counsel may confer with a witness while a question is pending or instruct a witness not to answer a question only if an objection based on privilege or work product may properly be made. The Final Rule also describes counsel's limited ability to make additional objections based on other constitutional or legal rights. The Final Rule provides that if an attorney has refused to comply with his or her obligations in the rules of this part, or has allegedly engaged in disorderly, dilatory, obstructionist, or contumacious conduct, or contemptuous language during an investigational hearing, the Bureau may take further action, including action to suspend or disbar the attorney from further participation in the investigation or further practice before the Bureau pursuant to 12 CFR 1081.107(c). The Final Rule also includes other nonsubstantive changes, including clarifying that the 30-day period that the witness has to sign and submit his or her transcript should be computed using calendar days.

Section 1080.10 Noncompliance With Civil Investigative Demands

This section of the Interim Final Rule authorizes the Director, the Assistant Director of the Office of Enforcement, and the General Counsel to initiate an action to enforce a CID in connection with the failure or refusal of a person to comply with, or to obey, a CID. In addition, they are authorized to seek civil contempt or other appropriate relief in cases where a court order enforcing a CID has been violated.

The Bureau received no comment on § 1080.10 of the Interim Final Rule and is adopting it as the Final Rule without substantive change.

Section 1080.11 Disposition

This section of the Interim Final Rule explains that an enforcement action may be instituted in Federal or State court or through administrative proceedings when warranted by the facts disclosed by an investigation. It further provides that the Bureau may refer investigations to appropriate Federal, State, or foreign government agencies as appropriate. This section of the Interim Final Rule also authorizes the Assistant Director of the Office of Enforcement to close the investigation when the facts of an investigation indicate an enforcement action is not necessary or warranted in the public interest.

One commenter indicated that the Bureau's authority to refer investigations to other law enforcement agencies should be limited to circumstances when it is expressly authorized to do so by the Dodd-Frank Act, an enumerated consumer financial law, or other Federal law, because of potential risks to the confidentiality of the investigatory files.

The Bureau's ability to refer matters to appropriate law enforcement agencies is inherent in the Bureau's authority and is a corollary to the Bureau's statutorily recognized ability to conduct joint investigations. The documentary materials and tangible things obtained by the Bureau pursuant to a CID are subject to the requirements and procedures relating to disclosure of records and information in part 1070 of this title. These procedures for sharing information with law enforcement agencies provide significant and sufficient protections for these materials.

The Bureau has amended § 1080.11 to clarify that the Assistant Director and any Deputy Assistant Director of the Office of Enforcement are authorized to close investigations.

The Bureau adopts § 1080.11 of the Interim Final Rule with the changes discussed above.

Section 1080.12 Orders Requiring Witnesses To Testify or Provide Other Information and Granting Immunity

This section of the Interim Final Rule authorizes the Assistant Director of the Office of Enforcement to request approval from the Attorney General for the issuance of an order requiring a witness to testify or provide other information and granting immunity under 18 U.S.C. 6004. The Interim Final Rule also sets forth the Bureau's right to review the exercise of these functions and states that the Bureau will entertain an appeal from an order requiring a witness to testify or provide other information only upon a showing that a substantial question is involved, the determination of which is essential to serve the interests of justice. Finally, this section of the Interim Final Rule describes the applicable rules and time limits for such appeals.

A commenter questioned whether this section of the Interim Final Rule would permit any Bureau employee to request that the Attorney General approve the issuance of an order granting immunity under 18 U.S.C. 6004 and requiring a witness to testify or provide information. The commenter noted that the Dodd-Frank Act authorizes the Bureau, with the Attorney General's permission, to compel a witness to testify under 18 U.S.C. 6004 if the witness invokes his or her privilege against self-incrimination. The commenter argued that this section should delegate the authority to seek permission to compel testimony to a specific individual to provide accountability and ensure that information is not disclosed to the Attorney General in a manner that violates the Right to Financial Privacy Act. The commenter noted that the FTC's analogous rule specifically lists the senior agency officials who are authorized to make such requests to the Attorney General, and identifies a liaison officer through whom such requests must be made. The commenter also suggested that § 1080.12(b) of the Interim Final Rule, which provides that the Assistant Director's exercise of this authority is subject to review by ''the Bureau,'' specify who will conduct this review.

The Final Rule provides that only the Director of the Bureau has the authority to request approval from the Attorney General for the issuance of an order requiring a witness to testify or provide other information and granting immunity under 18 U.S.C. 6004. This change addresses the concern that requests for witness immunity would be made without oversight. Limiting this authority to the Director provides sufficient accountability.

Section 1080.13 Custodians

This section of the Interim Final Rule describes the procedures for designating a custodian and deputy custodian for material produced pursuant to a CID in an investigation. It also states that these materials are for the official use of the Bureau, but, upon notice to the custodian, must be made available for examination during regular office hours by the person who produced them.

A commenter suggested that the Bureau should detail the particular duties of custodians designated under this section and that, without an enumerated list of duties, the custodian would not have any responsibilities regarding CID materials. The commenter noted that the FTC Act requires the custodian to take specific actions, while the Dodd-Frank Act does not. The commenter suggested specifying a series of custodial duties, including (1) taking and maintaining custody of all materials submitted pursuant to CIDs or subpoenas that the Bureau issues,

including transcripts of oral testimony taken by the Bureau; (2) maintaining confidentiality of those materials as required by applicable law; (3) providing the materials to either House of Congress upon request, after ten days notice to the party that owns or submitted the materials; (4) producing any materials as required by a court of competent jurisdiction; and (5) complying at all times with the Trade Secrets Act.

Section 1052 of the Dodd-Frank Act sets forth the duties of the Bureau's custodian. Sections 1052(c)(3) through (c)(6) of the Dodd-Frank Act give the custodian responsibility for receiving documentary material, tangible things, written reports, answers to questions, and transcripts of oral testimony given by any person in compliance with any CID. Section 1052(d) of the Dodd-Frank Act, as well as the Bureau's Rules for Disclosure of Records and Information in part 1070 of this title, outline the requirements for the confidential treatment of demand material. Section 1052(g) addresses custodial control and provides that a person may file, in the district court of the United States for the judicial district within which the office of the custodian is situated, a petition for an order of such court requiring the performance by the custodian of any duty imposed upon him by section 1052 of the Dodd-Frank Act or by Bureau rule. These duties and obligations do not require additional clarification by rule.

The Final Rule clarifies that the custodian has the powers and duties of both section 1052 of the Dodd-Frank Act and 12 CFR 1070.3.

The Bureau adopts § 1080.13 of the Interim Final Rule with the changes discussed above.

Section 1080.14 Confidential Treatment of Demand Material and Non-Public Nature of Investigations

Section 1080.14 of the Interim Final Rule explains that documentary materials, written reports, answers to questions, tangible things, or transcripts of oral testimony received by the Bureau in any form or format pursuant to a CID are subject to the requirements and procedures relating to disclosure of records and information in part 1070 of this title. This section of the Interim Final Rule also states that investigations generally are non-public. A Bureau investigator may disclose the existence of an investigation to the extent necessary to advance the investigation.

A commenter recommended that the Bureau revise this section to mandate that Bureau investigations remain confidential. The commenter noted the potential reputation risk to an entity if an investigation is disclosed to the public. In addition, the commenter argued that failing to conduct investigations confidentially will increase litigation risk. One commenter recommended that the Bureau issue a public absolution of a company if the Bureau does not maintain the confidentiality of an investigation.

Section 1080.14 of the Interim Final Rule provides that investigations generally will not be disclosed to the public, but permits Bureau investigators to disclose the existence of an investigation when necessary to advance the investigation. The Interim Final Rule does not contemplate publicizing an investigation, but rather disclosing the existence of the investigation to, for example, a potential witness or third party with potentially relevant information when doing so is necessary to advance the investigation. This limited exception sufficiently balances the concerns expressed by the commenter with the Bureau's need to obtain information efficiently.

Thus, the Bureau adopts § 1080.14 of the Interim Final Rule as the Final Rule without change.

VII. Section 1022(b)(2) Provisions

In developing the Final Rule, the Bureau has considered the potential benefits, costs, and impacts, and has consulted or offered to consult with the prudential regulators, HUD, the SEC, the Department of Justice, and the FTC, including with regard to consistency with any prudential, market, or systemic objectives administered by such agencies.[1]

The Final Rule neither imposes any obligations on consumers nor is expected to have any appreciable impact on their access to consumer financial products or services. Rather, the Final Rule provides a clear, efficient mechanism for investigating compliance with the Federal consumer financial laws, which benefits consumers by creating a systematic process to protect them from unlawful behavior.

The Final Rule imposes certain obligations on covered persons who receive CIDs in Bureau investigations. Specifically, as described above, the Final Rule sets forth the process for complying with or objecting to CIDs for documentary material, tangible things, written reports or answers to questions, and oral testimony. Most obligations in the Final Rule stem from express language in the Dodd-Frank Act and do not impose additional burdens on covered persons.

To the extent that the Final Rule includes provisions not expressly required by statute, these provisions benefit covered persons by providing clarity and certainty. In addition, the Final Rule vests the Bureau with discretion to modify CIDs or extend the time for compliance for good cause. This flexibility benefits covered persons by enabling the Bureau to assess the cost of compliance with a civil investigative demand in a particular circumstance and take appropriate steps to mitigate any unreasonable compliance burden.

Moreover, because the Final Rule is largely based on section 20 of the FTC Act and its corresponding regulations, it should present an existing, stable model of investigatory procedures to covered persons. This likely familiarity to covered persons should further reduce the compliance costs for covered persons.

The Final Rule provides that requests for extensions of time to file petitions to modify or set aside CIDs are disfavored. This may impose a burden on covered entities in some cases, but it may also lead to a more expeditious resolution of matters, reducing uncertainty. Furthermore, the Final Rule has no unique impact on insured depository institutions or insured credit unions with less than $10 billion in assets as described in section 1026(a) of the Dodd-Frank Act. Nor does the Final Rule have a unique impact on rural consumers.

A commenter suggested that the Bureau conduct a nonpublic study of the impact of complying with a CID on the entities who have been subjected to them by other agencies, with specific focus on those that were found not to have violated the law. As the commenter implicitly recognizes, such data does not currently exist and thus was not reasonably available to the Bureau in finalizing the Interim Final Rule. Moreover, as explained above, most of the costs associated with complying with a CID result from the Dodd-Frank Act, which authorizes the Bureau to issue such demands.

A commenter asserted that disfavoring extensions of petitions to

[1] Section 1022(b)(2)(A) of the Dodd-Frank Act addresses the consideration of the potential benefits and costs of regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act; and the impact on consumers in rural areas. Section 1022(b)(2)(B) addresses consultation between the Bureau and other Federal agencies during the rulemaking process. The manner and extent to which these provisions apply to procedural rules and benefits, costs and impacts that are compelled by statutory changes rather than discretionary Bureau action is unclear. Nevertheless, to inform this rulemaking more fully, the Bureau performed the described analyses and consultations.

modify or set aside CIDs will require the recipient to conduct a full review of the demanded material within the normal 20-day period in order to comply with the deadline for filing a petition. Under the Final Rule, recipients of a CID are not required to comply fully within twenty days; rather, they are required simply to decide whether they will comply with the demand at all. The Assistant Director of the Office of Enforcement and the Deputy Assistant Directors of the Office of Enforcement have the discretion to negotiate and approve the terms of satisfactory compliance with CIDs and, for good cause shown, may extend the time prescribed for compliance. Thus, the Final Rule provides reasonable steps to mitigate compliance burden while simultaneously protecting the Bureau's law enforcement interests.

Another commenter stated that the four interim final rules that the Bureau promulgated together on July 28, 2011 failed to satisfy the rulemaking requirements under section 1022 of the Dodd-Frank Act. Specifically, the commenter stated that ''the CFPB's analysis of the costs and benefits of its rules does not recognize the significant costs the CFPB imposes on covered persons.'' The Bureau believes that it appropriately considered the benefits, costs, and impacts of the Interim Final Rule pursuant to section 1022. Notably, the commenter did not identify any specific costs to covered persons that are not discussed in Part C of the **SUPPLEMENTARY INFORMATION** to the Interim Final Rule.

VIII. Procedural Requirements

As noted in publishing the Interim Final Rule, under the Administrative Procedure Act, 5 U.S.C. 553(b), notice and comment is not required for rules of agency organization, procedure, or practice. As discussed in the preamble to the Interim Final Rule, the Bureau confirms its finding that this is a procedural rule for which notice and comment is not required. In addition, because the Final Rule relates solely to agency procedure and practice, it is not subject to the 30-day delayed effective date for substantive rules under section 553(d) of the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* Because no notice of proposed rulemaking is required, the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601(2) do not apply. Finally, the Bureau has determined that this Final Rule does not impose any new recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval under 44 U.S.C. 3501. *et seq.*

List of Subjects in 12 CFR Part 1080

Administrative practice and procedure, Banking, Banks, Consumer protection, Credit, Credit unions, Investigations, Law enforcement, National banks, Savings associations, Trade practices.

For the reasons set forth in the preamble, the Bureau of Consumer Financial Protection revises part 1080 to Chapter X in Title 12 of the Code of Federal Regulations to read as follows:

PART 1080—RULES RELATING TO INVESTIGATIONS

Sec.

Authority: Pub. L. 111–203, Title X, 12 U.S.C. 5481 *et seq.*

§ 1080.1 Scope.

The rules of this part apply to Bureau investigations conducted pursuant to section 1052 of the Dodd-Frank Act, 12 U.S.C. 5562.

§ 1080.2 Definitions.

For the purposes of this part, unless explicitly stated to the contrary:

Bureau means the Bureau of Consumer Financial Protection.

Bureau investigation means any inquiry conducted by a Bureau investigator for the purpose of ascertaining whether any person is or has been engaged in any conduct that is a violation.

Bureau investigator means any attorney or investigator employed by the Bureau who is charged with the duty of enforcing or carrying into effect any Federal consumer financial law.

Custodian means the custodian or any deputy custodian designated by the Bureau for the purpose of maintaining custody of information produced pursuant to this part.

Director means the Director of the Bureau or a person authorized to perform the functions of the Director in accordance with the law.

Documentary material means the original or any copy of any book, document, record, report, memorandum, paper, communication, tabulation, chart, log, electronic file, or other data or data compilation stored in any medium, including electronically stored information.

Dodd-Frank Act means the Dodd-Frank Wall Street Reform and Consumer Financial Protection Act of 2010, as amended, Public Law 111–203 (July 21, 2010), Title X, codified at 12 U.S.C. 5481 *et seq.*

Electronically stored information (ESI) means any information stored in any electronic medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form.

Office of Enforcement means the office of the Bureau responsible for enforcement of Federal consumer financial law.

Person means an individual, partnership, company, corporation, association (incorporated or unincorporated), trust, estate, cooperative organization, or other entity.

Violation means any act or omission that, if proved, would constitute a violation of any provision of Federal consumer financial law.

§ 1080.3 Policy as to private controversies.

The Bureau shall act only in the public interest and will not initiate an investigation or take other enforcement action when the alleged violation is merely a matter of private controversy and does not tend to affect adversely the public interest.

§ 1080.4 Initiating and conducting investigations.

The Assistant Director of the Office of Enforcement and the Deputy Assistant Directors of the Office of Enforcement have the nondelegable authority to initiate investigations. Bureau investigations are conducted by Bureau investigators designated and duly authorized under section 1052 of the Dodd-Frank Act, 12 U.S.C. 5562, to conduct such investigations. Bureau investigators are authorized to exercise and perform their duties in accordance with the laws of the United States and the regulations of the Bureau.

§ 1080.5 Notification of purpose.

Any person compelled to furnish documentary material, tangible things, written reports or answers to questions, oral testimony, or any combination of

such material, answers, or testimony to the Bureau shall be advised of the nature of the conduct constituting the alleged violation that is under investigation and the provisions of law applicable to such violation.

§ 1080.6 Civil investigative demands.

(a) *In general.* In accordance with section 1052(c) of the Act, the Director of the Bureau, the Assistant Director of the Office of Enforcement, and the Deputy Assistant Directors of the Office of Enforcement, have the nondelegable authority to issue a civil investigative demand in any Bureau investigation directing the person named therein to produce documentary material for inspection and copying or reproduction in the form or medium requested by the Bureau; to submit tangible things; to provide a written report or answers to questions; to appear before a designated representative at a designated time and place to testify about documentary material, tangible things, or other information; and to furnish any combination of such material, things, answers, or testimony.

(1) *Documentary material.* (i) Civil investigative demands for the production of documentary material shall describe each class of material to be produced with such definiteness and certainty as to permit such material to be fairly identified, prescribe a return date or dates that will provide a reasonable period of time within which the material so demanded may be assembled and made available for inspection and copying or reproduction, and identify the custodian to whom such material shall be made available. Documentary material for which a civil investigative demand has been issued shall be made available as prescribed in the civil investigative demand.

(ii) Production of documentary material in response to a civil investigative demand shall be made under a sworn certificate, in such form as the demand designates, by the person to whom the demand is directed or, if not a natural person, by any person having knowledge of the facts and circumstances relating to such production, to the effect that all of the documentary material required by the demand and in the possession, custody, or control of the person to whom the demand is directed has been produced and made available to the custodian.

(2) *Tangible things.* (i) Civil investigative demands for tangible things shall describe each class of tangible things to be produced with such definiteness and certainty as to permit such things to be fairly identified, prescribe a return date or dates which will provide a reasonable period of time within which the things so demanded may be assembled and submitted, and identify the custodian to whom such things shall be submitted.

(ii) Submissions of tangible things in response to a civil investigative demand shall be made under a sworn certificate, in such form as the demand designates, by the person to whom the demand is directed or, if not a natural person, by any person having knowledge of the facts and circumstances relating to such production, to the effect that all of the tangible things required by the demand and in the possession, custody, or control of the person to whom the demand is directed have been submitted to the custodian.

(3) *Written reports or answers to questions.* (i) Civil investigative demands for written reports or answers to questions shall propound with definiteness and certainty the reports to be produced or the questions to be answered, prescribe a date or dates at which time written reports or answers to questions shall be submitted, and identify the custodian to whom such reports or answers shall be submitted.

(ii) Each reporting requirement or question in a civil investigative demand shall be answered separately and fully in writing under oath. Responses to a civil investigative demand for a written report or answers to questions shall be made under a sworn certificate, in such form as the demand designates, by the person to whom the demand is directed or, if not a natural person, by any person responsible for answering each reporting requirement or question, to the effect that all of the information required by the demand and in the possession, custody, control, or knowledge of the person to whom the demand is directed has been submitted to the custodian.

(4) *Oral testimony.* (i) Civil investigative demands for the giving of oral testimony shall prescribe a date, time, and place at which oral testimony shall be commenced, and identify a Bureau investigator who shall conduct the investigation and the custodian to whom the transcript of such investigation shall be submitted. Oral testimony in response to a civil investigative demand shall be taken in accordance with the procedures for investigational hearings prescribed by §§ 1080.7 and 1080.9 of this part.

(ii) Where a civil investigative demand requires oral testimony from an entity, the civil investigative demand shall describe with reasonable particularity the matters for examination and the entity must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on its behalf. Unless a single individual is designated by the entity, the entity must designate the matters on which each designee will testify. The individuals designated must testify about information known or reasonably available to the entity and their testimony shall be binding on the entity.

(b) *Manner and form of production of ESI.* When a civil investigative demand requires the production of ESI, it shall be produced in accordance with the instructions provided by the Bureau regarding the manner and form of production. Absent any instructions as to the form for producing ESI, ESI must be produced in the form in which it is ordinarily maintained or in a reasonably usable form.

(c) *Meet and confer.* The recipient of a civil investigative demand shall meet and confer with a Bureau investigator within 10 calendar days after receipt of the demand or before the deadline for filing a petition to modify or set aside the demand, whichever is earlier, to discuss and attempt to resolve all issues regarding compliance with the civil investigative demand. The Assistant Director of the Office of Enforcement and the Deputy Assistant Directors of the Office of Enforcement may authorize the waiver of this requirement for routine third-party civil investigative demands or in other circumstances where he or she determines that a meeting is unnecessary. The meeting may be in person or by telephone.

(1) *Personnel.* The recipient must make available at the meeting personnel with the knowledge necessary to resolve any issues relevant to compliance with the demand. Such personnel could include individuals knowledgeable about the recipient's information or records management systems and/or the recipient's organizational structure.

(2) *ESI.* If the civil investigative demand seeks ESI, the recipient shall ensure that a person familiar with its ESI systems and methods of retrieval participates in the meeting.

(3) *Petitions.* The Bureau will not consider petitions to set aside or modify a civil investigative demand unless the recipient has meaningfully engaged in the meet and confer process described in this subsection and will consider only issues raised during the meet and confer process.

(d) *Compliance.* The Assistant Director of the Office of Enforcement and the Deputy Assistant Directors of the Office of Enforcement are authorized to negotiate and approve the terms of satisfactory compliance with civil investigative demands and, for good

cause shown, may extend the time prescribed for compliance.

(e) *Petition for order modifying or setting aside demand—in general.* Any petition for an order modifying or setting aside a civil investigative demand shall be filed with the Executive Secretary of the Bureau with a copy to the Assistant Director of the Office of Enforcement within 20 calendar days after service of the civil investigative demand, or, if the return date is less than 20 calendar days after service, prior to the return date. Such petition shall set forth all factual and legal objections to the civil investigative demand, including all appropriate arguments, affidavits, and other supporting documentation. The attorney who objects to a demand must sign any objections.

(1) *Statement.* Each petition shall be accompanied by a signed statement representing that counsel for the petitioner has conferred with counsel for the Bureau pursuant to section 1080.6(c) in a good-faith effort to resolve by agreement the issues raised by the petition and has been unable to reach such an agreement. If some of the matters in controversy have been resolved by agreement, the statement shall specify the matters so resolved and the matters remaining unresolved. The statement shall recite the date, time, and place of each such meeting between counsel, and the names of all parties participating in each such meeting.

(2) *Extensions of time.* The Assistant Director of the Office of Enforcement and the Deputy Assistant Directors of the Office of Enforcement are authorized to rule upon requests for extensions of time within which to file such petitions. Requests for extensions of time are disfavored.

(3) *Bureau investigator response.* Bureau investigators may, without serving the petitioner, provide the Director with a statement setting forth any factual and legal response to a petition for an order modifying or setting aside the demand.

(4) *Disposition.* The Director has the authority to rule upon a petition for an order modifying or setting aside a civil investigative demand. The order may be served on the petitioner via email, facsimile, or any other method reasonably calculated to provide notice of the order to the petitioner.

(f) *Stay of compliance period.* The timely filing of a petition for an order modifying or setting aside a civil investigative demand shall stay the time permitted for compliance with the portion challenged. If the petition is denied in whole or in part, the ruling will specify a new return date.

(g) *Public disclosure.* All such petitions and the Director's orders in response to those petitions are part of the public records of the Bureau unless the Bureau determines otherwise for good cause shown. Any showing of good cause must be made no later than the time the petition is filed.

§ 1080.7 Investigational hearings.

(a) Investigational hearings, as distinguished from hearings in adjudicative proceedings, may be conducted pursuant to a civil investigative demand for the giving of oral testimony in the course of any Bureau investigation, including inquiries initiated for the purpose of determining whether or not a respondent is complying with an order of the Bureau.

(b) Investigational hearings shall be conducted by any Bureau investigator for the purpose of hearing the testimony of witnesses and receiving documentary material, tangible things, or other information relating to any subject under investigation. Such hearings shall be under oath or affirmation and stenographically reported, and a transcript thereof shall be made a part of the record of the investigation. The Bureau investigator conducting the investigational hearing also may direct that the testimony be recorded by audio, audiovisual, or other means, in which case the recording shall be made a part of the record of the investigation as well.

(c) In investigational hearings, the Bureau investigators shall exclude from the hearing room all persons except the person being examined, his or her counsel, the officer before whom the testimony is to be taken, any investigator or representative of an agency with which the Bureau is engaged in a joint investigation, and any individual transcribing or recording such testimony. At the discretion of the Bureau investigator, and with the consent of the person being examined, persons other than those listed in this paragraph may be present in the hearing room. The Bureau investigator shall certify or direct the individual transcribing the testimony to certify on the transcript that the witness was duly sworn and that the transcript is a true record of the testimony given by the witness. A copy of the transcript shall be forwarded promptly by the Bureau investigator to the custodian designated in section 1080.13.

§ 1080.8 Withholding requested material.

(a) Any person withholding material responsive to a civil investigative demand or any other request for production of material shall assert a claim of privilege not later than the date set for the production of material. Such person shall, if so directed in the civil investigative demand or other request for production, submit, together with such claim, a schedule of the items withheld which states, as to each such item, the type, specific subject matter, and date of the item; the names, addresses, positions, and organizations of all authors and recipients of the item; and the specific grounds for claiming that the item is privileged. The person who submits the schedule and the attorney stating the grounds for a claim that any item is privileged must sign it.

(b) A person withholding material solely for reasons described in this subsection shall comply with the requirements of this subsection in lieu of filing a petition for an order modifying or setting aside a civil investigative demand pursuant to section 1080.6(e).

(c) Disclosure of privileged or protected information or communications produced pursuant to a civil investigative demand shall be handled as follows:

(1) The disclosure of privileged or protected information or communications shall not operate as a waiver with respect to the Bureau if:

(i) The disclosure was inadvertent;

(ii) The holder of the privilege or protection took reasonable steps to prevent disclosure; and

(iii) The holder promptly took reasonable steps to rectify the error, including notifying a Bureau investigator of the claim of privilege or protection and the basis for it.

(2) After being notified, the Bureau investigator must promptly return, sequester, or destroy the specified information and any copies; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if he or she disclosed it before being notified; and, if appropriate, may sequester such material until such time as a hearing officer or court rules on the merits of the claim of privilege or protection. The producing party must preserve the information until the claim is resolved.

(3) The disclosure of privileged or protected information or communications shall waive the privilege or protection with respect to the Bureau as to undisclosed information or communications only if:

(i) The waiver is intentional;

(ii) The disclosed and undisclosed information or communications concern the same subject matter; and

(iii) They ought in fairness to be considered together.

§ 1080.9 Rights of witnesses in investigations.

(a) Any person compelled to submit documentary material, tangible things, or written reports or answers to questions to the Bureau, or to testify in an investigational hearing, shall be entitled to retain a copy or, on payment of lawfully prescribed costs, request a copy of the materials, things, reports, or written answers submitted, or a transcript of his or her testimony. The Bureau, however, may for good cause deny such a request and limit the witness to inspection of the official transcript of the testimony. Upon completion of transcription of the testimony of the witness, the witness shall be offered an opportunity to read the transcript of his or her testimony. Any changes by the witness shall be entered and identified upon the transcript by the Bureau investigator with a statement of the reasons given by the witness for making such changes. The transcript shall then be signed by the witness and submitted to the Bureau unless the witness cannot be found, is ill, waives in writing his or her right to signature, or refuses to sign. If the signed transcript is not submitted to the Bureau within 30 calendar days of the witness being afforded a reasonable opportunity to review it, the Bureau investigator, or the individual transcribing the testimony acting at the Bureau investigator's direction, shall sign the transcript and state on the record the fact of the waiver, illness, absence of the witness, or the refusal to sign, together with any reasons given for the failure to sign.

(b) Any witness compelled to appear in person at an investigational hearing may be accompanied, represented, and advised by counsel as follows:

(1) Counsel for a witness may advise the witness, in confidence and upon the initiative of either counsel or the witness, with respect to any question asked of the witness where it is claimed that a witness is privileged to refuse to answer the question. Counsel may not otherwise consult with the witness while a question directed to the witness is pending.

(2) Any objections made under the rules in this part shall be made only for the purpose of protecting a constitutional or other legal right or privilege, including the privilege against self-incrimination. Neither the witness nor counsel shall otherwise object or refuse to answer any question. Any objection during an investigational hearing shall be stated concisely on the record in a nonargumentative and nonsuggestive manner. Following an objection, the examination shall proceed and the testimony shall be taken, except for testimony requiring the witness to divulge information protected by the claim of privilege or work product.

(3) Counsel for a witness may not, for any purpose or to any extent not allowed by paragraphs (b)(1) and (2) of this section, interrupt the examination of the witness by making any objections or statements on the record. Petitions challenging the Bureau's authority to conduct the investigation or the sufficiency or legality of the civil investigative demand shall be addressed to the Bureau in advance of the hearing in accordance with § 1080.6(e). Copies of such petitions may be filed as part of the record of the investigation with the Bureau investigator conducting the investigational hearing, but no arguments in support thereof will be allowed at the hearing.

(4) Following completion of the examination of a witness, counsel for the witness may, on the record, request that the Bureau investigator conducting the investigational hearing permit the witness to clarify any of his or her answers. The grant or denial of such request shall be within the sole discretion of the Bureau investigator conducting the hearing.

(5) The Bureau investigator conducting the hearing shall take all necessary action to regulate the course of the hearing to avoid delay and to prevent or restrain disorderly, dilatory, obstructionist, or contumacious conduct, or contemptuous language. Such Bureau investigator shall, for reasons stated on the record, immediately report to the Bureau any instances where an attorney has allegedly refused to comply with his or her obligations under the rules in this part, or has allegedly engaged in disorderly, dilatory, obstructionist, or contumacious conduct, or contemptuous language in the course of the hearing. The Bureau will thereupon take such further action, if any, as the circumstances warrant, including actions consistent with those described in 12 CFR 1081.107(c) to suspend or disbar the attorney from further practice before the Bureau or exclude the attorney from further participation in the particular investigation.

§ 1080.10 Noncompliance with civil investigative demands.

(a) In cases of failure to comply in whole or in part with Bureau civil investigative demands, appropriate action may be initiated by the Bureau, including actions for enforcement.

(b) The Director, the Assistant Director of the Office of Enforcement, and the General Counsel of the Bureau are authorized to:

(1) Institute, on behalf of the Bureau, an enforcement proceeding in the district court of the United States for any judicial district in which a person resides, is found, or transacts business, in connection with the failure or refusal of such person to comply with, or to obey, a civil investigative demand in whole or in part if the return date or any extension thereof has passed; and

(2) Seek civil contempt or other appropriate relief in cases where a court order enforcing a civil investigative demand has been violated.

§ 1080.11 Disposition.

(a) When the facts disclosed by an investigation indicate that an enforcement action is warranted, further proceedings may be instituted in Federal or State court or pursuant to the Bureau's administrative adjudicatory process. Where appropriate, the Bureau also may refer investigations to appropriate Federal, State, or foreign governmental agencies.

(b) When the facts disclosed by an investigation indicate that an enforcement action is not necessary or would not be in the public interest, the investigational file will be closed. The matter may be further investigated, at any time, if circumstances so warrant.

(c) The Assistant Director of the Office of Enforcement and the Deputy Assistant Directors of the Office of Enforcement are authorized to close Bureau investigations.

§ 1080.12 Orders requiring witnesses to testify or provide other information and granting immunity.

The Director has the nondelegable authority to request approval from the Attorney General of the United States for the issuance of an order requiring a witness to testify or provide other information and granting immunity under 18 U.S.C. 6004.

§ 1080.13 Custodians.

(a) The Bureau shall designate a custodian and one or more deputy custodians for material to be delivered pursuant to a civil investigative demand in an investigation. The custodian shall have the powers and duties prescribed by 12 CFR 1070.3 and section 1052 of the Act, 12 U.S.C. 5562. Deputy custodians may perform all of the duties assigned to custodians.

(b) Material produced pursuant to a civil investigative demand, while in the custody of the custodian, shall be for the official use of the Bureau in accordance with the Act; but such material shall upon reasonable notice to the custodian

be made available for examination by the person who produced such material, or his or her duly authorized representative, during regular office hours established for the Bureau.

§ 1080.14 Confidential treatment of demand material and non-public nature of investigations.

(a) Documentary materials, written reports, answers to questions, tangible things or transcripts of oral testimony the Bureau receives in any form or format pursuant to a civil investigative demand are subject to the requirements and procedures relating to the disclosure of records and information set forth in part 1070 of this title.

(b) Bureau investigations generally are non-public. Bureau investigators may disclose the existence of an investigation to potential witnesses or third parties to the extent necessary to advance the investigation.

Dated: June 4, 2012.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2012–14047 Filed 6–28–12; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1082

[Docket No. CFPB–2011–0005]

RIN 3170–AA02

State Official Notification Rule

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule.

SUMMARY: The Dodd-Frank Wall Street Reform and Consumer Financial Protection Act of 2010 (Dodd-Frank Act) requires the Bureau of Consumer Financial Protection (Bureau) to prescribe rules establishing procedures that govern the process by which State Officials notify the Bureau of actions undertaken pursuant to the authority granted to the States to enforce the Dodd-Frank Act or regulations prescribed thereunder. This final State Official Notification Rule (Final Rule) sets forth the procedures to govern this process.

DATES: The Final Rule is effective June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Veronica Spicer, Office of Enforcement, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552, at (202) 435–7545.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Financial Protection Act of 2010 (Dodd-Frank Act) was signed into law on July 21, 2010. Title X of the Dodd-Frank Act established the Bureau to regulate the offering and provision of consumer financial products or services under the Federal consumer financial laws. Section 1042 of the Dodd-Frank Act, 12 U.S.C. 5552, governs the enforcement powers of the States under the Dodd-Frank Act. Under section 1042(a), a State attorney general or regulator (State Official) may bring an action to enforce Title X of the Dodd-Frank Act and regulations issued thereunder. Prior to initiating any such action, the State Official is required to provide notice of the action to the Bureau and the prudential regulator, if any, pursuant to section 1042(b) of the Dodd-Frank Act. Section 1042(b) further authorizes the Bureau to intervene in the State Official's action as a party, remove the action to a Federal district court, and appeal any order or judgment.

Pursuant to section 1042(c) of the Dodd-Frank Act, the Bureau is required to issue regulations implementing the requirements of section 1042. On July 28, 2011, the Bureau promulgated the State Official Notification Rule (Interim Final Rule) with a request for comment. The comment period for the Interim Final Rule ended on September 26, 2011. After reviewing and considering the issues raised by the comments, the Bureau now promulgates the Final Rule establishing a procedure for the timing and content of the notice required to be provided by State Officials pursuant to section 1042(b) of the Dodd-Frank Act, 12 U.S.C. 5552(b).

II. Summary of the Final Rule

Like the Interim Final Rule, the Final Rule implements a procedure for the timing and content of the notice required by section 1042(b), sets forth the responsibilities of the recipients of the notice, and specifies the rights of the Bureau to participate in actions brought by State Officials under section 1042(a) of the Dodd-Frank Act. In drafting the Final Rule, the Bureau endeavored to create a process that would provide both the Bureau and, where applicable, the prudential regulators with timely notice of pending actions and account for the investigation and litigation needs of State regulators and law enforcement agencies. In keeping with this approach, the Final Rule provides for a default notice period of at least ten calendar days, with exceptions for emergencies and other extenuating circumstances, and requires substantive notice that is both straightforward and comprehensive. The Final Rule further makes clear that the Bureau can intervene as a party in an action brought by a State Official under Title X of the Dodd-Frank Act or a regulation prescribed thereunder, provides for the confidential treatment of non-public information contained in the notice if a State so requests, and provides that provision of notice shall not be deemed a waiver of any applicable privilege. In addition, the Final Rule specifies that the notice provisions do not create any procedural or substantive rights for parties in litigation against the United States or against a State that brings an action under Title X of the Dodd-Frank Act or a regulation prescribed thereunder.

III. Legal Authority

Section 1042(c) of the Dodd-Frank Act authorizes the Bureau to prescribe regulations implementing the requirements of section 1042(b). In addition, the Bureau has general rulemaking authority pursuant to section 1022(b)(1) of the Dodd-Frank Act to prescribe rules to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws and to prevent evasions thereof.

IV. Overview of Comments Received

In response to the Interim Final Rule, the Bureau received several comments. Four letters were received from associations representing the financial industry, two letters were received from financial industry regulators and supervisors, and one letter was received from an individual consumer. The Bureau also received a comment letter from a financial industry regulator in response to its **Federal Register** notification of November 21, 2011, regarding the information collection requirements associated with the Interim Final Rule pursuant to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. All of the comments are available for review on *www.regulations.gov.*

The financial industry associations' comments fell into several general categories. Several comments expressed concerns about the Bureau's ability to maintain confidentiality for notification materials received by the Bureau. Other commenters requested clarity as to the type of actions for which the Bureau requires notification. One commenter requested that the Bureau require uniform interpretation by States of all Federal law within the Bureau's jurisdiction.

The comment letters received from industry regulators and supervisors focused on several concerns. Several commenters requested clarification of the types of actions for which the Bureau requires notification. The commenters also expressed concerns about the timing of the notice requirement prior to bringing an action, and one of the commenters requested clarification as to the application of the notification requirement to actions involving credit unions.

The comment letter from an individual consumer did not contain any specific comments or suggestions pertaining to the Interim Final Rule.

The comments received by the Bureau are discussed in more detail below in part V of the **SUPPLEMENTARY INFORMATION**.

V. Section-by-Section Summary

Section 1082.1(a) Notice Requirement

Section 1082.1(a) of the Interim Final Rule sets out the timing and process for notice by State Officials under non-emergency circumstances. The section requires State Officials to provide notice no later than ten days prior to initiating an action to enforce Title X of the Dodd-Frank Act or any regulation prescribed thereunder. The section also identifies to whom and how the notice should be sent and sets out an exception to the timing of the notice.

Several commenters asked the Bureau to clarify the types of proceedings subject to notification under this section. Commenters were concerned about lack of clarity in the use of the term ''action.'' The commenters noted that State regulators often pursue various courses of ''action,'' many of which do not rise to the level of a court or administrative proceeding, such as examination findings, confidential memorandums of understanding, licensing actions, and other similar ''actions.'' Commenters also asked the Bureau to clarify when it would consider an action to be one for the enforcement of any provisions of ''the Act or any regulation prescribed thereunder'' pursuant to § 1082.1(a)(1) of the Interim Final Rule. Specifically, the commenters asked whether notice is required when a State Official brings an action: (1) Pursuant to an enumerated Federal consumer financial law, other than Title X, or its implementing regulations, which the Bureau now has jurisdiction to enforce; or (2) pursuant to a State law that is predicated on Federal law, specifically Title X, but does not bring the action directly under Title X.

The Final Rule amends the Interim Final Rule to clarify the types of proceedings subject to the notice requirement. The Final Rule provides that an action requiring notification under this section is any adjudicative proceeding before a court or an administrative or regulatory body to determine whether a violation of any provision of Title X of the Dodd-Frank Act or any regulation prescribed thereunder has occurred.

Initiating an action under this section would include, but not be limited to, the filing of a complaint, motion for relief, or other document which initiates an action in a court or administrative or regulatory body. The Final Rule does not apply, for example, to examination findings or licensing proceedings. With regards to the substance of actions covered, the Final Rule does not apply to actions brought under the enumerated consumer laws, as defined in section 1002(12) of the Dodd-Frank Act, or the laws for which authorities are transferred to the Bureau under subtitles F and H of the Dodd-Frank Act, though some of those enumerated statutes have their own respective notification requirements that must be complied with. Nor would the Final Rule require notification of actions under State laws that are predicated on violations of Title X or regulations issued thereunder.

The Bureau, however, encourages State Officials to consult with the Bureau whenever interpretation of Federal consumer financial law, as defined in section 1002(14) of the Dodd-Frank Act, the regulations promulgated under Federal consumer financial law, or State law predicated on violations of Federal consumer financial law is relevant to a State regulatory or law enforcement matter, even if it is not the type of action for which notification is required. State Officials are also encouraged to consult with the Bureau when in doubt as to whether a particular anticipated activity is covered by this Final Rule. State Officials that wish to consult with the Bureau in this context may contact the Bureau via electronic mail at *Enforcement@cfpb.gov.*

The Bureau was also asked to clarify the application of § 1082.1(a) to covered entities approaching the $10 billion asset threshold relevant to the Bureau's supervisory authority under sections 1025 and 1026 of the Dodd-Frank Act or to those that fall below the threshold at a point in time. Section 1042 of the Dodd-Frank Act and paragraph 1082.1(a) apply to all actions brought by State Officials under Title X of the Dodd-Frank Act or any regulation promulgated thereunder, against any covered person, regardless of whether or not the entity's assets are above or below the threshold amount.

The Bureau also received several comments raising policy concerns. One commenter noted that it would not be prudent to impede a regulator's ability to apply the law in a timely manner simply because of a ten-day advance notice requirement. The Bureau agrees that delaying initiation of an action for the ten calendar day advance notice requirement may not always be in the public interest. The Bureau refers State Officials to § 1082.1(b), which governs *Emergency Actions* and is intended to account for these situations. In addition, under § 1082.1(a)(5), the Bureau may set an alternative deadline for the notice where the State Official demonstrates good cause.

Another commenter recommended that the Bureau require uniform interpretations of Federal law among various regulators at the Federal and State levels to discourage State attorneys general and other State regulators from initiating enforcement actions based on interpretations of Federal law that are not supported by the Bureau. The Bureau believes that it can achieve appropriate uniformity through notification and intervention, which are the mechanisms provided in section 1042(b) the Dodd-Frank Act. The Bureau also has authority to intervene in actions as otherwise provided for by law (including the Federal Rules of Civil Procedure), and may file amicus briefs in appropriate circumstances, which may assist in the uniform interpretation of Federal law. The Bureau, however, encourages State Officials and other Federal law enforcement agencies to consult with the Bureau regarding issues related to enforcement of Federal consumer financial law, especially the Dodd-Frank Act's prohibition on unfair, deceptive and abusive acts and practices. The Bureau will make resources available through its Office of Enforcement to provide consultation on such issues as needed, even if the action is not one for which the Bureau requires notification. Government officials that wish to consult with the Bureau in this context may contact the Bureau via electronic mail at *Enforcement@cfpb.gov.*

Other commenters recommended specific changes to § 1082.1(a) of the Interim Final Rule. One commenter recommended that the Bureau include in its Final Rule a requirement that State Officials bringing an action also notify ''other state regulatory officials,'' such as ''state consumer credit commissioners and prudential bank

regulators.'' Another commenter recommended that the Bureau amend § 1082.1(a)(3) to require notification of prudential regulators by electronic mail instead of the current text, which permits notice ''by mail or electronic mail.''

The Bureau declines to adopt these recommendations. First, section 1042(b)(1) of the Dodd-Frank Act limits the recipients of the notice to the Bureau and the prudential regulator, if any. Section 1002(24) of the Dodd-Frank Act defines the term ''prudential regulator'' as certain Federal regulatory agencies. While notification to State regulators may also be appropriate and should be considered by State Officials, such notification is within the discretion of the State Official. Second, the Bureau believes that allowing State Officials to notice the prudential regulator by regular mail, in addition to electronic mail, provides flexibility to State Officials subject to the notice requirement and will promote compliance with this section.

On its own initiative, the Bureau also amended the Final Rule to clarify that the State Official has ten *calendar* days prior to initiating the action to provide notice.

The Bureau adopts § 1082.1(a) of the Interim Final Rule with the changes discussed above.

Section 1082.1(b) Emergency Actions

Section 1082.1(b) of the Interim Final Rule sets out the process for the provision of notice in emergency circumstances. The section lays out the acceptable reasons for not providing notice in accordance with § 1082.1(a), and establishes a deadline to provide notice of no more than 48 hours after the initiation of an action. The section also identifies to whom and how the notice should be sent and provides an exception to the timing of notice.

The Bureau received two comments concerning § 1082.1(b) of the Interim Final Rule. One commenter argued that the emergency exception was too broad and suggested that the Bureau include in the Final Rule specific criteria for the Bureau's determination of when an emergency exception to the ten-day notification requirement is warranted as being ''in the public interest.'' Along similar lines, another commenter recommended that the Bureau remove the ''in the public interest'' language from the Final Rule and suggested that the exception to the ten-day notification requirement should only be permitted when delaying for ten days would cause ''irreparable and imminent harm or similar emergency circumstances.''

The Bureau has made minor technical revisions to the Interim Final Rule.

The Bureau adopts § 1082.1(b) of the Interim Final Rule with the changes discussed above. The Final Rule reflects the Bureau's view that determinations under § 1082.1(b) should be made on a case-by-case basis, taking into account the particular facts and circumstances of each case and that it is not necessary to include in the Final Rule specific criteria for determining when an emergency exception to the ten-day notice requirement is warranted as being ''in the public interest.'' The Bureau encourages State Officials to consult with the Office of Enforcement to determine instances when the emergency exception may apply.

Section 1082.1(c) Contents of Notice

In § 1082.1(c) of the Interim Final rule, the Bureau specifies the information that must be included in the notice provided by State Officials. This section also details certain additional information that must be provided when notice is not given until after an action has been initiated.

One commenter asked the Bureau to clarify the term ''materially different'' as used in § 1082.1(c)(5) of the Interim Final Rule. Under that section, the State Official must update the information provided in the notice if the State Official ''intends to file a complaint, motion for relief, or similar document that is materially different'' than the information initially provided. By way of clarification, material changes are those changes that substantively affect the legal or factual allegations of an action. Material changes would include, among other things, substantive changes in the factual allegations of an action, substantive changes in the citation to a State Official's legal authority to bring such an action, changes in the number of counts charged, changes in legal theories relied upon, and adding additional parties to an action. This list of material changes is not intended to be exhaustive, but is representative of the types of changes that would trigger a supplemental notification requirement under § 1082.1(c)(5). The Bureau encourages State Officials to consult with the Office of Enforcement on a case-by-case basis to determine if changes to documents filed in an action amount to ''material'' changes, requiring further notification.

Another commenter stated that § 1082.1(c) of the Interim Final Rule is inconsistent with section 1042(b) of the Dodd-Frank Act because § 1082.1(c) permits a State Official to provide a complete and unredacted copy of any complaint or action initiating document ''in its form as of the date the notice is provided.'' The commenter stated that section 1042 of the Dodd-Frank Act requires the State Official to provide the complete and ''final'' complaint at the time of initial notification.

Because § 1082.1(b) of the Interim Final Rule requires notification ten days in advance of a State Official filing a complaint or other action initiating document, it is impractical to require the State to provide the Bureau with the ''final'' version of these documents. To the extent the commenter is concerned that the notice will be inaccurate, § 1082.1(c)(5) requires supplemental notice if there are any material changes to the information provided to the Bureau in the initial notification documents.

As discussed below, § 1082.1(c) of the Interim Final Rule was also amended to require State Officials to identify, as part of the notification, any limitations the State Official requires on the disclosure of the substance or fact of the notice to any person or entity outside of the recipient agency. The Bureau also made some minor technical revisions to § 1082.1(c).

The Bureau adopts § 1082.1(c) of the Interim Final Rule with the changes discussed above.

Section 1082.1(d) Bureau Response

Section 1082.1(d) of the Interim Final Rule describes how the Bureau may intervene or otherwise participate in an action initiated by a State Official.

Several commenters suggested changes to this section of the Interim Final Rule. Some commenters recommended that the Bureau revise the Interim Final Rule to provide clear standards for when it would be appropriate for the Bureau to exercise its power to intervene under § 1082.1(d). Further, one commenter suggested that the Interim Final Rule should be amended to specify under which provisions of law the Bureau may legally intervene.

Section 1042(b)(2) of the Dodd-Frank Act authorizes the Bureau to intervene in any action brought by a State Official pursuant to the authority granted to the State under section 1042(a) of the Dodd-Frank Act. The Bureau reserves the right to intervene or otherwise participate in any action where it lawfully may do so, whether under section 1042(b)(2) of the Dodd-Frank Act or under another provision of law (including the Federal Rules of Civil Procedure). As a result, the Bureau declines to amend the Interim Final Rule as recommended and will determine which actions are appropriate for intervention on a case-by-case basis.

The Bureau made some minor technical revisions to § 1082.1(d).

The Bureau adopts § 1082.1(d) of the Interim Final Rule with the changes discussed above.

Section 1082.1(e) Confidentiality and Privilege

Section 1082.1(e) of the Interim Final Rule governs the recipient agencies' treatment of the information provided in the notice. The Interim Final Rule provides that the substance and fact of the notice shall not be disclosed by the Bureau or the prudential regulator prior to the information becoming public and also establishes certain exceptions to this requirement. These exceptions include (1) disclosures required by law, (2) disclosures consented to by the State Official, and (3) disclosures made to another government entity to protect the public interest after consultation with the State Official. In addition, the Interim Final Rule states that the provision of notice shall not be deemed a waiver of any applicable privilege.

One commenter raised two concerns with respect to this section. First, the commenter stated that the Bureau does not have the authority to limit a prudential regulator's ability to disclose such information and asserted that prudential regulators actually have an obligation to alert entities they supervise of such a notification. Second, the commenter asserted that the Bureau has no legal basis for its assertion that information provided by State Officials pursuant to the notification requirement shall not be deemed a waiver of any applicable privilege.

Section 1082.1(e) is promulgated pursuant to the Bureau's exclusive authority, under section 1042(c) of the Dodd-Frank Act, to prescribe regulations implementing the notice requirement. That authority necessarily includes the power to determine how the notice will be provided and how any non-public information contained therein will be treated by those who receive it. The Bureau, however, has revised the Interim Final Rule to emphasize that the restrictions on disclosure emanate from the nature of the information as belonging to the State. That information, including the fact of notice itself, is typically both sensitive and confidential. There is nothing in the Dodd-Frank Act to suggest that Congress intended section 1042(b) to prevent State Officials from keeping the substance and fact of their law enforcement actions confidential vis-à-vis third parties. Accordingly, the Final Rule amends the Interim Final Rule to provide that the substance and fact of the notice shall be subject to any limitations on disclosure required by the State Official pursuant to section 1082.1(c)(viii), subject to certain exceptions. As set forth in section 1082.1(e) of the Interim Final Rule, these exceptions include (1) disclosures required by law, (2) disclosures consented to by the State Official, and (3) disclosures made to another government entity to protect the public interest after consultation with the State Official.

With respect to the commenter's assertion that prudential regulators actually have an obligation to alert entities they supervise if they receive notification of an action by a State Official, the commenter provided no support for this assertion nor is the Bureau aware of any.

With respect to the commenter's privilege concerns, the provision of notification by a State Official to the Bureau pursuant to the Final Rule will not constitute a waiver of any applicable privilege. The disclosure by State Officials of the notification materials required by the Final Rule constitutes a compelled disclosure to the Bureau of information required by law, as opposed to a voluntary disclosure or a disclosure to an adversary that would constitute a waiver of applicable privileges. Moreover, the Bureau's rulemaking authority under sections 1022 and 1042 of the Dodd-Frank Act includes the authority to prescribe rules governing the implications of compliance with the statutory notice mandate. This provision furthers that mandate by encouraging compliance.

Finally, other commenters were concerned about the disclosure of confidential and/or privileged material contained in documentation maintained by the Bureau, including State notification documents provided to the Bureau. One commenter expressed specific concern regarding maintaining confidentiality when sending electronic mail to an anonymous address such as *Enforcement@cfpb.gov.*

Section 1082.1(e) of the Final Rule expressly provides that the State Official may impose limitations on the disclosure of the substance or fact of the notice to any entity outside of the recipient agency, subject to certain exceptions. Further, the Bureau will comply with the confidentiality procedures promulgated in its Interim Final Rule governing the Disclosure of Records and Information, 12 CFR 1070, to the extent applicable, and any future amendments to that Rule. Finally, the Bureau notes that its electronic mail system, which includes the incoming mailbox for *Enforcement@cfpb.gov* and *ExecSec@cfpb.gov,* is a secured web-based electronic mail system and access to these secured accounts is limited to select personnel within the Office of Enforcement and the Office of the Executive Secretary.

The Bureau adopts § 1082.1(e) of the Interim Final Rule with the changes discussed above.

Section 1082.1(f) No Private Right of Action or Defense

Section 1082.1(f) of the Interim Final Rule clarifies that § 1082.1 does not create any right, benefit, or defense which is enforceable against the United States or State Officials enforcing Title X of the Dodd-Frank Act or any regulation prescribed thereunder.

The Bureau received one comment on this section, which stated that to the extent the Interim Final Rule sets out rights enforceable under the Dodd-Frank Act or other statutes, the Interim Final Rule cannot remove those rights. Thus, the commenter recommended that the Bureau delete § 1082.1(f).

The Bureau adopts § 1082.1(f) of the Interim Final Rule without change in the Final Rule. By way of clarification, § 1082.1(f) of the Final Rule does not bar the exercise of any pre-existing rights; it merely makes clear that the Final Rule creates no additional rights.

VI. Section 1022 Analysis

In developing the Final Rule, the Bureau has considered the potential benefits, costs, and impacts as required by section 1022(b)(2)(A) of the Dodd-Frank Act.[1] In addition, the Bureau has consulted or offered to consult with the prudential regulators, the Department of Housing and Urban Development, the Securities and Exchange Commission, the Department of Justice, and the Federal Trade Commission before and after issuing the Interim Final Rule, including with regard to consistency with any prudential, market, or systemic

[1] Section 1022(b)(2)(A) of the Dodd-Frank Act addresses the consideration of the potential benefits and costs of regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act; and the impact on consumers in rural areas. Section 1022(b)(2)(B) requires that the Bureau ''consult with the appropriate prudential regulators or other Federal agencies prior to proposing a rule and during the comment process regarding consistency with prudential, market, or systemic objectives administered by such agencies.'' The manner and extent to which these provisions apply to a rulemaking of this kind that does not establish standards of conduct is unclear and to benefits, costs and impacts that are compelled by statutory changes rather than discretionary Bureau action is unclear. Nevertheless, to inform this rulemaking more fully, the Bureau performed the described analyses and consultations.

objectives administered by such agencies.

The Final Rule implements the Dodd-Frank Act's requirement to provide notice to the Bureau and prudential regulators when a State initiates an action under Title X of the Dodd-Frank Act or a regulation prescribed thereunder. The Final Rule will help ensure more efficient and consistent implementation of the State notification requirement, which will benefit both consumers and covered persons. In particular, the Final Rule provides that the notice shall be subject to any limitations on disclosure imposed by the State Official subject to certain limitations, establishes notification deadlines, including an exception for emergency proceedings, and specifies the content of the notice.

The Final Rule neither imposes any obligations on consumers nor has any direct impact on their access to consumer financial products or services. Further, the Final Rule has no unique impact on insured depository institutions or insured credit unions with less than $10 billion in assets as described in section 1026(a) of the Dodd-Frank Act. Finally, the Final Rule does not have a unique impact on rural consumers.

A commenter stated that the four interim final rules that the Bureau promulgated together on July 28, 2011 failed to satisfy the rulemaking requirements under section 1022 of the Dodd-Frank Act. Specifically, the commenter stated that ''the CFPB's analysis of the costs and benefits of its rules does not recognize the significant costs the CFPB imposes on covered persons.'' The Bureau believes that it fully considered the benefits, costs, and impacts of the Interim Final Rule pursuant to section 1022. Notably, the commenter did not identify any specific costs to covered persons imposed by the State Notification Rule that are not discussed in part C of the **SUPPLEMENTARY INFORMATION** to the Interim Final Rule.

VII. Procedural Requirements

1. Administrative Procedure Act

One commenter questioned whether the Interim Final Rule is exempt from the notice-and-comment requirements of section 553(b) of the Administrative Procedure Act (APA), 5 U.S.C. 553. The commenter argued that the Interim Final Rule is not properly characterized as relating solely to agency organization, procedure or practice because it requires the submission of information regarding covered persons to Federal officials and also establishes rules for the treatment of such information, which could result in potential harm to covered persons. The commenter further urged the Bureau to seek comment on similar rulemakings in the future.

The notice-and-comment procedures described in section 553(b) of the APA do not apply to rules of agency organization, procedure, or practice, or when the agency for good cause finds that notice and public comment on the rules being promulgated are impracticable or unnecessary. Both the Interim Final Rule and Final Rule relate to agency organization, procedure, or practice because they establish procedures for State Officials to provide notice to the Bureau; the requirement to provide the notice itself derives from section 1042(b)(1)(A) of the Dodd-Frank Act—not the Bureau's regulations. In any event, for the reasons discussed in the preamble to the Interim Final Rule, the Bureau had good cause for issuing the Interim Final Rule without prior notice and an opportunity for comment. The Bureau nevertheless solicited comment on the Interim Final Rule. Moreover, because the Final Rule merely finalizes the Interim Final Rule, to which it is substantially similar, the Bureau for good cause finds that additional notice and public comment on the Final Rule is unnecessary.

In addition, because the Final Rule relates solely to agency procedure and practice, it is not subject to the 30-day delayed effective date for substantive rules under section 553(d) of the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* Even if this requirement applied, the Bureau finds there is good cause for the Final Rules to take effect immediately upon publication in the **Federal Register**. The Final Rule is substantially similar to the Interim Final Rule, which became effective on July 29, 2011. Thus, no purpose would be served by delaying the Final Rule's effective date.

2. Regulatory Flexibility Act

Because no notice of proposed rulemaking was required, the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601(2), do not apply.

3. Paperwork Reduction Act

The collection of information requirements contained in this Final Rule have been approved by the Office of Management and Budget (OMB) in accordance with the PRA under OMB control number 3170–0019. The estimated time per response was 30 minutes. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

List of Subjects in 12 CFR Part 1082

Banks, Banking, Consumer protection, Credit, Credit unions, Federal Reserve System, Investigations, Law enforcement, National banks, Savings associations, State and local governments, Trade practices.

For the reasons set forth in the preamble, the Bureau of Consumer Financial Protection revises part 1082 to Chapter X in Title 12 of the Code of Federal Regulations to read as follows:

PART 1082—STATE OFFICIAL NOTIFICATION RULES

Authority: 12 U.S.C. 5481 *et seq.*

§ 1082.1 Procedures for notifying the Bureau of Consumer Financial Protection when a State Official takes an action to enforce Title X of the Dodd-Frank Wall Street Reform and Consumer Financial Protection Act of 2010.

(a) *Notice requirement.* (1) Pursuant to 12 U.S.C. 5552(b) and except as provided in paragraph (b) of this section, every State attorney general and State regulator (State Official) shall provide the notice described in paragraph (c) of this section to the Office of Enforcement of the Bureau of Consumer Financial Protection (the Bureau), the office of the Bureau responsible for enforcement of Federal consumer financial law pursuant to Title X of the Dodd-Frank Wall Street Reform and Consumer Financial Protection Act of 2010, as amended, Public Law 111–203 (July 21, 2010), codified at 12 U.S.C. 5481 *et seq.* (the Dodd-Frank Act), and the Office of the Executive Secretary of the Bureau at least ten calendar days prior to initiating any action against any covered person. For purposes of this section, an action requiring notification is any adjudicative proceeding before a court or an administrative or regulatory body to determine whether a violation of any provision of Title X of the Dodd-Frank Act or any regulation prescribed thereunder has occurred. Initiating an action under this section would include but not be limited to the filing of a complaint, motion for relief, or other document which initiates an action or a proceeding.

(2) Notice shall be provided to the Office of Enforcement and the Office of the Executive Secretary, or their successor offices, via electronic mail to *Enforcement@cfpb.gov* and *ExecSec@cfpb.gov*. In the event of technical problems preventing the delivery of notice, the Office of

Enforcement or its successor entity should be contacted.

(3) On the same date that notice is provided to the Office of Enforcement and the Office of the Executive Secretary pursuant to paragraph (a)(1) of this section, a copy of the notice shall be sent to the relevant prudential regulator, if any, or the designee thereof, by mail or electronic mail.

(4) Notice shall be deemed to have been provided as of the date of transmitting or mailing the materials described in paragraph (c) of this section.

(5) The Office of Enforcement, or its successor entity, in consultation with a State Official, may provide, for good cause shown, an alternative deadline for the notice described in paragraph (a)(1) of this section.

(b) *Emergency actions.* (1) Pursuant to 12 U.S.C. 5552(b), in the event that a State Official initiates or intends to initiate an action and, in order to protect the public interest or prevent irreparable and imminent harm, is unable to provide timely notice as described in paragraph (a) of this section, the State Official shall provide the notice described in paragraph (c) of this section as soon as is practicable and not later than 48 hours after initiation of the action.

(2) Notice shall be provided in accordance with the procedures set forth in paragraphs (a)(2) through (4) of this section.

(3) The Office of Enforcement, or its successor entity, in consultation with a State Official, may provide, for good cause shown, an alternative deadline for the notice described in paragraph (b)(1) of this section.

(c) *Contents of notice.* (1) Pursuant to 12 U.S.C. 5552(b), the notice required under paragraphs (a) and (b) of this section shall include a written description of the anticipated action, including:

(i) The court or body in which the action is to be initiated;

(ii) The identity of the parties to the action;

(iii) The nature of the action to be initiated;

(iv) The anticipated date of initiating the action;

(v) The alleged facts underlying the action;

(vi) A contact name, electronic mail address, and phone number of an individual involved with the matter in the office of the State Official with whom the Bureau may consult;

(vii) A determination as to whether there may be a need to coordinate the prosecution of the action so as not to interfere with any action, including any rulemaking, undertaken by the Bureau, a prudential regulator, or another Federal agency; and

(viii) A statement by the State Official setting forth any limitations on the disclosure of the substance or fact of the notice to any person or entity outside of the recipient agency.

(2) The notice required under paragraphs (a) and (b) of this section shall further include a complete and unredacted copy of any complaint, motion for relief, or similar document that is the subject of the notice, in its form as of the date the notice is provided. To the extent the complaint, motion for relief, or similar document contains the information described in paragraph (c)(1) of this section, provision of the complaint, motion for relief, or similar document shall be deemed sufficient notice of that information.

(3) In the event that notice is provided after the initiation of an action, the written description shall also include the following, in addition to the information described in paragraph (c)(1) of this section:

(i) A brief description of any proceeding that occurred as a result of the initiation of the action, including any orders issued by a court or other body;

(ii) Any case number, matter number, or designation assigned to the action; and

(iii) Information on scheduled court or other administrative or regulatory proceedings.

(4) In the event that notice is provided after the initiation of an action, in addition to the requirements set forth in paragraph (c)(3) of this section, the notice shall further include a complete, unredacted copy of any document filed by any party in relation to the action and any orders issued by the court or other body.

(5) If the State Official, after providing the notice described in paragraphs (c)(1) and (c)(2) of this section, intends to file a complaint, motion for relief, or similar document that is materially different from the document included with the notice, the State Official shall provide a copy of that document prior to filing, in accordance with the method described in paragraph (a)(2) of this section.

(d) *Bureau response.* In any action described in paragraphs (a) and (b) of this section, the Bureau may:

(1) Intervene in the action as a party;

(2) Upon intervening,

(i) Remove the action to the appropriate United States district court, if the action was not originally brought there; and

(ii) Be heard on all matters arising in the action;

(3) Appeal any order or judgment, to the same extent as any other party in the proceeding may; and

(4) Otherwise participate in the action as appropriate.

(e) *Confidentiality and privilege.* (1) The information described in paragraph (c) of this section, including the complaint, motion for relief, or other document, as well as the fact that notice has been provided, shall be subject to any limitations on disclosure imposed by the State Official pursuant to paragraph (c)(1)(viii) of this section; provided, however, that the recipient may disclose such information:

(i) As required by law;

(ii) When the information is or becomes publicly available;

(iii) With the consent of the State Official; or

(iv) To another State or Federal government entity when necessary to protect the public interest, after consultation with the State Official who provided the notice.

(2) Provision of notice by a State Official and disclosure of information pursuant to paragraph (e)(1) of this section shall not be deemed a waiver of any applicable privilege.

(f) *No private right of action or defense.* The requirements set forth in this section are not intended to, do not, and may not be relied upon to create any right, benefit, or defense, substantive or procedural, enforceable at law by a party against the United States or any State enforcing the provisions of the Dodd-Frank Act or any regulation prescribed thereunder.

Dated: June 4, 2012.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2012–14062 Filed 6–28–12; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1071

[Docket No.: CFPB–2012–0020]

RIN 3170–AA27

Equal Access to Justice Act Implementation Rule

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Interim final rule with request for public comment.

SUMMARY: The Equal Access to Justice Act (EAJA or the Act) requires agencies

that conduct adversary adjudications to award attorney fees and other litigation expenses to certain parties other than the United States in certain circumstances. EAJA also requires agencies that conduct adversary adjudications to establish procedures for the submission and consideration of applications for the award of fees and other expenses. The Consumer Financial Protection Bureau (Bureau) now issues an interim final rule establishing such procedures and seeks public comments.

DATES: This interim final rule takes effect on June 29, 2012. Comments must be received on or before August 28, 2012 to be assured of consideration.

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

• *Electronic: www.regulations.gov*. Follow the instructions for submitting comments.

• *Mail or Hand Delivery/Courier:* Monica Jackson, Office of the Executive Secretary, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552.

Instructions: All submissions must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. In general, all comments received will be posted to *http://www.regulations.gov*. In addition, 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. An appointment to inspect comments can be made 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. Submit only information that you wish to make publicly available. Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments will not be edited to remove any identifying or contact information such as name and address information, email addresses, or telephone numbers.

FOR FURTHER INFORMATION CONTACT: John R. Coleman, Office of the General Counsel, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552; (202) 435–7254.

SUPPLEMENTARY INFORMATION:

I. Background

Originally enacted in 1980, EAJA provides that ''[a]n agency that conducts an adversary adjudication shall award, to a prevailing party other than the United States, fees and other expenses incurred by that party in connection with that proceeding, unless the adjudicative officer of the agency finds that the position of the agency was substantially justified or that special circumstances make an award unjust.'' 5 U.S.C. 504(a)(1). The Administrative Conference of the United States (ACUS) was charged with coordination of the procedural rules adopted by various agencies to implement EAJA. To carry out this responsibility, ACUS issued model rules implementing EAJA (46 FR 32900, June 25, 1981), after receiving public comment on draft model rules (46 FR 15895, March 10, 1981). ACUS published revised model rules in 1986 that reflected the amendments Congress made when it re-authorized the Act in 1985. 51 FR 16659 (May 6, 1986), previously *codified at* 1 CFR part 315 (1995); *see* Administrative Conference of the U.S., Federal Administrative Procedure Sourcebook at 419 (2d ed. 1992). ACUS did not publish model rules reflecting amendments to the Act made since 1985 before ACUS was temporarily defunded in 1996.

In preparing regulations implementing the Act, the Bureau has used the 1986 ACUS model rules as a point of departure, modifying them to put them in plain language, to reflect more recent amendments to the Act, and to make certain changes the Bureau believes are warranted for reasons explained in the following section-by-section analysis. Since the preamble to the draft model rules explained their formulation and the preamble to the final model rules summarized and responded to the public comments submitted concerning the draft rules, the Bureau does not repeat here the rationale of the model rules. Rather, the Bureau notes where its rule differs from the model rules and explains significant provisions, as follows:

1. The Bureau's rule is divided into three subparts, as are the model rules, and maintains the same sequence with the following exception: The Bureau's rule starts at § 1071.100 and omits model rule § 315.107, ''Rulemaking on maximum rates for attorney fees,'' and § 315.108, ''Awards against other agencies.'' The revised numbering causes Bureau § 1071.106 to correspond to model rule § 315.109.

2. Section 1071.100, ''Purpose of this rule,'' inserts a new paragraph (b), ''When an eligible party will receive an award,'' which reflects amendments to EAJA made by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. 104–121, Title II, 110 Stat. 857 (1996). This paragraph is modeled on the EAJA rules of the Federal Trade Commission (FTC), 16 CFR 3.81(a)(1)(ii), but includes additional language to clarify the circumstances under which the Bureau's notice of charges may constitute a demand. This clarifying language is consistent with the Congressional intent in promulgating SBREFA. Legislative history suggests that Congress intended the term ''demand'' as used in the SBREFA amendments to mean ''an express written demand that leads directly to an adversary adjudication or civil action.'' *See* 142 Cong. Rec. E571–01, E573 (1996) (statement of Rep. Hyde). The Congressional Record further clarifies that ''the 'demand' at issue would be the government's demand that was *pending upon commencement* of the adjudication or action.'' *Id.* (emphasis added). Accordingly, the Bureau's notice of charges would constitute the agency's demand only where it was not preceded by an express written demand.

3. Section 1071.102, ''Proceedings covered,'' is modified and simplified from model rule § 315.103 and identifies the specific proceedings before the Bureau that are covered by EAJA. Incorporation of paragraphs (b) and (c) of model rule § 315.103 into the Bureau rule is not necessary because it is clear which Bureau proceedings are covered by EAJA.

4. Section 1071.103(b) inserts paragraph (6), which does not appear in the corresponding model rule § 315.104(b), in order to conform with the SBREFA amendments to EAJA.

5. Section 1071.104, ''Standards for awards,'' inserts paragraph (b), which does not appear in the corresponding model rule § 315.105, in order to conform with the SBREFA amendments to EAJA. The provision in paragraph (b) of model rule § 315.105 was moved to § 1071.104(a)(2). The last sentence in paragraph (a)(1) is modeled on the comparable rule of the Department of the Treasury governing the standards for awards under EAJA, 31 CFR 6.5, and clarifies that although the Bureau bears the burden of proof that its position was substantially justified, the fact that the Bureau did not prevail in the underlying proceeding does not create a presumption that the its position was not substantially justified.

6. Unlike model rule § 315.106(b), the corresponding paragraph (b) of § 1071.105 does not specify a rate for attorney fees, but instead refers back to the corresponding statutory provision in EAJA that sets forth the maximum hourly rate for attorney fees. This modification is intended to eliminate the need to promulgate a revised rule whenever the statutory maximum is increased. Most recently, the maximum

amount of fees that may normally be awarded to an attorney or agent was increased from $75 per hour to $125 per hour pursuant to 1996 amendments to EAJA. 5 U.S.C. 504(b)(1)(A)(ii). Section 1071.105 modifies the model rule to permit recovery of expert fees at the ''reasonable rate at which the Bureau pays witnesses with similar expertise'' instead of the ''highest rate'' paid by the Bureau.

7. Model rule § 315.107, ''Rulemaking on maximum rates for attorney fees,'' does not appear in the Bureau rule. Since frequent rulemaking on this subject is not foreseen, a rule concerning it is not deemed necessary.

8. Section 315.108 of the model rules, ''Awards against other agencies,'' does not appear in the Bureau rule because it is not anticipated that another agency of the United States will participate in an adversary proceeding before the Bureau. In the event another agency did so participate, it is anticipated that the adjudicative officer would take appropriate action in the absence of an express rule.

9. Section 1071.106, ''Delegation of authority,'' is a simplified version of the corresponding model rule, § 315.109.

10. Section 1071.200, ''Contents of application,'' is modeled on the corresponding FTC rule governing the contents of an application for recovery of awards under EAJA, 16 CFR 3.82(a), which provides a more comprehensive list of requirements than the corresponding model rule, § 315.201(a).

11. The provisions in paragraph (b) of model rule § 315.202 have been moved to § 1071.201(b) to consolidate the provisions relating to the net worth exhibit into a single section. The provisions in paragraph (b) of corresponding model rule § 315.202 regarding the presumptively public nature of the net worth exhibit can be found in § 1071.201(c).

12. Section 1071.202, ''Documentation of fees and expenses,'' is modified from the corresponding model rule, § 315.203, to conform with the SBREFA amendments to EAJA.

13. Section 1071.203, ''When an application may be filed,'' is modified from the corresponding model rule, § 315.204, to conform with the SBREFA amendments to EAJA.

14. Paragraph (c) of § 1071.203 defines the date of final Bureau disposition. This is significant for paragraph (a), which makes reference to final disposition. In particular, paragraph (a) reiterates the statutory provision, set forth at 5 U.S.C. 504(a)(2), that a party may file an application for an award within thirty days of the Bureau's final disposition of the adversary adjudication as to which the award is sought.

15. Section 1071.300, ''Filing and service of documents,'' incorporates the provisions of §§ 1081.111, 1081.112 and 1081.113 concerning service and filing in adjudication proceedings. The section also requires the applicant to serve a copy of the application for fees and expenses on the General Counsel of the Bureau.

16. Section 1071.304, ''Settlement,'' revises the corresponding model rule, § 315.305, to make explicit that no application for recovery of fees and expense may be filed if the settlement of the underlying proceeding provides that each side shall bear its own expenses.

17. Section 1071.306, ''Decision,'' is modified from the corresponding model rule, § 315.307, to conform with the SBREFA amendments to EAJA.

18. Section 1071.307, ''Bureau review,'' is modified from the corresponding model rule, § 315.308, so that Bureau review of an adjudicatory officer's decision concerning a fee application follows the same procedures as Bureau review of a hearing officer's decision in the underlying matter.

19. Section 1071.309, ''Payment of award,'' sets forth a 60 day deadline in which the Bureau must pay the amount awarded to the applicant.

II. Regulatory Requirements

The rule relates solely to agency procedure and practice and, thus, is not subject to the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(b). Although the rule is exempt from these requirements, the Bureau invites comment on it.

Because no notice of proposed rulemaking is required, these regulations are not a ''rule'' as defined by the Regulatory Flexibility Act, 5 U.S.C. 601(2). The regulations in this part do not contain any information collection requirement that requires the approval of OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 12 CFR Part 1071

Administrative practice and procedure, Banking, Banks, Consumer protection, Credit, Credit unions, Equal access to justice, Law enforcement, National banks, Savings associations.

Authority and Issuance

■ For the reasons set forth in the preamble, the Bureau adds part 1071 to Chapter X in Title 12 of the Code of Federal Regulations to read as follows:

PART 1071—RULE IMPLEMENTING EQUAL ACCESS TO JUSTICE ACT

Subpart A—General

Sec.

Subpart B—Information Required from Applicants

Subpart C—Procedures for Considering Applications

Authority: 5 U.S.C. 504.

Subpart A—General

§ 1071.100 Purpose.

(a) *In general.* The Equal Access to Justice Act (the Act), 5 U.S.C. 504, provides for the award of attorney fees and other expenses to eligible individuals and entities who are parties to certain administrative proceedings (adversary adjudications) before the Bureau of Consumer Financial Protection (the Bureau). An eligible party may receive an award when it prevails over the Bureau, unless the Bureau's position in the proceeding was substantially justified or special circumstances make an award unjust. This part describes the parties eligible for awards and the proceedings that are covered. This part also explains how to apply for awards, and the procedures and standards that the Bureau will use in ruling on those applications.

(b) *When an eligible party will receive an award.* An eligible party will receive an award when:

(1) It prevails in the adversary adjudication, unless the Bureau's position in the proceeding was substantially justified or special circumstances make an award unjust. Whether or not the position of the Bureau was substantially justified will be determined on the basis of the administrative record as a whole that is made in the adversary proceeding for

which fees and other expenses are sought; or

(2) The Bureau's demand is substantially in excess of the decision of the adjudicative officer and is unreasonable when compared with that decision, under all the facts and circumstances of the case, unless the party has committed a willful violation of law or otherwise acted in bad faith, or special circumstances make an award unjust. ''Demand'' means the express final written demand made by the Bureau prior to initiation of the adversary adjudication, but does not include a recitation by the Bureau of the statutory penalty in the notice of charges or elsewhere when accompanied by an express demand for a lesser amount. The relief requested in the Bureau's notice of charges issued pursuant to 12 CFR 1081.200(b)(3) may constitute the Bureau's demand only where the notice of charges was not preceded by an express final written demand.

§ 1071.101 When the Act applies.

The Act applies to any adversary adjudication pending before the Bureau at any time after July 21, 2011.

§ 1071.102 Proceedings covered.

The Act applies to all adjudicative proceedings under part 1081 as defined in § 1081.103.

§ 1071.103 Eligibility of applicants.

(a) To be eligible for an award of attorney fees and other expenses under the Act, the applicant must be a party to the adversary adjudication for which it seeks an award. The term ''party'' is defined in 5 U.S.C. 551(3). The applicant must show that it meets all conditions of eligibility set out in this subpart.

(b) The types of eligible applicants are as follows:

(1) An individual with a net worth of not more than $2 million;

(2) The sole owner of an unincorporated business who has a net worth of not more than $7 million, including both personal and business interests, and not more than 500 employees;

(3) A charitable or other tax-exempt organization described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) with not more than 500 employees;

(4) A cooperative association as defined in section 15(a) of the Agricultural Marketing Act (12 U.S.C. 1141j(a)) with not more than 500 employees; or

(5) Any other partnership, corporation, association, or public or private organization with a net worth of not more than $7 million and not more than 500 employees.

(6) For purposes of receiving an award for fees and expenses for defending against an excessive Bureau demand, any small entity, as that term is defined under 5 U.S.C. 601(6).

(c) For purposes of eligibility, the net worth and number of employees of an applicant shall be determined as of the date the proceeding was initiated.

(d) An applicant who owns an unincorporated business will be considered an ''individual'' rather than a ''sole owner of an unincorporated business'' if the issues on which the applicant prevails are related primarily to personal interests rather than to business interests.

(e) The employees of an applicant include all persons who regularly perform services for remuneration for the applicant, under the applicant's direction and control. Part-time employees shall be included on a proportional basis.

(f) The net worth and number of employees of the applicant and all of its affiliates shall be aggregated to determine eligibility. Any individual or group of individuals, corporation or other entity that directly or indirectly controls or owns a majority of the voting shares or other interest of the applicant, or any corporation or entity of which the applicant directly or indirectly owns or controls a majority of the voting shares or other interest, will be considered an affiliate of that business for purposes of this part, unless the adjudicative officer determines that such treatment would be unjust and contrary to the purposes of the Act in light of the actual relationship between the affiliated entities. In addition, the adjudicative officer may determine that financial relationships of the applicant other than those described in this paragraph constitute special circumstances that would make an award unjust.

(g) An applicant that participates in a proceeding primarily on behalf of one or more other persons or entities that would be ineligible is not itself eligible for an award.

§ 1071.104 Standards for awards.

(a) For a prevailing party:

(1) An eligible prevailing applicant may receive an award for fees and expenses incurred after initiation of the adversary adjudication in connection with the entire adversary adjudication, or on a substantive portion of the adversary adjudication that is sufficiently significant and discrete to merit treatment as a separate unit, unless the position of the Bureau was substantially justified. The burden of proof that an award should not be made to an eligible prevailing applicant because the Bureau's position was substantially justified is on counsel for the Bureau. However, no presumption arises that the Bureau's position was not substantially justified simply because the Bureau did not prevail.

(2) An award will be reduced or denied if the applicant has unduly or unreasonably protracted the proceeding or if special circumstances make the award sought unjust.

(b) For a party defending against an excessive demand:

(1) An eligible applicant will receive an award for fees and expenses incurred after initiation of the adversary adjudication related to defending against the portion of a Bureau demand that is substantially in excess of the decision of the adjudicative officer and is unreasonable when compared with that decision under all the facts and circumstances of the case.

(2) An award will be denied if the applicant has committed a willful violation of law or otherwise acted in bad faith or if special circumstances make an award unjust.

§ 1071.105 Allowable fees and other expenses.

(a) Subject to the limitations in paragraph (b) of this section, awards will be based on rates customarily charged, in the locale of the hearing, by persons engaged in the business of acting as attorneys, agents and expert witnesses, even if the services were made available without charge or at a reduced rate to the applicant.

(b) No award for the fee of any attorney or agent under this rule may exceed the hourly rate specified in 5 U.S.C. 504(b)(1)(A). No award to compensate an expert witness may exceed the reasonable rate at which the Bureau pays witnesses with similar expertise. However an award may also include the reasonable expenses of the attorney, agent or witness as a separate item, if the attorney, agent or witness ordinarily charges clients separately for such expenses.

(c) In determining the reasonableness of the fee sought for an attorney, agent or expert witness, the adjudicative officer shall consider the following:

(1) If the attorney, agent or witness is in private practice, his or her customary fee for similar services, or, if an employee of the applicant, the fully allocated cost of the services;

(2) The prevailing rate for similar services in the community in which the

attorney, agent or witness ordinarily performs services;

(3) The time actually spent in the representation of the applicant;

(4) The time reasonably spent in light of the difficulty or complexity of the issues in the proceeding; and

(5) Such other factors as may bear on the value of the services provided.

(d) The reasonable cost of any study, analysis, engineering report, test, project or similar matter prepared on behalf of a party may be awarded, to the extent that the charge for the services does not exceed the prevailing rate for similar services, and the study or other matter was necessary for preparation of the applicant's case.

(e) An award of fees or expenses under the Act is limited to fees and expenses incurred after initiation of the adversary adjudication and, with respect to excessive demands, the fees and expenses incurred in defending against the excessive portion of the demand.

§ 1071.106 Delegations of authority.

The Director may delegate authority to take final action on matters pertaining to the Equal Access to Justice Act in particular cases.

Subpart B—Information Required from Applicants

§ 1071.200 Contents of application.

An application for an award of fees and expenses under the Act shall contain the following:

(a) Identity of the applicant and the proceeding for which the award is sought;

(b) A showing that the applicant has prevailed; or, if the applicant has not prevailed, a showing that the Bureau's demand was substantially in excess of the decision of the adjudicative officer and was unreasonable when compared with that decision, under the facts and circumstances of that case;

(c) Identification of the Bureau position(s) in the proceeding that the applicant alleges was (were) not substantially justified; or, identification of the Bureau's demand that is alleged to be excessive and unreasonable and an explanation as to why the demand was excessive and unreasonable;

(d) A brief description of the type and purpose of the organization or business (unless the applicant is an individual).

(e) A statement of how the applicant meets the eligibility criteria of § 1071.103;

(f) The amount of fees and expenses incurred after the initiation of the adversary adjudication, or in the case of a claim for defending against an allegedly excessive demand, the amount of fees and expenses incurred after the initiation of the adjudicative proceeding attributable to the allegedly excessive portion of the demand;

(g) Any other matter the applicant wishes the Bureau to consider in determining whether and in what amount an award should be made; and

(h) A written verification under oath or under penalty of perjury that the information provided is true and correct, accompanied by the signature of the applicant or an authorized officer or attorney.

§ 1071.201 Net worth exhibit.

(a) The application shall also include a detailed exhibit showing that the applicant's net worth did not exceed $2 million (if an individual) or $7 million (for all other applicants, including their affiliates) when the proceeding was initiated. The exhibit may be in any form convenient to the applicant that provides full disclosure of the applicant's and its affiliates' assets and liabilities and is sufficient to determine whether the applicant qualifies under the standards in this subpart. The adjudicative officer may require an applicant to file additional information to determine its eligibility for an award.

(b) However, an applicant may omit this exhibit if:

(1) It attaches a copy of a ruling by the Internal Revenue Service that it qualifies as an organization described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) or, in the case of a tax-exempt organization not required to obtain a ruling from the Internal Revenue Service on its exempt status, a statement that describes the basis for the applicant's belief that it qualifies under such section;

(2) It states that it is a cooperative association as defined in section 15(a) of the Agricultural Marketing Act (12 U.S.C. 1141j(a));

(3) In the case of an application for an award related to an allegedly excessive demand by the Bureau, it demonstrates that it is a small entity as that term is defined by 5 U.S.C. 601(6).

(c) Ordinarily, the net worth exhibit will be included in the public record of the proceeding. However, an applicant that objects to public disclosure of information in any portion of the exhibit and believes there are legal grounds for withholding it from disclosure may submit that exhibit directly to the adjudicative officer in a sealed envelope labeled ''Confidential Financial Information,'' accompanied by a motion to withhold the information from public disclosure. The motion shall describe the information sought to be withheld and explain, in detail, why it falls within one or more of the specific exemptions from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 522(b)(1) through (9), why public disclosure of the information would adversely affect the applicant, and why disclosure is not required in the public interest. The material in question shall be served on Bureau counsel but need not be served on any other party to the proceeding. If the adjudicative officer finds that the information should not be withheld from disclosure, it shall be placed in the public record of the proceeding. Otherwise, any request to inspect or copy the exhibit shall be handled in accordance with the Bureau's established procedures under the Freedom of Information Act, 12 CFR subpart B.

§ 1071.202 Documentation of fees and expenses.

The application shall be accompanied by full documentation of the fees and expenses incurred after initiation of the adversary adjudication, including the cost of any study, engineering report, test, or project for which an award is sought. With respect to a claim for fees and expenses involving an excessive demand by the Bureau, the application shall be accompanied by full documentation of the fees and expenses incurred after initiation of the adversary adjudication, including the cost of any study, engineering report, test, or project for which an award is sought attributable to the portion of the demand alleged to be excessive and unreasonable. A separate itemized statement shall be submitted for each professional firm or individual whose services are covered by the application, showing the hours spent in connection with the proceeding by each individual, a description of the specific services performed, the rate at which each fee has been computed, any expenses for which reimbursement is sought, the total amount claimed, and the total amount paid or payable by the applicant or by any other person or entity for the services provided. The adjudicative officer may require the applicant to provide vouchers, receipts, or other substantiation for any expenses claimed.

§ 1071.203 When an application may be filed.

(a) An application may be filed not later than 30 days after the final disposition of the proceeding to which the application relates.

(b) If review or reconsideration is sought or taken of a decision, proceedings for the award of fees shall

be stayed pending final disposition of the underlying controversy.

(c) For purposes of this subpart, *final disposition* means the later of—

(1) The date that the Director's final order issued pursuant to § 1081.405 is final and unappealable, both within the agency and to the courts; or

(2) The date that the Bureau issues any other final resolution of a proceeding, such as a consent agreement, settlement or voluntary dismissal, that is not subject to a petition for reconsideration.

Subpart C—Procedures for Considering Applications

§ 1071.300 Filing and service of documents.

(a) Any application for an award or other pleading or document related to an application shall be filed and served on all parties to the proceeding in the same manner as other pleadings in proceedings under part 1081.

(b) In addition, a copy of each application for fees and expenses shall be served on the General Counsel of the Bureau.

§ 1071.301 Answer to application.

(a) Within 30 days after service of an application, counsel representing the Bureau may file an answer to the application. Unless Bureau counsel requests an extension of time for filing or files a statement of intent to negotiate under paragraph (b) of this section, failure to file an answer within the 30-day period may be treated as consent to the award requested.

(b) If Bureau counsel and the applicant believe that the issues in the fee application can be settled, they may jointly file a statement of their intent to negotiate a settlement. The filing of this statement shall extend the time for filing an answer for an additional 30 days and further extensions may be granted by the adjudicative officer upon joint request by Bureau counsel and the applicant.

(c) The answer shall explain in detail any objections to the award requested and identify the facts relied on in support of Bureau counsel's position. If the answer is based on any alleged facts not already in the record of the proceeding, Bureau counsel shall include with the answer either supporting affidavits or a request for further proceedings under § 1071.305 of this part.

§ 1071.302 Reply.

Within 15 days after service of an answer, the applicant may file a reply. If the reply is based on any alleged facts not already in the record of the proceeding, the applicant shall include with the reply either supporting affidavits or a request for further proceedings under § 1071.305 of this part.

§ 1071.303 Comments by other parties.

Any party to a proceeding other than the applicant and Bureau counsel may file comments on an application within 30 days after it is served or on an answer within 15 days after it is served. A commenting party may not participate further in proceedings on the application unless the adjudicative officer determines that the public interest requires such participation in order to permit full exploration of matters raised in the comments.

§ 1071.304 Settlement.

The applicant and Bureau counsel may agree on a proposed settlement of the award before final action on the application, either in connection with a settlement of the underlying proceeding or after the underlying proceeding has been concluded, in accordance with the Bureau's standard settlement procedures. If a prevailing party and Bureau counsel agree on a proposed settlement of an award before an application has been filed, the application shall be filed with the proposed settlement. If a proposed settlement of an underlying proceeding provides that each side shall bear its own expenses and the settlement is accepted, no application may be filed.

§ 1071.305 Further proceedings.

(a) Ordinarily, the determination of an award will be made on the basis of the written record. However, on request of either the applicant or Bureau counsel, or on his or her own initiative, the adjudicative officer may order further proceedings, such as an informal conference, oral argument, additional written submissions or an evidentiary hearing. Such further proceedings shall be held only when necessary for full and fair resolution of the issues arising from the application, and shall be conducted as promptly as possible.

(b) A request that the adjudicative officer order further proceedings under this section shall specifically identify the information sought or the disputed issues and shall explain why the additional proceedings are necessary to resolve the issues.

§ 1071.306 Recommended decision.

The adjudicative officer shall issue a recommended decision on the application within 60 days after the time for filing a reply, or where further proceedings are held, within 60 days after completion of such proceedings.

(a) For a decision involving a prevailing party: The decision shall include written findings and conclusions on the applicant's eligibility and status as a prevailing party, and an explanation of the reasons for any difference between the amount requested and the amount awarded. The decision shall include, if at issue, findings on whether the agency's position was substantially justified, whether the applicant unduly protracted the proceedings, or whether special circumstances make an award unjust.

(b) For a decision involving an allegedly excessive Bureau demand: The decision on the application shall include written findings and conclusions on the applicant's eligibility and an explanation of the reasons why the Bureau's demand was or was not determined to be substantially in excess of the underlying decision of the adjudicative officer and was or was not unreasonable when compared with that decision. That determination shall be based upon all the facts and circumstances of the case. The decision on the application shall also include, if at issue, findings on whether the applicant has committed a willful violation of law or otherwise acted in bad faith, or whether special circumstances make an award unjust.

§ 1071.307 Bureau review.

Either the applicant or Bureau counsel may seek review of the recommended decision on the fee application by filing a notice of appeal under § 1081.402(a), or the Director may decide to review the decision on his or her own initiative, in accordance with § 1081.402(b). If neither the applicant nor Bureau counsel seeks review and the Director does not take review on his or her own initiative, the Director will adopt the recommended decision on the application as the final decision of the Bureau within 30 days of the issuance of the recommended decision. Whether to review a decision is a matter within the discretion of the Director. If review is taken, the Director will issue a final decision on the application or remand the application to the adjudicative officer for further proceedings.

§ 1071.308 Judicial review.

Judicial review of final Bureau decisions on awards may be sought as provided in 5 U.S.C. 504(c)(2).

§ 1071.309 Payment of award.

An applicant seeking payment of an award shall submit to the Bureau a copy of the Bureau's final decision granting the award, accompanied by a statement

that the applicant will not seek review of the decision in the United States courts. An applicant shall be paid the amount awarded within 60 days of entry of the final decision unless judicial review of the award or of the underlying decision of the adversary adjudication has been sought by the applicant or any other party to the proceeding.

Dated: June 4, 2012.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2012–14046 Filed 6–28–12; 8:45 am]

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Part IV

Department of Defense

Defense Acquisition Regulations System

48 CFR Parts 205, 208, 212, *et al.*
Defense Acquisition Regulations System; Defense Federal Acquisition Regulation Supplement; Only One Offer (DFARS Case 2011–D013); Defense Federal Acquisition Regulation Supplement: Shipping Instructions (DFARS Case 2011–D052) and Defense Federal Acquisition Regulation Supplement: Applicability of Hexavalent Chromium Policy to Commercial Items (DFARS Case 2011–D047); Final Rules

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 205, 208, 212, 214, 215, 216, 252

RIN 0750–AH11

Defense Acquisition Regulations System; Defense Federal Acquisition Regulation Supplement; Only One Offer (DFARS Case 2011–D013)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to address acquisitions using competitive procedures in which only one offer is received. This rule implements a DoD Better Buying Power initiative. The revisions to this rule are part of DoD's retrospective plan under Executive Order 13563 completed in August 2011.

DATES: *Effective Date:* June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION: DoD's full plan can be accessed at *http://exchange.regulations.gov/exchange/topic/eo-13563*.

I. Background

DoD published a proposed rule in the **Federal Register** at 76 FR 44293 on July 25, 2011, to address acquisitions using competitive procedures in which only one offer is received. This rule was initiated to implement one of the aspects of the initiative on promoting real competition that was presented by the Under Secretary of Defense for Acquisition, Technology, and Logistics (AT&L) in a memorandum dated November 3, 2010. This memorandum was further implemented by memoranda from the Director, Defense Procurement and Acquisition Policy, dated November 24, 2010, and April 27, 2011.

Some of the other background events leading up to publication of this rule are summarized as follows:

- In 2007, an Acquisition Advisory (SARA) panel report discussed methods to encourage competition focused on longer solicitation periods as well as improved requirements generation and market research/industry communication.
- In 2008, the Office of Management and Budget and Office of Federal Procurement Policy issued a memorandum detailing agencies' efforts to improve competition where only one offer was received. These efforts involved such steps as limiting contract length, minimizing unique or brand name specifications, and enhancing acquisition planning.
- In 2010, the Government Accountability Office studied reasons why only one offer is received, and concluded that several factors contributed, such as a strong incumbent, restrictive Government requirements, and/or bundling of requirements into larger acquisitions.

The comment period closed on September 23, 2011, but was re-opened on September 27, 2011 (76 FR 59623) through October 7, 2011. DoD received comments on the proposed rule from 19 respondents.

II. Discussion and Analysis of the Public Comments

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

A. Summary of Significant Changes From the Proposed Rule

1. *DFARS 215.371–1.* A section on policy has been added at DFARS 215.371–1 to replace the proposed paragraph DFARS 215.371(a). The policy statement is completely rewritten to shift the emphasis away from whether the circumstances described at FAR 15.403–1(c)(1)(ii) constitute adequate price competition, to an emphasis on the objectives of the rule, i.e., to increase competition and, if only one offer is received nevertheless, to make sure that the price is fair and reasonable and that the statutory requirements for obtaining certified cost or pricing data are met.

2. *DFARS 215.371–2.* A section has been added to address the efforts to promote competition, similar to the coverage in the proposed rule at DFARS 215.371(c)(1). In response to public comments, two FAR references have been added to provide considerations on revising requirements to promote competition (FAR 6.502(b) and 11.002).

3. *DFARS 215.371–3 has been added to address the process for obtaining fair and reasonable prices, replacing the proposed paragraph DFARS 215.371(c)(2*). The contracting officer is not required to obtain further cost or pricing data if the contracting officer determines that the offered price is fair and reasonable on the basis of cost or price analysis and that adequate price competition exists, in accordance with FAR 15.403–1(c)(1)(ii), or another exception to the statutory requirement for certified cost or pricing data applies (see Truth in Negotiations Act (10 U.S.C. 2306a) and FAR 15.403–4). Otherwise, the contracting officer must obtain additional cost or pricing data, and that data must be certified, unless an exception to the requirement for certified cost or pricing data applies. The following table provides a summary of the requirement for cost or pricing data and whether the data must be certified, depending on whether the contracting officer can determine the price to be fair and reasonable and whether an exception to the requirement for certified cost or pricing data applies.

	Circumstance 1	Circumstance 2	Circumstance 3	Circumstance 4	Circumstance 5
Contracting officer (c.o.) determines price fair & reasonable?	YES	YES	YES	NO	NO
C.o. determines adequate price competition? (approved 1 level above c.o.)	YES	NO	NO	X*	X
Another TINA exception applies?		YES	NO	YES	NO
Cost or pricing data required?	NO	NO	YES	YES	YES

	Circumstance 1	Circumstance 2	Circumstance 3	Circumstance 4	Circumstance 5
Data must be certified?	N/A	N/A	YES	NO	YES

* Note that the contracting officer cannot determine that adequate price competition exists if cannot determine that the price is fair and reasonable.

4. Two exceptions have been added at DFARS 215.371–4 (proposed at DFARS 215.371(e)):

• An exception to the 30-day resolicitation period has been added to address the application to small business set-asides.

• The final rule states that it does not apply to broad agency announcements.

5. Waivers are now addressed at DFARS 215.371–5 (proposed at DFARS 215.371(d)), but the coverage of waivers is otherwise unchanged.

6. The proposed statement at DFARS 215.403–1(c)(1)(B) has been modified to reference back to the procedures at DFARS 215.371–3 for ensuring a fair and reasonable price if only one offer is received. DFARS 215.371–3 makes it clear that adequate price competition, as described at FAR 15.403–1(c)(1)(ii), cannot be used for the purpose of determining that a price is fair and reasonable.

7. The rule no longer addresses acquisitions under FAR subpart 13.5, because that statutory authority has expired.

8. Statements have been added at DFARS 208.404(a) and 214.404–1(2) to specify clearly the deviation from the statements in the corresponding FAR sections.

B. Analysis of Public Comments

1. Meaning of ''Only One Offer''

Comment: One respondent stated that what constitutes one offer should be more clearly defined. The respondent questioned whether this includes only technically acceptable, timely offers.

Response: For the purpose of DFARS 215.371, an offer includes any timely offer or late offer accepted by the contracting officer. There is no requirement for each offer to meet the requirements at FAR 15.403–1(c)(1)(i) in order to count as more than one offer received. However, if after evaluations the contracting officer determines only one responsive offer was received, the contracting officer will need to review the standards at FAR 15.403–1(c) to determine if adequate price competition exists or another exception applies, and take the appropriate steps to ensure a fair and reasonable price.

Comment: One respondent questioned whether this rule is applicable to the solicitation of quotations. The respondent noted that quotations are solicited routinely when using the procedures of FAR subpart 8.4.

Response: This rule is applicable to quotes as well as offers. Quotes should be treated the same as offers, for the purposes of this rule. The term ''offer'' used in the provision is comprehensive enough to apply to all competitive acquisitions subject to the final rule. Specifically, the term ''offer'' appropriately applies to acquisitions exceeding the simplified acquisition threshold conducted under FAR parts 8, 12, 14, 15, and 16. FAR defines ''offer'' to include responses to invitations for bids (sealed bidding) and responses to requests for proposals (negotiation), but to exclude responses to requests for quotations (RFQs). However, DFARS parts 208 and 216 already use the term ''offer'' in reference to orders awarded under those subparts. Finally, the final rule does not apply to acquisitions below the simplified acquisition threshold awarded based on quotations received. Therefore, the provisions in the final rule, because they use the term ''offer,'' can be used appropriately for competitions under FAR parts 8, 12, 14, 15, and 16 exceeding the simplified acquisition threshold.

2. Promoting Competition

a. General

Comment: One respondent asked whether the policy should promote the receipt of two or more offers on all competitive procedures exceeding the simplified acquisition threshold.

Response: The intent of the DoD Better Buying Power initiative is to promote competition on all competitive solicitations. The policy at DFARS 215.371–1(a) does promote the receipt of two or more offers in response to competitive solicitations, unless an exception applies.

Comment: One respondent stated that the proposed rule approach to increasing competition ''mistakenly conflates a post-proposal requirement for submitting cost or pricing data after receipt of offer with steps needed to increase DoD competition, but does nothing to address the root causes of the lack of competition.''

Response: The rule requires the contracting officer to consult with the requiring activity as to whether the requirement should be revised in order to promote more competition and requires resolicitation if the solicitation allowed fewer than 30 days for receipt of proposals. The post-proposal requirement for cost or pricing data addresses the second objective of the rule—to obtain fair and reasonable prices.

Comment: One respondent stated that the rule may result in decreased competition. This respondent pointed to unintended reduction in the number of competitors and in the ability to maintain long term strategic defense capabilities, because of a shift to ''lowest price possible.'' Further, according to this respondent, some potential offerors may not be willing to participate if they may subsequently be required to submit cost or pricing data.

Response: The intent of the rule is not to seek the lowest price, but a best value at a competitive price. If two or more offerors respond to a requirement or if the contracting officer determines that the offered price is fair and reasonable and an exception to the requirement for certified cost or pricing data applies, then the contracting officer is not required to ask for additional cost or pricing data.

b. Time Period for Response

Comment: Various respondents were in favor of extending solicitation periods to allow potential offerors more time to assemble a competitive offer. One respondent stated that this is generally a step in the right direction, and another stated that this will likely result in increased competition. One respondent stated that the proposed 30 additional days is both reasonable and appropriate.

Response: None required.

Comment: One respondent stated that it is difficult to understand why any solicitation would be advertised for less than 30 days if not covered by one of the excepted circumstances. The respondent recommended that DoD should issue conforming instructions that all solicitations must comport with the rule at FAR 5.203, except as specified in the proposed exception at DFARS 215.371(e)(1)(ii) (now at 215.371–4) for contingencies. FAR 5.203(c) requires agencies to allow at least a 30-day response time for receipt of bids or proposals from the date of issuance of a solicitation, if the

proposed contract action is expected to exceed the simplified acquisition threshold, except for acquisition of commercial items (paragraph (a)) or in the general category of ''annual forecast'' (paragraph (h)).

This respondent also stated that adding transactional process time in all cases where only a single offer is received in response to a competitive solicitation is contrary to sound acquisition policy.

Response: Federal Supply Schedules and indefinite-delivery/indefinite-quantity contracts allow for shorter solicitation times. The final rule does not require added transactional time in all cases. Encouraging competition is sound acquisition policy. The rule also allows the head of the contracting activity to waive the 30-day solicitation requirement, when appropriate.

Comment: One respondent was concerned that resoliciting will expose the fact to industry prematurely that there was only one offeror. Since this respondent saw little probability that the additional 30 days would result in additional offerors, this respondent foresaw that the offeror would not reduce the price, but would raise the price under the resolicitation.

Response: If there is still only one offer after resolicitation and negotiations ensue, the rule states that the contracting officer should not negotiate a higher price than was originally proposed. As defined in FAR 2.101, ''should'' means ''an expected course of action unless inappropriate for a particular circumstance.'' An offeror raising the price because there is no competition would not be an appropriate reason for negotiating a higher price.

Comment: Another respondent stated that by virtually mandating a 30-day solicitation period, this rule will delay the acquisition of critical items and, in many cases, not offer any cost savings. This respondent recommended use of other methods than resolicitation for determining price reasonableness if it is believed that resolicitation will not result in reduced pricing.

Response: The Government does not require that all solicitations be announced for 30 days. If market research indicates a commercial market with multiple potential offerors that will be able to respond in fewer than 30 days, then the contracting officer may issue the solicitation for fewer than 30 days. Resolicitation is used to increase competition, not as a method to determine price reasonableness. For specifics with regard to application in FAR parts 12 and 16, see also the responses in sections II.B.6.b. and 6.d. of this preamble.

Comment: One respondent requested that the new rule should specify which parts of the DFARS are subject to the 30-day requirement.

Response: The rule specifies the parts to which it is applicable (DFARS parts 205, 208, 212, 214, 215, and 216). It may apply indirectly to other parts to the extent that the acquisition procedures of these parts are used. An exception has been added to state specifically that the rule does not apply to broad agency announcements. An exception to the 30-day resolicitation requirement, if only one offer is received, has also been added for small business set-asides.

c. Requirements

Comment: Several respondents agreed that encouraging revised statements of work in appropriate circumstances would likely result in increased competition, and were in favor of these proposed revisions. One respondent stated that the reason why only one offer was received in part is likely because the requirement is too restrictive in its content, so that rewording the requirement can facilitate more offers.

Several respondents stated that the proposed rule did not adequately address the process for amending the solicitation when only one offer is received due to flawed solicitation requirements, specifications, contract types, etc. One respondent stated that DoD should set forth guidelines and/or criteria for determining when and how a solicitation should be revised.

Response: It is a duty of the competition advocate to challenge requirements that are not stated in terms of functions to be performed, performance required, or essential physical characteristics and identify any condition or action that has the effect of unnecessarily restricting competition (FAR 6.502(b)(1)). FAR 11.002 provides policy on stating requirements in a way to maximize competition. A cross reference to these FAR citations has been added at DFARS 215.371–2(a).

3. Fair and Reasonable Prices

a. Relationship Between Adequate Price Competition and Determination of Fair and Reasonable Price

FAR references:

Current coverage at FAR 15.403–1(c) provides three circumstances in which a price is based on adequate price competition, for the purpose of deciding whether there is an exemption to the requirement for certified cost or pricing data:

- In the first circumstance, two or more responsible offerors, competing independently, submit priced offers that satisfy the Government's expressed requirement, if award will be made to the offeror whose proposal represents the best value where price is a substantial factor in source selection, and there is no finding that the price of the otherwise successful offeror is unreasonable. In this circumstance, there is a presumption of price reasonableness. Any finding that the price is unreasonable must be supported by a statement of the facts and approved at a level above the contracting officer.
- In the second circumstance, there was a reasonable expectation, based on market research, that two or more responsible offerors, competing independently, would submit priced offers in response to the solicitation's expressed requirement, even though only one offer is received from a responsible offeror; and the determination that the proposed price is based on adequate price competition and is reasonable, must be approved at a level above the contracting officer. This standard for adequate price competition was added to the two pre-existing standards in the FAR in October 1995 (FAC 90–32) as a result of sections 1202 and 1251 of the Federal Acquisition Streamlining Act of 1994 (Pub. L. 105–355). These sections required the FAR to provide clear standards for application of the exceptions to the requirement for submission of cost or pricing data (including adequate price competition).
- In the third circumstance, price analysis clearly demonstrates that the proposed price is reasonable in comparison with current or recent prices for the same or similar items, adjusted to reflect changes in market conditions under contracts that resulted from adequate price competition. Note that the requirement that price analysis be based on contracts that resulted from adequate price competition does not cover buys in which the price is determined fair and reasonable based on certified cost or pricing data from previous production buys. This standard has been in the regulations since May 1964, when adequate price competition was first addressed in the Armed Services Procurement Regulation (3–807.1(b)).

Comment: One respondent fully supported DoD's proposal that 30-day solicitations that produce only one offer should trigger a price or cost analysis. This respondent stated that it has long advocated the position that adequate price competition does not exist where

only one offer is received pursuant to a competitive solicitation.

Other respondents wanted to preserve the exception at FAR 15.403–1(c)(1)(ii) as a valid exemption from the requirement for certified cost or pricing data, while some acknowledged the need for better enforcement of FAR 15.403–1(c)(1)(ii)(B), i.e., the need to determine at a level above the contracting officer that the price is reasonable.

One respondent had reservations about the apparent elimination of agency discretion to find adequate price competition when a single offer is received, following the expectation of multiple offers. The respondent expressed concern that because the FAR does not reflect the same approach, there is a risk of confusion in the acquisition community. This respondent cited a GAO 2010 study, which recommended case-by-case analysis of single offers, not elimination of the discretion to find adequate price competition when a single offer is received. This respondent also quoted a 2009 DoD statement that ''the receipt of a single offer does not necessarily indicate a lack of competition (DoD's 2009 Competition Report).

Several respondents stated that the current FAR reflects the processes required of the contracting officer to protect DoD's interests in a fair and reasonable price in those situations where competition was expected, but, for whatever reason, is not achieved.

Another respondent considered that the requirement at FAR 15.403–1(c)(1)(ii) has been misused, because contracting officers confuse the adequate price competition definition of expected competition in the exception as also covering the adequate price competition pricing method of comparing proposals in FAR 15.404–1(b)(2)(i). FAR 15.404–1(b)(2)(i) states that one price analysis technique is ''Comparison of proposed prices received in response to the solicitation. Normally, adequate price competition establishes a fair and reasonable price (see FAR 15.403–1(c)(1)).'' The respondent recommended that we clarify the need for separate price analysis before concluding that the standard for adequate price competition has been met.

Similarly, another respondent recommended more rigorous enforcement of the existing price reasonableness test in FAR 15.403–1(c)(1)(ii) and (iii) for adequate price competition, without further regulatory change to prohibit DoD contracting officers from using the exception. Another respondent concurred that the problem is not the tool but the improper use of the tool. The respondent recommended maintaining the standards at FAR 15.403–1(c)(1)(ii). A third respondent stated that current methods are adequate to attain the desired benefit, but without ''completely undercutting the existing acquisition process.''

Response: In response to public comments, DoD has reassessed the proposed statement of policy at DFARS 215.371 in order to better reflect the fundamental purpose of the rule. The policy statement at DFARS 215.371–1 has been revised to clarify that if only one offer is received in response to a competitive solicitation, it is DoD policy—

- To take the required actions to promote competition; and
- To ensure, if the steps to promote competition still do not result in more than one offer, a fair and reasonable price and compliance with the statutory requirements for certified cost or pricing data, unless an exception applies.

The proposed rule statement that the circumstance of ''reasonable expectation * * * that two or more offerors, competing independently, would submit priced offers,'' as further described at FAR 15.403–1(c)(1)(ii), does not constitute adequate price competition if only one offer is received'' is not included in the final rule. The second element in the statement of policy, which reflects one of the ultimate goals of the proposed rule, shifts the focus from determining the existence of ''adequate price competition'' to achieving a ''fair and reasonable price.''

There are two citations in the FAR that have contributed to the confusion regarding the relationship between the determination that adequate price competition exists and the determination that a price is fair and reasonable.

Until a recent technical amendment, FAR 15.403–1(c)(1)(ii), which addresses ''only one offer,'' included as a standard for adequate price competition the requirement that ''The determination that the proposed price is based on adequate price competition, is reasonable, and is approved at a level above the contracting officer;''. The technical amendment restored the original wording, which had become inadvertently unclear in the process of a major rewrite of FAR part 15, to read as follows:

''The determination that the proposed price is based on adequate price competition and is reasonable has been approved at a level above the contracting officer;''

This makes it unambiguous that it is the price that must be reasonable, not the determination, and that this determination of reasonable price is an essential part of the determination that adequate price competition exists.

However, FAR 15.404–1(b)(2)(i) makes the statement that ''Normally, adequate price competition establishes a fair and reasonable price (see FAR 15.403–1(c)(1)).'' This statement is overly broad. Although ''adequate price competition'' and ''fair and reasonable price'' are inextricably linked, only adequate price competition as described at FAR 15.403–1(c)(1)(i) can be used as the basis to determine that the price is fair and reasonable. FAR 15.403–1(c)(1)(i) involves the receipt of offers from two or more responsible sources, competing independently. That this is what was intended at FAR 15.404–1(b)(2)(i) is clear from the lead-in sentence, which addresses the comparison of proposed prices received in response to the solicitation as a price analysis technique.

The perception that ''based on adequate price competition'' can be used as sufficient basis to determine that a price is fair and reasonable is clearly untenable for the standards in FAR 15.403–1(c)(1)(ii) and (iii), both of which require a determination of price reasonableness as part of the determination that adequate price competition exists. Since there is no adequate price competition under FAR 15.403–1(c)(1)(ii) until a level above the contracting officer has found the price to be ''reasonable,'' the determination that the price is fair and reasonable in the case of only one offer cannot be based on ''adequate price competition,'' as in the case when multiple offers are received, but must be based on another type of cost or price analysis. The cost or price analysis in the case of paragraph (ii) is not subject to the particular restrictions imposed in paragraph (iii).

The respondents, therefore, have a point when they state that the problem with the determination that ''only one offer'' can constitute adequate price competition lies primarily in the misuse of that determination as a basis to assume that the price is fair and reasonable.

Therefore, DoD has revised the final rule to emphasize that, although FAR 15.403–1(c)(1)(ii) may be used to determine that adequate price competition exists for purposes of an exemption from the requirement to obtain certified cost or pricing data, that determination of adequate price competition can only be made in conjunction with the determination that

the price is fair and reasonable, based on cost or price analysis, not just relying on ''adequate price competition.'' If the price can be determined to be fair and reasonable based on cost or price analysis and the appropriate determination is approved at one level above the contracting officer that the other criteria for adequate price competition have been met, or another exception to the requirement for certified cost or pricing data applies, then there is no need for any additional cost or pricing data.

Comment: One respondent expressed serious concerns that full and open competition is no longer the model to determine a fair and reasonable price when single offers are received, and that a price achieved through full and open competition is only a starting point for further negotiation.

Response: As already stated, ''full and open competition'' (i.e., adequate price competition) cannot be the basis for determining a fair and reasonable price when only one offer is received, because the determination that adequate price competition exists cannot be made until a separate determination has been made that the price is fair and reasonable.

Comment: One respondent considered it ''inexplicable'' that the proposed rule does not recognize the requirements of FAR 15.403–1(c)(1)(iii) to perform price analysis as contributing to the informed contracting officer decision about adequate price competition and price reasonableness.

Response: Although a prior memorandum of November 24, 2010, from the Director, Defense Procurement and Acquisition Policy (DPAP), included a restriction of reliance on the standard at FAR 14.303–1(c)(1)(iii) for determining adequate price competition, the subsequent DPAP memorandum of April 27, 2011, and the proposed rule only restricted reliance on the exception at FAR 15.403–1(c)(1)(ii). Therefore, FAR 15.403–1(c)(1)(iii) could still be relied upon to determine adequate price competition, if the criteria can be met. Note that this exception only applies if the prices of the prior contracts resulted from adequate price competition.

Comment: One respondent questioned the lack of empirical data to back up the statement in the September 14, 2010, Carter memo that DoD contracting officers were not performing cost or price analysis on single bid offers.

Response: Although DoD does not have extensive data, there is concern based on anecdotal evidence that when there was an expectation of competition but only one offer was received, in too many instances there was not a serious independent cost or price analysis to determine that the price was fair and reasonable. The GAO Report of July 2010 (GAO–10–833, Federal Contracting: Opportunities Exist to Increase Competition and Assess Reasons When Only One Offer Is Received), found that some contracting approaches (about 10 percent of sample reviewed) did not reflect sound procurement or management practices, including some with very limited documentation of the reasonableness of proposed prices.

b. Requirement for More Data

i. Statutory Exemptions From Requirement To Submit Certified Cost or Pricing Data

Comment: Several respondents requested clarification of when data other than certified cost or pricing data applies. Several respondents were further concerned that the proposed rule conflicted with underlying legislation and regulation that prohibit requesting (certified) cost or pricing data in certain circumstances. The respondent requested clarification of the rule to exempt procurements for commercial items or procurement to which another exception applies. The respondent reiterated that agencies are statutorily prohibited from requiring certified cost or pricing data where any exception applies.

Another respondent stated that the rule should state explicitly that unless a waiver is granted or it is a commercial item, the data would always be certified cost or pricing data. This respondent recommended a specific change in the final rule, adding a new paragraph DFARS 215.371(c)(2)(i) to specifically add the requirement to ''Determine if an exception to certified cost or pricing data is necessary and/or applicable.''

Further, another respondent stated that submission of other than certified cost or pricing data should never be a substitute for the submission of certified cost or pricing data. Accordingly, the respondent believed that if only one offer is received, then the submission of certified cost or pricing data should be required in order to conclude that a fair and reasonable price has been established.

Response: The final rule has been revised to make it clearer when additional cost or pricing data is required and when that data must be certified. DFARS 215.371–3(b)(2)(i) states that ''For acquisitions that exceed the cost or pricing data threshold, if no exception at FAR 15.403–1(c) applies, the cost or pricing data shall be certified.'' The rule does not override any of the statutory exemptions from the requirement to require certified cost or pricing data, as set forth at FAR 15.403–1(c).

ii. Impact of Requesting Unnecessary Additional Data

Comment: One respondent stated that although obtaining insight into some single offer procurements may be appropriate, the respondent believes that the goal can be better achieved by better enforcing the existing rules. The respondent cited FAR 15.402(a)(3), which states that ''Contracting officers shall obtain the type and quality of data necessary to establish a fair and reasonable price, but not more data than is necessary. Requesting unnecessary data can lead to increased proposal preparation costs, generally extend acquisition lead time, and consume additional contractor and Government resources.''

Similarly, another respondent objected that the proposed rule effectively shifts the burden for price reasonableness to the offeror, by requiring them to provide either certified cost or pricing data or data other than certified cost or pricing data automatically, in response to several new clauses authorizing the contracting officer to demand such data when a single offer is received. According to the respondent, this rule creates the de facto presumption that any single offer outcome is unreasonable. This respondent recommended that supporting data should be restricted to pricing data and prohibit the contracting officer from requesting cost data or profit figures (per the SARA panel). The respondent further stated that if cost data is necessary, it should not require certification.

Several respondents feared a negative impact because of the proposed rule requirement for submission of cost or pricing data when only one offer is received.

One respondent stated that the uncertainty at the time of offer as to whether cost or pricing data will later be required, imposes an unanticipated burden of gathering such data. The respondent was concerned that this uncertainty may increase prices, drive away competitors, especially nontraditional suppliers, from submitting offers, and thus increase the number of single offers received.

Another respondent stated that the demand for additional data will add to the enormous industry bid and proposal cost burden. The respondent further stated that requiring cost or pricing data is contrary to sound acquisition policy

and will negatively impact mission performance accomplishment.

Response: The final rule has been revised to narrow the circumstances in which the contracting officer will request additional cost or pricing data. The rule now clarifies that, in competitive environments when only one offer is received, the contracting officer is only required to obtain enough data to establish fair and reasonable prices and to comply with any statutory requirement for certified cost or pricing data. If the contracting officer determines that the proposed price is fair and reasonable (through cost or price analysis using any data from the same or similar products or services previously procured) and that adequate price competition exists (the determination approved at one level above the contracting officer) or another exception to the requirement for certified cost or pricing data applies, then no further data is required. However, if the contracting officer cannot make the preceding determination, then the contracting officer must request additional cost or pricing data, and that data must be certified, unless another exception to the requirement for certified cost or pricing data applies (e.g., commercial items, or below the certified cost or pricing data threshold).

The provision at DFARS 252.215–7008 has been revised in the final rule so that it no longer automatically requires additional data if only one offer is received. The provision notifies offerors that the contracting officer may request additional cost or pricing data if only one offer was received and if additional cost or pricing data is required in order to determine whether the price is fair and reasonable. In addition, the provision has been revised so that an offeror, by submission of its offer, agrees to provide any data requested by the contracting officer in accordance with FAR 52.215–20.

c. Negotiations

Comment: Several respondents commented on the requirement that the negotiated price should not exceed the offered price. One respondent asked whether a FAR deviation from FAR 15.306(d), Exchanges with offerors after establishment of the competitive range, was being processed for DFARS 215.371(c)(2)(ii), which states in part that ''If the contracting officer decides to enter negotiations, the negotiated price should not exceed the offered price.''

Response: FAR 1.304 provides that agency regulations may be inconsistent with the FAR as provided in FAR subpart 1.4, Deviations from the FAR. FAR 1.404(b) provides that for DoD, class deviations are controlled, processed, and approved in accordance with the DFARS. DPAP is the approval authority for class deviations or changes to the DFARS that constitute a permanent deviation from the FAR. Incorporation of a policy or procedures in the DFARS is sufficient to establish that a policy or procedure different from the FAR is applicable to DoD. DoD only processes a deviation from the FAR as a separate document when there is insufficient time to incorporate the changes in the DFARS or the incorporation in the DFARS is inappropriate for some other reason.

Comment: One respondent stated that both discussions and negotiations could reveal errors that would lead to revised proposals either lower or higher than the offered price. Additionally, the respondent expressed concern that the definition of ''should'' is different to each individual. Another respondent recommended striking the limitation that negotiated price should not exceed offered price from paragraph (c) of proposed DFARS 252.215–70XX.

Response: The term ''should'' is defined at FAR 2.101 (see response to third comment under section II.B.2.b.). If discussions or negotiations reveal errors that would lead to revised proposals, then that could constitute sufficient rationale to diverge from the norm of ''should'' and negotiate a higher price.

Comment: One respondent cited the 20 percent likelihood that there will be only one offer as cause for offerors to back away from making an initial offer, because if there is only one offer, then the offeror will be forced to negotiate further with their offered price as ceiling. The respondent also sees an impact on contracting officers because of the difference between the FAR and the DFARS, causing ''more confusion among DoD contracting officers about the negotiation process.''

Response: The rule has been revised so that negotiations only ensue when the contracting officer cannot determine that the offered price is fair and reasonable (also see response to previous section II.B.3.b.ii.).

Comment: One respondent had some technical comment with regard to entering negotiations under DFARS part 214. The respondent recommended inclusion of several references (at DFARS 214.404–1(1) and (2) and 214.408–1(b)) to FAR 14.404–1(f), which allows sealed bidding to convert to negotiated in lieu of cancellation required by FAR 14.404–1(c).

Response: The DFARS supplementation of FAR 14.404–1 has added a reference to FAR 15.404–1(f) to clarify that the DFARS procedures at DFARS 215.371 supersede the procedures at FAR 14.404–1(f).

4. Exceptions in Proposed Rule

a. Simplified Acquisition Threshold

Comment: Three respondents recommended increasing the proposed threshold for application of the rule from the simplified acquisition threshold to $10 million. One respondent stated that the rule should exempt acquisitions less than $10 million, in order to return the highest level of benefit from the burdens imposed by submission of cost or pricing data and negotiation.

Similarly, another respondent recommended the $10 million threshold in order to focus the requirements on the competitions in which fostering effective competition would have the most beneficial impact to DoD and for which a failure to perform adequate cost or price analysis of single offers could result in the most detriment to DoD.

A third respondent provided the rationale that, especially for procurement of services, for many procurements of less than $10 million associated with re-competes, other contractors determine that based on a cost-benefit analysis, the cost of writing and submitting a proposal exceed the potential benefits associated with the acquisition.

Response: The simplified acquisition threshold is currently $150,000, with higher thresholds for contingency operations or to facilitate the defense against nuclear, biological, chemical, or radiological attack (which are exempt from this rule). Another possible threshold that was considered is the threshold for certified cost or pricing data ($650,000). DoD decided to retain the simplified acquisition threshold as the threshold for application of this rule. It is not to the benefit of DoD to exempt acquisitions up to $10 million from this rule, or even $650,000, especially as the final rule has been revised to eliminate any unnecessary burden. It is important at every dollar value to maximize competition and determine that prices are fair and reasonable. The primary reasons that buys below the simplified acquisition threshold have been exempted from this rule are because—

- 41 U.S.C. 1901 requires that in order to ''promote efficiency and economy in contracting and to avoid unnecessary burdens,'' the FAR shall provide simplified procedures for acquisitions not greater than the simplified acquisition threshold; and

• It is simply not feasible to apply the rule to the huge volume of very low dollar value buys, a large majority of which are conducted electronically.

b. Contingency Contracting

Comment: One respondent viewed the exception for contingency contracting as a serious defect. The respondent referenced the Commission on Wartime Contracting as evidence that DoD's non-competitive procurement practices in contingency operations have resulted in billions of dollars of waste. The respondent, therefore, recommended that either the exception be deleted, or a rigorous set of guidelines be included in the final rule, to limit the instances in which such an exception could be granted.

Response: An exception for actions in support of contingency operations is provided due to the urgent nature of actions and the need for flexibility in theater in order to remain responsive. Application of the exception does not eliminate the need for the contracting officer to seek maximum practicable competition and ensure that the price is fair and reasonable. The intent of the proposed rule is to drive behavior to enhance real competition whenever possible and to obtain a fair and reasonable price. To establish a rigorous set of guidelines to limit instances in which an exception could be granted in a contingency environment could severely limit the flexibility of the contracting officer in these instances. DoD is also reviewing the findings/recommendations of the Commission on Wartime Contracting and placement of additional safeguards and remedies to promote competition in a contingency environment.

5. Waiver

Comment: One respondent criticized the waiver provision for being ''unlimited'' and imposing ''no restrictions or guidance on when or how the head of the contracting activity should exercise this authority. According to this respondent, if there are no reasonable restrictions on granting of waivers, then it is unlikely that DoD's practice will change.

Response: The requirement to resolicit for an additional 30 days may be waived by the head of the contracting activity (HCA). The intent of including this waiver provision is to maintain flexibility and allow the HCA to exercise the authority of the position. Typically, this position is filled by a senior acquisition professional who has demonstrated sound business judgment and acumen. DoD relies on those in charge to exercise good judgment in the execution of their duties. This waiver authority cannot be delegated below one level above the contracting officer. DoD has not seen evidence of abuse of this waiver authority.

Comment: One respondent recommended that the rule should allow requesting a waiver of the requirement to resolicit for an additional 30 days if the contracting officer has determined fair and reasonable prices through price or cost analysis or negotiations with the offeror, and the waiver has been approved by the PARC (Principal Assistant Responsible for Contracting).

Response: The purpose of the 30-day resolicitation requirement is to promote effective competition. Determination that the offered price is fair and reasonable may provide supporting rationale for granting a waiver, but does not by itself constitute sufficient grounds to grant a waiver. More important reasons for granting a waiver would be urgency of the requirement or market research that indicates that an additional 30 days is unlikely to result in additional offers.

The final rule continues to allow the waiver authority to be delegated to one level above the contracting officer (which would include the PARC). An approval one level above the contracting officer ensures a layer of review and provides a mechanism for checks and balances. Waiver of the 30-day resolicitation period does not relieve the contracting officer of the need to determine the price fair and reasonable.

6. Applicability to Parts Other Than DFARS Parts 214 and 215

a. Part 208

Comment: Several respondents recommended that the proposed rule should not apply to DFARS subpart 208.4, Federal Supply Schedules.

i. Timing and Complexity

Comment: One respondent stated that the purpose for the GSA Federal Supply Schedule is to provide the Government an expedited means to procure commercial supplies and services at the substantially lower costs associated with volume buying. Therefore, expanding the DoD memos to DFARS subpart 208.4 (as well as DFARS parts 212, 213, and 216), ''eviscerates their intention'' and will overload the acquisition process.

Another respondent provided an example of an agency that frequently posts RFQs using the GSA eBuy tool for fewer than 30 days. The RFQs are available to all vendors on the relevant GSA schedule. Although multiple responses are generally received, occasionally there is only one quote received. According to this respondent, lengthening the RFQ response time to 30 days would impede the goal of simplifying and streamlining the procurement process.

Response: DoD recognizes that the Federal Supply Schedule program directed and managed by GSA provides a simplified and flexible process for obtaining commercial supplies and services. The schedule program, because it does not require contracting officers to seek competition outside of the schedule holders or to synopsize the requirement, can be very efficient. DoD also believes that effective competition promotes greater efficiency and productivity in defense spending, and that DoD needs to do more to promote competition when only one offer is received in response to a competitive solicitation. The final rule requires, when only one offer is received in response to a competitive solicitation, that the contracting officer promote competition by trying to revise the requirements document and by permitting more time for receipt of offers. In addition, the final rule does not eliminate the efficiencies or flexibilities inherent in FAR part 8 transactions.

RFQs using the GSA eBuy tool are frequently posted for less than 30 days and generally receive more than one response. The final rule still permits requests for quotation to be solicited for fewer than 30 days, and only requires a resolicitation for 30 days (or a waiver) in those cases when only one offer was received. Market research can provide contracting officers the insight required to determine the solicitation response time required to ensure effective competition without needlessly lengthening the RFQ response time to 30 days. In many cases, market research will indicate that multiple offers will be received in response to an RFQ open for under 30 days. In other cases, market research will indicate that contracting officers need to keep RFQs open for 30 days to encourage effective competition. Finally, market research will indicate that additional time will likely not result in additional offers, and provide contracting officers with the rationale to support a waiver of the resolicitation requirement.

ii. Authority of GSA

Comment: One respondent stated that GSA is vested with the exclusive statutory authority for the pricing policies and procedures governing contracts and orders under the Federal Supply Schedule (40 U.S.C. chapter 5

and 41 U.S.C. 152(3)). Any modifications must be approved by GSA and incorporated into the General Services Acquisition Regulation (GSAR).

Response: DoD understands GSA's exclusive statutory authority for directing and managing the Federal Supply Schedule (FSS) program, and is not modifying the FSS program with this final rule. Instead, the final rule merely supplements GSA's existing guidance on the FSS program to ensure FSS program use by DoD contracting officers is consistent with DoD's policies for promoting competition. Specifically, the final rule augments GSA's policies and procedures for the FSS program by providing DoD contracting officers specific instructions when only one offer is received in response to a competitive FSS solicitation. DoD has periodically issued additional guidance and instructions to govern use of the FSS within DoD.

iii. Sufficiency of FAR and GSAR Processes

Comment: According to several respondents, the proposed regulations are unnecessarily duplicative, because the FAR and the GSAR already provide a framework for the effective and efficient procurement of goods and services at fair and reasonable prices. The respondents noted that under the FSS, GSA has already determined that the prices for products and the rates for services are fair and reasonable (FAR 8.404(d)). According to the respondents, ordering agencies are not required to make a separate determination of fair and reasonable prices of supplies and fixed price services, except for a price evaluation as required by FAR 8.405–2(d). In such cases, agencies are only responsible for considering the level of effort and labor mix and making a determination whether the total price is fair and reasonable.

Response: Existing regulations already anticipate that contracting officers can achieve prices below those determined fair and reasonable by GSA by pursuing additional competition and/or price negotiations. Even though GSA has already negotiated fair and reasonable pricing under the FSS program, the FAR permits contracting officers to seek additional discounts before placing an order. Agencies are required to seek price reductions from the fair and reasonable contract prices for orders exceeding the simplified acquisition threshold (see FAR 8.405–4). As a practical matter, contracting officers routinely achieve such impressive discounts that award at published FSS prices is discouraged. Similarly, existing DFARS regulations provide specific guidance to DoD contracting officers that govern competitions under FSS.

The final rule provides specific guidance to DoD contracting officers when only one offer is received. The final rule augments existing DoD guidance on FSS competitions. The final rule also provides additional guidance to DoD contracting officers that govern the establishment of price in one offer competitions. The final rule is consistent with the existing requirements for competitions under the FSS program and with the standard for determining fair and reasonable prices.

iv. Technical

Comment: One respondent stated that the threshold of ''exceeding $150,000'' at DFARS 208.405–70(c)(1), which provides criteria for orders placed on a competitive basis, appears to create a conflict with DFARS 215.371(e)(ii), which creates no threshold for the ''attack items,'' i.e., items to facilitate against or recovery from nuclear, biological, chemical, or radiological attack.

Response: The final rule supplements, but does not conflict with, the competition requirements in DFARS 208.405–70(c)(1). The final rule provides additional policies and procedures when one offer is received in response to a competitive solicitation. The final rule, at DFARS 215.371–4, exempts certain acquisitions, including ''attack items'' from the new policies and procedures for one offer competitions.

Comment: One respondent noted that FAR 8.404 specifically states that FAR part 15 is not applicable to FSS orders. Therefore, this statement would have to be addressed in the DFARS, in order to make DFARS part 215 applicable.

Response: As requested by the respondent, the final rule adds specific language at DFARS 208.404(a) to make DFARS 215.371 applicable.

Comment: One respondent recommended creating a clause for orders (DFARS 208.405–70(d) and 215.506(S–70)).

Response: The final rule includes provisions at DFARS 252.215–7007, Notice of Intent to Resolicit, and DFARS 252.215–7008, Only One Offer, that apply to all competitive acquisitions, including orders, subject to the final rule. The final rule does not include an additional clause for orders.

b. Part 212

Several respondents recommended that the proposed rule should not apply to commercial items (DFARS part 212), for the following reasons:

i. Timeframe for Response

Comment: Several respondents noted that FAR 12.205(c) specifically provides for fewer than 30 days response time for receipt of offers for commercial items. One respondent stated that the proposed rule is inconsistent with FAR 12.205(c). Another respondent noted that acquisition requirements and processes for the procurement of commercial items were supposed to more closely resemble those customarily used in the commercial marketplace, which the respondent considers to be the reason for allowing shorter response times for receipt of offers for commercial items. This respondent noted that the DFARS proposed rule does not foster the policy behind commercial item acquisitions. A third respondent noted that there is an expectation that an agency can acquire IT in 30 days or fewer, in order to respond to a cyber threat. However, according to the respondent, contracting officers will never be able to respond in 30 days or fewer, because by default, an agency will post the request for quote for the required 30 days, just to avoid the risk of having to do it over again.

Response: Current regulations permit response times under 30 days for commercial items. Shorter response times may more closely resemble commercial practice and may speed the acquisition of critical IT and other items. The final rule still permits response times under 30 days, and only requires a resolicitation for 30 days (or a waiver) in those cases when only one offer was received. Market research can provide contracting officers the insight required to determine the solicitation response time required to ensure effective competition without needlessly lengthening every solicitation's response time to 30 days. In many cases, market research will indicate that multiple offers will be received in response to an RFP/RFQ open for fewer than 30 days. In other cases, market research will indicate that contracting officers need to give potential offerors at least 30 days to encourage effective competition. Similarly, market research will indicate those cases where additional time will likely not result in additional offers, and will provide contracting officers with the rationale to support a waiver of the resolicitation requirement. The final rule also recognizes that certain requirements are too urgent to permit a 30-day solicitation response period, and includes an exception for acquisitions in support of contingency, humanitarian or peacekeeping operations, or to facilitate defense against or recovery from nuclear, biological, chemical, or

radiological attack. Finally, the final rule also permits waivers of the 30-day resolicitation requirement, when necessary and justified.

ii. Other Ways To Determine Fair and Reasonable Prices

Comment: One respondent suggested that excluding commercial contracts would be one means to narrow the scope of the proposed rule to those contracts that might return the highest level of benefit. The respondent noted that in the case of commercial contracts, competitive pricing can often be verified without resort to additional data from the contractor, which is one reason that the law prohibits requesting certified cost or pricing data for commercial contracts.

Response: Competitive pricing can often be verified without resort to additional data from the contractor. The final rule has been revised to provide that, when a single offer is received in response to a competitive solicitation, the contracting officer should try to determine through cost or price analysis that the offered price is fair and reasonable and whether an exception to the requirement for certified cost or pricing data applies, before requesting any additional data from the contractor. The final rule refers contracting officers to the existing exceptions to the requirement to submit certified cost or pricing data, including the commercial item exception.

iii. Access to the DoD Market

Comment: One respondent viewed the application of the proposed rule to acquisition of commercial items as an added barrier to entry into the DoD market.

Response: Typically, commercial vendors cite the requirement for certified cost or pricing data as a key deterrent to doing business with the DoD. The final rule does not change the commercial item exemption to the requirement for certified cost or pricing data. In addition, by ensuring adequate proposal preparation time is provided to potential offerors, the final rule encourages commercial item vendors to participate in DoD's competitions. Finally, the final rule implements key policies necessary to improve the efficiency and productivity of DoD's procurements. While DoD does not believe that the final rule creates barriers to entry, commercial vendors will need to make business decisions about their participation in the DoD marketplace.

c. Subpart 13.5

The FAR subpart 13.5 test program is no longer in effect. The final rule deletes all references to the FAR subpart 13.5 test program.

d. Part 216

Various respondents did not agree with application of the proposed rule to DFARS part 216.

i. 30-Day Resolicitation

Comment: One respondent stated that the rule should clarify whether the 30-day requirement also applies to delivery/task orders solicited under a multiple award/indefinite-delivery/indefinite-quantity type contract, noting that competition is limited to the primes under these contracts. Another respondent stated that the proposed rule should not require resolicitation for an additional 30 days if the other prime contractors indicate that they will not provide an offer if additional days are provided.

Another respondent stated that the rule should not apply to multiple-award contracts when only two or three contractors were awarded the base contract, and one or more of the base contract awardees is excluded from submitting a proposal due to an organizational conflict of interest. In such case, only receiving one proposal will not be the result of inadequate competition and 30-day resolicitation would interfere with deliveries without resulting in increased competition.

Response: The final rule applies to the prime contractor awardees in a multiple-award contract scenario. If the prime contractors state that they are not going to provide an offer if additional days are provided, or if there is an organizational conflict of interest for one or more of the prime contractors, then the contracting officer may pursue a waiver to the 30-day resolicitation requirement in accordance with DFARS 215.371–5 of the final rule.

ii. Adequate Price Competition

Comment: One respondent stated that multiple-award contracts are already awarded based on adequate price competition.

Response: Consistent with the fair opportunity rules at FAR 16.505(b), the final rule is intended to promote real competition when only one offer is received to ensure the integrity of the competitive contracting process is maintained for each task or delivery order, even when the multiple-award contracts were awarded based on adequate price competition.

iii. Cost or Pricing Data

Comment: One respondent stated that cost or pricing data was submitted and evaluated at time of award and does not need to be submitted if only one offer is received.

Response: Even if cost or pricing data was submitted at the time of award, the contracting officer must consider price or cost in the selection decision as one of the factors for each task or delivery order issued. If only one offer is received for a task or delivery order, the contracting officer may not rely on adequate price competition to determine that the price of the task or delivery order is fair and reasonable. The contracting officer may make the determination that the offered price is fair and reasonable and is based on adequate price competition (approved one level above the contracting officer) or that another exception to the requirement for certified cost or pricing data applies. However, if the contracting officer cannot make this determination and must request additional cost or pricing data, that cost or pricing data must be certified unless an exception applies.

e. Part 219

Comment: One respondent recommended that the proposed rule should not apply to small business set-asides. Another respondent requested clarification as to whether the proposed rule was intended to be applicable to small business programs. Although the rule did not specifically make any changes to FAR part 19, there may be impact through references in FAR 19.502–4 (Methods of conducting set-asides) to conducting the set-aside using the procedures of FAR parts 13, 14, or 15; and FAR 19.806 (Pricing the 8(a) contract) requires the contracting officer to price the 8(a) contract in accordance with FAR subpart 15.4. More specifically, the respondent pointed to FAR 19.502–2(a), which provides that ''If the contracting officer received only one acceptable offer from a responsible small business concern in response to a set-aside, the contracting officer should make an award to that firm.'' There is comparable language in FAR 19.1305(c) for HUBZone set-asides, 19.1405(c) for service-disabled veteran-owned small business set-aside procedures, 19.1505(d) for women-owned small business program set-asides.

Response: An exception has been added at DFARS 215.371–4(b) to the 30-day resolicitation requirement at DFARS 215.371–2. The final rule does not preclude any requirement that was set-aside under the authority of FAR

19.1305, 19.1405 or 19.1505 from being awarded, if only one acceptable offer was received.

The intent still is to ensure that prices and/or costs obtained by the offeror are fair, reasonable, and in the best interest of the Government, even by small businesses. Based on market research, the contracting officer is reasonably expected not to set-aside a requirement for competition, unless there is a ''reasonable expectation that offers will be received from two or more small business concerns and that award will be made at a fair market price.'' If only one acceptable offer is received from a competitive set-aside, then the procedures at DFARS 215.371–3 for determination of a fair and reasonable price apply equally to small business set-asides.

f. Part 235

Comment: One respondent recommended that the final rule should explicitly exclude competitions for basic and applied research conducted under FAR 35.016. The respondent commented that, although the proposed rule does not address research competitions under FAR 35.016 utilizing Broad Agency Announcements as the solicitation method, the amplifying memorandum of April 27, 2011, stated that the policy applies to all competitive procurements of supplies and services that exceed the simplified acquisition threshold. The respondent provided several reasons why the entire issue of ''one bid'' is problematic for broad agency announcements, because offers under broad agency announcement sometimes trickle in over an extended open period, and often individual offers can be entertained at any time.

Response: Although the final rule does not specifically address FAR part 35, acquisitions under FAR part 35 are generally subject to the procedures of FAR part 15 and DFARS part 215. The procedures of DFARS 215.371 should not apply to broad agency announcements under FAR 35.006. The requirement for resolicitation if the original solicitation is for less than 30 days is not likely to affect a broad agency announcement, because they are usually issued for an extended period of time. However, because contracts awarded under broad agency announcements, although competitively awarded, are not awarded on the basis of price competition, the approach at DFARS 215.371 would not be appropriate for a broad agency announcement. Responses to a broad agency announcement are expected to propose varying technical/scientific approaches. Proposals need not be evaluated against each other since they are not submitted in accordance with a common work statement. Therefore, to make it clear that DFARS 215.371 does not apply to awards under broad agency announcement, an exception has been added at DFARS 215.371–4(a)(1)(iii). DFARS 215.371–4(a)(2) states that the applicability of an exception does not eliminate the need for the contracting officer to ensure that the price is fair and reasonable.

7. Regulatory Flexibility

Two respondents questioned the Initial Regulatory Flexibility Analysis (IRFA) and made recommendations for reducing the impact on small business.

Comment: These respondents questioned the assertion that the rule will not affect small business entities. One respondent stated that 5,148 small business awards over $150,000 is not an insubstantial figure. Another respondent stated that there could be adverse effects, especially with respect to commercial and low-dollar contracts sought by small businesses. According to this respondent, small businesses may be disproportionately impacted, because they may lack the resources to provide cost or pricing data. Another respondent disagreed with the conclusion of the IRFA that the burden for submission of cost or pricing data is already covered in the FAR. According to this respondent, the IRFA did not acknowledge that this rule will increase the requirement for submission of cost or pricing data by small businesses, because submission of cost or pricing data is not currently a requirement for full and open competition.

Response: The final rule has, however, reduced the impact on all businesses, including small businesses. As rewritten, the final rule is not inconsistent with the current FAR requirements to determine that the price is fair and reasonable when only one offer is received. It uses the FAR clause 52.215–20, but includes a mechanism whereby the FAR clause only becomes effective if only one offer is received, and the contracting officer cannot determine that the offered price is fair and reasonable without requiring additional data. This is part of the current FAR requirement to determine that adequate price competition exists if only one offer is received.

With regard to impact on commercial and low-dollar value contracts sought by small businesses, the rule does not apply at all to contracts with dollar values below the simplified acquisition threshold. For acquisitions above the simplified acquisition threshold, the contracting officer will only request the data necessary to determine a fair and reasonable price. No certified cost or pricing data is required for commercial items. A small business that is offering items to the Government in quantities that exceed the simplified acquisition threshold and are not commercial items should have an accounting system adequate to provide cost or pricing data upon request.

Comment: Another comment on the IRFA was that it does not explain the relationship between the submission of cost or pricing data and increased competition.

Response: As clarified in the revised policy of the final rule, there is no relationship between submission of cost or pricing data and increased competition. The submission of cost or pricing data is to determine whether the offered price is fair and reasonable, when the efforts to increase competition nevertheless resulted in only one offer and the contracting officer could not make that determination without additional data.

Comment: One respondent further recommended exclusion of—

- Set-asides for small business; and
- Acquisitions using full and open competition procedures that result in single offers from small businesses.

Response: An exception to the 30-day resolicitation requirement has been added at DFARS 215.371–4(b) for small business set-asides, because the FAR specifically provides at FAR 19.5, 19.305(c), 19.1405(c), and 19.1505(d) that if only one acceptable offer is received under these set-aside programs, the contracting officer should award to that concern.

The final rule does not include any exception for when the single offer comes from a small business, because it is important to increase competition and allow all businesses sufficient time to respond to a solicitation, which could be of benefit to other small businesses.

In all cases, it is still essential to determine that the price is fair and reasonable.

8. Executive Order Requirements for Cost/Benefit Analysis

Comment: Two respondents commented on the need for cost/benefit analysis as required by Executive Orders 12866 and 13563. One respondent recommended that DoD should consider performing a cost/benefit analysis before finalizing the proposed rule. According to the respondent, the proposed rule will affect a significant number of procurements and may create burdens on procurement professionals and contractors that are not commensurate

with the benefits anticipated. Another respondent noted that there is a lack of empirical support for the proposed rule. According to the respondent, without further cost/benefit data to support the rulemaking, it fails to demonstrate that this rule is needed to cure the underlying problem of single offer competition.

Response: The purpose of this rule is not just to save money but to ensure the integrity of the process. More competition benefits all parties, including small businesses. Although it is possible to demonstrate that increased competition strengthens the industrial base and has a beneficial impact on pricing, the benefits are not readily quantifiable. DoD is tracking improvement in the percentage of effective competition (more than one offer). DoD has always had a fiduciary responsibility to determine that prices are fair and reasonable. The most basic pricing policy at FAR 15.402 is that the contracting officer shall purchase supplies and services from responsible sources at fair and reasonable prices. Unless certified cost or pricing data is required by law (see FAR 15.403–4), the contracting officer is required to obtain data other than certified cost or pricing data as necessary to establish a fair and reasonable price. This rule provides a mechanism to accomplish that goal when a competitive solicitation does not result in more than one offer. As revised, the final rule does not impose unnecessary burdens. See also the last response in section II.B.3.a. and the responses in section II.B.3.b.ii.

9. Additional Recommendations

a. Delay Implementation

Comments: One respondent recommended that DoD delay implementation of the rule until the Comptroller General studies one-offer contracts and issues a report (section 847 of the proposed Senate version of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2012 (S. 1253) requires such a review).

Response: The NDAA for FY 2012, as enacted, did not contain such a requirement for a study of one-offer contracts. DoD needs to take action to improve competition and ensure fair and reasonable prices. DoD will remain ready to reassess any future recommendations on how progress towards these goals can be improved.

b. Sunset Date

Comment: One respondent recommended that the rule should sunset automatically 12 months after the effective date, or, at the latest, at any time after that if the DoD Competition Report data reveals that single offer competitions are 15 percent or less of the total number of acquisition awards.

Response: If the policies and procedures of this rule are beneficial, then there is no need to sunset them after a specific amount of time or if certain effective competition goals are reached. The policies of the final rule are sound policies to maintain, regardless of the percentage of effective competition achieved. Improvement in the rate of effective competition would imply that the policies are working. However, if effective competition is still only 85 percent, then the remaining 15 percent needs to be addressed, continuing to promote more effective competition and ensuring a fair and reasonable price.

c. Line Item for Cost or Pricing Data

Comment: One respondent recommended authorization or requirement that contracting officers include optional contract line items to pay directly for the provision of cost or pricing data not required at the time of submission.

Response: This cost or pricing data is requested prior to contract award and is still considered part of the bid or proposal costs, which are costs incurred in preparing, submitting, and supporting bids and proposals. Bid or proposal costs are only allowable as indirect expenses on contracts, to the extent that those costs are allocable and reasonable (FAR 31.205–18(c)).

d. Use of E-Proposals

Comment: One respondent requested authorization of broader use of e-proposals in the solicitation and contract formation processes in order to offset some of the timing burden caused by a 30-day solicitation period and/or by late notice of the solicitation's requirements to prospective offerors.

Response: E-solicitations and e-proposals are already broadly used. The solicitation can authorize electronic commerce methods for submission of offers. Some offerors prefer e-proposals, but others do not want e-proposals to be mandated. The goal of this rule is to provide sufficient time for interested offerors to respond.

e. Market Research and Price Analysis Capability

Comment: One respondent recommended training and rewarding of market research capability and price analysis capability within each DoD component or the centralization of market research capability.

Response: This recommendation is outside the scope of this rule.

f. Support Enhanced Communication

Comment: One respondent recommended continued support of enhanced communication with industry about requirements and solutions throughout the acquisition cycle.

Response: DoD wholly supports this recommendation.

10. Technical

Comment: One respondent suggested that the coverage should be at DFARS subpart 215.4 rather than DFARS 215.371.

Response: The reason for putting the coverage in DFARS 215.371 rather than in DFARS subpart 215.4 is because the rule covers more than just contract pricing. It also involves seeking to increase competition through review of the requirements and ensuring adequate time for submission of offers.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

A Final Regulatory Flexibility Analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* and is summarized as follows:

This rule implements the initiative on promoting real competition that was presented by the Under Secretary of Defense for Acquisition, Technology, & Logistics in a memorandum dated November 3, 2010. The objective of the rule is to promote competition and ensure fair and reasonable prices, by implementing DoD policy with regard to acquisitions when only one offer is received to ensure that—

- Adequate time is allowed for receipt of offers;

• The requirements do not present unnecessary barriers to competition; and

• Cost or pricing data is obtained and negotiations are held, as necessary, to obtain a fair and reasonable price, when only one offer is received in response to a competitive solicitation and the contracting officer cannot determine that the offered price is fair and reasonable.

The legal basis is 41 U.S.C. 1303 and 48 CFR chapter 1.

Two respondents questioned the Initial Regulatory Flexibility Analysis and made recommendations for reducing the impact on small business. See section II.B.7 for analysis of public comments on regulatory flexibility.

No comments were filed by the Chief Counsel for Advocacy of the Small Business Administration.

The proposed rule provided the following data: that it would affect all small entities that respond to a Federal solicitation for proposals, valued at more than $150,000, and no other offer is received.

TABLE—DOD COMPETITIVE AWARDS VALUED ABOVE $150,000

	All	Only one offer	1 Offer/SB
New Contracts or P.O.	54,240	14,747	3,542
New Orders under FSS	4,246	1,654	818
New Orders, Non-Part 8	12,883	2,935	788

The impact of this rule has been reduced significantly by eliminating the requirement for additional data and subsequent negotiation if the contracting officer can determine that the offered price is fair and reasonable and that adequate price competition exists (approved at one level above the contracting officer).

The rule imposes no reporting, recordkeeping, or other information collection requirements. The submission of certified cost or pricing data or other than certified cost or pricing data is covered in FAR subpart 15.4 and associated clauses in FAR 52.215, OMB clearances 9000–013.

There are no known significant alternatives to the rule that would adequately implement the DoD policy. DoD considered higher thresholds for applicability of the rule (cost or pricing data threshold or $10 million), but determined that higher thresholds would be detrimental to the effectiveness of the rule. There is no significant economic impact on small entities. The impact of this rule on small business is expected to be predominantly positive, by allowing more opportunity for competition.

V. Paperwork Reduction Act

The rule does not impose any additional information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35). The submission of certified cost or pricing data or data other than certified cost or pricing data required to assess whether a price is fair and reasonable is covered in FAR subpart 15.4 and associated clauses in FAR 52.215, OMB clearance number 9000–013, in the amount of 10,101,684 hours.

List of Subjects in 48 CFR Parts 205, 208, 212, 214, 215, 216, 252

Government procurement.

Ynette R. Shelkin,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 205, 208, 212, 214, 215, 216, and 252 are amended as follows:

PART 205—PUBLICIZING CONTRACT ACTIONS

■ 1. The authority citation for 48 CFR part 205 is revised to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend section 205.203 by adding paragraph (S–70) to read as follows:

205.203 Publicizing and response time.

* * * * *

(S–70) When using competitive procedures, if a solicitation allowed fewer than 30 days for receipt of offers and resulted in only one offer, the contracting officer shall resolicit, allowing an additional period of at least 30 days for receipt of offers, except as provided in 215.371–4 and 215.371–5.

PART 208—REQUIRED SOURCES OF SUPPLIES AND SERVICES

■ 3. The authority citation for 48 CFR part 208 is revised to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 4. Revise section 208.404 to read as follows:

208.404 Use of Federal Supply Schedules.

(a)(i) In accordance with 208.405–70(c)(2), if only one offer is received in response to an order exceeding $150,000 that is placed on a competitive basis, the procedures at 215.371 apply.

(ii) Departments and agencies shall comply with the review, approval, and reporting requirements established in accordance with subpart 217.78 when placing orders for supplies or services in amounts exceeding the simplified acquisition threshold.

(iii) When a schedule lists both foreign and domestic items that will meet the needs of the requiring activity, the ordering office must apply the procedures of part 225 and FAR part 25, Foreign Acquisition. When purchase of an item of foreign origin is specifically required, the requiring activity must furnish the ordering office sufficient information to permit the determinations required by part 225 and FAR part 25 to be made.

■ 5. Amend section 208.405–70 by revising paragraph (c), redesignating paragraph (d) as paragraph (e), and adding new paragraph (d) to read as follows:

208.405–70 Additional ordering procedures.

* * * * *

(c)(1) An order exceeding $150,000 is placed on a competitive basis only if the contracting officer provides a fair notice of the intent to make the purchase, including a description of the supplies to be delivered or the services to be performed and the basis upon which the contracting officer will make the selection, to—

(i) As many schedule contractors as practicable, consistent with market research appropriate to the circumstances, to reasonably ensure that offers will be received from at least three contractors that can fulfill the requirements, and the contracting officer—

(A)(*1*) Receives offers from at least three contractors that can fulfill the requirements; or

(*2*) Determines in writing that no additional contractors that can fulfill the requirements could be identified despite reasonable efforts to do so (documentation should clearly explain efforts made to obtain offers from at least three contractors); and

(B) Ensures all offers received are fairly considered; or

(ii) All contractors offering the required supplies or services under the applicable multiple award schedule, and affords all contractors responding to the notice a fair opportunity to submit an offer and have that offer fairly considered.

(2) If only one offer is received, follow the procedures at 215.371.

(d) Use the provisions at 252.215–7007, Notice of Intent to Resolicit, and 252.215–7008, Only One Offer, as prescribed at 215.408(3) and (4), respectively.

* * * * *

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 6. The authority citation for 48 CFR part 212 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 7. Add section 212.205 to read as follows:

212.205 Offers.

(c) When using competitive procedures, if only one offer is received, the contracting officer shall follow the procedures at 215.371.

■ 8. Amend section 212.301 by redesignating paragraphs (f)(iv)(F) through (N) as paragraphs (f)(iv)(G) through (O) and adding new paragraph (f)(iv)(F) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

(f) * * *

(iv) * * *

(F) Use the provisions at 252.215–7007, Notice of Intent to Resolicit, and 252.215–7008, Only One Offer, as prescribed at 215.408(3) and (4), respectively.

* * * * *

PART 214—SEALED BIDDING

■ 9. The authority citation for 48 CFR part 214 is revised to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 10. Add section 214.201–6 to read as follows:

214.201–6 Solicitation provisions.

(2) Use the provisions at 252.215–7007, Notice of Intent to Resolicit, and 252.215–7008, Only One Offer, as prescribed at 215.408(3) and (4), respectively.

■ 11. Add section 214.209 to read as follows:

214.209 Cancellation of invitations before opening.

If an invitation for bids allowed fewer than 30 days for receipt of offers, and resulted in only one offer, the contracting officer shall cancel and resolicit, allowing an additional period of at least 30 days for receipt of offers, as provided in 215.371.

■ 12. Revise section 214.404–1 to read as follows:

214.404–1 Cancellation of invitations after opening.

(1) The contracting officer shall make the written determinations required by FAR 14.404–1(c) and (e)(1).

(2) If only one offer is received, follow the procedures at 215.371 in lieu of the procedures at FAR 14.404–1(f).

■ 13. Add sections 214.408 and 214.408–1 to subpart 214.4 to read as follows:

214.408 Award.

214.408–1 General.

(b) For acquisitions that exceed the simplified acquisition threshold, if only one offer is received, follow the procedures at 215.371.

PART 215—CONTRACTING BY NEGOTIATION

■ 14. The authority citation for 48 CFR parts 215, 216, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 15. Add sections 215.371 through 215.371–5 to subpart 215.3 to read as follows:

Subpart 215.3—Source Selection

Sec.

* * * * *

215.371 Only one offer.

215.371–1 Policy.

It is DoD policy, if only one offer is received in response to a competitive solicitation—

(a) To take the required actions to promote competition (see 215.371–2); and

(b) To ensure that the price is fair and reasonable (see 215.371–3) and to comply with the statutory requirement for certified cost or pricing data (see FAR 15.403–4).

215.371–2 Promote competition.

Except as provided in sections 215.371–4 and 215.371–5, if only one offer is received when competitive procedures were used and the solicitation allowed fewer than 30 days for receipt of proposals, the contracting officer shall—

(a) Consult with the requiring activity as to whether the requirements document should be revised in order to promote more competition (see FAR 6.502(b) and 11.002); and

(b) Resolicit, allowing an additional period of at least 30 days for receipt of proposals.

215.371–3 Fair and reasonable price.

(a) If there was ''reasonable expectation …that two or more offerors, competing independently, would submit priced offers'' but only one offer is received, this circumstance does not constitute adequate price competition unless an official at one level above the contracting officer approves the determination that the price is reasonable (see FAR 15.403–1(c)(1)(ii)).

(b) Except as provided in section 215.371–4(a), if only one offer is received when competitive procedures were used and the solicitation allowed at least 30 days for receipt of proposals (unless the 30-day requirement is not applicable in accordance with 215.371–4(b) or has been waived in accordance with section 215.371–5), the contracting officer shall—

(1) Determine through cost or price analysis that the offered price is fair and reasonable and that adequate price competition exists (with approval of the determination at one level above the contracting officer) or another exception to the requirement for certified cost or pricing data applies (see FAR 15.403–1(c) and 15.403–4). In these circumstances, no further cost or pricing data is required; or

(2)(i) Obtain from the offeror cost or pricing data necessary to determine a fair and reasonable price and comply with the requirement for certified cost or pricing data at FAR 15.403–4, in accordance with FAR provision 52.215–20. For acquisitions that exceed the cost or pricing data threshold, if no exception at FAR 15.403–1(c) applies, the cost or pricing data shall be certified; and

(ii) Enter into negotiations with the offeror as necessary to establish a fair and reasonable price. The negotiated price should not exceed the offered price.

215.371–4 Exceptions.

(a)(1) The requirements at sections 215.371–2 and 215.371–3 do not apply to acquisitions—

(i) At or below the simplified acquisition threshold;

(ii) In support of contingency, humanitarian or peacekeeping operations, or to facilitate defense against or recovery from nuclear, biological, chemical, or radiological attack; or

(iii) Of basic or applied research or development, as specified in FAR 35.016(a), that use a broad agency announcement.

(2) The applicability of an exception in paragraph (a)(1) of this section does not eliminate the need for the contracting officer to seek maximum practicable competition and to ensure that the price is fair and reasonable.

(b)(1) The requirements at section 215.371–2 do not apply to small business set-asides under FAR subpart 19.5 or set-asides under the HUBZone Program (see FAR 19.1305(c)), the Service-Disabled Veteran-Owned Small Business Procurement Program (see FAR 19.1405(c)), or the Woman-Owned Small Business Program (see FAR 19.1505(d)).

(2) The requirements at section 215.371–3 do apply to such set-asides.

215.371–5 Waiver.

(a) The head of the contracting activity is authorized to waive the requirement at 215.371–2 to resolicit for an additional period of at least 30 days.

(b) This waiver authority cannot be delegated below one level above the contracting officer.

■ 16. The 215.403 section heading is revised to read as follows:

215.403 Obtaining certified cost or pricing data.

■ 17. Section 215.403–1 is amended by revising paragraph (c)(1) to read as follows:

* * * * *

(c) *Standards for exceptions from certified cost or pricing data requirements*—(1) *Adequate price competition.*

(A) For acquisitions under dual or multiple source programs—

(*1*) The determination of adequate price competition must be made on a case-by-case basis. Even when adequate price competition exists, in certain cases it may be appropriate to obtain additional information to assist in price analysis.

(*2*) Adequate price competition normally exists when—

(*i*) Prices are solicited across a full range of step quantities, normally including a 0–100 percent split, from at least two offerors that are individually capable of producing the full quantity; and

(*ii*) The reasonableness of all prices awarded is clearly established on the basis of price analysis (see FAR 15.404–1(b)).

(B) If only one offer is received in response to a competitive solicitation, see 215.371–3.

* * * * *

■ 18. Amend section 215.408 by adding paragraphs (3) and (4) to read as follows:

215.408 Solicitation provisions and contract clauses.

* * * * *

(3) Use the provision at 252.215–7007, Notice of Intent to Resolicit, in competitive solicitations that will be solicited for fewer than 30 days, unless an exception at 215.371–4 applies or the requirement is waived in accordance with 215.371–5.

(4)(i) Use the provision at 252.215–7008, Only One Offer, in competitive solicitations, unless an exception at 215.371–4(a)(1) applies.

(ii) In solicitations that include 252.215–7008, Only One Offer, also include the provision at FAR 52.215–20, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data, with any appropriate alternate as prescribed at FAR 15.408–1, but that provision will only take effect as specified in 252.215–7008.

PART 216—TYPES OF CONTRACTS

■ 19. Amend section 216.505–70 by revising paragraph (d) to read as follows:

216.505–70 Orders under multiple award contracts.

* * * * *

(d) When using the procedures in this subsection—

(1) The contracting officer should keep contractor submission requirements to a minimum;

(2) The contracting officer may use streamlined procedures, including oral presentations;

(3) If only one offer is received, the contracting officer shall follow the procedures at 215.371.

(4) The competition requirements in FAR part 6 and the policies in FAR subpart 15.3 do not apply to the ordering process, but the contracting officer shall consider price or cost under each order as one of the factors in the selection decision; and

(5) The contracting officer should consider past performance on earlier orders under the contract, including quality, timeliness, and cost control.

■ 20. Amend section 216.506 by adding paragraph (S–70) to read as follows:

216.506 Solicitation provisions and contract clauses.

* * * * *

(S–70) Use the provisions at 252.215–7007, Notice of Intent to Resolicit, and 252.215–7008, Only One Offer, as prescribed at 215.408(3) and (4), respectively.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 21. Add sections 252.215–7007 and 252.215–7008 to read as follows:

252.215–7007 Notice of Intent to Resolicit.

As prescribed at 215.408(3), use the following provision:

NOTICE OF INTENT TO RESOLICIT (JUN 2012)

This solicitation provides offerors fewer than 30 days to submit proposals. In the event that only one offer is received in response to this solicitation, the Contracting Officer may cancel the solicitation and resolicit for an additional period of at least 30 days in accordance with 215.371–2.

(End of provision)

252.215–7008 Only One Offer.

As prescribed at 215.408(4), use the following provision:

ONLY ONE OFFER (JUN 2012)

(a) The provision at FAR 52.215–20, Requirements for Certified Cost or Pricing Data and Data other Than Certified Cost or Pricing Data, with any alternate included in this solicitation, does not take effect unless the Contracting Officer notifies the offeror that—

(1) Only one offer was received; and

(2) Additional cost or pricing data is required in order to determine whether the price is fair and reasonable or to comply with the statutory requirement for certified cost or pricing data (10 U.S.C. 2306a and FAR 15.403–3).

(b) Upon such notification, the offeror agrees, by submission of its offer, to provide any data requested by the Contracting Officer in accordance with FAR 52.215–20.

(c) If negotiations are conducted, the negotiated price should not exceed the offered price.

(End of provision)

[FR Doc. 2012–15569 Filed 6–28–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 242, 247, and 252

RIN 0750–AH53

Defense Federal Acquisition Regulation Supplement: Shipping Instructions (DFARS Case 2011–D052)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to update the form used by contractors to request shipping instructions and the associated contract clause and clause prescription to cover both commercial and Government bills of lading, and to relocate the coverage within the DFARS.

DATES: *Effective Date:* June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Meredith Murphy, Procurement Analyst, telephone 571–372–6098.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 77 FR 4637 on January 30, 2012, to relocate information from DFARS subpart 242.14 to DFARS part 247 to align with changes to the Federal Acquisition Regulation and to update DD Form 1659, Application for U.S. Government Shipping Documentation/Instructions, to provide for use of both commercial and Government bills of lading. No respondents submitted public comments in response to the proposed rule.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Regulatory Flexibility Act

DoD certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because there are no substantive changes being made by this rule. The rule makes only two minor changes in terminology in the DD Form 1659 and the associated clause at DFARS 252.247–7028 (formerly DFARS 252.242–7003) in order to clarify that the DD Form 1659 can be used to request a bill of lading that inputs these shipments into the Defense Transportation System (DTS). The purpose of this form is to obtain shipping instructions, a practice that has been in effect for many years. Requesting shipping instructions does not impose a hardship on any entity. No comments were received from any entities concerning the impact of the proposed change on small business.

IV. Paperwork Reduction Act

This rule affects the certification and information collection requirements in the clause at DFARS 252.247–7028 (formerly DFARS 252.242–7003), Application for U.S. Government Shipping Documentation/Instructions, and the associated DD form 1659 (same title as the clause), currently approved under OMB Control Number 0704–0250, titled DFARS Part 242, Contract Administration and Audit Services, in the amount of 276,773 hours, in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The impact, however, is negligible, because only minor changes in terminology are being made. There are no substantive changes made either to the form or the associated clause at DFARS 252.247–7028 (formerly 252.242–7003). No public comments were received on the paperwork impact in response to the proposed rule.

List of Subjects in 48 CFR Parts 212, 242, 247, and 252.

Government procurement.

Ynette R. Shelkin,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 242, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 242, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 212.301 by adding paragraph (f)(iv)(P) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

(f) * * *

(iv) * * *

(P) Use the clause at 252.247–7028, Application for U.S Government Shipping Documentation/Instructions, as prescribed in 247.207.

* * * * *

PART 242—CONTRACT ADMINISTRATION AND AUDIT SERVICES

Subpart 242.14—[Removed]

■ 3. Remove subpart 242.14.

PART 247—TRANSPORTATION

■ 4. The authority citation for 48 CFR part 247 is revised to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 5. Add subpart 247.1, consisting of section 247.101, to read as follows:

Subpart 247.1—General

247.101 Policies.

(h) *Shipping documents covering f.o.b. origin shipments.*

(i) Procedures for the contractor to obtain bills of lading are in the clause at 252.247–7028, Application for U.S. Government Shipping Documentation/Instructions.

(ii) The term ''commercial bills of lading'' includes the use of any commercial form or procedure.

■ 6. Revise section 247.207 to read as follows:

247.207 Solicitation provisions, contract clauses, and special requirements.

(1) Use the clause at 252.247–7003, Pass-Through of Motor Carrier Fuel Surcharge Adjustment to the Cost Bearer, in solicitations and contracts for carriage in which a motor carrier, broker, or freight forwarder will provide or arrange truck transportation services that provide for a fuel-related adjustment.

(2) Use the clause at 252.247–7028, Application for U.S. Government Shipping Documentation/Instructions, when shipping under Bills of Lading and Domestic Route Order under FOB origin contracts, Export Traffic Release regardless of FOB terms, or foreign military sales shipments.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.242–7003 [Removed and Reserved]

■ 7. Remove and reserve section 252.242–7003.

■ 8. Add section 252.247–7028 to read as follows:

252.247–7028 Application for U.S. Government Shipping Documentation/ Instructions.

As prescribed in 247.207, use the following clause:

APPLICATION FOR U.S. GOVERNMENT SHIPPING DOCUMENTATION/ INSTRUCTIONS (JUN 2012)

(a) Except as provided in paragraph (b) of this clause, the Contractor shall request bills of lading by submitting a DD Form 1659, Application for U.S. Government Shipping Documentation/Instructions, to the—

(1) Transportation Officer, if named in the contract schedule; or

(2) Contract administration office.

(b) If an automated system is available for shipment requests, use service/agency systems (e.g., Navy's Global Freight Management–Electronic Transportation Acquisition (GFM–ETA) and Financial Air Clearance Transportation System (FACTS) Shipment Processing Module, Air Force's Cargo Movement Operations System, DCMA's Shipment Instruction Request (SIR) E-tool, and DLA's Distribution Standard System Vendor Shipment Module in lieu of DD Form 1659.

(End of clause)

[FR Doc. 2012–15568 Filed 6–28–12; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 244, and 252

RIN 0750–AH39

Defense Federal Acquisition Regulation Supplement: Applicability of Hexavalent Chromium Policy to Commercial Items (DFARS Case 2011–D047)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to clarify the applicability to commercial items of DoD policies relating to the use of material containing hexavalent chromium.

DATES: *Effective Date:* June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Mr. Dustin Pitsch, telephone 571–372–6090.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a final rule (DFARS Case 2009–D004) in the **Federal Register** at 76 FR 25569 on May 5, 2011, to implement in the DFARS the DoD policy addressing the serious human health and environmental risks related to the use of hexavalent chromium. Hexavalent chromium is a chemical that has been used in numerous DoD weapons systems platforms due to its corrosion protection properties. However, hexavalent chromium is a known carcinogen. The final rule, codified in a new DFARS clause 252.223–7008, minimized the use of materials containing hexavalent chromium in items acquired by DoD. Shortly after the final rule was published, DoD became aware of a drafting oversight and the need to correct the text of final rule to reflect DoD's intent that the rule should apply to commercial items. This rule corrects that oversight.

DoD published a proposed rule in the **Federal Register** at 76 FR 71926 on November 21, 2011, to clarify the applicability to commercial items of DoD policies relating to the use of materials containing hexavalent chromium. One respondent submitted a public comment in response to the proposed rule.

II. Discussion and Analysis of the Public Comments

DoD reviewed the public comment in the development of the final rule, which is discussed as follows.

Comment: The respondent stated that requiring different standards for chromated defense products than are required of commercial products imposes a significant cost related to the need for additional training and wastes already limited factory space. The respondent also stated that bringing defense product finishes into line with commercial finishes without sacrificing performance and maintaining a single process should improve production, efficiency, and quality.

Response: This comment is out of scope as the rule does not modify the DoD policy relating to the use of hexavalent chromium, it only clarifies the applicability of the previously published final rule. As such, the respondent's concerns are misplaced because this rule does not create any new requirements for commercial products; it simply makes clear the scope of applicability of DFARS clause 252.223–7008.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because this rule is just correcting a drafting oversight in rule 2009–D004 published on May 5, 2011 (76 FR 25569).

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 212, 244, and 252

Government procurement.

Mary Overstreet,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 212, 244, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 244, and 252 continue to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 212.301 by—

■ a. Redesignating paragraphs (f)(iv)(G) through (P) as paragraphs (f)(iv)(H) through (Q); and

■ b. Adding new paragraph (f)(iv)(G) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

(f) * * *

(iv) * * *

(G) Use the clause at 252.223–7008, Prohibition of Hexavalent Chromium, as prescribed at 223.7306.

* * * * *

PART 244—SUBCONTRACTING POLICIES AND PROCEDURES

■ 3. Revise section 244.403 to read as follows:

244.403 Contract clause.

Use the clause at 252.244–7000, Subcontracts for Commercial Items and Commercial Components (DoD Contracts), in solicitations and contracts for supplies or services other than commercial items that contain any of the clauses listed in the clause at 252.244–7000.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Revise section 252.244–7000 to read as follows:

252.244–7000 Subcontracts for Commercial Items and Commercial Components (DoD Contracts).

As prescribed in 244.403, use the following clause:

SUBCONTRACTS FOR COMMERCIAL ITEMS AND COMMERCIAL COMPONENTS (DOD CONTRACTS) (JUN 2012)

In addition to the clauses listed in paragraph (c) of the Subcontracts for Commercial Items clause of this contract (Federal Acquisition Regulation 52.244–6), the Contractor shall include the terms of the following clauses, if applicable, in subcontracts for commercial items or commercial components, awarded at any tier under this contract:

(a) 252.223–7008, Prohibition of Hexavalent Chromium (MAY 2011), if the subcontract is for supplies, maintenance and repair services, or construction materials.

(b) 252.225–7009, Restriction on Acquisition of Certain Articles Containing Specialty Metals (JUN 2012) (10 U.S.C. 2533b), if flow down is required in accordance with paragraph (e) of DFARS clause 252.225–7009.

(c) 252.225–7039, Contractors Performing Private Security Functions (JUN 2012) (Section 862 of Pub. L. 110–181, as amended by section 853 of Pub. L. 110–417 and sections 831 and 832 of Pub. L. 111–383), if the subcontract will be performed in areas of contingency operations, complex contingency operations, or other military operations or exercises designated by the Combatant Commander.

(d) 252.227–7015, Technical Data—Commercial Items (DEC 2011), if applicable (see 227.7102–4(a)), if flow down is required in accordance with paragraph (e) of DFARS clause 252.227–7015.

(e) 252.227–7037, Validation of Restrictive Markings on Technical Data (JUN 2012), if applicable (see 227.7102–4(c)), if the subcontract or supplier at any tier requires the delivery of technical data.

(f) 252.236–7013, Requirement for Competition Opportunity for American Steel Producers, Fabricators, and Manufacturers (JAN 2009) (Pub. L. 110–329, Division E, Section 108), if the subcontract involves the acquisition of steel as a construction material.

(g) 252.237–7010, Prohibition on Interrogation of Detainees by Contractor Personnel (NOV 2010) (Section 1038 of Pub. L. 111–84), if the subcontract may require subcontractor personnel to interact with detainees in the course of their duties.

(h) 252.237–7019, Training for Contractor Personnel Interacting with Detainees (SEP 2006) (Section 1092 of Pub. L. 108–375), if the subcontract may require subcontractor personnel to interact with detainees in the course of their duties.

(i) 252.246–7003, Notification of Potential Safety Issues (JAN 2007), if flow down is required in accordance with paragraph (f) of DFARS clause 252.246–7003.

(j) 252.247–7023, Transportation of Supplies by Sea (MAY 2002) (10 U.S.C. 2631), if flow down is required in accordance with paragraph (h) of DFARS clause 252.247–7023.

(k) 252.247–7024, Notification of Transportation of Supplies by Sea (MAR 2000) (10 U.S.C. 2631), if flow down is required in accordance with paragraph (b) of DFARS clause 252.247–7024.

(End of clause)

[FR Doc. 2012–15565 Filed 6–28–12; 8:45 am]

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