ENVIRONMENTAL PROTECTION AGENCY

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

[EPA–HQ–OAR–2007–0492; FRL–9761–8]

RIN 2060–AO47

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on its review of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the EPA is making revisions to the suite of standards for PM to provide requisite protection of public health and welfare and to make corresponding revisions to the data handling conventions for PM and to the ambient air monitoring, reporting, and network design requirements. The EPA also is making revisions to the prevention of significant deterioration (PSD) permitting program with respect to the NAAQS revisions.

With regard to primary (health-based) standards for fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), the EPA is revising the annual $PM_{2.5}$ standard by lowering the level to 12.0 micrograms per cubic meter (μg/m^3) so as to provide increased protection against health effects associated with long- and short-term exposures (including premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease), and to retain the 24-hour $PM_{2.5}$ standard at a level of 35 μg/m^3. The EPA is revising the Air Quality Index (AQI) for $PM_{2.5}$ to be consistent with the revised primary $PM_{2.5}$ standards. With regard to the primary standard for particles generally less than or equal to 10 μm in diameter (PM_{10}), the EPA is retaining the current 24-hour PM_{10} standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10-2.5}$). With regard to the secondary (welfare-based) PM standards, the EPA is generally retaining the current suite of secondary standards (i.e., 24-hour and annual $PM_{2.5}$ standards and a 24-hour PM_{10} standard). Non-visibility welfare effects are addressed by this suite of secondary standards, and PM-related visibility impairment is addressed by the secondary 24-hour $PM_{2.5}$ standard.

DATES: The final rule is effective on March 18, 2013.

ADDRESSES: Section X.B requests comments on an information collection request regarding changes to the monitoring requirements. Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2007–0492, to the EPA by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: a-and-r-Docket@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* Docket No. EPA–HQ–OAR–2007–0492, Environmental Protection Agency, Mail code 6102T, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Please include a total of two copies.
- *Hand Delivery:* Docket No. EPA–HQ–OAR–2007–0492, Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2007–0492. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* Comments on this information collection request should also be sent to the Office of Management and Budget (OMB). See section X.B below for additional information regarding submitting comments to OMB.

Docket: The EPA has established a docket for this action under Docket No. EPA–HQ–OAR–2007–0492. All documents in the docket are listed on the *www.regulations.gov* Web site. This includes documents in the rulemaking docket (Docket ID No. EPA–HQ–OAR–2007–0492) and a separate docket, established for 2009 Integrated Science Assessment (Docket No. EPA–HQ–ORD–2007–0517), that has have been incorporated by reference into the rulemaking docket. All documents in these dockets are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and may be viewed, with prior arrangement, at the EPA Docket Center. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566–1742. For additional information about EPA's public docket visit the EPA Docket Center homepage at: *http://www.epa.gov/epahome/dockets.htm.*

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

Availability of Related Information

A number of the documents that are relevant to this rulemaking are available through the EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html.*

These documents include the *Plan for Review of the National Ambient Air Quality Standards for Particulate Matter* (U.S. EPA, 2008a), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html,* the *Integrated Science Assessment for Particulate Matter* (U.S. EPA, 2009a), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html,* the *Quantitative Health Risk Assessment for Particulate Matter* (U.S. EPA, 2010a), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html,* the *Particulate Matter Urban-Focused Visibility Assessment* (U.S. EPA 2010b), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html,* and the *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards* (U.S. EPA, 2011a), available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

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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 rulemaking is being done pursuant to these statutory requirements. The schedule for completing this review is established by a court order.

In 2006, the EPA completed its last review of the PM NAAQS. In that review, the EPA took three principal actions: (1) With regard to fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), at that time, the EPA revised the level of the primary 24-hour $PM_{2.5}$ standard from 65 to 35 μg/m^3 and retained the level of the primary annual $PM_{2.5}$ standard; (2) With regard to the primary standards for particles less than or equal to 10 μm in diameter (PM_{10}), the EPA retained the primary 24-hour PM_{10} standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10-2.5}$) and revoked the primary annual PM_{10} standard; and (3) the EPA also revised the secondary standards to be identical in all respects to the primary standards.

In subsequent litigation, the U.S. Court of Appeals for the District of Columbia Circuit remanded the primary annual $PM_{2.5}$ standard to the EPA because the Agency had failed to explain adequately why the standard provided the requisite protection from both short- and long-term exposures to fine particles, including protection for at-risk populations such as children. The court remanded the secondary $PM_{2.5}$ standards to the EPA because the Agency failed to explain adequately why setting the secondary standards identical to the primary standards provided the required protection for public welfare, including protection from PM-related visibility impairment.

The EPA initiated this review in June 2007. Between 2007 and 2011, the EPA prepared draft and final Integrated Science Assessments, Risk and Exposure Assessments, and Policy Assessments. Multiple drafts of all of these documents were subject to review by the public and were peer reviewed by the EPA's Clean Air Scientific Advisory Committee (CASAC). The EPA proposed revisions to the primary and secondary PM NAAQS on June 29, 2012 (77 FR 38890). This final rulemaking is the final step in the review process.

In this rulemaking, the EPA is revising the suite of standards for PM to provide requisite protection of public health and welfare. The EPA is revising the PSD permitting regulations to address the changes in the PM NAAQS. In addition, the EPA is updating the AQI for $PM_{2.5}$ and making changes in the data handling conventions for PM and ambient air monitoring, reporting, and network design requirements to correspond with the changes to the PM NAAQS.

B. Summary of Major Provisions

With regard to the primary standards for fine particles, the EPA is revising the annual $PM_{2.5}$ standard by lowering the level from 15.0 to 12.0 μg/m^3 so as to provide increased protection against health effects associated with long-and short-term exposures. The EPA is retaining the level (35 μg/m^3) and the form (98th percentile) of the 24-hour $PM_{2.5}$ standard to continue to provide supplemental protection against health effects associated with short-term exposures. This action provides increased protection for children, older adults, persons with pre-existing heart and lung disease, and other at-risk populations against an array of $PM_{2.5}$-related adverse health effects that include premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease. The EPA also is eliminating spatial averaging provisions as part of the form of the annual standard to avoid potential disproportionate impacts on at-risk populations.

The final decisions for the primary annual and 24-hour $PM_{2.5}$ standards are within the ranges that CASAC advised the Agency to consider. These decisions are based on an integrative assessment of an extensive body of new scientific evidence, which substantially strengthens what was known about $PM_{2.5}$-related health effects in the last review, including extended analyses of key epidemiological studies, and evidence of health effects observed at lower ambient $PM_{2.5}$ concentrations, including effects in areas that likely met the current standards. The revised suite of $PM_{2.5}$ standards also reflects consideration of a quantitative risk assessment that estimates public health risks likely to remain upon just meeting the current and various alternative standards. Based on this information, the Administrator concludes that the current primary $PM_{2.5}$ standards are not requisite to protect public health with an adequate margin of safety, as required by the CAA, and that these revisions are warranted to provide the appropriate degree of increased public health protection.

With regard to the primary standard for thoracic coarse particles ($PM_{10-2.5}$), the EPA is retaining the current 24-hour PM_{10} standard, with a level of 150 μg/m^3 and a one-expected exceedance form, to continue to provide protection against effects associated with short-term exposure to $PM_{10-2.5}$ including premature mortality and increased hospital admissions and emergency department visits. In reaching this decision, the Administrator concludes that the available health evidence and air quality information for $PM_{10-2.5}$, taken together with the considerable uncertainties and limitations associated with that information, suggests that a standard is needed to protect against short-term exposure to all types of $PM_{10-2.5}$ and that the degree of public health protection provided against short-term exposures to $PM_{10-2.5}$ does not need to be increased beyond that provided by the current PM_{10} standard.

With regard to the secondary PM standards, the Administrator is retaining the current suite of secondary PM standards, except for a change to the form of the annual $PM_{2.5}$ standard. Specifically, the EPA is retaining the current secondary 24-hour $PM_{2.5}$ and PM_{10} standards, and is revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. This suite of secondary standards addresses PM-related non-visibility welfare effects including ecological effects, effects on materials, and climate impacts. With respect to PM-related visibility impairment, the Administrator has identified a target degree of protection, defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction), a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, and a level of 30 deciviews (dv), which she judges to be requisite to protect public welfare with regard to visual air quality (VAQ). The EPA's analysis of monitoring data provides the basis for concluding that the current secondary 24-hour $PM_{2.5}$ standard would provide sufficient protection, and in some areas greater protection, relative to this target protection level. Adding a distinct secondary standard to address visibility would not affect this protection. Since sufficient protection from visibility impairment will be provided for all areas of the country without adoption of a distinct secondary standard, and adoption of a distinct secondary standard will not change the degree of over-protection of VAQ provided for some areas of the country by the secondary 24-hour $PM_{2.5}$ standard, the Administrator judges that adoption of a distinct secondary standard, in addition to the current suite of secondary standards, is not needed to provide requisite protection for both visibility and non-visibility related welfare effects.

The revisions to the PM NAAQS trigger a process under which states (and tribes, if they choose) will make recommendations to the Administrator regarding designations, identifying areas of the country that either meet or do not meet the revised NAAQS. States will also review, modify and supplement their existing state implementation plans (SIPs), as needed. With regard to these implementation-related activities, the EPA intends to promulgate a separate implementation rule on a schedule that provides timely clarity to the states, tribes, and other parties responsible for NAAQS implementation. The NAAQS revisions also affect the applicable air permitting requirement, but cause no significant change to the transportation conformity and general conformity processes. The EPA is revising its PSD regulations to provide limited grandfathering from the requirements that result from the revised PM NAAQS.

On other topics, the EPA is changing the AQI for $PM_{2.5}$ to be consistent with the revised primary $PM_{2.5}$ NAAQS. The EPA also is revising the data handling procedures for $PM_{2.5}$ consistent with the revised $PM_{2.5}$ NAAQS including the computations necessary for determining when the standards are met and the measurement data that are appropriate for comparison to the standards. With regard to monitoring-related activities, the EPA is updating several aspects of the monitoring regulations and specifically requiring that a small number of $PM_{2.5}$ monitors be relocated to be collocated with measurements of other pollutants (e.g., nitrogen dioxide, carbon monoxide) in the near-road environment.

C. Costs and Benefits

In setting the NAAQS, the EPA may not consider the costs of implementing the standards. This was confirmed by the United States Supreme Court in *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001), as noted in section II.A of this rule. As has traditionally been done in NAAQS rulemaking, the EPA has conducted a Regulatory Impact Analysis (RIA) to provide the public with information on the potential costs and benefits of attaining several alternative $PM_{2.5}$ standards. In NAAQS rulemaking, the RIA is done for informational purposes only, and the final decisions on the NAAQS in this rulemaking are not in any way based on consideration of the information or analyses in the RIA. The RIA fulfills the requirements of Executive Orders 13563 and 12866. The summary of the RIA, which is discussed in more detail below in section X.A, estimates benefits ranging from $4,000 million to $9,100 million at a 3 percent discount rate and $3,600 million to $8,200 million at a 7 percent discount rate in 2020 and costs ranging from $53 million to $350 million per year at a 7 percent discount rate.

II. Background

A. Legislative Requirements

Two sections of the CAA govern the establishment, review and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in her ''judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;'' ''the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;'' and ''for which * * * [the Administrator] plans to issue air quality criteria * * *'' Air quality criteria are intended to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air * * *'' 42 U.S.C. 7408(b). Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [1] A secondary standard, as defined in section 109(b)(2), must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' [2]

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *See Lead Industries Association* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir 1980); *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1186 (D.C. Cir. 1981); *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512, 533 (D.C. Cir. 2009); *Association of Battery Recyclers* v. *EPA,* 604 F. 3d 613, 617–18 (D.C. Cir. 2010). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, *see Lead Industries* v. *EPA,* 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of at-risk population(s), and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *See Lead Industries Association* v. *EPA,* 647 F.2d at 1161–62; *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 495 (2001).

In setting standards that are ''requisite'' to protect public health and welfare, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, the EPA may not consider the costs of implementing the standards. *See* generally, *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001). Likewise, ''[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.'' *American Petroleum Institute* v. *Costle,* 665 F. 2d at 1185.

Section 109(d)(1) requires that ''not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards * * * and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate * * *'' Section 109(d)(2) requires that an independent scientific review committee ''shall complete a review of the criteria * * * and the national primary and secondary ambient air quality standards * * * and shall recommend to the Administrator any new * * * standards and revisions of existing criteria and standards as may be appropriate. * * *'' Since the early 1980's, this independent review function has been performed by the CASAC.[3]

B. Review of the Air Quality Criteria and Standards for PM

1. Previous PM NAAQS Reviews

The EPA initially established NAAQS for PM under section 109 of the CAA in 1971. Since then, the Agency has made a number of changes to these standards to reflect continually expanding scientific information, particularly with respect to the selection of indicator[4] and level. Table 1 provides a summary of the PM NAAQS that have been promulgated to date. These decisions are briefly discussed below.

TABLE 1—SUMMARY OF NATIONAL AMBIENT AIR QUALITY STANDARDS PROMULGATED FOR PM 1971–2006 [a]

Final rule	Indicator	Averaging time	Level	Form
1971—36 FR 8186 April 30, 1971.	TSP	24-hour	260 µg/m³ (primary) 150 µg/m³ (secondary)	Not to be exceeded more than once per year.
		Annual	75 µg/m³ (primary)	Annual average.
1987—52 FR 24634 July 1, 1987.	PM_{10}	24-hour	150 µg/m³	Not to be exceeded more than once per year on average over a 3-year period.
		Annual	50 µg/m³	Annual arithmetic mean, averaged over 3 years.

[1] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

[2] Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

[3] The CASAC PM Review Panel is comprised of the seven members of the chartered CASAC, supplemented by fifteen subject-matter experts appointed by the Administrator to provide additional scientific expertise relevant to this review of the PM NAAQS. Lists of current CASAC members and review panels are available at: *http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CommitteesandMembership?OpenDocument.* Members of the CASAC PM Review Panel are listed in the CASAC letters providing advice on draft assessment documents (Samet, 2009a–f, 2012a–d).

[4] Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes, such that the indicator for a PM NAAQS has historically been defined in terms of particle size ranges.

TABLE 1—SUMMARY OF NATIONAL AMBIENT AIR QUALITY STANDARDS PROMULGATED FOR PM 1971–2006 [a]—Continued

Final rule	Indicator	Averaging time	Level	Form
1997—62 FR 38652 July 18, 1997.	$PM_{2.5}$	24-hour	65 µg/m³	98th percentile, averaged over 3 years.[b]
		Annual	15.0 µg/m³	Annual arithmetic mean, averaged over 3 years.[c d]
	PM_{10}	24-hour	150 µg/m³	Initially promulgated 99th percentile, averaged over 3 years; when 1997 standards for PM_{10} were vacated, the form of 1987 standards remained in place (not to be exceeded more than once per year on average over a 3-year period).
		Annual	50 µg/m³	Annual arithmetic mean, averaged over 3 years.
2006—71 FR 61144 October 17, 2006.	$PM_{2.5}$	24-hour	35 µg/m³	98th percentile, averaged over 3 years.[b]
		Annual	15.0 µg/m³	Annual arithmetic mean, averaged over 3 years.[c e]
	PM_{10}	24-hour	150 µg/m³	Not to be exceeded more than once per year on average over a 3-year period.

[a] When not specified, primary and secondary standards are identical.

[b] The level of the 24-hour standard is defined as an integer (zero decimal places) as determined by rounding. For example, a 3-year average 98th percentile concentration of 35.49 µg/m³ would round to 35 µg/m³ and thus meet the 24-hour standard and a 3-year average of 35.50 µg/m³ would round to 36 and, hence, violate the 24-hour standard (40 CFR part 50, appendix N).

[c] The level of the annual standard is defined to one decimal place (i.e., 15.0 µg/m³) as determined by rounding. For example, a 3-year average annual mean of 15.04 µg/m³ would round to 15.0 µg/m³ and, thus, meet the annual standard and a 3-year average of 15.05 µg/m³ would round to 15.1 µg/m³ and, hence, violate the annual standard (40 CFR part 50, appendix N).

[d] The level of the standard was to be compared to measurements made at sites that represent "community-wide air quality" recording the highest level, or, if specific requirements were satisfied, to average measurements from multiple community-wide air quality monitoring sites ("spatial averaging").

[e] The EPA tightened the constraints on the spatial averaging criteria by further limiting the conditions under which some areas may average measurements from multiple community-oriented monitors to determine compliance (*See* 71 FR 61165 to 61167, October 17, 2006).

In 1971, the EPA established NAAQS for PM based on the original air quality criteria document (DHEW, 1969; 36 FR 8186, April 30, 1971). The reference method specified for determining attainment of the original standards was the high-volume sampler, which collects PM up to a nominal size of 25 to 45 µm (referred to as total suspended particles or TSP). The primary standards (measured by the indicator TSP) were 260 µg/m³, 24-hour average, not to be exceeded more than once per year, and 75 µg/m³, annual geometric mean. The secondary standard was 150 µg/m³, 24-hour average, not to be exceeded more than once per year.

In October 1979, the EPA announced the first periodic review of the criteria and NAAQS for PM, and significant revisions to the original standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In that decision, the EPA changed the indicator for PM from TSP to PM_{10}, the latter including particles with an aerodynamic diameter less than or equal to a nominal 10 µm, which delineates thoracic particles (i.e., that subset of inhalable particles small enough to penetrate beyond the larynx to the thoracic region of the respiratory tract). The EPA also revised the primary standards by (1) replacing the 24-hour TSP standard with a 24-hour PM_{10} standard of 150 µg/m³ with no more than one expected exceedance per year and (2) replacing the annual TSP standard with a PM_{10} standard of 50 µg/m³, annual arithmetic mean. The secondary standard was revised by replacing it with 24-hour and annual PM_{10} standards identical in all respects to the primary standards. The revisions also included a new reference method for the measurement of PM_{10} in the ambient air and rules for determining attainment of the new standards. On judicial review, the revised standards were upheld in all respects. *Natural Resources Defense Council* v. *EPA,* 902 F. 2d 962 (D.C. Cir. 1990).

In April 1994, the EPA announced its plans for the second periodic review of the criteria and NAAQS for PM, and promulgated significant revisions to the NAAQS in 1997 (62 FR 38652, July 18, 1997). Most significantly, the EPA determined that although the PM NAAQS should continue to focus on thoracic particles (PM_{10}), the fine and coarse fractions of PM_{10} should be considered separately. New standards were added, using $PM_{2.5}$ as the indicator for fine particles. The PM_{10} standards were retained for the purpose of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or $PM_{10-2.5}$).[5] The EPA established two new $PM_{2.5}$ standards: an annual standard of 15.0 µg/m³, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple monitors sited to represent community-wide air quality[6] and a 24-hour standard of 65 µg/m³, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor[7] within an area. Also, the EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and rules for determining attainment of the new standards. To continue to address thoracic coarse particles, the annual PM_{10} standard was retained, while the form, but not the level, of the 24-hour PM_{10} standard was revised to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by making them identical in all respects to the primary standards.

Following promulgation of the revised PM NAAQS in 1997, petitions for review were filed by a large number of

[5] See 40 CFR parts 50, 53, and 58 for more information on reference and equivalent methods for measuring PM in ambient air.

[6] Monitoring stations sited to represent *community-wide* air quality would typically be at the neighborhood or urban-scale; however, where a population-oriented micro or middle-scale $PM_{2.5}$ monitoring station represents many such locations throughout a metropolitan area, these smaller scales might also be considered to represent community-wide air quality [40 CFR part 58, appendix D, 4.7.1(b)].

[7] *Population-oriented* monitoring (or sites) means residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day (40 CFR 58.1).

parties, addressing a broad range of issues. In May 1998, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit issued an initial decision that upheld the EPA's decision to establish fine particle standards, holding that ''the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards.'' *American Trucking Associations* v. *EPA,* 175 F. 3d 1027, 1055–56 (D.C. Cir. 1999), rehearing granted in part and denied in part, 195 F. 3d 4 (D.C. Cir. 1999), affirmed in part and reversed in part, *Whitman* v. *American Trucking Associations,* 531 U.S. 457 (2001). The panel also found ''ample support'' for the EPA's decision to regulate coarse particle pollution, but vacated the 1997 $P.M._{10}$ standards, concluding, in part, that PM_{10} is a ''poorly matched indicator for coarse particulate pollution'' because it includes fine particles. *Id.* at 1053–55. Pursuant to the court's decision, the EPA removed the vacated 1997 $P.M._{10}$ standards from the CFR (69 FR 45592, July 30, 2004) and deleted the regulatory provision (at 40 CFR 50.6(d)) that controlled the transition from the pre-existing 1987 $P.M._{10}$ standards to the 1997 $P.M._{10}$ standards. The pre-existing 1987 $P.M._{10}$ standards remained in place (65 FR 80776, December 22, 2000). The court also upheld the EPA's determination not to establish more stringent secondary standards for fine particles to address effects on visibility (175 F. 3d at 1027).

More generally, the panel held (over a strong dissent) that the EPA's approach to establishing the level of the standards in 1997, both for the PM and for the ozone NAAQS promulgated on the same day, effected ''an unconstitutional delegation of legislative authority.'' *Id.* at 1034–40. Although the panel stated that ''the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable,'' it remanded the rule to the EPA, stating that when the EPA considers these factors for potential non-threshold pollutants ''what EPA lacks is any determinate criterion for drawing lines'' to determine where the standards should be set. Consistent with the EPA's long-standing interpretation and D.C. Circuit precedent, the panel also reaffirmed its prior holdings that in setting NAAQS, the EPA is ''not permitted to consider the cost of implementing those standards.'' *Id.* at 1040–41.

On EPA's petition for rehearing, the panel adhered to its position on these points. *American Trucking Associations* v. *EPA,* 195 F. 3d 4 (D.C. Cir. 1999). The full Court of Appeals denied the EPA's request for rehearing *en banc,* with five judges dissenting. *Id.* at 13. Both sides filed cross appeals on these issues to the United States Supreme Court, which granted certiorari. In February 2001, the Supreme Court issued a unanimous decision upholding the EPA's position on both the constitutional and cost issues. *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 464, 475–76. On the constitutional issue, the Court held that the statutory requirement that NAAQS be ''requisite'' to protect public health with an adequate margin of safety sufficiently cabined the EPA's discretion, affirming the EPA's approach of setting standards that are neither more nor less stringent than necessary. The Supreme Court remanded the case to the Court of Appeals for resolution of any remaining issues that had not been addressed in that court's earlier rulings. *Id.* at 475–76. In March 2002, the Court of Appeals rejected all remaining challenges to the standards, holding under the statutory standard of review that the EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not ''arbitrary and capricious.'' *American Trucking Association* v. *EPA,* 283 F. 3d 355, 369–72 (D.C. Cir. 2002).

In October 1997, the EPA published its plans for the next periodic review of the air quality criteria and NAAQS for PM (62 FR 55201, October 23, 1997). After CASAC and public review of several drafts, the EPA's National Center for Environmental Assessment (NCEA) finalized the *Air Quality Criteria Document for Particulate Matter* (henceforth, AQCD or the ''Criteria Document'') in October 2004 (U.S. EPA, 2004) and OAQPS finalized an assessment document, *Particulate Matter Health Risk Assessment for Selected Urban Areas* (Abt Associates, 2005), and the *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information,* in December 2005 (henceforth, ''Staff Paper,'' U.S. EPA, 2005). In conjunction with its review of the Staff Paper, CASAC provided advice to the Administrator on revisions to the PM NAAQS (Henderson, 2005a). In particular, most CASAC PM Panel members favored revising the level of the primary 24-hour $PM_{2.5}$ standard within the range of 35 to 30 μg/m³ with a 98th percentile form, in concert with revising the level of the primary annual $PM_{2.5}$ standard within the range of 14 to 13 μg/m³ (Henderson, 2005a, p.7). For thoracic coarse particles, the Panel had reservations in recommending a primary 24-hour $PM_{10-2.5}$ standard, and agreed that there was a need for more research on the health effects of thoracic coarse particles (Henderson, 2005b). With regard to secondary standards, most Panel members strongly supported establishing a new, distinct secondary $PM_{2.5}$ standard to protect urban visibility (Henderson, 2005a, p. 9).

On January 17, 2006, the EPA proposed to revise the primary and secondary NAAQS for PM (71 FR 2620) and solicited comment on a broad range of options. Proposed revisions included: (1) Revising the level of the primary 24-hour $PM_{2.5}$ standard to 35 μg/m³; (2) revising the form, but not the level, of the primary annual $PM_{2.5}$ standard by tightening the constraints on the use of spatial averaging; (3) replacing the primary 24-hour PM_{10} standard with a 24-hour standard defined in terms of a new indicator, $PM_{10-2.5}$, which was qualified so as to include any ambient mix of $PM_{10-2.5}$ dominated by particles generated by high-density traffic on paved roads, industrial sources, and construction sources, and to exclude any ambient mix of particles dominated by rural windblown dust and soils and agricultural and mining sources (71 FR 2667 to 2668), set at a level of 70 μg/m³ based on the 3-year average of the 98th percentile of 24-hour $PM_{10-2.5}$ concentrations; (4) revoking the primary annual PM_{10} standard; and (5) revising the secondary standards by making them identical in all respects to the proposed suite of primary standards for fine and coarse particles.[8] Subsequent to the proposal, CASAC provided additional advice to the EPA in a letter to the Administrator requesting reconsideration of CASAC's recommendations for both the primary and secondary $PM_{2.5}$ standards as well as the standards for thoracic coarse particles (Henderson, 2006a).

On October 17, 2006, the EPA published revisions to the PM NAAQS to provide increased protection of public health and welfare (71 FR 61144). With regard to the primary and secondary standards for fine particles, the EPA revised the level of the primary 24-hour $PM_{2.5}$ standard to 35 μg/m³, retained the level of the primary annual $PM_{2.5}$ standard at 15.0 μg/m³, and

[8] In recognition of an alternative view expressed by most members of the CASAC PM Panel, the Agency also solicited comments on a subdaily (4- to 8-hour averaging time) secondary $PM_{2.5}$ standard to address visibility impairment, considering alternative standard levels within a range of 20 to 30 μg/m³ in conjunction with a form within a range of the 92nd to 98th percentile (71 FR 2685, January 17, 2006).

revised the form of the primary annual $PM_{2.5}$ standard by adding further constraints on the optional use of spatial averaging. The EPA revised the secondary standards for fine particles by making them identical in all respects to the primary standards. With regard to the primary and secondary standards for thoracic coarse particles, the EPA retained the level and form of the 24-hour PM_{10} standard (such that the standard remained at a level of 150 μg/m³ with a one-expected exceedance form and retained the PM_{10} indicator) and revoked the annual PM_{10} standard. The EPA also established a new Federal Reference Method (FRM) for the measurement of $PM_{10\text{-}2.5}$ in the ambient air (71 FR 61212 to 13). Although the standards for thoracic coarse particles were not defined in terms of a $PM_{10\text{-}2.5}$ 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 the ''EPA's final rule on the NAAQS for PM does not reflect several important aspects of the CASAC's advice'' (Henderson *et al.,* 2006b, p. 1). With regard to the primary $PM_{2.5}$ annual standard, CASAC expressed serious concerns regarding the decision to retain the level of the standard at 15 μg/m³. Specifically, CASAC stated, ''It is the CASAC's consensus scientific opinion that the decision to retain without change the annual $PM_{2.5}$ standard does not provide an 'adequate margin of safety * * * requisite to protect the public health' (as required by the Clean Air Act), leaving parts of the population of this country at significant risk of adverse health effects from exposure to fine PM'' (Henderson *et al.,* 2006b, p. 2). Furthermore, CASAC pointed out that its recommendations ''were consistent with the mainstream scientific advice that EPA received from virtually every major medical association and public health organization that provided their input to the Agency'' (Henderson *et al.,* 2006b, p. 2).[9] With regard to EPA's final decision to retain the 24-hour PM_{10} standard for thoracic coarse particles, CASAC had mixed views with regard to the decision to retain the 24-hour standard and the continued use of PM_{10} as the indicator of coarse particles, while also recognizing the need to have a standard in place to protect against effects associated with short-term exposures to thoracic coarse particles (Henderson *et al.,* 2006b, p. 2). With regard to the EPA's final decision to revise the secondary $PM_{2.5}$ standards to be identical in all respects to the revised primary $PM_{2.5}$ standards, CASAC expressed concerns that its advice to establish a distinct secondary standard for fine particles to address visibility impairment was not followed and emphasized ''that continuing to rely on the primary standard to protect against all PM-related adverse environmental and welfare effects assures neglect, and will allow substantial continued degradation, of visual air quality over large areas of the country'' (Henderson et al, 2006b, p. 2).

2. Litigation Related to the 2006 PM Standards

Several parties filed petitions for review following promulgation of the revised PM NAAQS in 2006. These petitions addressed the following issues: (1) Selecting the level of the primary annual $PM_{2.5}$ standard; (2) retaining PM_{10} as the indicator of a standard for thoracic coarse particles, retaining the level and form of the 24-hour PM_{10} standard, and revoking the PM_{10} annual standard; and (3) setting the secondary $PM_{2.5}$ standards identical to the primary standards. On February 24, 2009, the U.S. Court of Appeals for the District of Columbia Circuit issued its opinion in the case *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir. 2009). The court remanded the primary annual $PM_{2.5}$ NAAQS to the EPA because the EPA failed to adequately explain why the standard provided the requisite protection from both short- and long-term exposures to fine particles, including protection for at-risk populations such as children. *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512, 520–27 (D.C. Cir. 2009). With regard to the standards for PM_{10}, the court upheld the EPA's decisions to retain the 24-hour PM_{10} standard to provide protection from thoracic coarse particle exposures and to revoke the annual PM_{10} standard. *American Farm Bureau Federation* v. *EPA,* 559 F. 2d at 533–38. With regard to the secondary $PM_{2.5}$ standards, the court remanded the standards to the EPA because the Agency's decision was ''unreasonable and contrary to the requirements of section 109(b)(2)'' of the CAA. The court further concluded that the EPA failed to adequately explain why setting the secondary PM standards identical to the primary standards provided the required protection for public welfare, including protection from visibility impairment. *American Farm Bureau Federation* v. *EPA,* 559 F. 2d at 528–32.

The decisions of the court with regard to these three issues are discussed further in sections III.A.2, IV.A.2, and VI.A.2 below. The EPA is responding to the court's remands as part of the current review of the PM NAAQS.

3. Current PM NAAQS Review

The EPA initiated the current review of the air quality criteria for PM in June 2007 with a general call for information (72 FR 35462, June 28, 2007). In July 2007, the EPA held two ''kick-off'' workshops on the primary and secondary PM NAAQS, respectively (72 FR 34003 to 34004, June 20, 2007).[10] These workshops provided an opportunity for a public discussion of the key policy-relevant issues around which the EPA would structure this PM NAAQS review and the most meaningful new science that would be available to inform our understanding of these issues.

Based in part on the workshop discussions, the EPA developed a draft Integrated Review Plan outlining the schedule, process, and key policy-relevant questions that would guide the evaluation of the air quality criteria for PM and the review of the primary and secondary PM NAAQS (U.S. EPA, 2007a). On November 30, 2007, the EPA held a consultation with CASAC on the draft Integrated Review Plan (72 FR 63177, November 8, 2007), which included the opportunity for public comment. The final Integrated Review Plan (U.S. EPA, 2008a) incorporated comments from CASAC (Henderson, 2008) and the public on the draft plan as well as input from senior Agency managers.[11 12]

[9] CASAC specifically identified input provided by the American Medical Association, the American Thoracic Society, the American Lung Association, the American Academy of Pediatrics, the American College of Cardiology, the American Heart Association, the American Cancer Society, the American Public Health Association, and the National Association of Local Boards of Health (Henderson *et al.*, 2006b, p. 2).

[10] See workshop materials available at: *http://www.regulations.gov/search/Regs/home.html#home* Docket ID numbers EPA–HQ–OAR–2007–0492–008; EPA–HQ–OAR–2007–0492–009; EPA–HQ–OAR–2007–0492–010; and EPA–HQ–OAR–2007–0492–012.

[11] The process followed in this review varies from the NAAQS review process described in section 1.1 of the Integrated Review Plan (U.S. EPA, 2008a). On May 21, 2009, Administrator Jackson called for key changes to the NAAQS review process including reinstating a policy assessment document that contains staff analyses of the scientific bases for alternative policy options for consideration by senior Agency management prior to rulemaking. In conjunction with this change, the EPA will no longer issue a policy assessment in the form of an advance notice of proposed rulemaking (ANPR) as

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A major element in the process for reviewing the NAAQS is the development of an Integrated Science Assessment. This document provides a concise evaluation and integration of the policy-relevant science, including key science judgments upon which the risk and exposure assessments build. As part of the process of preparing the PM Integrated Science Assessment, NCEA hosted a peer review workshop in June 2008 on preliminary drafts of key Integrated Science Assessment chapters (73 FR 30391, May 27, 2008). CASAC and the public reviewed the first external review draft Integrated Science Assessment (U.S. EPA, 2008b; 73 FR 77686, December 19, 2008) at a meeting held on April 1 to 2, 2009 (74 FR 2688, February 19, 2009). Based on CASAC (Samet, 2009e) and public comments, NCEA prepared a second draft Integrated Science Assessment (U.S. EPA, 2009b; 74 FR 38185, July 31, 2009), which was reviewed by CASAC and the public at a meeting held on October 5 and 6, 2009 (74 FR 46586, September 10, 2009). Based on CASAC (Samet, 2009f) and public comments, NCEA prepared the final Integrated Science Assessment titled *Integrated Science Assessment for Particulate Matter,* December 2009 (U.S. EPA, 2009a; 74 FR 66353, December 15, 2009).

Building upon the information presented in the PM Integrated Science Assessment, the EPA prepared Risk and Exposure Assessments that provide a concise presentation of the methods, key results, observations, and related uncertainties. In developing the Risk and Exposure Assessments for this PM NAAQS review, OAQPS released two planning documents: *Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment* and *Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Urban Visibility Impact Assessment* (henceforth, Scope and Methods Plans, U.S. EPA, 2009c,d; 74 FR 11580, March 18, 2009). These planning documents outlined the scope and approaches that staff planned to use in conducting quantitative assessments as well as key issues that would be addressed as part of the assessments. In designing and conducting the initial health risk and visibility impact assessments, the Agency considered CASAC comments (Samet 2009a,b) on the Scope and Methods Plans made during an April 2009 consultation (74 FR 7688, February 19, 2009) as well as public comments. CASAC and the public reviewed two draft assessment documents, *Risk Assessment to Support the Review of the $PM_{2.5}$ Primary National Ambient Air Quality Standards: External Review Draft,* September 2009 (U.S. EPA, 2009e) and *Particulate Matter Urban-Focused Visibility Assessment—External Review Draft,* September 2009 (U.S. EPA, 2009f) at a meeting held on October 5 and 6, 2009 (74 FR 46586, September 10, 2009). Based on CASAC (Samet 2009c,d) and public comments, OAQPS staff revised these draft documents and released second draft assessment documents (U.S. EPA, 2010d,e) in January and February 2010 (75 FR 4067, January 26, 2010) for CASAC and public review at a meeting held on March 10 and 11, 2010 (75 FR 8062, February 23, 2010). Based on CASAC (Samet, 2010a,b) and public comments on the second draft assessment documents, the EPA revised these documents and released final assessment documents titled *Quantitative Health Risk Assessment for Particulate Matter,* June 2010 (henceforth, ''Risk Assessment,'' U.S. EPA, 2010a) and *Particulate Matter Urban-Focused Visibility Assessment—Final Document,* July 2010 (henceforth, ''Visibility Assessment,'' U.S. EPA, 2010b) (75 FR 39252, July 8, 2010).

Based on the scientific and technical information available in this review as assessed in the Integrated Science Assessment and Risk and Exposure Assessments, the EPA staff prepared a Policy Assessment. The Policy Assessment is intended to help ''bridge the gap'' between the relevant scientific information and assessments and the judgments required of the Administrator in reaching decisions on the NAAQS (Jackson, 2009, attachment, p. 2). *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 521. The Policy Assessment is not a decision document; rather it presents the EPA staff conclusions related to the broadest range of policy options that could be supported by the currently available information. A preliminary draft Policy Assessment (U.S. EPA, 2009g) was released in September 2009 for informational purposes and to facilitate discussion with CASAC at the October 5 and 6, 2009 meeting on the overall structure, areas of focus, and level of detail to be included in the Policy Assessment. The EPA considered CASAC's comments on this preliminary draft in developing a first draft Policy Assessment (U.S. EPA, 2010c; 75 FR 4067, January 26, 2010) that built upon the information presented and assessed in the final Integrated Science Assessment and second draft Risk and Exposure Assessments. The EPA presented an overview of the first draft Policy Assessment at a CASAC meeting on March 10, 2010 (75 FR 8062, February 23, 2010) and it was discussed during public CASAC teleconferences on April 8 and 9, 2010 (75 FR 8062, February 23, 2010) and May 7, 2010 (75 FR 19971, April 16, 2010).

The EPA developed a second draft Policy Assessment (U.S. EPA, 2010f; 75 FR 39253, July 8, 2010) based on CASAC (Samet, 2010c) and public comments on the first draft Policy Assessment. CASAC reviewed the second draft document at a meeting on July 26 and 27, 2010 (75 FR 32763, June 9, 2010). The EPA staff considered CASAC (Samet, 2010d) and public comments on the second draft Policy Assessment in preparing a final Policy Assessment titled *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards,* April, 2011 (U.S. EPA, 2011a; 76, FR 22665, April 22, 2011). This document includes final staff conclusions on the adequacy of the current PM standards and alternative standards for consideration.

The schedule for the rulemaking in this review is subject to a court order in a lawsuit filed in February 2012 by a group of plaintiffs who alleged that the EPA had failed to perform its mandatory duty, under section 109(d)(1), to complete a review of the PM NAAQS within the period provided by statute. *American Lung Association and National Parks Conservation Association* v. *EPA,* D.D.C. No. 12–cv–00243 (consol. with No. 12–cv–00531) Court orders in that case provide that the EPA sign a notice of proposed rulemaking concerning its review of the PM NAAQS no later than June 14, 2012 and a notice of final rulemaking no later than December 14, 2012.

On June 14, 2012, the EPA issued its proposed decision to revise the NAAQS for PM (77 FR 38890, June 29, 2012) (henceforth ''proposal''). In the proposal, the EPA identified revisions to the standards, based on the air quality criteria for PM, and to related data handling conventions and ambient air monitoring, reporting, and network design requirements. The EPA proposed revisions to the PSD permitting program with respect to the proposed NAAQS revisions. The Agency also proposed

discussed in the Integrated Review Plan (U.S. EPA, 2008a, p. 3). For more information on the overall process followed in this review including a description of the major elements of the process for reviewing NAAQS see Jackson (2009).

[12] All written comments submitted to the Agency are available in the docket for this PM NAAQS review (EPA–HQ–OAR–2007–0429). Transcripts of public meetings and teleconferences held in conjunction with CASAC's reviews are also included in the docket.

changes to the AQI for $PM_{2.5}$, consistent with the proposed primary $PM_{2.5}$ standards. The proposal solicited public comments on alternative primary and secondary standards and related matters. The proposal is summarized in section II.D below.

The EPA held two public hearings to receive public comment on the proposed revisions to the PM NAAQS (77 FR 39205, July 2, 2012). One hearing took place in Philadelphia, PA on July 17, 2012 and a second hearing took place in Sacramento, CA on July 19, 2012. At these public hearings, the EPA heard testimony from 168 individuals representing themselves or specific interested organizations.

The EPA received more than 230,000 comments from members of the public and various interest groups on the proposed revisions to the PM NAAQS by the close of the public comment period on August 31, 2012. Major issues raised in the public comments are discussed throughout the preamble of this final action. A more detailed summary of all significant comments, along with the EPA's responses (henceforth ''Response to Comments'') can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2007–0492) (U.S. EPA, 2012a).

In the proposal, the EPA recognized that there were a number of new scientific studies on the health effects of PM that had been published since the mid-2009 cutoff date for inclusion in the Integrated Science Assessment.[13] As in the last PM NAAQS review, the EPA committed to conduct a provisional review and assessment of any significant ''new'' studies published since the close of the Integrated Science Assessment, including studies submitted to the EPA during the public comment period. The purpose of the provisional science assessment was to ensure that the Administrator was fully aware of the ''new'' science that has developed since 2009 before making final decisions on whether to retain or revise the current PM NAAQS. The EPA screened and surveyed the recent health literature, including studies submitted during the public comment period, and conducted a provisional assessment (U.S. EPA, 2012b) that places the results of those studies of potentially greatest policy relevance in the context of the findings of the Integrated Science Assessment (U.S. EPA, 2009a). This provisional assessment, including a summary of the key conclusions, can be found in the rulemaking docket (EPA–HQ–OAR–2007–0492).

The provisional assessment found that the ''new'' studies expand the scientific information considered in the Integrated Science Assessment and provide important insights on the relationship between PM exposure and health effects. The provisional assessment also found that the ''new'' studies generally strengthen the evidence that long- and short-term exposures to fine particles are associated with a wide range of health effects. Some of the ''new'' epidemiological studies report effects in areas with lower $PM_{2.5}$-concentrations than those in earlier studies considered in the Integrated Science Assessment. ''New'' toxicological and epidemiological studies continue to link various health effects with a range of fine particle sources and components. With regard to thoracic coarse particles, the provisional assessment recognized that a limited number of ''new'' studies provide evidence of an association with short-term $PM_{10-2.5}$ exposures and increased asthma-related emergency department visits in children, but continue to provide no evidence of an association between long-term $PM_{10-2.5}$ exposure and mortality. Further, the provisional assessment found that the results reported in ''new'' studies do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Integrated Science Assessment.

The EPA believes it was important to conduct a provisional assessment in this proceeding, so that the Administrator would be aware of the science that developed too recently for inclusion in the Integrated Science Assessment. However, it is also important to note that the EPA's review of that science to date has been limited to screening, surveying, and preparing a provisional assessment of these studies. Having performed this limited provisional assessment, the EPA must decide whether to consider the ''new'' studies in this review and to take such steps as may be necessary to include them in the basis for the final decision, or to reserve such action for the next review of the PM NAAQS.

As in prior NAAQS reviews, the EPA is basing its decision in this review on studies and related information included in the Integrated Science Assessment, Risk and Exposure Assessment, and Policy Assessment, which have undergone CASAC and public review. The studies assessed in the Integrated Science Assessment, and the integration of the scientific evidence presented in that document, have undergone extensive critical review by the EPA, CASAC, and the public during the development of the Integrated Science Assessment. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by the EPA but also by the statutorily-mandated independent advisory committee, CASAC, and have been subject as well to the public review that accompanies this process. As described above, the provisional assessment did not and could not provide that kind of in-depth critical review.

This decision is consistent with the EPA's practice in prior NAAQS reviews. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria. *See* e.g., 36 FR 8186 (April 30, 1971) (the EPA based original NAAQS for six pollutants on scientific studies discussed in air quality criteria documents and limited consideration of comments to those concerning validity of scientific basis); 38 FR 25678, 25679–25680 (September 14, 1973) (the EPA revised air quality criteria for sulfur oxides to provide basis for reevaluation of secondary NAAQS). This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the CAA concerning CASAC review of air quality criteria. The EPA has consistently followed this approach. 52 FR 24634, 24637 (July 1, 1987) (after review by CASAC, the EPA issued a post-proposal addendum to the PM Air Quality Criteria Document, to address certain new scientific studies not included in the 1982 Air Quality Criteria Document); 61 FR 25566, 25568 (May 22, 1996) (after review by CASAC, the EPA issued a post-proposal supplement to the 1982 Air Quality Criteria Document to address certain new health studies not included in the 1982 Air Quality Criteria Document or 1986

[13] For ease of reference, these studies will be referred to as ''new'' studies or ''new'' science, using quotation marks around the word *new*. Referring to studies that were published too recently to have been included in the 2009 Integrated Science Assessment as ''new'' studies is intended to clearly differentiate such studies from those that have been published since the last review and which are included in the Integrated Science Assessment (these studies are sometimes referred to as new (without quotation marks) or more recent studies, to indicate that they were not included in the Integrated Science Assessment and thus are newly available in this review).

Addendum). The EPA reaffirmed this approach in its decision not to revise the ozone NAAQS in 1993, as well as in its final decision on the PM NAAQS in the 1997 and 2006 reviews. 58 FR 13008, 13013 to 13014 (March 9, 1993) (ozone review); 62 FR 38652, 38662 (July 18, 1997) and 71 FR 61141, 61148 to 61149 (October 17, 2006) (PM reviews) (The EPA conducted a provisional assessment but based the final PM decisions on studies and related information included in the air quality criteria that had been reviewed by CASAC).

As discussed in the EPA's 1993 decision not to revise the NAAQS for ozone, 'new' studies may sometimes be of such significance that it is appropriate to delay a decision on revision of NAAQS and to supplement the pertinent air quality criteria so the ''new'' studies can be taken into account (58 FR, 13013 to 13014, March 9, 1993). In this proceeding, the provisional assessment of recent studies concludes that, taken in context, the ''new'' information and findings do not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Integrated Science Assessment (U.S. EPA, 2012b). For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking. Accordingly, the EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review. The EPA will consider the ''new'' published studies for purposes of decision making in the next periodic review of the PM NAAQS, which will provide the opportunity to fully assess them through a more rigorous review process involving the EPA, CASAC, and the public.

C. Related Control Programs To Implement PM Standards

States are primarily responsible for ensuring attainment and maintenance of NAAQS once the EPA has established them. Under section 110 of the CAA and related provisions, states are to submit, for the EPA's approval, SIPs that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the PSD permitting program (CAA sections 160 to 169). In addition, federal programs provide for nationwide reductions in emissions of PM and other air pollutants through the federal motor vehicle and motor vehicle fuel control program under title II of the Act (CAA sections 202 to 250) which involves controls for emissions from mobile sources and controls for the fuels used by these sources, and new source performance standards (NSPS) for stationary sources under section 111 of the CAA.

Currently, there are 35 areas in the U.S. that are designated as nonattainment for the current annual $PM_{2.5}$ standard and 32 areas in the U.S. that are designated as nonattainment for the current 24-hour $PM_{2.5}$ standards. With the revisions to the PM NAAQS that are being finalized in this rule, the EPA will work with the states to conduct a new area designation process. Those states with new nonattainment areas will be required to develop SIPs to attain the standards. In developing their attainment plans, states will have to take into account projected emission reductions from federal and state rules that have already been adopted at the time of plan submittal. A number of significant emission reduction programs that will lead to reductions of PM and its precursors are in place today or are expected to be in place by the time any new SIPs will be due. Examples of such rules include regulations for onroad and nonroad engines and fuels, the utility and industrial boilers toxics rules, and various other programs already adopted by states to reduce emissions from key emissions sources. States will then evaluate the level of additional emission reductions needed for each nonattainment area to attain the standards ''as expeditiously as practicable'' and adopt new state regulations, as appropriate. Section IX includes additional discussion of designation and implementation issues associated with the revised PM NAAQS.

D. Summary of Proposed Revisions to the PM NAAQS

For reasons discussed in the proposal, the Administrator proposed to revise the current primary and secondary PM standards. With regard to the primary $PM_{2.5}$ standards, the Administrator proposed to revise the level of the annual $PM_{2.5}$ standard from 15.0 μg/m³ to a level within a range of 12.0 to 13.0 μg/m³ and to retain the level of the 24-hour $PM_{2.5}$ standard at 35 μg/m³. The Administrator also proposed to eliminate spatial averaging provisions as part of the form of the annual standard to avoid potential disproportionate impacts on at-risk populations. The EPA proposed to revise the AQI for $PM_{2.5}$, consistent with the proposed primary $PM_{2.5}$ standards.

With regard to the primary coarse particle standard, the EPA proposed to retain the current 24-hour PM_{10} standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10\text{-}2.5}$).

With regard to the secondary PM standards, the EPA proposed to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment. The separate secondary standard was proposed to be defined in terms of a $PM_{2.5}$ visibility index, which would use speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction, translated to the deciview (dv) scale, similar to the Regional Haze Program; a 24-hour averaging time; a 90th percentile form averaged over 3 years; and a level set at one of two options—either 30 or 28 dv. The EPA also proposed to retain the current secondary standards generally to address non-visibility welfare effects.

The EPA also proposed to revise the data handling procedures consistent with the revised primary and secondary standards for $PM_{2.5}$ including the computations necessary for determining when these standards are met and the measurement data that are appropriate for comparison to the standards. With regard to monitoring-related activities, the EPA proposed to update several aspects of the monitoring regulations and specifically to require that a small number of $PM_{2.5}$ monitors be relocated to be collocated with measurements of other pollutants (e.g., nitrogen dioxide, carbon monoxide) in the near-road environment.

E. Organization and Approach to Final PM NAAQS Decisions

This action presents the Administrator's final decisions on the review of the current primary and secondary $PM_{2.5}$ and PM_{10} standards. Consistent with the decisions made by the EPA in the last review and with the conclusions in the Integrated Science Assessment and Policy Assessment, fine and thoracic coarse particles continue to be considered as separate subclasses of PM pollution. Primary standards for fine particles and for thoracic coarse particles are addressed in sections III and IV, respectively. Changes to the AQI for $PM_{2.5}$, consistent with the revised primary $PM_{2.5}$ standards, are addressed in section V. Secondary standards for fine and coarse particles are addressed in section VI. Related data handling conventions and exceptional events are addressed in section VII. Updates to the monitoring regulations are addressed in section VIII. Implementation activities, including PSD-related actions, are addressed in section IX. Section X addresses applicable statutory and executive order reviews.

Today's final decisions addressing standards for fine and coarse particles are based on a thorough review in the Integrated Science Assessment of scientific information on known and potential human health and welfare effects associated with exposure to these subclasses of PM at levels typically found in the ambient air. These final decisions also take into account: (1) Staff assessments in the Policy Assessment of the most policy-relevant information in the Integrated Science Assessment as well as a quantitative health risk assessment and urban-focused visibility assessment based on that information; (2) CASAC advice and recommendations, as reflected in its letters to the Administrator, its discussions of drafts of the Integrated Science Assessment, Risk and Exposure Assessments, and Policy Assessment at public meetings, and separate written comments prepared by individual members of the CASAC PM Review Panel; (3) public comments received during the development of these documents, both in connection with CASAC meetings and separately; and (4) extensive public comments received on the proposed rulemaking.

III. Rationale for Final Decisions on the Primary $PM_{2.5}$ Standards

This section presents the Administrator's final decision regarding the need to revise the current primary $PM_{2.5}$ standards and, more specifically, regarding revisions to the level and form of the existing primary annual $PM_{2.5}$ standard in conjunction with retaining the existing primary 24-hour $PM_{2.5}$ standard. As discussed more fully below, the rationale for the final decision is based on a thorough review, in the Integrated Science Assessment, of the latest scientific information, published through mid-2009, on human health effects associated with long- and short-term exposures to fine particles in the ambient air. The final decisions also take into account: (1) Staff assessments of the most policy-relevant information presented and assessed in the Integrated Science Assessment and staff analyses of air quality and human risks presented in the Risk Assessment and the Policy Assessment, upon which staff conclusions regarding appropriate considerations in this review are based; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the Integrated Science Assessment, Risk Assessment, and Policy Assessment at public meetings, in separate written comments, and in CASAC's letters to the Administrator; (3) the multiple rounds of public comments received during the development of these documents, both in connection with CASAC meetings and separately; and (4) extensive public comments received on the proposal.

In developing this final rule, the Administrator recognizes that the CAA requires her to reach a public health policy judgment as to what standards would be requisite—neither more nor less stringent than necessary—to protect public health with an adequate margin of safety, based on scientific evidence and technical assessments that have inherent uncertainties and limitations. This judgment requires making reasoned decisions as to what weight to place on various types of evidence and assessments, and on the related uncertainties and limitations. Thus, in selecting the final standards, the Administrator is seeking not only to prevent fine particle concentrations that have been demonstrated to be harmful but also to prevent lower fine particle concentrations that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

As discussed below, as well as in more detail in the proposal, a substantial amount of new research has been conducted since the close of the science assessment in the last review of the $PM_{2.5}$ NAAQS (U.S. EPA, 2004), with important new information coming from epidemiological studies, in particular. This body of evidence includes hundreds of new epidemiological studies conducted in many countries around the world. In its assessment of the evidence judged to be most relevant to making decisions on elements of the primary $PM_{2.5}$ standards, the EPA has placed greater weight on U.S. and Canadian studies using $PM_{2.5}$ measurements, since studies conducted in other countries may reflect different demographic and air pollution characteristics.[14]

The newly available research studies as well as the earlier body of scientific evidence presented and assessed in the Integrated Science Assessment have undergone intensive scrutiny through multiple layers of peer review and opportunities for public review and comment. In developing this final rule, the EPA has drawn upon an integrative synthesis of the entire body of evidence concerning exposure to ambient fine particles and a broad range of health endpoints (U.S. EPA, 2009a, Chapters 2, 4, 5, 6, 7, and 8) focusing on those health endpoints for which the Integrated Science Assessment concludes that there is a *causal* or *likely causal relationship* with long- or short-term $PM_{2.5}$ exposures. The EPA has also considered health endpoints for which the Integrated Science Assessment concludes there is evidence *suggestive of a causal relationship* with long-term $PM_{2.5}$ exposures.

The EPA has also drawn upon a quantitative risk assessment based upon the scientific evidence described and assessed in the Integrated Science Assessment. These analyses, discussed in the Risk Assessment (U.S. EPA, 2010a) and Policy Assessment (U.S. EPA, 2011a, chapter 2), have also undergone intensive scrutiny through multiple layers of peer review and multiple opportunities for public review and comment.

Although important uncertainties remain in the qualitative and quantitative characterizations of health effects attributable to ambient fine particles, progress has been made in addressing these uncertainties in this review. The EPA's review of this information has been extensive and deliberate. This intensive evaluation of the scientific evidence and quantitative assessments has provided a comprehensive and adequate basis for regulatory decision making at this time.

This section describes the integrative synthesis of the evidence and technical information contained in the Integrated Science Assessment, the Risk Assessment, and the Policy Assessment with regard to the current and alternative standards. The EPA notes that the final decision for retaining or revising the current primary $PM_{2.5}$ standards is a public health policy judgment made by the Administrator. The Administrator's final decision draws upon scientific information and analyses related to health effects and risks; judgments about uncertainties that are inherent in the scientific evidence and analyses; CASAC advice; and comments received in response to the proposal.

In presenting the rationale for the final decisions on the primary $PM_{2.5}$ standards, this section begins with a summary of the approaches used in setting the initial primary $PM_{2.5}$ NAAQS in 1997 and in reviewing and revising those standards in 2006 (section III.A.1). The DC Circuit Court of Appeals remand of the primary annual $PM_{2.5}$ standard in 2009 is discussed in section III.A.2. Taking into consideration this

[14] Nonetheless, the Administrator recognizes the importance of all studies, including international studies, in the Integrated Science Assessment's considerations of the weight of the evidence that informs causality determinations.

history, section III.A.3 describes the EPA's general approach used in the current review for considering the need to retain or revise the current suite of fine particle standards, taking into account public comment on the proposed approach.

The scientific evidence and quantitative risk assessment were presented in sections III.B and III.C of the proposal, respectively (77 FR 38906 to 38917, June 29, 2012) and are outlined in sections III.B and III.C below. Subsequent sections of this preamble provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for concluding that it is appropriate to revise the suite of current primary $PM_{2.5}$ standards (section III.D), as well as a more complete discussion of the Administrator's rationale for retaining or revising the specific elements of the primary $PM_{2.5}$ standards, namely the indicator (section III.E.1); averaging time (section III.E.2); form (section III.E.3); and level (section III.E.4). A summary of the final decisions to revise the suite of primary $PM_{2.5}$ standards is presented in section III.F.

A. Background

There are currently two primary $PM_{2.5}$ standards providing public health protection from effects associated with fine particle exposures. The annual standard is set at a level of 15.0 µg/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 $PM_{2.5}$ standards that, in the Administrator's judgment, protect public health with an adequate margin of safety. Such information can be in the form of air quality distributions over which health effect associations have been observed in scientific studies or in the form of concentration-response functions that support quantitative risk assessment. However, evidence- and risk-based approaches using information from epidemiological studies to inform decisions on $PM_{2.5}$ standards are complicated by the recognition that no population threshold, below which it can be concluded with confidence that $PM_{2.5}$-related effects do not occur, can be discerned from the available evidence.[15] As a result, any general approach to reaching decisions on what standards are appropriate necessarily requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards. This includes consideration of how to weigh the uncertainties in the reported associations across the distributions of $PM_{2.5}$ concentrations in the studies and the uncertainties in quantitative estimates of risk, in the context of the entire body of evidence before the Agency. Such approaches are consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

1. General Approach Used in Previous Reviews

The general approach used to translate scientific information into standards in the previous PM NAAQS reviews focused on consideration of alternative standard levels that were somewhat below the long-term mean $PM_{2.5}$ concentrations reported in key epidemiological studies (U.S. EPA, 2011a, section 2.1.1). This approach recognized that the strongest evidence of $PM_{2.5}$-related associations occurs where the bulk of the data exists, which is over a range of concentrations around the long-term (i.e., annual) mean.

In setting primary $PM_{2.5}$ annual and 24-hour standards for the first time in 1997, the Agency relied primarily on an evidence-based approach that focused on epidemiological evidence, especially from short-term exposure studies of fine particles judged to be the strongest evidence at that time (U.S. EPA, 2011a, section 2.1.1.1). The EPA selected a level for the annual standard that was at or below the long-term mean $PM_{2.5}$ concentrations in studies providing evidence of associations with short-term $PM_{2.5}$ exposures, placing greatest weight on those short-term exposure studies that reported clearly statistically significant associations with mortality and morbidity effects. Further consideration of long-term mean $PM_{2.5}$ concentrations associated with mortality and respiratory effects in children did not provide a basis for establishing a lower annual standard level. The EPA did not place much weight on quantitative risk estimates from the very limited risk assessment conducted, but did conclude that the risk assessment results confirmed the general conclusions drawn from the epidemiological evidence that a serious public health problem was associated with ambient PM levels allowed under the then current PM_{10} standards (62 FR 38665/1, July 18, 1997).

The EPA considered the epidemiological evidence and data on air quality relationships to set an annual $PM_{2.5}$ standard that was intended to be the ''generally controlling'' standard; i.e., the primary means of lowering both long- and short-term ambient concentrations of $PM_{2.5}$.[16] In conjunction with the annual standard, the EPA also established a 24-hour $PM_{2.5}$ standard to provide supplemental protection against days with high peak concentrations, localized ''hotspots,'' and risks arising from seasonal emissions that might not be well controlled by an annual standard (62 FR 38669/3).

In 2006, the EPA used a different evidence-based approach to assess the appropriateness of the levels of the 24-hour and annual $PM_{2.5}$ standards (U.S. EPA, 2011a, section 2.1.1.2). Based on an expanded body of epidemiological evidence that was stronger and more robust than that available in the 1997 review, including additional studies of both short- and long-term exposures, the EPA decided that using evidence of effects associated with periods of exposure that were most closely matched to the averaging time of each standard was the most appropriate public health policy approach for evaluating the scientific evidence to inform selecting the level of each standard. Thus, the EPA relied upon evidence from the short-term exposure studies as the principal basis for revising the level of the 24-hour $PM_{2.5}$ standard from 65 to 35 µg/m³ to protect against effects associated with short-term exposures. The EPA relied upon evidence from long-term exposure

[15] The term ''evidence-based'' approach or consideration generally refers to using the information in the scientific evidence to inform judgments on the need to retain or revise the NAAQS. The term ''risk-based'' generally refers to using the quantitative information in the Risk Assessment to inform such judgments.

[16] In so doing, the EPA noted that because an annual standard would focus control programs on annual average $PM_{2.5}$ concentrations, it would not only control long-term exposure levels, but would also generally control the overall distribution of 24-hour exposure levels, resulting in fewer and lower 24-hour peak concentrations. Alternatively, a 24-hour standard that focused controls on peak concentrations could also result in lower annual average concentrations. Thus, the EPA recognized that either standard could provide some degree of protection from both short- and long-term exposures, with the other standard serving to address situations where the daily peaks and annual averages are not consistently correlated (62 FR 38669, July 18, 1997). In the circumstances presented in that review, the EPA determined that it was appropriate to focus on the annual standard as the standard best suited to control both annual and daily air quality distributions (62 FR 38670).

studies as the principal basis for retaining the level of the annual $PM_{2.5}$ standard at 15 µg/m[3] to protect against effects associated with long-term exposures. This approach essentially took the view that short-term studies were not appropriate to inform decisions relating to the level of the annual standard, and long-term studies were not appropriate to inform decisions relating to the level of the 24-hour standard. With respect to quantitative risk-based considerations, the EPA determined that the estimates of risks likely to remain upon attainment of the 1997 suite of $PM_{2.5}$ standards were indicative of risks that could be reasonably judged important from a public health perspective and, thus, supported revision of the standards. However, the EPA judged that the quantitative risk assessment had important limitations and did not provide an appropriate basis for selecting the levels of the revised standards in 2006 (71 FR 61174/1–2, October 17, 2006).

2. Remand of Primary Annual $PM_{2.5}$ Standard

As noted above in section II.B.2, several parties filed petitions for review in the U.S. Court of Appeals for the District of Columbia Circuit following promulgation of the revised PM NAAQS in 2006. These petitions challenged several aspects of the final rule including the level of the primary $PM_{2.5}$ annual standard. The primary 24-hour $PM_{2.5}$ standard was not challenged by any of the litigants and, thus, was not considered in the court's review and decision.

On judicial review, the D.C. Circuit remanded the primary annual $PM_{2.5}$ NAAQS to the EPA on grounds that the Agency failed to adequately explain why the annual standard provided the requisite protection from both short- and long-term exposures to fine particles including protection for at-risk populations. *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir. 2009). With respect to human health protection from short-term $PM_{2.5}$ exposures, the court considered the different approaches used by the EPA in the 1997 and 2006 p.m. NAAQS decisions, as summarized in section III.A.1 above. The court found that the EPA failed to adequately explain why a primary 24-hour $PM_{2.5}$ standard by itself would provide the protection needed from short-term exposures and remanded the primary annual $PM_{2.5}$ standard to the EPA ''for further consideration of whether it is set at a level requisite to protect the public health while providing an adequate margin of safety from the risk of short-term exposures to $PM_{2.5}$.'' *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 520–24.

With respect to protection from long-term exposure to fine particles, the court found that the EPA failed to adequately explain how the primary annual $PM_{2.5}$ standard provided an adequate margin of safety for children and other at-risk populations. The court found that the EPA did not provide a reasonable explanation of why certain morbidity studies, including a study of children in Southern California showing lung damage associated with long-term $PM_{2.5}$ exposure (Gauderman et al., 2000) and a multi-city study (24-Cities Study) evaluating decreased lung function in children associated with long-term $PM_{2.5}$ exposures (Raizenne *et al.,* 1996), did not warrant a more stringent annual $PM_{2.5}$ standard. *Id.* at 522–23. Specifically, the court found that:

> EPA was unreasonably confident that, even though it relied solely upon long-term mortality studies, the revised standard would provide an adequate margin of safety with respect to morbidity among children. Notably absent from the final rule, moreover, is any indication of how the standard will adequately reduce risk to the elderly or to those with certain heart or lung diseases despite (a) the EPA's determination in its proposed rule that those subpopulations are at greater risk from exposure to fine particles and (b) the evidence in the record supporting that determination. *Id.* at 525.

In addition, the court held that the EPA had not adequately explained its decision to base the level of the annual standard essentially exclusively on the results of long-term studies and the 24-hour standard level essentially exclusively on the results of short-term studies. *See* 559 F. 3d at 522 (''[e]ven if the long-term studies available today are useful for setting an annual standard * * * it is not clear why the EPA no longer believes it useful to look as well to short-term studies in order to design the suite of standards that will most effectively reduce the risks associated with short-term exposure''); *see* also *Id.* at 523–24 (holding that the EPA had not adequately explained why a standard based on levels in short-term exposure studies alone provided appropriate protection from health effects associated with short-term $PM_{2.5}$ exposures given the stated need to lower the entire air quality distribution, and not just peak concentrations, in order to control against short-term effects).

In remanding the primary annual $PM_{2.5}$ standard for reconsideration, the court did not vacate the standard, *Id.* at 530, so the standard remains in effect and is therefore the standard considered by the EPA in this review.

3. General Approach Used in the Policy Assessment for the Current Review

This review is based on an assessment of a much expanded body of scientific evidence, more extensive air quality data and analyses, and a more comprehensive quantitative risk assessment relative to the information available in past reviews, as presented and assessed in the Integrated Science Assessment and Risk Assessment and discussed in the Policy Assessment. As a result, the EPA's general approach to reaching conclusions about the adequacy of the current suite of $PM_{2.5}$ standards and potential alternative standards that are appropriate to consider was broader and more integrative than in past reviews. Our general approach also reflected consideration of the issues raised by the court in its remand of the primary annual $PM_{2.5}$ standard as discussed in section III.A.2 above, since decisions made in this review, and the rationales for those decisions, will comprise the Agency's response to the remand.

The EPA's general approach took into account both evidence-based and risk-based considerations and the uncertainties related to both types of information, as well as advice from CASAC (Samet, 2010c,d) and public comments on the first and second draft Policy Assessments (U.S. EPA, 2010c,f). In so doing, the EPA staff developed a final Policy Assessment (U.S. EPA, 2011a) which provided as broad an array of policy options as was supported by the available information, recognizing that the selection of a specific approach to reaching final decisions on the primary $PM_{2.5}$ standards will reflect the judgments of the Administrator as to what weight to place on the various approaches and types of information available in the current review.

The Policy Assessment concluded it was most appropriate to consider the protection against $PM_{2.5}$-related mortality and morbidity effects, associated with both long- and short-term exposures, afforded by the annual and 24-hour standards taken together, as was done in the 1997 review, rather than to consider each standard separately, as was done in the 2006 review (U.S. EPA, 2011a, section 2.1.3).[17] As the EPA recognized in 1997,

[17] By utilizing this approach, the Agency also is responsive to the remand of the 2006 standard. As noted in section III.A.2, the D.C. Circuit, in remanding the 2006 primary annual $PM_{2.5}$ standard, concluded that the Administrator had failed to

Continued

there are various ways to combine two standards to achieve an appropriate degree of public health protection. The extent to which these two standards are interrelated in any given area depends in large part on the relative levels of the standards, the peak-to-mean ratios that characterize air quality patterns in an area, and whether changes in air quality designed to meet a given suite of standards are likely to be of a more regional or more localized nature.

In considering the combined effect of annual and 24-hour standards, the Policy Assessment recognized that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in lower annual average $PM_{2.5}$ concentrations but also in fewer and lower peak 24-hour $PM_{2.5}$ concentrations. The Policy Assessment also recognized that changes designed to meet a 24-hour standard would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations but also in lower annual average $PM_{2.5}$ concentrations. Thus, either standard could be viewed as providing protection from effects associated with both short- and long-term exposures, with the other standard serving to address situations where the daily peak and annual average concentrations are not consistently correlated.

In considering the currently available evidence, the Policy Assessment recognized that the short-term exposure studies were primarily drawn from epidemiological studies that associated variations in area-wide health effects with monitor(s) that measured the variation in daily $PM_{2.5}$ concentrations over the course of several years. The strength of the associations in these data was demonstrably in the numerous ''typical'' days within the air quality distribution, not in the peak days. *See* also 71 FR 61168, October 17, 2006 and *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 523, 524 (making the same point). The quantitative risk assessments conducted for this and previous reviews demonstrated the same point; that is, much, if not most of the aggregate risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low-to mid-range, below the peak 24-hour concentrations (U.S. EPA, 2011a, section 2.2.2; U.S. EPA, 2010a, section 3.1.2.2). In addition, there was no evidence suggesting that risks associated with long-term exposures were likely to be disproportionately driven by peak 24-hour concentrations.[18]

For these reasons, the Policy Assessment concluded that strategies that focused primarily on reducing peak days were less likely to achieve reductions in the $PM_{2.5}$ concentrations that were most strongly associated with the observed health effects. Furthermore, the Policy Assessment concluded that a policy approach that focused on reducing peak exposures would most likely result in more uneven public health protection across the U.S. by either providing inadequate protection in some areas or overprotecting in other areas (U.S. EPA, 2011a, p. 2–9; U.S. EPA, 2010a, section 5.2.3). This is because, as discussed above, reductions based on control of peak days are less likely to control the bulk of the air quality distribution.

The Policy Assessment concluded that a policy goal of setting a ''generally controlling'' annual standard that will lower a wide range of ambient 24-hour $PM_{2.5}$ concentrations, as opposed to focusing on control of peak 24-hour $PM_{2.5}$ concentrations, was the most effective and efficient way to reduce total population risk and so provide appropriate protection. This approach, in contrast to one focusing on a generally controlling 24-hour standard, would likely reduce aggregate risks associated with both long- and short-term exposures with more consistency and would likely avoid setting national standards that could result in relatively uneven protection across the country, due to setting standards that are either more or less stringent than necessary in different geographical areas (U.S. EPA, 2011a, p. 2–9).

The Policy Assessment also concluded that an annual standard intended to serve as the primary means for providing protection from effects associated with both long- and short-term $PM_{2.5}$ exposures cannot be expected to offer sufficient protection against the effects of all short-term $PM_{2.5}$ exposures. As a result, in conjunction with a generally controlling annual standard, the Policy Assessment concluded it was appropriate to consider setting a 24-hour standard to provide supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods (U.S. EPA, 2011a, p. 2–10).

The Policy Assessment's consideration of the protection afforded by the current and alternative suites of standards focused on $PM_{2.5}$-related health effects associated with long-term exposures for which the magnitude of quantitative estimates of risks to public health generated in the risk assessment was appreciably larger in terms of overall incidence and percent of total mortality or morbidity effects than for short-term $PM_{2.5}$-related effects. Nonetheless, the EPA also considered health effects and estimated risks associated with short-term exposures. In both cases, the Policy Assessment placed greatest weight on health effects that had been judged in the Integrated Science Assessment to have a causal or likely causal relationship with $PM_{2.5}$ exposures, while also considering health effects judged to be suggestive of a causal relationship or evidence that focused on specific at-risk populations. The Policy Assessment placed relatively greater weight on statistically significant associations that yielded relatively more precise effect estimates and that were judged to be robust to confounding by other air pollutants. In the case of short-term exposure studies, the Policy Assessment placed greatest weight on evidence from large multi-city studies, while also considering associations in single-city studies.

In translating information from epidemiological studies into the basis for reaching staff conclusions on the adequacy of the current suite of standards, the Policy Assessment considered a number of factors. As an initial matter, the Policy Assessment considered the extent to which the currently available evidence and related uncertainties strengthens or calls into question conclusions from the last review regarding associations between fine particle exposures and health effects. The Policy Assessment also considered evidence of health effects in at-risk populations and the potential impacts on such populations. Further, the Policy Assessment explored the extent to which $PM_{2.5}$-related health effects had been observed in areas where air quality distributions extend to lower concentrations than previously reported or in areas that would likely have met the current suite of standards.

In translating information from epidemiological studies into the basis for reaching staff conclusions on

adequately explain why an annual standard was sufficiently protective in the absence of consideration of the long-term mean $PM_{2.5}$ concentrations in short-term exposure studies as well, and likewise had failed to explain why a 24-hour standard was sufficiently protective in the absence of consideration of the effect of an annual standard on reducing the overall distribution of 24-hour average $PM_{2.5}$ concentrations. 559 F. 3d at 520–24.

[18] In confirmation, a number of studies have presented analyses excluding higher PM concentration days and reported a limited effect on the magnitude of the effect estimates or statistical significance of the association (e.g., Dominici, 2006b; Schwartz et al., 1996; Pope and Dockery, 1992).

standard levels for consideration (U.S. EPA, 2011a, sections 2.1.3 and 2.3.4), the Policy Assessment first recognized the absence of discernible thresholds in the concentration-response functions from long- and short-term $PM_{2.5}$ exposure studies (U.S. EPA, 2011a, section 2.4.3).[19] In the absence of any discernible thresholds, the Agency's general approach for identifying appropriate standard levels for consideration involved characterizing the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in epidemiological studies. In so doing, the Policy Assessment recognized that there is no single factor or criterion that comprises the ''correct'' approach, but rather there are various approaches that are reasonable to consider for characterizing the confidence in the associations and the limitations and uncertainties in the evidence. Identifying the implications of various approaches for reaching conclusions on the range of alternative standard levels that is appropriate to consider can help inform the final decisions to either retain or revise the standards. Today's final decisions also take into account public health policy judgments as to the degree of health protection that is to be achieved.

In reaching staff conclusions on the range of annual standard levels that was appropriate to consider, the Policy Assessment focused on identifying an annual standard that provided requisite protection from effects associated with both long- and short-term exposures. In so doing, the Policy Assessment explored different approaches for characterizing the range of $PM_{2.5}$ concentrations over which our confidence in the nature of the associations for both long- and short-term exposures is greatest, as well as the extent to which our confidence is reduced at lower $PM_{2.5}$ concentrations.

First, the Policy Assessment recognized that the approach that most directly addressed this issue considered studies that analyzed confidence intervals around concentration-response relationships and in particular, analyses that averaged across multiple concentration-response models rather than considering a single concentration-response model.[20] The Policy Assessment explored the extent to which such analyses had been published for studies of health effects associated with long- or short-term $PM_{2.5}$ exposures. Such analyses could potentially be used to characterize a concentration below which uncertainty in a concentration-response relationship substantially increases or is judged to be indicative of an unacceptable degree of uncertainty about the existence of a continuing concentration-response relationship. The Policy Assessment concluded that identifying this area of uncertainty in the concentration-response relationship could be used to inform identification of alternative standard levels that are appropriate to consider.

Further, the Policy Assessment explored other approaches that considered different statistical metrics from epidemiological studies. The Policy Assessment first took into account the general approach used in previous PM reviews which focused on consideration of alternative standard levels that were somewhat below the long-term mean $PM_{2.5}$ concentrations reported in epidemiological studies using air quality distributions based on composite monitor concentrations.[21] This approach recognized that the strongest evidence of $PM_{2.5}$-related associations occurs at concentrations around the long-term (i.e., annual) mean. In using this approach, the Policy Assessment placed greatest weight on those long- and short-term exposure studies that reported statistically significant associations with mortality and morbidity effects.

In extending this approach, the Policy Assessment also considered information beyond a single statistical metric of $PM_{2.5}$ concentrations (i.e., the mean) to the extent such information was available. Pursuant to an express comment from CASAC (Samet 2010d, p. 2), the Policy Assessment utilized distributional statistics (i.e., statistical characterization of an entire distribution of data) to identify the broader range of $PM_{2.5}$ concentrations that had the most influence on the calculation of relative risk estimates in both long- and short-term exposure epidemiological studies. Thus, the Policy Assessment considered the part of the distribution of $PM_{2.5}$ concentrations in which the data analyzed in the study (i.e., air quality and population-level data, as discussed below) were most concentrated, specifically, the range of $PM_{2.5}$ concentrations around the long-term mean over which our confidence in the magnitude and significance of associations observed in the epidemiological studies was greatest. The Policy Assessment then focused on the lower part of the distribution to characterize where the data became appreciably more sparse and, thus, where our understanding of the magnitude and significance of the associations correspondingly became more uncertain. The Policy Assessment recognized there was no single percentile value within a given distribution that was most appropriate or ''correct'' to use to characterize where our confidence in the associations becomes appreciably lower. The Policy Assessment concluded that the range from the 25th to 10th percentiles is a reasonable range to consider as a region where we had appreciably less confidence in the associations observed in epidemiological studies.[22]

In considering distributional statistics from epidemiological studies, the final Policy Assessment focused on two types of population-level metrics that CASAC advised were most useful to consider in identifying the $PM_{2.5}$ concentrations

[19] The epidemiological studies evaluated in the Integrated Science Assessment that examined the shape of concentration-response relationships and the potential presence of a threshold focused on cardiovascular-related hospital admissions and emergency department visits associated with short-term PM_{10} exposures and premature mortality associated with long-term $PM_{2.5}$ exposure (U.S. EPA, 2009a, sections 6.5, 6.2.10.10 and 7.6). Overall, the Integrated Science Assessment concluded that the studies evaluated support the use of a no-threshold, log-linear model but recognized that ''additional issues such as the influence of heterogeneity in estimates between cities, and the effect of seasonal and regional differences in PM on the concentration-response relationship still require further investigation'' (U.S. EPA, 2009a, section 2.4.3).

[20] This is distinct from confidence intervals around concentration-response relationships that are related to the magnitude of effect estimates generated at specific $PM_{2.5}$ concentrations (i.e., point-wise confidence intervals) and that are relevant to the precision of the effect estimate across the air quality distribution, rather than to our confidence in the existence of a continuing concentration-response relationship across the entire air quality distribution on which a reported association was based.

[21] Using the term ''composite monitor'' does not imply that the EPA can identify one monitor that represents the air quality evaluated in a specific study area. Rather, the composite monitor concentration represents the average concentration across monitors within each area with more than one monitor included in a given study as typically reported in epidemiological studies. For multi-city studies, this metric reflects concentrations averaged across multiple monitors or from single monitors within each area and then averaged across study areas for an overall study mean $PM_{2.5}$ concentration. This is consistent with the epidemiological evidence considered in other NAAQS reviews.

[22] In the PM NAAQS review completed in 2006, the Staff Paper similarly recognized that the evidence of an association in any epidemiological study is ''strongest at and around the long-term average where the data in the study are most concentrated. For example, the interquartile range of long-term average concentrations within a study [with a lower bound of the 25th percentile] or a range within one standard deviation around the study mean, may reasonably be used to characterize the range over which the evidence of association is strongest'' (U.S. EPA, 2005, p. 5–22). A range of one standard deviation around the mean represents approximately 68 percent of normally distributed data, and below the mean falls between the 25th and 10th percentiles.

most influential in generating the health effect estimates reported in the epidemiological studies.[23] Consistent with CASAC advice, the most relevant information was the distribution of health events (e.g., deaths, hospitalizations) occurring within a study population in relation to the distribution of $PM_{2.5}$ concentrations. However, in recognizing that access to health event data can be restricted, the Policy Assessment also considered the number of study participants within each study area as an appropriate surrogate for health event data.

The Policy Assessment recognized that an approach considering analyses of confidence intervals around concentration-response functions was intrinsically related to an approach that considered different distributional statistics. Both of these approaches could be employed to understand the broader distribution of $PM_{2.5}$ concentrations which correspond to the health events reported in epidemiological studies. In applying these approaches, the Policy Assessment, consistent with CASAC advice (Samet, 2010d, p. 3), considered $PM_{2.5}$ concentrations from long- and short-term $PM_{2.5}$ exposure studies using composite monitor distributions.

In reaching staff conclusions on alternative standard levels that were appropriate to consider, the Policy Assessment also included a broader consideration of the uncertainties and limitations of the current scientific evidence. Most notably, these uncertainties are related to the heterogeneity observed in the epidemiological studies in the eastern versus western parts of the U.S., the relative toxicity of $PM_{2.5}$ components, and the potential role of co-pollutants (U.S. EPA, 2011a, pp. 2–25 to 2–26). The limitations and uncertainties associated with the currently available scientific evidence, including the availability of fewer studies toward the lower range of alternative annual standard levels being considered in this proposal, are summarized in section III.B below and further discussed in section III.B.2 of the proposal.

The Policy Assessment recognized that the level of protection afforded by the NAAQS relies both on the level and the form of the standard. The Policy Assessment concluded that a policy approach that used data based on composite monitor distributions to identify alternative standard levels, and then compared those levels to concentrations at maximum monitors to determine whether an area meets a given standard, inherently has the potential to build in some margin of safety (U.S. EPA, 2011a, p. 2–14).[24] This conclusion was consistent with CASAC's comments on the second draft Policy Assessment, in which CASAC expressed its preference for focusing on an approach using composite monitor distributions ''because of its stability, and for the additional margin of safety it provides'' when ''compared to the maximum monitor perspective'' (Samet, *et al.,* 2010d, pp. 2 to 3).

In reaching staff conclusions on alternative 24-hour standard levels that are appropriate to consider for setting a 24-hour standard intended to supplement the protection afforded by a generally controlling annual standard, the Policy Assessment considered currently available short-term $PM_{2.5}$ exposure studies. The evidence from these studies informed our understanding of the protection afforded by the suite of standards against effects associated with short-term exposures. In considering the short-term exposure studies, the Policy Assessment evaluated both the distributions of 24-hour $PM_{2.5}$ concentrations, with a focus on the 98th percentile concentrations (to the extent such data were available) to match the form of the current 24-hour $PM_{2.5}$ standard, as well as the long-term mean $PM_{2.5}$ concentrations reported in these studies. In addition to considering the epidemiological evidence, the Policy Assessment also considered air quality information based on county-level 24-hour and annual design values[25] to understand the policy implications of the alternative standard levels supported by the underlying science. In particular, the Policy Assessment considered the extent to which different combinations of alternative annual and 24-hour standards would support the policy goal of focusing on a generally controlling annual standard in conjunction with a 24-hour standard that would provide supplemental protection. In so doing, the Policy Assessment discussed the roles that each standard might be expected to play in the protection afforded by alternative suites of standards.

Beyond these evidence-based considerations, the Policy Assessment also considered the quantitative risk estimates and the key observations presented in the Risk Assessment. This assessment included an evaluation of 15 urban case study areas and estimated risk associated with a number of health endpoints associated with long- and short-term $PM_{2.5}$ exposures (U.S. EPA, 2010a). As part of the risk-based considerations, the Policy Assessment considered estimates of the magnitude of $PM_{2.5}$-related risks associated with recent air quality levels and air quality simulated to just meet the current and alternative suites of standards using alternative simulation approaches. The Policy Assessment also characterized the risk reductions, relative to the risks remaining upon just meeting the current standards, associated with just meeting alternative suites of standards. In so doing, the Policy Assessment recognized the uncertainties inherent in such risk estimates, and took such uncertainties into account by considering the sensitivity of the ''core'' risk estimates to alternative assumptions and methods likely to have substantial impact on the estimates. In addition, the Policy Assessment considered additional analyses characterizing the representativeness of the urban study areas within a broader national context to understand the roles that the annual and 24-hour standards may play in affording protection against effects related to both long- and short-term $PM_{2.5}$ exposures.

Based on the approach discussed above, the Policy Assessment reached conclusions related to the primary $PM_{2.5}$ standards that reflected an

[23] The second draft Policy Assessment focused on the distributions of ambient $PM_{2.5}$ concentrations and associated population data across areas included in several multi-city studies for which such data were available in seeking to identify the most influential range of concentrations (U.S. EPA, 2010f, section 2.3.4.1). In its review of the second draft Policy Assessment, CASAC advised that it ''would be preferable to have information on the concentrations that were most influential in generating the health effect estimates in individual studies'' (Samet, 2010d, p.2). Therefore, in the final Policy Assessment, the EPA considered population-level data (i.e., area-specific health event data and study area population data) along with corresponding $PM_{2.5}$ concentrations to generate a cumulative distribution of the population-level data relative to long-term mean $PM_{2.5}$ concentrations to determine the most influential part of the air quality distribution (U.S. EPA, 2011a, Figure 2–7 and associated text).

[24] Statistical metrics (e.g., means) based on composite monitor distributions may be identical to or below the same statistical metrics based on maximum monitor distributions. For example, some areas may have only one monitor, in which case the composite and maximum monitor distributions will be identical in those areas. Other areas may have multiple monitors that may be very close to the monitor measuring the highest concentrations, in which case the composite and maximum monitor distributions could be similar in those areas. As noted in Hassett-Sipple et al. (2010), for studies involving a large number of areas, the composite and maximum concentrations are generally within 5 percent of each other (77 FR 38905, fn. 30). Still other areas may have multiple monitors that may be separately impacted by local sources in which case the composite and maximum monitor distributions could be quite different (U.S. EPA, 2011a, p. 2–14). See further discussion of this issue in section III.E.4.c.i below.

[25] Design values are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance.

understanding of both evidence-based and risk-based considerations to inform two overarching questions related to: (1) The adequacy of the current suite of $PM_{2.5}$ standards and (2) revisions to the standards that were appropriate to consider in this review to protect against health effects associated with both long- and short-term exposures to fine particles. When evaluating the health protection afforded by the current or any alternative suites of standards considered, the Policy Assessment took into account the four basic elements of the NAAQS: The indicator, averaging time, form, and level.

The general approach for reviewing the primary $PM_{2.5}$ standards described above provided a comprehensive basis that helped to inform the Administrator's judgments in reaching her proposed and final decisions to revise the current suite of primary fine particle NAAQS and in responding to the remand of the 2006 primary annual $PM_{2.5}$ standard.

B. Overview of Health Effects Evidence

This section outlines the key information presented in section III.B of the proposal (77 FR 38906 to 38911, June 29, 2012) and discussed more fully in the Integrated Science Assessment (Chapters 2, 4, 5, 6, 7, and 8) and the Policy Assessment (Chapter 2) related to health effects associated with fine particle exposures. Section III.B. of the proposal discusses available information on the health effects associated with exposures to $PM_{2.5}$, including the nature of such health effects (section III.B.1) and associated limitations and uncertainties (section III.B.2), at-risk populations (section III.B.3), and potential $PM_{2.5}$-related impacts on public health (section III.B.4). As was true in the last two reviews, evidence from epidemiological, controlled human exposure and animal toxicological studies played a key role in the Integrated Science Assessment's evaluation of the scientific evidence.

The 2006 PM NAAQS review concluded that there was ''strong epidemiological evidence'' for linking long-term $PM_{2.5}$ exposures with cardiovascular-related and lung cancer mortality and respiratory-related morbidity and for linking short-term $PM_{2.5}$ exposures with cardiovascular-related and respiratory-related mortality and morbidity (U.S. EPA, 2004, p. 9–46; U.S. EPA, 2005, p. 5–4). Overall, the evidence from epidemiological, toxicological, and controlled human exposure studies supported ''likely causal associations'' between $PM_{2.5}$ and both mortality and morbidity from cardiovascular and respiratory diseases, based on ''an assessment of strength, robustness, and consistency in results'' (U.S. EPA, 2004, p. 9–48).[26]

In this review, based on the expanded body of evidence, the EPA finds that:

(1) In looking across the extensive new scientific evidence available in this review, our overall understanding of health effects associated with fine particle exposures has been greatly expanded. The currently available evidence is largely consistent with evidence available in the last review and substantially strengthens what is known about the effects associated with fine particle exposures.

(2) A number of large multi-city epidemiological studies have been conducted throughout the U.S., including extended analyses of long-term exposure studies that were important to inform decision-making in the last review. The body of currently available scientific evidence has also been expanded greatly by the publication of a number of new multi-city, time-series studies that have used uniform methodologies to investigate the effects of short-term $PM_{2.5}$ exposures on public health. This body of evidence provides a more expansive data base and considers multiple locations representing varying regions and seasons that provide evidence of the influence of different air pollution mixes on $PM_{2.5}$-associated health effects. These studies provide more precise estimates of the magnitude of effects associated with short-term $PM_{2.5}$ exposure than most smaller-scale single-city studies that were more commonly available in the last review. These studies have reported consistent increases in morbidity and/or premature mortality related to ambient $PM_{2.5}$ concentrations, with the strongest evidence reported for cardiovascular-related effects.

(3) In addition, the findings of new toxicological and controlled human exposure studies greatly expand and provide stronger support for a number of potential biological mechanisms or pathways for cardiovascular and respiratory effects associated with long- and short-term PM exposures. These studies provide coherence and biological plausibility for the effects observed in epidemiological studies.

(4) Using a more formal framework for reaching causal determinations than used in prior reviews,[27] the EPA concludes that a causal relationship exists between both long- and short-term exposures to $PM_{2.5}$ and premature mortality and cardiovascular effects and a likely causal relationship exists between long- and short-term $PM_{2.5}$ exposures and respiratory effects. Further, there is evidence suggestive of a causal relationship between long-term $PM_{2.5}$ exposures and other health effects, including developmental and reproductive effects (e.g., low birth weight, infant mortality) and carcinogenic, mutagenic, and genotoxic effects (e.g., lung cancer mortality).[28]

(5) The newly available evidence significantly strengthens the link between long- and short-term exposure to $PM_{2.5}$ and premature mortality, while providing indications that the magnitude of the $PM_{2.5}$-mortality association with long-term exposures may be larger than previously estimated. The strongest evidence comes from recent studies investigating long-term exposure to $PM_{2.5}$ and cardiovascular-related mortality. The evidence supporting a causal relationship between long-term $PM_{2.5}$ exposure and mortality also includes consideration of new studies that demonstrated an improvement in community health following reductions in ambient fine particles.

(6) Several new studies have examined the association between cardiovascular effects and long-term $PM_{2.5}$ exposures in multi-city studies conducted in the U.S. and Europe. While studies were not available in the last review with regard to long-term exposure and cardiovascular-related morbidity, recent studies have provided new evidence linking long-term exposure to $PM_{2.5}$ with an array of cardiovascular effects such as heart attacks, congestive heart failure, stroke, and mortality. This evidence is coherent with studies of short-term exposure to $PM_{2.5}$ that have observed associations with a continuum of effects ranging from subtle changes in indicators of cardiovascular health to serious clinical events, such as increased hospitalizations and emergency department visits due to cardiovascular disease and cardiovascular mortality.

(7) Extended analyses of studies available in the last review as well as new epidemiological studies conducted in the U.S. and abroad provide stronger evidence of respiratory-related morbidity effects associated with long-term $PM_{2.5}$ exposure. The strongest evidence for respiratory-related

[26] The term ''likely causal association'' was used in the 2004 Criteria Document to summarize the strength of the available evidence available in the last review for $PM_{2.5}$. However, this terminology was not based on a formal framework for evaluating evidence for inferring causation. Since the last review, the EPA has developed a more formal framework for reaching causal determinations with standardized language to express evaluation of the evidence (U.S. EPA, 2009a, section 1.5).

[27] The causal framework draws upon the assessment and integration of evidence from across epidemiological, controlled human exposure, and toxicological studies, and the related uncertainties that ultimately influence our understanding of the evidence. This framework employs a five-level hierarchy that classifies the overall weight of evidence and causality using the following categorizations: causal relationship, likely to be causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (U.S. EPA, 2009a, Table 1–3). The development of the causal framework reflects considerable input from CASAC and the public, with CASAC concluding that, ''The five-level classification of strength of evidence for causal inference has been systemically applied [for PM]; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future ISAs'' (Samet, 2009f, p. 1).

[28] These causal inferences are based not only on the more expansive epidemiological evidence available in this review but also reflect consideration of important progress that has been made to advance our understanding of a number of potential biologic modes of action or pathways for PM-related cardiovascular and respiratory effects (U.S. EPA, 2009a, chapter 5).

effects is from studies that evaluated decrements in lung function growth, increased respiratory symptoms, and asthma development. The strongest evidence from short-term $PM_{2.5}$ exposure studies has been observed for increased respiratory-related emergency department visits and hospital admissions for chronic obstructive pulmonary disease (COPD) and respiratory infections.

(8) The body of scientific evidence is somewhat expanded from the 2006 review but is still limited with respect to associations between long-term $PM_{2.5}$ exposures and developmental and reproductive effects as well as cancer, mutagenic, and genotoxic effects. The strongest evidence for an association between $PM_{2.5}$ and developmental and reproductive effects comes from epidemiological studies of low birth weight and infant mortality, especially due to respiratory causes during the post-neonatal period (i.e., 1 month–12 months of age). With regard to cancer effects, ''[m]ultiple epidemiologic studies have shown a consistent positive association between $PM_{2.5}$ and lung cancer mortality, but studies have generally not reported associations between $PM_{2.5}$ and lung cancer incidence'' (U.S. EPA 2009a p. 2–13).

(9) Efforts to evaluate the relationships between PM composition and health effects continue to evolve. While many constituents of $PM_{2.5}$ can be linked with differing health effects, the evidence is not yet sufficient to allow differentiation of those constituents or sources that may be more closely related to specific health outcomes nor to exclude any individual component or group of components associated with any source categories from the fine particle mixture of concern.

(10) Specific groups within the general population are at increased risk for experiencing adverse health effects related to PM exposures. The currently available evidence expands our understanding of previously identified at-risk populations (i.e., children, older adults, and individuals with pre-existing heart and lung disease) and supports the identification of additional at-risk populations (e.g., persons with lower socioeconomic status, genetic differences). Evidence for PM-related effects in these at-risk populations has expanded and is stronger than previously observed. There is emerging, though still limited, evidence for additional potentially at-risk populations, such as those with diabetes, people who are obese, pregnant women, and the developing fetus.

(11) The population potentially affected by $PM_{2.5}$ is large. In addition, large subgroups of the U.S. population have been identified as at-risk populations. While individual effect estimates from epidemiological studies may be small in size, the public health impact of the mortality and morbidity associations can be quite large given the extent of exposure. Taken together, this suggests that exposure to ambient $PM_{2.5}$ concentrations can have substantial public health impacts.

(12) While the currently available scientific evidence is stronger and more consistent than in previous reviews, providing a strong basis for decision making in this review, the EPA recognizes that important uncertainties and limitations in the health effects evidence remain. Epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in responses between cities and geographic regions within the U.S. This heterogeneity may be attributed, in part, to differences in the fine particle composition or related to exposure measurement error, which can introduce bias and increased uncertainty in associated health effect estimates. Variability in the associations observed across $PM_{2.5}$ epidemiological studies may be due in part to exposure error related to measurement-related issues, the use of central fixed-site monitors to represent population exposure to $PM_{2.5}$, models used in lieu of or to supplement ambient measurements, and our limited understanding of factors that may influence exposures (e.g., topography, the built environment, weather, source characteristics, ventilation usage, personal activity patterns, photochemistry). In addition, where $PM_{2.5}$ and other pollutants (e.g., ozone, nitrogen dioxide, and carbon monoxide) are correlated, it can be difficult to distinguish the effects of the various pollutants in the ambient mixture (i.e., co-pollutant confounding).[29]

While uncertainties and limitations still remain in the available health effects evidence, the Administrator judges the currently available scientific data base to be stronger and more consistent than in previous reviews providing a strong basis for decision making in this review.

C. Overview of Quantitative Characterization of Health Risks

In addition to a comprehensive evaluation of the health effects evidence available in this review, the EPA conducted an expanded quantitative risk assessment for selected health endpoints to provide additional information and insights to inform decisions on the primary $PM_{2.5}$ NAAQS.[30] As discussed in section III.C of the proposal, the approach used to develop quantitative risk estimates associated with $PM_{2.5}$ exposures was built on the approach used and lessons learned in the last review and focused on improving the characterization of the overall confidence in the risk estimates, including related uncertainties, by incorporating a number of enhancements, in terms of both the methods and data used in the analyses.

The goals of this quantitative risk assessment were largely the same as those articulated in the risk assessment conducted for the last review. These goals included: (1) To provide estimates of the potential magnitude of premature mortality and/or selected morbidity effects in the population associated with recent ambient levels of $PM_{2.5}$ and with simulating just meeting the current and alternative suites of $PM_{2.5}$ standards in 15 selected urban study areas,[31] including, where data were available, consideration of impacts on at-risk populations; (2) to develop a better understanding of the influence of various inputs and assumptions on the risk estimates to more clearly differentiate among alternative suites of standards; and (3) to gain insights into the distribution of risks and patterns of risk reductions and the variability and uncertainties in those risk estimates. In addition, the quantitative risk assessment included nationwide estimates of the potential magnitude of premature mortality associated with long-term exposure to recent ambient $PM_{2.5}$ concentrations to more broadly characterize this risk on a national scale and to support the interpretation of the more detailed risk estimates generated for selected urban study areas.

The expanded and updated risk assessment conducted in this review included estimates of risk for: (1) All-cause, ischemic heart disease-related, cardiopulmonary-related, and lung cancer-related mortality associated with long-term $PM_{2.5}$ exposure; (2) non-accidental, cardiovascular-related, and respiratory-related mortality associated with short-term $PM_{2.5}$ exposure; and (3) cardiovascular-related and respiratory-related hospital admissions and asthma-related emergency department visits

[29] A copollutant meets the criteria for potential confounding in PM-health associations if: (1) It is a potential risk factor for the health effect under study; (2) it is correlated with PM; and (3) it does not act as an intermediate step in the pathway between PM exposure and the health effect under study (U.S. EPA, 2004, p. 8–10).

[30] The quantitative risk assessment conducted for this review is more fully described and presented in the Risk Assessment (U.S. EPA, 2010a) and summarized in detail in the Policy Assessment (U.S. EPA, 2011a, sections 2.2.2. and 2.3.4.2). The scope and methodology for this risk assessment were developed over the last few years with considerable input from CASAC and the public as described in section II.B.3 above.

[31] The Risk Assessment concluded that these 15 urban study areas were generally representative of urban areas in the U.S. likely to experience relatively elevated levels of risk related to ambient $PM_{2.5}$ exposure with the potential for better characterization at the higher end of that distribution (U.S. EPA, 2011a, p. 2–42; U.S. EPA, 2010a, section 4.4, Figure 4–17). The representativeness analysis also showed that the 15 urban study areas do not capture areas with the highest baseline morality risks or the oldest populations (both of which can result in higher $PM_{2.5}$-related mortality estimates). However, some of the areas with the highest values for these attributes had relatively low $PM_{2.5}$ concentrations (e.g., urban areas in Florida) and, consequently, the Risk Assessment concluded failure to include these areas in the set of urban study areas was unlikely to exclude high $PM_{2.5}$-risk locations (U.S. EPA, 2010a, section 4.4.1).

associated with short-term $PM_{2.5}$ exposure.[32]

The Risk Assessment included a core set of risk estimates supplemented by an alternative set of risk results generated using single-factor and multi-factor sensitivity analyses. The core set of risk estimates was developed using the combination of modeling elements and input data sets identified in the Risk Assessment as having higher confidence relative to inputs used in the sensitivity analyses. The results of the sensitivity analyses provided information to evaluate and rank the potential impacts of key sources of uncertainty on the core risk estimates. In addition, the sensitivity analyses represented a set of reasonable alternatives to the core set of risk estimates that fell within an overall set of plausible risk estimates surrounding the core estimates.

The EPA recognized that there were many sources of variability and uncertainty inherent in the inputs to its quantitative risk assessment.[33] The design of the risk assessment included a number of elements to address these issues in order to increase the overall confidence in the risk estimates generated for the 15 urban study areas, including using guidance from the World Health Organization (WHO, 2008) as a framework for characterizing uncertainty in the analyses.[34]

With respect to the sources of variability, the Risk Assessment considered those that contributed to differences in risk across urban study areas, but did not directly affect the degree of risk reduction associated with the simulation of just meeting current or alternative standard levels (e.g., differences in baseline incidence rates, demographics and population behavior). The Risk Assessment also focused on factors that not only introduced variability into risk estimates across study areas, but also played an important role in determining the magnitude of risk reductions upon simulation of just meeting current or alternative standard levels (e.g., peak-to-mean ratios of ambient $PM_{2.5}$ concentrations within individual urban study areas and the nature of the rollback approach used to simulate just meeting the current or alternative standards). Key sources of potential variability that were likely to affect population risks included the following: (1) Intra-urban variability in ambient $PM_{2.5}$ concentrations, including $PM_{2.5}$ composition; (2) variability in the patterns of reductions in $PM_{2.5}$ concentrations associated with different rollback approaches when simulating just meeting the current or alternative standards; (3) co-pollutant exposures; (4) factors related to demographic and socioeconomic status; (5) behavioral differences across urban study areas (e.g., time spent outdoors); (6) baseline incidence rates; and (7) longer-term temporal variability in ambient $PM_{2.5}$ concentrations reflecting meteorological trends as well as future changes in the mix of $PM_{2.5}$ sources, including changes in air quality related to future regulatory actions.

With regard to uncertainties, single and multi-factor sensitivity analyses were combined with a qualitative analysis to assess the impact of potential sources of uncertainty on the core risk estimates. Key sources of uncertainty included: (1) Characterizing intra-urban population exposure in the context of epidemiological studies linking $PM_{2.5}$ to specific health effects; (2) statistical fit of the concentration-response functions for short-term exposure-related health endpoints; (3) shape of the concentration-response functions; (4) specifying the appropriate lag structure for short-term exposure studies; (5) transferability of concentration-response functions from study locations to urban study area locations for long-term exposure-related health endpoints; (6) use of single-city versus multi-city studies in the derivation of concentration-response functions; (7) impact of historical air quality on estimates of health risk associated with long-term $PM_{2.5}$ exposures; and (8) potential variation in effect estimates reflecting compositional differences in $PM_{2.5}$.

Beyond characterizing uncertainty and variability, a number of design elements were included in the risk assessment to increase the overall confidence in the risk estimates generated for the 15 urban study areas (U.S. EPA, 2011a, pp. 2–38 to 2–41). These elements included: (1) Use of a deliberative process for specifying components of the risk model that reflects consideration of the latest research on $PM_{2.5}$ exposure and risk (U.S. EPA, 2010a, section 5.1.1); (2) integration of key sources of variability into the design as well as the interpretation of risk estimates (U.S. EPA, 2010a, section 5.1.2); (3) assessment of the degree to which the urban study areas are representative of areas in the U.S. experiencing higher $PM_{2.5}$-related risk (U.S. EPA, 2010a, section 5.1.3); and (4) identification and assessment of important sources of uncertainty and the impact of these uncertainties on the core risk estimates (U.S. EPA, 2010a, section 5.1.4). Further, additional analyses examined potential bias and overall confidence in the risk estimates. Greater confidence is associated with risk estimates based on simulated annual mean $PM_{2.5}$ concentrations that are within the region of the air quality distribution used in deriving the concentration-response functions where the bulk of the data reside (e.g., within one standard deviation around the long-term mean $PM_{2.5}$ concentration) (U.S. EPA, 2011a, p. 2–38).

Key observations and insights from the $PM_{2.5}$ risk assessment, together with important caveats and limitations, were discussed in section III.C.3 of the proposal. In general, in considering the set of quantitative risk estimates and related uncertainties and limitations related to long- and short-term $PM_{2.5}$ exposure together with consideration of the health endpoints which could not be quantified, the Policy Assessment concluded this information provided strong evidence that risks estimated to remain upon simulating just meeting the current suite of $PM_{2.5}$ standards are important from a public health perspective, both in terms of severity and magnitude of effects. Patterns of increasing estimated risk reductions were generally observed as either the annual or 24-hour standard level, or both, were reduced over the ranges considered in the Risk Assessment.

The magnitude of both long- and short-term exposure-related risk estimated to remain upon just meeting the current suite of standards as well as alternative standard levels was strongly associated with the simulated change in annual mean $PM_{2.5}$ concentrations. Although long- and short-term exposure-related mortality rates have similar patterns in terms of the subset of urban study areas experiencing risk reductions for the current suite of standard levels, the magnitude of risk remaining is higher for long-term exposure-related mortality and substantially lower for short-term exposure-related mortality. Short-term exposure-related morbidity risk estimates were greater for cardiovascular-related than respiratory-related events and emergency

[32] The evidence available for these selected health effect endpoints generally focused on the entire population, although some information was available to support analyses that considered differences in estimated risk for at-risk populations including older adults and persons with pre-existing cardiovascular and respiratory diseases.

[33] *Variability* refers to the heterogeneity of a variable of interest within a population or across different populations. *Uncertainty* refers to the lack of knowledge regarding the actual values of inputs to an analysis (U.S. EPA, 2010a, p. 3–63).

[34] The extent to which key sources of potential variability were (or were not) fully captured in the design of the risk assessment are discussed in section 3.5.2 of the Risk Assessment (U.S. EPA, 2010a, pp. 3–67 to 3–69).

department visits for asthma-related events were significant: Furthermore, most of the aggregate risk associated with short-term exposures was not primarily driven by the small number of days with $PM_{2.5}$ concentrations in the upper tail of the air quality distribution, but rather by the large number of days with $PM_{2.5}$ concentrations at and around the mean of the distribution, that is, the 24-hour average concentrations that are in the low- to mid-range, well below the peak 24-hour concentrations (U.S. EPA, 2011a, p. 2–3).

With regard to characterizing estimates of $PM_{2.5}$-related risk associated with simulation of alternative standards, the Policy Assessment recognized that greater overall confidence was associated with estimates of *risk reduction* than for estimates of *absolute risk remaining* (U.S. EPA, 2011a, p. 2–94). Furthermore, the Policy Assessment recognized that estimates of absolute risk remaining for each of the alternative standard levels considered, particularly in the context of long-term exposure-related mortality, may be underestimated.[35] In addition, the Policy Assessment observed that in considering the overall confidence associated with the quantitative analyses, the Risk Assessment recognized that: (1) Substantial variability existed in the magnitude of risk remaining across urban study areas and (2) in general, higher confidence was associated with risk estimates based on $PM_{2.5}$ concentrations near the mean $PM_{2.5}$ concentrations in the underlying epidemiological studies providing the concentration-response functions (e.g., within one standard deviation of the mean $PM_{2.5}$ concentration reported). Furthermore, although the Risk Assessment estimated that the alternative 24-hour standard levels considered (when controlling) would result in additional estimated risk reductions beyond those estimated for alternative annual standard levels alone, these additional estimated reductions were highly variable. Conversely, the Risk Assessment recognized that alternative annual standard levels, when controlling, resulted in more consistent risk reductions across urban study areas, thereby potentially providing a more consistent degree of public health protection (U.S. EPA, 2010a, p. 5–17).

D. Conclusions on the Adequacy of the Current Primary $PM_{2.5}$ Standards

1. Introduction

The initial issue to be addressed in the current review of the primary $PM_{2.5}$ standards is whether, in view of the advances in scientific knowledge and other information reflected in the Integrated Science Assessment, the Risk Assessment, and the Policy Assessment, the existing standards should be retained or revised. In considering the adequacy of the current suite of $PM_{2.5}$ standards, the Administrator has considered the large body of evidence presented and assessed in the Integrated Science Assessment (U.S. EPA, 2009a), the quantitative assessment of risks, staff conclusions and associated rationales presented in the Policy Assessment, views expressed by CASAC, and public comments. The Administrator has taken into account both evidence- and risk-based considerations[36] in developing final conclusions on the adequacy of the current primary $PM_{2.5}$ standards.

a. Evidence- and Risk-based Considerations in the Policy Assessment

In considering the available epidemiological evidence in this review, the Policy Assessment took a broader approach than was used in the last review. This approach reflected the more extensive and stronger body of evidence available since the last review on health effects related to both long- and short-term exposure to $PM_{2.5}$. As discussed in section III.A.3 above, this broader approach focused on setting the annual standard as the ‘‘generally controlling’’ standard for lowering both short- and long-term $PM_{2.5}$ concentrations and so providing requisite protection to public health. In conjunction with such an annual standard, this approach focused on setting the 24-hour standard to provide supplemental protection against days with high peak $PM_{2.5}$ concentrations.

In addressing the question whether the evidence now available in this review supports consideration of standards that are more protective than the current $PM_{2.5}$ standards, the Policy Assessment considered whether: (1) Statistically significant health effects associations with long- or short-term exposures to fine particles occur in areas that would likely have met the current $PM_{2.5}$ standards [see *American Trucking Associations,* 283 F. 3d at 369, 376 (revision of level of PM NAAQS justified when health effects are observed in areas meeting the existing standard)], and (2) associations with long-term exposures to fine particles extend down to lower air quality concentrations than had previously been observed. With regard to associations observed in long-term $PM_{2.5}$ exposure studies, the Policy Assessment recognized that extended follow-up analyses of the ACS and Harvard Six Cities studies provided consistent and stronger evidence of an association with mortality at lower air quality distributions than had previously been observed (U.S. EPA, 2011a, pp. 2–31 to 2–32). The original and reanalysis of the ACS study reported positive and statistically significant effects associated with a long-term mean $PM_{2.5}$ concentration of 18.2 μg/m^3 across 50 metropolitan areas for 1979 to 1983 (Pope *et al.,* 1995; Krewski *et al.,* 2000).[37] In extended analyses, positive and statistically significant effects of approximately similar magnitude were associated with declining $PM_{2.5}$ concentrations, from an aggregate long-term mean in 58 metropolitan areas of 21.2 μg/m^3 in the original monitoring period (1979 to 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

[35] Based on the consideration of both the qualitative and quantitative assessments of uncertainty, the Risk Assessment concluded that it is unlikely that the estimated risks are over-stated, particularly for premature mortality related to long-term $PM_{2.5}$ exposures. In fact, the Policy Assessment and the Risk Assessment concluded that the core risk estimates for this category of health effects may well be biased low based on consideration of alternative model specifications evaluated in the sensitivity analyses (U.S. EPA, 2011a, p. 2–41; U.S. EPA, 2010a, p. 5–16; Figures 4–7 and 4–8). In addition, the Policy Assessment recognized that the currently available scientific information included evidence for a broader range of health endpoints and at-risk populations beyond those included in the quantitative risk assessment, including decrements in lung function growth and respiratory symptoms in children as well as reproductive and developmental effects (U.S. EPA, 2011a, section 2.2.1).

[36] Evidence-based considerations include the assessment of epidemiological, toxicological, and controlled human exposure studies evaluating long- or short-term exposures to $PM_{2.5}$, with supporting evidence related to dosimetry and potential pathways/modes of action, as well as the integration of evidence across each of these disciplines, as assessed in the Integrated Science Assessment (U.S. EPA, 2009a) and focus on the policy-relevant considerations as discussed in section III.B above and in the Policy Assessment (U.S. EPA, 2011a, section 2.2.1). Risk-based considerations draw from the results of the quantitative analyses presented in the Risk Assessment (U.S. EPA, 2010a) and focus on the policy-relevant considerations as discussed in section III.C above and in the Policy Assessment (U.S. EPA, 2011a, section 2.2.2).

[37] The study periods referred to in the Policy Assessment (U.S. EPA, 2011a) and in this final rule reflect the years of air quality data that were included in the analyses, whereas the study periods identified in the Integrated Science Assessment (U.S. EPA, 2009a) reflect the years of health event data that were included.

with a long-term mean $PM_{2.5}$ concentration of 18.0 μg/m³ for 1980 to 1985 (Dockery *et al.,* 1993; Krewski *et al.,* 2000). In an extended follow-up of this study, the aggregate long-term mean concentration across all years evaluated was 16.4 μg/m³ for 1980 to 1988 [38] (Laden *et al.,* 2006). In an additional analysis of the extended follow-up of the Harvard Six Cities study, investigators reported that the concentration-response relationship was linear and ''clearly continuing below the level'' of the current annual standard (U.S. EPA, 2009a, p. 7–92; Schwartz *et al.,* 2008).

Cohort studies conducted since the last review provided additional evidence of mortality associated with air quality distributions that are generally lower than those reported in the ACS and Harvard Six Cities studies, with effect estimates that were similar or, in some studies, significantly greater in magnitude than in the ACS and Harvard Six Cities studies (see also, section III.D.1.a of the proposal, 77 FR 38918 to 28919; U.S. EPA, 2011a, pp. 2–32 to 2–33). The Women's Health Initiative (WHI) study reported positive and most often statistically significant associations between long-term $PM_{2.5}$ exposure and cardiovascular-related mortality as well as morbidity effects, with much larger relative risk estimates for mortality than in the ACS and Harvard Six Cities studies, at an aggregate long-term mean $PM_{2.5}$ concentration of 12.9 μg/m³ for 2000 (Miller *et al.,* 2007).[39]

Using the Medicare cohort, Eftim *et al.* (2008) reported somewhat higher effect estimates than in the ACS and Harvard Six Cities studies with aggregate long-term mean concentrations of 13.6 μg/m³ and 14.1 μg/m³, respectively, for 2000 to 2002. Zeger *et al.* (2008) reported associations between long-term $PM_{2.5}$ exposure and mortality for the eastern region of the U.S. at an aggregated long-term $PM_{2.5}$ median concentration of 14.0 μg/m³, although no association was reported for the western region with an aggregate long-term $PM_{2.5}$ median concentration of 13.1 μg/m³ (U.S. EPA, 2009a, p. 7–88).[40]

Premature mortality in children reported in a national infant mortality study as well as mortality in a cystic fibrosis cohort including both children and adults reported positive but statistically nonsignificant effects associated with long-term aggregate mean concentrations of 14.8 μg/m³ and 13.7 μg/m³, respectively (Woodruff *et al.,* 2008; Goss *et al.,* 2004).

With respect to respiratory morbidity effects associated with long-term $PM_{2.5}$ exposure, the across-city mean of 2-week average $PM_{2.5}$ concentrations reported in the initial Southern California Children's Health Study was approximately 15.1 μg/m³ (Peters *et al.,* 1999). These results were found to be consistent with results of cross-sectional analyses of the 24-Cities Study (Dockery *et al.,* 1996; Raizenne *et al.,* 1996), which reported a long-term cross-city mean $PM_{2.5}$ concentration of 14.5 μg/m³.[41] In this review, extended analyses of the Southern California Children's Health Study provide stronger evidence of $PM_{2.5}$-related respiratory effects, at lower air quality concentrations than had previously been reported, with a four-year aggregate mean concentration of 13.8 μg/m³ across the 12 study communities (McConnell *et al.,* 2003; Gauderman *et al.,* 2004, U.S. EPA, 2009a, Figure 7–4).

In also considering health effects for which the Integrated Science Assessment concluded evidence was suggestive of a causal relationship, the Policy Assessment noted a limited number of birth outcome studies that reported positive and statistically significant effects related to aggregate long-term mean $PM_{2.5}$ concentrations down to approximately 12 μg/m³ (U.S. EPA, 2011a, p. 2–33).

Collectively, the Policy Assessment concluded that currently available evidence provided support for associations between long-term $PM_{2.5}$ exposure and mortality and morbidity effects that extend to distributions of $PM_{2.5}$ concentrations that are lower than those that had previously been associated with such effects, with aggregate long-term mean $PM_{2.5}$ concentrations extending to well below the level of the current annual standard.

The Policy Assessment also considered the long-term mean $PM_{2.5}$ concentrations in short-term exposure studies in assessing the appropriateness of the level of the current annual standard. See *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 522, 523–24 (remanding 2006 standard because the EPA had not adequately explained its choice not to consider long-term means of short-term exposure studies in assessing adequacy of primary annual $PM_{2.5}$ standard). In light of the mixed findings reported in single-city, short-term exposure studies, the Policy Assessment placed comparatively greater weight on the results from multi-city studies in considering the adequacy of the current suite of standards (U.S. EPA, 2011a, pp. 2–34 to 2–35).

With regard to associations reported in short-term $PM_{2.5}$ exposure studies, the Policy Assessment recognized that long-term mean concentrations reported in new multi-city U.S. and Canadian studies provided evidence of associations between short-term $PM_{2.5}$ exposure and mortality at similar air quality distributions to those that had previously been observed in an 8-cities Canadian study (Burnett and Goldberg, 2003; aggregate long-term mean $PM_{2.5}$ concentration of 13.3 μg/m³). In a multi-city time-series analysis of 112 U.S. cities, Zanobetti and Schwartz (2009) reported a positive and statistically significant association with all-cause, cardiovascular-related (e.g., heart attacks, stroke), and respiratory-related mortality and short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 13.2 μg/m³ (U.S. EPA, 2009a, Figure 6–24). Furthermore, city-specific effect estimates indicated the association between short-term exposure to $PM_{2.5}$ and total mortality and cardiovascular- and respiratory-related mortality was consistently positive for an overwhelming majority (99 percent) of the 112 cities across a wide range of air quality concentrations (long-term mean concentrations ranging from 6.6 μg/m³ to 24.7 μg/m³; U.S. EPA, 2009a, Figure 6–24, p. 6–178 to 179). The EPA staff noted that for all-cause mortality, city-specific effect estimates were statistically significant for 55 percent of the 112 cities, with long-term city-mean $PM_{2.5}$ concentrations ranging from 7.8 μg/m³ to 18.7 μg/m³ and 24-hour $PM_{2.5}$ city-mean 98th percentile concentrations ranging from 18.4 to 64.9

[38] Aggregate mean concentration provided by study author (personal communication from Dr. Francine Laden, 2009).

[39] The Policy Assessment noted that in comparison to other long-term exposure studies, the Miller et al. (2007) study was more limited in that it was based on only one year of air quality data (U.S. EPA, 2011a, p. 2–82). The proposal further noted that the air quality data considered were extrapolated from that one single year of air quality data (2000) to the whole study, and that the air quality data post-dated the years of health events considered (i.e., 1994 to 1998) (77 FR 38918, fn 62).

[40] Zeger et al. (2008) also reported positive and statistically significant effects for the central region, with an aggregate long-term mean $PM_{2.5}$ concentration of 10.7 μg/m³. However, in contrast to the eastern and western risk estimates, the central risk estimate increased with adjustment for COPD (used as a proxy for smoking status). Due to the potential for confounding bias influencing the risk estimate for the central region, the Policy Assessment did not focus on the results reported in the central region to inform the adequacy of the current suite of standards or alternative annual standard levels (U.S. EPA, 2011a, p. 2–32).

[41] See *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 525 (noting the importance of these studies, as well as EPA's failure to properly take them into account).

μg/m^3 (personal communication with Dr. Antonella Zanobetti, 2009).[42]

With regard to cardiovascular and respiratory morbidity effects, in the first analysis of the Medicare cohort conducted by Dominici *et al.* (2006a) across 204 U.S. counties, investigators reported a statistically significant association with hospitalizations for cardiovascular and respiratory diseases and short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 13.4 μg/m^3. Furthermore, a sub-analysis restricted to days with 24-hour average concentrations of $PM_{2.5}$ at or below 35 μg/m^3 indicated that, in spite of a reduced statistical power from a smaller number of study days, statistically significant associations were still observed between short-term exposure to $PM_{2.5}$ and hospital admissions for cardiovascular and respiratory diseases (Dominici, 2006b).[43] In an extended analysis of this cohort, Bell *et al.* (2008) reported a positive and statistically significant increase in cardiovascular hospitalizations associated with short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 12.9 μg/m^3. 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/m^3, not only indicated that effects are occurring in areas that would meet the current standards but also suggested that the overall health effects observed across the U.S. are not primarily driven by the higher end of the $PM_{2.5}$ air quality distribution (Bell, 2009a, personal communication from Dr. Michelle Bell regarding air quality data for Bell *et al.,* 2008 and Dominici *et al.,* 2006a).

Collectively, the Policy Assessment concluded that the findings from short-term $PM_{2.5}$ exposure studies provided evidence of $PM_{2.5}$-associated health effects occurring in areas that would likely have met the current suite of $PM_{2.5}$ standards (U.S. EPA, 2011a, p. 2–35). These findings were further bolstered by evidence of statistically significant $PM_{2.5}$-related health effects occurring in analyses restricted to days in which 24-hour average $PM_{2.5}$ concentrations were below 35 μg/m^3 (Dominici, 2006b).

In evaluating the currently available scientific evidence, as summarized in section III.B of the proposal, the Policy Assessment first concluded that there was stronger and more consistent and coherent support for associations between long- and short-term $PM_{2.5}$ exposures and a broad range of health outcomes than was available in the last review, providing the basis for fine particle standards at least as protective as the current $PM_{2.5}$ standards (U.S. EPA, 2011a, p. 2–26). Having reached this initial conclusion, the Policy Assessment addressed the question of whether the available evidence supported consideration of standards that were more protective than the current standards. In so doing, the Policy Assessment considered whether there was now evidence that health effect associations have been observed in areas that likely met the current suite of $PM_{2.5}$ standards. As discussed above, long- and short-term $PM_{2.5}$ exposure studies provided evidence of associations with mortality and cardiovascular and respiratory effects both at lower ambient $PM_{2.5}$ concentrations than had been observed in the previous review and at concentrations allowed by the current standards (U.S. EPA, 2011a, p. 2–35).

In reviewing this information, the Policy Assessment recognized that important limitations and uncertainties associated with this expanded body of scientific evidence, as discussed in section III.B.2 of the proposal, needed to be carefully considered in determining the weight to be placed on the body of studies available in this review. Taking these limitations and uncertainties into consideration, the Policy Assessment concluded that the currently available evidence clearly calls into question whether the current suite of primary $PM_{2.5}$ standards protects public health with an adequate margin of safety from effects associated with long- and short-term exposures. Furthermore, the Policy Assessment concluded this evidence provides strong support for considering fine particle standards that would afford increased protection beyond that afforded by the current standards (U.S. EPA, 2011a, p. 2–35).

In addition to evidence-based consideration, the Policy Assessment also considered the extent to which health risks estimated to occur upon simulating just meeting the current $PM_{2.5}$ standards may be judged to be important from a public health perspective, taking into account key uncertainties associated with the quantitative health risk estimates. In so doing, the Policy Assessment first noted that the quantitative risk assessment addresses: (1) The core $PM_{2.5}$-related risk estimates; (2) the related uncertainty and sensitivity analyses, including additional sets of reasonable risk estimates generated to supplement the core analysis; (3) an assessment of the representativeness of the urban study areas within a national context;[44] and (4) consideration of patterns in design values and air quality monitoring data to inform interpretation of the risk estimates, as discussed in section III.C above.

In considering the health risks estimated to remain upon simulation of just meeting the current suite of standards and considering both the qualitative and quantitative assessment of uncertainty completed as part of the assessment, the Policy Assessment concluded these risks are important from a public health standpoint and provided strong support for consideration of alternative standards that would provide increased protection beyond that afforded by the current $PM_{2.5}$ (U.S. EPA, 2011a, pp. 2–47 to 2–48). This conclusion reflected consideration of both the severity and the magnitude of the effects. For example, the Risk Assessment indicated the possibility that premature deaths related to ischemic heart disease associated with long-term $PM_{2.5}$ exposure alone would likely be on the order of thousands of deaths per year in the 15 urban study areas upon simulating just meeting the current standards[45] (U.S. EPA, 2011a, pp. 2–46 to 2–47). Moreover, additional risks were anticipated for premature mortality related to cardiopulmonary effects and lung cancer associated with long-term $PM_{2.5}$ exposure as well as mortality and cardiovascular- and respiratory-related morbidity effects (e.g., hospital admissions, emergency department visits) associated with short-term $PM_{2.5}$ exposures. Based on the consideration of both qualitative and

[42] Single-city Bayes-adjusted effect estimates for the 112 cities analyzed in Zanobetti and Schwartz (2009) were provided by the study authors (personal communication with Dr. Antonella Zanobetti, 2009; see also U.S. EPA, 2009a, Figure 6–24).

[43] This sub-analysis was not included in the original publication (Dominici *et al.,* 2006a). The study authors provided sub-analysis results for the Administrator's consideration as a letter to the docket following publication of the proposed rule in January 2006 (personal communication with Dr. Francesca Dominici, 2006b). As noted in section III.A.3, this study is part of the basis for the conclusion that there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations.

[44] Based on analyses of the representativeness of the 15 urban study areas in the broader national context, the Policy Assessment concludes that these study areas are generally representative of urban areas in the U.S. likely to experience relatively elevated levels of risk related to ambient $PM_{2.5}$ exposures (U.S. EPA, 2011a, p. 2–42).

[45] Premature mortality for all causes attributed to $PM_{2.5}$ exposure was estimated to be on the order of tens of thousands of deaths per year on a national scale based on 2005 air quality data (U.S. EPA, 2010a, Appendix G, Table G–1).

quantitative assessments of uncertainty completed as part of the quantitative risk assessment, the Risk Assessment concluded that it was unlikely that the estimated risks are over-stated, particularly for mortality related to long-term $PM_{2.5}$ exposure, and may well be biased low based on consideration of alternative model specifications evaluated in the sensitivity analyses (U.S. EPA, 2010a, p. 5–16; U.S. EPA, 2011a, p. 2–41). Furthermore, the currently available scientific information summarized in section III.B of the proposal provided evidence for a broader range of health endpoints and at-risk populations beyond those included in the quantitative risk assessment (U.S. EPA, 2011a, p. 2–47).

b. CASAC Advice

The CASAC, based on its review of drafts of the Integrated Science Assessment, the Risk Assessment, and the Policy Assessment, provided an array of advice both with regard to interpreting the scientific evidence and quantitative risk assessment, as well as with regard to consideration of the adequacy of the current $PM_{2.5}$ standards (Samet, 2009a,b,c,d,e,f; Samet 2010a,b,c,d). With regard to the adequacy of the current standards, CASAC concluded that the ''currently available information clearly calls into question the adequacy of the current standards'' (Samet, 2010d, p. i) and that the current standards are ''not protective'' (Samet, 2010d, p. 1). Further, in commenting on the first draft Policy Assessment, CASAC noted:

> With regard to the integration of evidence-based and risk-based considerations, CASAC concurs with EPA's conclusion that the new data strengthens the evidence available on associations previously considered in the last round of the assessment of the $PM_{2.5}$ standard. CASAC also agrees that there are significant public health consequences at the current levels of the standard that justify consideration of lowering the $PM_{2.5}$ NAAQS further (Samet, 2010c, p. 12).

c. Administrator's Proposed Conclusions Concerning the Adequacy of the Current Primary $PM_{2.5}$ Standards

At the time of the proposal, in considering the body of scientific evidence, the Administrator concluded there was stronger and more consistent and coherent support for associations between long- and short-term $PM_{2.5}$ exposure and a broader range of health outcomes than was available in the last review, providing the basis for fine particle standards at least as protective as the current $PM_{2.5}$ standards. In particular, the Administrator recognized in section III.D.4 of the proposal that the Integrated Science Assessment concluded that the results of epidemiological and experimental studies form a plausible and coherent data set that supports a causal relationship between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects and a likely causal relationship between long- and short-term $PM_{2.5}$ exposures and respiratory effects. Furthermore, the Administrator reflected that effects had been observed at lower ambient $PM_{2.5}$ concentrations than what had been observed in the last review, including at ambient $PM_{2.5}$ concentrations in areas that likely met the current $PM_{2.5}$ NAAQS. With regard to the results of the quantitative risk assessment, the Administrator noted that the Risk Assessment concluded that the risks estimated to remain upon simulation of just meeting the current standards were important from a public health standpoint in terms of both the severity and magnitude of the effects.

At the time of the proposal, in considering whether the current suite of $PM_{2.5}$ standards should be revised to provide requisite public health protection, the Administrator carefully considered the staff conclusions and rationales presented in the Policy Assessment, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator placed primary consideration on the evidence obtained from the epidemiological studies and provisionally found the evidence of serious health effects reported in long- and short-term exposure studies conducted in areas that would have met the current standards to be compelling, especially in light of the extent to which such studies are part of an overall pattern of positive and frequently statistically significant associations across a broad range of studies that collectively represent a strong and robust body of evidence.

As discussed in the Integrated Science Assessment and Policy Assessment, the Administrator recognized that much progress has been made since the last review in addressing some of the key uncertainties that were important considerations in establishing the current suite of $PM_{2.5}$ standards. For example, progress made since the last review provides increased confidence in the long- and short-term exposure studies as a basis for considering whether any revision of the annual standard is appropriate and increased confidence in the short-term exposure studies as a basis for considering whether any revision of the 24-hour standard is appropriate.[46]

Based on her consideration of these conclusions, as well as consideration of CASAC's conclusion that the evidence and risk assessment clearly called into question the adequacy of the public health protection provided by the current $PM_{2.5}$ NAAQS and public comments on the proposal, the Administrator provisionally concluded that the current primary $PM_{2.5}$ standards, taken together, were not requisite to protect public health with an adequate margin of safety and that revision was needed to provide increased public health protection. The Administrator provisionally concluded that the scientific evidence and information on risk provided strong support for consideration of alternative standards that would provide increased public health protection beyond that afforded by the current $PM_{2.5}$ standards.

2. Comments on the Need for Revision

This section addresses general comments based on relevant facts that either support or oppose any change to the current suite of primary $PM_{2.5}$ standards. Comments on specific long- and short-term exposure studies that relate to consideration of the appropriate levels of the annual and 24-hour standards are addressed in section III.E.4 below. Many public comments asserted that the current $PM_{2.5}$ standards are insufficient to protect public health with an adequate margin of safety and that revisions to the standards are therefore appropriate, indeed necessitated.

Among those calling for revisions to the current standards were the Children's Health Protection Advisory Committee (CHPAC); major medical and public health groups including the American Heart Association (AHA), American Lung Association (ALA), American Public Health Association (APHA), American Thoracic Society (ATS); the Physicians for Social Responsibility (PSR); major environmental groups such as the Clean Air Council, Clean Air Task Force, Earthjustice, Environmental Defense Fund (EDF), National Resources Defense Council (NRDC), and Sierra Club; many environmental justice organizations as

[46] The EPA notes that this increased confidence in the long- and short-term associations generally reflects less uncertainty as to the likely causal nature of such associations, but does not address directly the question of the extent to which such associations remain toward the lower end of the range of ambient $PM_{2.5}$ concentrations. This question is central to the Agency's evaluation of the relevant evidence to determine appropriate standards levels, as discussed below in section III.E.4.

well as medical doctors, academic researchers, health professionals, and many private citizens. For example, the American Heart Association and other major national public health and medical organizations stated that, ''[o]ur organizations are keenly aware of the public health and medical threats from particulate matter'' and called on the EPA to ''significantly strengthen'' both the annual and 24-hour $PM_{2.5}$ standards ''to help us protect the health of our patients and our nation'' (AHA *et al.,* 2012, pp. 1 and 13). AHA *et al.* and ALA *et al.,* as well as a group of more than 350 physicians, environmental health researchers, and public health and medical professionals articulated similar comments on the available evidence:

> Ample scientific evidence supports adopting tighter standards to protect the health of people who are most susceptible to the serious health effects of these pollutants. More than 10,000 peer-reviewed scientific studies have been published since 1997 when EPA adopted the current annual standard. These studies validate and extend earlier epidemiologic research linking both acute and chronic fine particle pollution with serious morbidity and mortality. The newer research has also expanded our understanding of the range of health outcomes associated with PM and has identified adverse respiratory and cardiovascular health effects at lower exposure levels than previously reported. As discussed and interpreted in the EPA's 2009 Integrated Science Assessment for Particulate Matter, the new evidence reinforces already strong existing studies and supports the conclusion that $PM_{2.5}$ is causally associated with numerous adverse health effects in humans at exposure levels far below the current standard. Such a conclusion demands prompt action to protect human health. (AHA *et al.,* 2012, pp. 1 to 2; ALA *et al.,* pp. 4 to 5; similar comment submitted by Rom *et al.,* 2012, p. 1).

All of these medical and public health commenters stated that the current $PM_{2.5}$ standards need to be revised, and that even more protective standards than those proposed by the EPA are needed to adequately protect public health, particularly for at-risk populations. Many environmental justice organizations and individual commenters also expressed such views.

The National Association of Clean Air Agencies (NACAA), the Northeast States for Coordinated Air Use Management (NESCAUM), and many State and local air agencies and health departments who commented on the $PM_{2.5}$ standards supported revision of the suite of current $PM_{2.5}$ standards, as did five state attorneys general (Schneiderman *et al.,* 2012) and the National Tribal Air Association (NTAA).

These commenters based their views chiefly on the body of evidence and technical analyses presented and discussed in the Integrated Science Assessment, the Risk Assessment, and the Policy Assessment finding the available scientific information to be stronger and more compelling than in the last review. These commenters generally placed much weight on CASAC's recommendation to revise the $PM_{2.5}$ standards to provide increased public health protection and on the EPA staff conclusions presented in the final Policy Assessment.

Some of these commenters specifically mentioned extended analyses of seminal long-term exposure studies—the ACS (Krewski *et al.,* 2009), Harvard Six Cities (Laden *et al.,* 2006), and Southern California Children's Health (Gauderman *et al.,* 2004) studies. These commenters also highlighted the availability of additional long-term exposure studies in this review, specifically a study of premature mortality in older adults (Eftim *et al.,* 2008) and the WHI study of cardiovascular morbidity and mortality effects in women (Miller *et al.,* 2007) providing stronger evidence of mortality and morbidity effects associated with long-term $PM_{2.5}$ exposures at lower concentrations than had previously been observed, including studies of effects in at-risk populations. For example, some commenters asserted:

> Evidence during the last review showed clearly that the annual average standard needed to be much lower than the standard of 15 μg/m³ that was first set in 1997. The evidence has only grown since then. Multiple, multi-city studies over long periods of time have shown clear evidence of premature death, cardiovascular and respiratory harm as well as reproductive and developmental harm at contemporary concentrations far below the level of the current (annual) standard (ALA *et al.,* 2012, p. 39; AHA *et al.,* 2012, p. 10).

These commenters also highlighted the availability of a number of short-term $PM_{2.5}$ exposure studies as providing evidence of mortality and morbidity effects at concentrations below the level of the current 24-hour $PM_{2.5}$ standard. Specifically, these commenters made note of multi-city studies of premature mortality (Zanobetti and Schwartz, 2009) and increased hospitalizations for cardiovascular and respiratory-related effects in older adults (Bell *et al.,* 2008). These commenters also asserted the importance of many of the single-city studies, arguing that these studies ''provide valuable information regarding impacts on susceptible populations and on health risk in areas with high peak to mean concentration ratios'' (ALA, *et al.,* 2012, p. 65). Collectively, considering the multi- and single-city short-term exposure studies, these commenters asserted ''the record clearly supports a more stringent 24-hour standard of 25 μg/m³ to provide uniform protection in all regions of the country particularly from short-term spikes in pollution and from the sub-daily exposures that trigger heart attacks and strokes'' (ALA *et al.,* 2012, p. 62). A group of more than 350 physicians, environmental health researchers, and public health and medical professionals argued, ''[s]tudies of short-term exposure demonstrate that $PM_{2.5}$ air pollution increases the risk of hospital admissions for heart and lung problems even when you exclude days with pollution concentrations at or above the current daily standard of 35 μg/m³. Daily concentrations must be capped at lower levels to protect against peak exposure days that occur due to local and seasonal sources of emissions'' (Rom *et al.,* 2012, p. 2).

In addition, many of these commenters generally concluded that progress had been made in reducing many of the uncertainties identified in the last review, in better understanding mechanisms by which $PM_{2.5}$ may be causing the observed health effects, and in improving our understanding of at-risk populations. Further, a number of commenters argued that by making the standards more protective, the $PM_{2.5}$ NAAQS would be more consistent with other existing standards (e.g., California's annual average standard of 12 μg/m³) (CARB, 2012; CA OEHHA, 2012). Other commenters argued that revising the primary $PM_{2.5}$ standards would be more consistent with the recommendations of the World Health Organization (WHO) and/or Canada (e.g., ALA *et al.,* 2012, p. 62; ISEE, 2012, p. 2; MOE-Ontario, 2012, p. 1).

With regard to the scope of the literature reviewed for $PM_{2.5}$-related health effects, some commenters asserted that the EPA inappropriately narrowed the scope of the review by excluding a number of categories of relevant studies, specifically related to studies of diesel pollution and traffic-related pollution (ALA, *et al.,* 2012, p. 17). These commenters argued that, based upon the exclusion of these types of studies, the Integrated Science Assessment ''came to the erroneous conclusion that the causal relationship between PM and cancer is merely suggestive. This conclusion does not square with the International Agency Research on Cancer (IARC) finding that diesel emissions are a known human carcinogen nor with the conclusions of the extended analyses of the [Harvard] Six Cities and ACS cohort studies that report positive and statistically significant associations between $PM_{2.5}$ and lung cancer.'' *Id.*

Some of these commenters also noted the results of the EPA's quantitative risk assessment, concluding that it showed that the risks estimated to remain when the current standards are met are large and important from a public health perspective and warrant increased protection. For example, ALA *et al.,* noted that the Risk Assessment indicated the quantitative risk analyses likely underestimated $PM_{2.5}$-related mortality (U.S. EPA, 2010a, p. 5–16) and argued that ''the measurements of risk should be treated conservatively'' (ALA, *et al.,* 2012, p. 73). These commenters also summarized an expanded analysis of alternative $PM_{2.5}$ standard levels that they argued documented the need for more protective standards (McCubbin, 2011).

In general, all of these commenters agreed on the importance of results from the large body of scientific studies reviewed in the Integrated Science Assessment and on the need to revise the suite of $PM_{2.5}$ standards as articulated in the EPA's proposal, while generally differing with the EPA's proposed judgments about the extent to which the standards should be revised based on this evidence, specifically for providing protection for at-risk populations.

The EPA generally agrees with these commenters' conclusion regarding the need to revise the current suite of $PM_{2.5}$ standards. The scientific evidence noted by these commenters was generally the same as that assessed in the Integrated Science Assessment and the Policy Assessment, and the EPA agrees that this evidence provides a strong basis for concluding that the current $PM_{2.5}$ standards, taken together, are not requisite to protect public health with an adequate margin of safety, and they need to be revised to provide increased protection. For reasons discussed in section III.E.4.c below, however, the EPA disagrees with aspects of these commenters' views on the level of protection that is appropriate.

The EPA disagrees with these commenters' views that diesel exhaust studies were excluded from the Integrated Science Assessment and were not considered when making the causality determination for cancer, mutagenicity, and genotoxicity. As discussed in section 7.5 of the Integrated Science Assessment, diesel exhaust studies were integrated within the broader body of scientific evidence that was considered in reaching the causality determination for these health endpoints. Additionally, as discussed in section 1.5.3 of the Integrated Science Assessment, the evidence from diesel exhaust studies was also considered as part of the collective evidence evaluated when making determinations for other, noncancer health outcomes (e.g., cardiovascular and respiratory effects).[47] Specifically, when evaluating this evidence, the focus was on understanding the effects of diesel exhaust particles.

It is important to recognize that the Integrated Science Assessment focused on experimental studies of diesel exhaust that evaluated exposures that were relevant to ambient concentrations, i.e., ''within one or two orders of magnitude of ambient PM concentrations'' (U.S. EPA, 2009a, section 1.3). The causal determination for cancer, mutagenicity, and genotoxicity presented in the Integrated Science Assessment represents an integration of experimental and observational evidence of exposures to ambient PM concentrations. The EPA fully considered the findings of studies that assessed these and other health effects associated with exposure to diesel particles in reaching causality determinations regarding health outcomes associated with $PM_{2.5}$ exposures. Furthermore, CASAC supported the EPA's change to the causal determination for cancer and long-term $PM_{2.5}$ concentrations from ''inadequate'' to ''suggestive'' (Samet, 2009f, p. 2).

With regard to traffic studies, the EPA disagrees with the commenters' views that traffic studies that focused on exposure indicators such as distance to roadways should have been included in the Integrated Science Assessment. These studies were excluded from consideration because they did not measure ambient concentrations of specific air pollutants, including $PM_{2.5}$, but instead were studies evaluating exposure to the undifferentiated ''traffic related air pollution'' mixture (ALA *et al.,* 2012, p. 17) (U.S. EPA, 2009a, section 1.3). As a result, these studies do not add to the collective body of evidence on the relationship between long- or short-term exposure to ambient concentrations of $PM_{2.5}$ and health effects.

Some of these commenters also identified ''new'' studies that were not included in the Integrated Science Assessment as providing further support for the need to revise the primary $PM_{2.5}$ standards. As discussed in section II.B.3 above, the EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone CASAC and public review and will consider the ''new'' studies for purposes of decision making in the next PM NAAQS review. Nonetheless, in provisionally evaluating commenters' arguments (see Response to Comments document), the EPA notes that its provisional assessment of ''new'' science found that such studies did not materially change the conclusions in the Integrated Science Assessment (U.S. EPA, 2012b).

Another group of commenters opposed revising the current $PM_{2.5}$ standards. These views were most extensively presented in comments from the Utility Air Regulatory Group (UARG), representing a group of electric generating companies and organizations and several national trade associations; the American Petroleum Institute (API) representing more than 500 oil and natural gas companies; the National Association of Manufacturers (NAM), the American Chemistry Council (ACC), the American Fuel & Petroleum Manufacturers (AFPM), the Alliance of Automobile Manufacturers (AAM), and other manufacturing associations; the Electric Power Research Institute (EPRI); and the Texas Commission on Environmental Quality (Texas CEQ). These commenters generally mentioned many of the same studies that were cited by the commenters who supported revising the standards, as well as other studies, but highlighted different aspects of these studies in reaching substantially different conclusions about their strength and the extent to which progress has been made in reducing uncertainties in the evidence since the last review. Furthermore, they asserted that the evidence that has become available since the last review does not establish a more certain risk or a risk of effects that are significantly different in character to those that provided a basis for the current standards, nor does the evidence demonstrate that the risk to public health upon attainment of the current standards would be greater than was

[47] In developing the second draft Integrated Science Assessment, the EPA reexamined the controlled human exposure and toxicological studies of fresh diesel and gasoline exhaust. This information, in addition to other considerations, supported a change in the causal determinations for ultrafine particles. Specifically, in reevaluating the causal determinations for short-term ultrafine particle exposures and cardiovascular and respiratory effects, the EPA changed the classification from ''inadequate'' to ''suggestive'' for both categories of health outcomes (Vandenberg, 2009, p. 3). CASAC agreed with the EPA's rationale for revising these causal determinations (Samet, 2009f, p. 10).

understood when the EPA established the current standards in 2006.

These commenters generally expressed the view that the current standards provide the requisite degree of public health protection. In supporting their view, these commenters generally argued that the EPA's conclusions are inconsistent with the current state of the science and questioned the underlying scientific evidence including the causal determinations reached in the Integrated Science Assessment. More specifically, this group of commenters argued that: (1) The EPA did not apply its framework for causal determination consistently across studies or health outcomes and, in the process, the EPA relied on a selective group of long- and short-term exposure studies to reach conclusions regarding causality; (2) toxicological and controlled human exposure studies do not provide supportive evidence that the health effects observed in epidemiological studies are biologically plausible; (3) uncertainties in the underlying health science are as great or greater than in 2006; (4) there is no evidence of greater risk since the last review to justify tightening the current annual $PM_{2.5}$ standard; and (5) ''new'' studies not included in the Integrated Science Assessment continue to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$. These comments are discussed in turn below.

(l) Some of these commenters asserted that the EPA did not apply its framework for causal determinations consistently across studies or health outcomes (e.g., ACC, 2012, Attachment A, pp. 1 to 2; API, 2012, Attachment 1, p. 30; NAM *et al.,* 2012, pp. 22 to 25; Texas CEQ, 2012, pp 2 to 3).[48] These commenters argued that the EPA downplayed epidemiological studies with null or inconsistent results, inappropriately used the Hill criteria when evaluating the epidemiological evidence, and used the same study and the same underlying database to conclude that there was a causal association between mortality and multiple criteria pollutants.

The EPA disagrees with these commenters' views. First, the EPA recognizes that the evaluation of the scientific evidence and its application of the causal framework used in the current PM NAAQS review was the subject of exhaustive and detailed review by CASAC and the public. As summarized in section II.B.3 above, prior to finalizing the Integrated Science Assessment, two drafts were released for CASAC and public review to evaluate the scientific integrity of the documents. Evidence related to the substantive issues raised by CASAC and public commenters with regard to the content of the first and second draft Integrated Science Assessments were discussed at length during these public CASAC meetings and considered in developing the final Integrated Science Assessment. CASAC supported the development of the EPA's causality framework and its use in the current PM NAAQS review and concluded:

> The five-level classification of strength of evidence for causal inference has been systematically applied; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future Integrated Science Assessments (Samet 2009f, p. 1).

These commenters asserted that during the application of the causal framework the EPA inappropriately relied on a selective group of long- and short-term exposure studies in reaching causal inferences (API, 2012, pp 12 to 17; ACC, 2012, Attachment A, pp 1 to 2; NAM *et al.,* 2012, pp. 22 to 25; Texas CEQ, 2012, pp 2 to 3). Additionally, these commenters expressed the view that the EPA focused on a subset of epidemiological studies that reported positive and statistically significant results while ignoring other studies, especially those that reported no statistically significant associations, those that reported potential thresholds, or those that highlighted uncertainties and limitations in study design or results. Furthermore, some of these commenters argued that epidemiological studies are observational in nature and cannot provide evidence of a causal association.

The EPA disagrees with these commenters' views on assessing the health effects evidence and on the conclusions regarding the causality determinations reached in the Integrated Science Assessment. In conducting a comprehensive evaluation of the evidence in the Integrated Science Assessment, the EPA recognized the distinction between the evaluation of the *relative scientific quality of individual study results* and the evaluation of the *pattern of results within the broader body of scientific evidence* and considered both in reaching causality determinations. The more detailed characterizations of individual studies included an assessment of the quality of the study based on specific criteria as described in the Integrated Science Assessment (U.S. EPA, 2009a, section 1.5.3).

In developing an integrated assessment of the health effects evidence for PM, the EPA emphasized the importance of examining the pattern of results across various studies and did not focus solely on statistical significance[49] as a criterion of study strength. This approach is consistent with views clearly articulated throughout the epidemiological and causal inference literature, specifically, that it is important not to focus on results of statistical tests to the exclusion of other information.[50] The concepts underlying the EPA's approach to evaluating statistical associations have been discussed in numerous publications, including a report by the U.S. Surgeon General on the health consequences of smoking (Centers for Disease Control and Prevention, 2004). This report cautions against over-reliance on statistical significance in evaluating the overall evidence for an exposure-response relationship. Criteria characterized by Hill (1965) also addressed the value, or lack thereof, of statistical tests in the determination of cause:

> No formal tests of significance can answer those [causal] questions. Such tests can, and should, remind us of the effects the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that, they contribute nothing to the 'proof' of our hypothesis (Hill, 1965, p. 299).

The statistical significance of individual study findings has played an important role in the EPA's evaluation of the study's results and the EPA has placed greater emphasis on studies reporting statistically significant results. However, in the broader evaluation of the evidence from many

[48] The EPA notes that the same concerns about the causal determinations presented in the Integrated Science Assessment were raised in comments to CASAC on the draft Integrated Science Assessments (e.g., UARG, 2009; API, 2009; ACC, 2012, Appendix B). CASAC, therefore, had the opportunity to consider these comments in reaching consensus conclusions on this issue.

[49] Statistical significance is an indicator of the precision of a study's results, which is influenced by a variety of factors including, but not limited to, the size of the study, exposure and measurement error, and statistical model specifications. Studies typically calculate ''p-values'' to determine whether the study results are statistically significant or whether the study results are likely to occur simply by chance. In general practice, effects are considered statistically significant if p values are less than 0.05.

[50] For example, Rothman (1998) stated, ''Many data analysts appear to remain oblivious to the qualitative nature of significance testing [and that] * * * statistical significance is itself only a dichotomous indicator. As it has only two values, significant or not significant * * *. Nevertheless, p-values still confound effect size with study size, the two components of estimation that we believe need to be reported separately.'' As a result, Rothman recommended that p-values be omitted as long as point and interval estimates are available.

epidemiological studies, and subsequently during the process of forming causality determinations in integrating evidence across epidemiological, controlled human exposure, and toxicological studies, the EPA has emphasized the *pattern of results* across epidemiological studies, and whether the effects observed were *coherent* across the scientific disciplines for drawing conclusions on the relationship between $PM_{2.5}$ and different health outcomes. Thus, the EPA did not limit its focus or consideration to just studies that reported positive associations or where the results were statistically significant.

In addition, some commenters asserted that the EPA inappropriately used the Hill criteria by failing to consider the limitations of studies with weak associations, thereby overstating the consistency of the observed associations (API, 2012, Attachment 1, pp. 30 to 35). These commenters argued that risk estimates greater than 3 to 4 reflect strong associations supportive of a causal link, while smaller risk estimates (i.e., 1.5 to 3) are considered to be weak and require other lines of evidence to demonstrate causality.

As discussed in section 1.5.3 of the Integrated Science Assessment, the EPA thoroughly considered the limitations of all studies during its evaluation of the scientific literature (U.S. EPA,, 2009a, p. 1–14). This collective body of evidence, including known uncertainties and limitations of the studies evaluated, were considered during the process of forming causality determinations as discussed in chapters 6 and 7 of the Integrated Science Assessment. For example, the EPA concluded that ''a causal relationship exists between short-term $PM_{2.5}$ exposure and cardiovascular effects,'' however, in reaching this conclusion, the Agency recognized and considered limitations of the current evidence that still requires further examination (U.S. EPA, 2009a., in section 6.2.12.1). Therefore, the EPA disagrees with these commenters' views that the Hill criteria were inappropriately used in that the limitations of studies were not considered.

The EPA also disagrees with the commenters' assertion that the magnitude of the association must be large to support a determination of causality. As discussed in the Integrated Science Assessment, the strength of the observed association is an important aspect to aid in judging causality and ''while large effects support causality, modest effects therefore do not preclude it'' (U.S. EPA, 2009a, Table 1–2, section 1.5.4). The weight of evidence approach used by the EPA encompasses a multitude of factors of which the magnitude of the association is only one component (U.S. EPA, 2009a, Table 1–3). An evaluation of the association across multiple investigators and locations supports the ''reproducibility of findings [which] constitutes one of the strongest arguments for causality'' (U.S. EPA, 2009a, Table 1–2). Even though the risk estimates for air pollution studies may be modest, the associations are consistent across hundreds of studies as demonstrated in the Integrated Science Assessment. Furthermore, the causality determinations rely on different lines of evidence, by integrating evidence across disciplines, including animal toxicological studies and controlled human exposure studies.

Furthermore, as summarized in section III.B above and discussed more fully in section III.B.3 of the proposal, the EPA recognizes that the population potentially affected by $PM_{2.5}$ is considerable, including large subgroups of the U.S. population that have been identified as at-risk populations (e.g., children, older adults, persons with underlying cardiovascular or respiratory disease). While individual effect estimates from epidemiological studies may be modest in size, the public health impact of the mortality and morbidity associations can be quite large given that air pollution is ubiquitous. Indeed, with the large population exposed, exposure to a pollutant causally associated at a population level with mortality and serious illness has significant public health consequences, virtually regardless of the relative risk. Taken together, this information indicates that exposure to ambient $PM_{2.5}$ concentrations has substantial public health impacts.

In addition, these commenters believed that the EPA downplayed null or inconsistent findings in numerous long-term mortality studies with reported $PM_{2.5}$ concentrations above and below the level of the current annual standard. The EPA disagrees that studies with null or inconsistent findings were not accurately presented and considered in the Integrated Science Assessment. For example, as discussed throughout section 7.6 and depicted in Figures 7–6 and 7–7 of the Integrated Science Assessment, the EPA presented the collective evidence from all studies that examined the association between long-term $PM_{2.5}$ exposure and mortality. Overall, across these studies there was evidence of consistent positive associations in different cohorts. That evidence, in combination with the biological plausibility provided by experimental and toxicological studies evaluated in sections 7.1 and 7.2 of the Integrated Science Assessment, supported a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality.

Lastly, some of these commenters argued that in some cases, the EPA used the same study and the same underlying database to conclude that there is a causal association between mortality and multiple criteria pollutants. These commenters argued, ''[i]n doing so, EPA attributes the cause of the mortality effects observed to whichever criteria pollutant it is reviewing at the time'' (API, 2012, pp. 14 to 16).

The EPA strongly disagrees that the Agency ''attributes the cause of mortality effects observed to whichever criteria pollutant it is reviewing at the time.'' The EPA consistently recognizes that other pollutants are also associated with health outcomes, as is reflected in the fact that the EPA has established regulations to limit emissions of particulate criteria pollutants as well as other gaseous criteria pollutants. Epidemiological studies often examine the association between short- and long-term exposures to multiple air pollutants and mortality within a common dataset in an attempt to identify the air pollutant(s) of the complex mixture most strongly associated with mortality. In evaluating these studies, the EPA employs specific study selection criteria to identify those studies most relevant to the review of the NAAQS. In its assessment of the health evidence regarding $PM_{2.5}$, the EPA has carefully evaluated the potential for confounding, effect measure modification, and the role of $PM_{2.5}$ as a component of a complex mixture of air pollutants (U.S. EPA, 2009a, p. 1–9). The EPA used a rigorous weight of evidence approach to inform causality that evaluated consistency across studies within a discipline, evidence for coherence across disciplines, and biological plausibility. Additionally, during this process, the EPA assessed the limitations of each study in the context of the collective body of evidence. It was the collective evidence, not one individual study that ultimately determined whether a causal relationship exists between a pollutant and health outcome. In the Integrated Science Assessment, the combination of epidemiological and experimental evidence formed the basis for the Agency concluding for the first time that a causal relationship exists between short- or long-term exposure to a criteria pollutant and mortality (U.S. EPA, 2009, sections 2.3.1.1 and 2.3.1.2).

Additionally, while the EPA has evaluated some of the studies used to inform the causality determination for PM in the Integrated Science Assessments for other criteria air pollutants, the Agency has done so in the context of examining the collective body of evidence for each of the respective criteria air pollutants. As such, the body of evidence to inform causality has varied from pollutant to pollutant resulting in the association between each criteria air pollutant and mortality being classified at a different level of the five-level hierarchy used to inform causation (e.g., U.S. EPA, 2008e, U.S. EPA, 2008f, U.S. EPA, 2010k).

The EPA notes that the final causality determinations presented in the Integrated Science Assessment reflected CASAC's recommendations on the second draft Integrated Science Assessment (Samet, 2009f, pp. 2 to 3). Specifically, CASAC supported the EPA's changes (in the second versus first draft Integrated Science Assessment) from ''likely causal'' to ''causal'' for long-term exposure to $PM_{2.5}$ and cardiovascular effects and for cancer and $PM_{2.5}$ (from ''inadequate'' to ''suggestive''). *Id.* Furthermore, CASAC recommended ''upgrading'' the causal classification for $PM_{2.5}$ and total mortality to ''causal'' for both the short- and long-term timeframes. *Id.* With regard to mortality, the ''EPA carefully reevaluated the body of evidence, including the collective evidence for biological plausibility for mortality effects, and determined that a causal relationship exists for short- and long-term exposure to $PM_{2.5}$ and mortality, consistent with the CASAC comments'' (Jackson, 2010).

(2) With regard to toxicological and controlled human exposure studies, these commenters argued that the available evidence does not provide coherence or biological plausibility for health effects observed in epidemiological studies (API, 2012, pp. 21 to 22, Attachment 1, pp. 25 to 29; AAM, 2012, pp. 15 to 16; Texas CEQ, 2012, p. 3). With regard to the issue of mechanisms, these commenters noted that although the EPA recognizes that new evidence is now available on potential mechanisms and plausible biological pathways, the evidence provided by toxicological and controlled human exposure studies still does not resolve all questions about how $PM_{2.5}$ at ambient concentrations could produce the mortality and morbidity effects observed in epidemiological studies. More specifically, for example, some of these commenters argued that:

> A review of the Integrated Science Assessment, however, suggests that the experimental evidence is inconsistent and not coherent with findings in epidemiology studies. Specifically, the findings of mild and reversible effects in most experimental studies conducted at elevated exposures are not consistent with the more serious associations described in epidemiology studies (e.g., hospital admissions and mortality). Also, both animal studies and controlled human exposure studies have identified no effect levels for acute and chronic exposure to PM and PM constituents at concentrations considerably above ambient levels. EPA should consider the experimental findings in light of these higher exposure levels and what the relevance may be for ambient exposures (API, 2012, Attachment 1, p. 25).

The EPA notes that in the review completed in 1997, the Agency considered the lack of demonstrated biological mechanisms for the varying effects observed in epidemiological studies to be an important caution in its integrated assessment of the health evidence upon which the standards were based (71 FR 61157, October 17, 2006). In the review completed in 2006, the EPA recognized the findings from additional research that indicated that different health responses were linked with different particle characteristics and that both individual components and complex particle mixtures appeared to be responsible for many biologic responses relevant to fine particle exposures. *Id.* Since that review, there has been a great deal of research directed toward advancing our understanding of biologic mechanisms. While this research has not resolved all questions, and further research is warranted (U.S. EPA, 2011a, section 2.5), it has provided important insights as discussed in section III.B.1 of the proposal (77 FR at 38906 to 38909) and discussed more fully in the Integrated Science Assessment (U.S. EPA, 2009a, Chapter 5).

As noted in the proposal, toxicological studies provide evidence to support the biological plausibility of cardiovascular and respiratory effects associated with long- and short-term PM exposures observed in epidemiological studies (77 FR 38906) and provide supportive mechanistic evidence that the cardiovascular morbidity effects observed in long-term exposure epidemiological studies are coherent with studies of cardiovascular-related mortality (77 FR 38907). The Integrated Science Assessment concluded that the new evidence available in this review ''greatly expands'' upon the evidence available in the last review ''particularly in providing greater understanding of the underlying mechanisms for $PM_{2.5}$ induced cardiovascular and respiratory effects for both short- and long-term exposures'' (U.S. EPA, 2009a, p. 2–17). The mechanistic evidence now available, taken together with newly available epidemiological evidence, increases the Agency's confidence that a causal relationship exists between long- and short-term exposure to $PM_{2.5}$ and cardiovascular effects and mortality.[51] In addition, CASAC supported the Integrated Science Assessment approach and characterization of potential mechanisms or modes of action (Samet, 2009e, pp. 7 to 8; Samet, 2009f, p. 11), as well as the findings of a causal relationship at the population level between exposure to $PM_{2.5}$ and mortality and cardiovascular effects (Samet, 2009f, pp. 2 to 3).[52]

Additionally, the EPA disagrees with commenters that the mild and reversible effects observed in controlled human exposure studies are inconsistent with the more serious effects observed in epidemiological studies. Ethical considerations regarding the types of studies that can be performed with human subjects generally limit the effects that can be evaluated to those that are transient, reversible, and of limited short-term consequence. The relatively small number of subjects recruited for controlled exposure studies should also be expected to have less variability in health status and risk factors than occurring in the general population.[53] Consequently, the severity

[51] See *American Trucking Associations* v. *EPA,* 175 F. 3d 1027, 1055–56 (DC Cir. 1999) reversed in part and affirmed in part *sub nom,* Whitman v. American Trucking Associations, 531 U.S. 457 (2001) holding that the EPA could establish NAAQS without identifying a biological mechanism (''To begin with, the statute itself requires no such proof. The Administrator may regulate air pollutants ''emissions of which, in his judgment, *cause or contribute* to air pollution which may *reasonably be anticipated* to endanger public health or welfare.'' (emphasis added by the court). Moreover, this court has never required the type of explanation petitioners seek from EPA. In fact, we have expressly held that EPA's decision to adopt and set air quality standards need only be based on 'reasonable extrapolations from some reliable evidence'* * *. Indeed, were we to accept petitioners' view, EPA (or any agency for that matter) would be powerless to act whenever it first recognizes clear trends of mortality or morbidity in areas dominated by a particular pathogen.'').

[53] For example, the EPA excludes from its controlled human exposure studies involving exposure to $PM_{2.5}$ any individual with a significant risk factor for experiencing adverse effects from such exposure. Thus, the EPA excludes *a priori* the following categories of persons: those with a history of angina, cardiac arrhythmias, and ischemic myocardial infarction or coronary bypass surgery; those with a cardiac pacemaker; those with uncontrolled hypertension (greater than 150 systolic and 90 diastolic); those with neurogenetive diseases; those with a history of bleeding diathesis; those taking beta-blockers; those using oral anticoagulants; those who are pregnant, attempting to become pregnant, or breastfeeding; those who

of health effects observed in controlled human exposure studies evaluating the effects of PM should be expected to be less than observed in epidemiologic studies. Nonetheless, that effects are observed in relatively healthy individuals participating in controlled exposure studies serves as an indicator that PM is initiating health responses and that more severe responses may reasonably be expected in a more diverse population.

It should also be noted that there is a small body of toxicological evidence demonstrating mortality in rodents exposed to PM (e.g., Killingsworth *et al.* 1997). Overall it is not surprising that lethality is not induced in more toxicological research, as these types of studies do not readily lend themselves to this endpoint. Epidemiological studies have observed associations between PM and mortality in communities with populations in the range of many thousands to millions of people. Clearly, it is not feasible to expose hundreds (if not thousands) of animals to ambient PM (potentially over many years) in a laboratory setting to induce enough lethalities to distinguish between natural deaths and those attributable to PM. Furthermore, the heterogeneous human populations sampled in epidemiological studies are comprised of individuals with different physical, genetic, health, and socioeconomic backgrounds which may impact the outcome. However, in toxicological studies, the rodent groups are typically inbred, such that inter-individual variability is minimized. Thus, if the rodent strain used is quite robust, PM-induced effects may not be observed at low exposure concentrations.

(3) In asserting that the uncertainties in the underlying health science are as great or greater than in the last review and therefore do not support revision to the standards at this time, commenters in this group variously discussed a number of issues related to: (a) Confounding, (b) heterogeneity in risk estimates, (c) exposure measurement error, (d) model specification, (e) the shape of the concentration-response relationship, and (f) understanding the relative toxicity of components within the mixture of fine particles. Each of these issues is addressed below and some are discussed in more detail in the Response to Comments document.

In summary, these commenters concluded that the substantial uncertainties present in the last review have not been resolved and/or that the uncertainty about the possible health risks associated with $PM_{2.5}$ exposure has not diminished. As discussed below, the EPA believes that the overall uncertainty about possible health risks associated with both long- and short-term $PM_{2.5}$ exposure has diminished to an important degree since the last review. While the EPA agrees that important uncertainties remain, and that future research directed toward addressing these uncertainties is warranted, the EPA disagrees with commenters' views that the remaining uncertainties in the scientific evidence are too great to warrant revising the current $PM_{2.5}$ NAAQS.

(a) Confounding

Some commenters have criticized the EPA for not adequately addressing the issue of confounding in both long- and short-term exposure studies of mortality and morbidity. This includes confounding due to copollutants, as well as unmeasured confounding.[54]

With regard to copollutant confounding, these commenters asserted that the EPA has not adequately interpreted the results from studies that examined the effect of copollutants on the relationship between long- and short-term $PM_{2.5}$ exposures and mortality and morbidity outcomes. These commenters contend that the EPA has inappropriately concluded that $PM_{2.5}$-related mortality and morbidity associations are generally robust to confounding. The commenters stated that statistically significant $PM_{2.5}$ associations in single-pollutant models in epidemiological studies do not remain statistically significant in copollutant models.

The loss of statistical significance or the reduction in the magnitude of the effect estimate when a co-pollutant model is used may be the result of factors other than confounding. These changes do not prove either the existence or absence of confounding. These impacts must be evaluated in a broader context that considers the entire body of evidence. The broader examination of this issue in the Integrated Science Assessment included a focus on evaluating the stability of the size of the effect estimates in epidemiological studies conducted by a number of research groups using single- and copollutant models (U.S. EPA, 2009a, sections 6.2.10.9, 6.3.8.5, and 6.5, Figures 6–5, 6–9, and 6–15). This examination found that, for most epidemiological studies, there was little change in effect estimates based on single- and copollutant models, although the Integrated Science Assessment recognized that in some cases, the $PM_{2.5}$ effect estimates were markedly reduced in size and lost statistical significance. Additionally, the EPA notes that these comments do not adequately reflect the complexities inherent in assessing the issue of copollutant confounding. As discussed in the proposal (77 FR 38907, 38909, and 38910) and more fully in the Integrated Science Assessment (U.S.EPA, 2009a, sections 6.2, 6.3, and 6.5), although copollutant models may be useful tools for assessing whether gaseous copollutants may be potential confounders, such models alone cannot determine whether copollutants are in fact confounders. Interpretation of the results of copollutant models is complicated by correlations that often exist among air pollutants, by the fact that some pollutants play a role in the atmospheric reactions that form other pollutants such as secondary fine particles, and by the statistical power of the studies in question inherent in the study methodology. For example, the every-third or sixth-day sampling schedule often employed for $PM_{2.5}$ measurements compared to daily measurements of gaseous copollutants drastically reduces the overall sample size to assess the effect of copollutants on the $PM_{2.5}$-morbidity or mortality relationship, such that the reduced sample size can lead to less precise effect estimates (e.g., wider confidence intervals).

The EPA recognizes that when $PM_{2.5}$ is correlated with gaseous pollutants it can be difficult to identify the effect of individual pollutants in the ambient mixture (77 FR 38910). However, based on the available evidence, the EPA

have experienced a respiratory infection within four weeks of exposure; those experiencing eye or abdominal surgery within six weeks of exposure; those with active allergies; those with a history of chronic illnesses such as diabetes, cancer, rheumatologic diseases, immunodeficiency state, known cardiovascular disease, or chronic respiratory diseases; smokers. The EPA "Application for Independent Review Board Approval of Human Subjects Research: Cardiopulmonary Effects of healthy Older GSTM1 Null and Sufficient individuals to Concentrated Ambient Air Particles (CAPTAIN)", Nov. 9, 2011, p. 9.

[54] The Integrated Science Assessment defines confounding as "a confusion of effects. Specifically, the apparent effect of the exposure of interest is distorted because the effect of an extraneous factor is mistaken for or mixed with the actual exposure effect (which may be null) (Rothman and Greenland, 1998)" (U.S. EPA, 2009a, p. 1–16). Epidemiological analyses attempt to adjust or control for these characteristics (i.e., potential confounders) that differ between exposed and non-exposed individuals (U.S. EPA, 2009a, section 1.5.3). Not all risk factors can be controlled for within a study design/model and are termed "unmeasured confounders." An unmeasured confounder is a confounder that has not previously been measured and therefore is not included in the study design/model.

concludes epidemiological studies continue to support the conclusion that $PM_{2.5}$ associations with mortality and morbidity outcomes are robust to the inclusion of gaseous copollutants in statistical models. The EPA evaluated the potential confounding effects of gaseous copollutants and, although it is recognized that uncertainties and limitations still remain, the Agency concluded the collective body of scientific evidence is ''stronger and more consistent than in previous reviews providing a strong basis for decision making in this review'' (77 FR 38910/1).

Several commenters offered detailed comments on the long-term $PM_{2.5}$ exposure studies arguing that associations from mortality studies are subjected to unmeasured confounding and as a result are not appropriately characterized as providing evidence of a causal relationship between long-term $PM_{2.5}$ exposure and mortality (e.g., UARG, 2012, pp. 10 to 11, Attachment A, pp. 17 to 23; API, 2012, pp. 13 to 14, Attachment 1, pp. 11 to 14, Attachment 7, pp. 2–10; ACC, 2012, p. 18 to 21; AFPM, 2012, p. 8; Texas CEQ, 2012, p. 4). Specifically, commenters cited two studies (i.e., Janes *et al.,* 2007 and Greven *et al.,* 2011) that used a new type of statistical analysis to examine associations between annual (long-term) and monthly (sub-chronic) $PM_{2.5}$ exposure and mortality. The commenters interpreted the results of these analyses as evidence of unmeasured confounding in the long-term $PM_{2.5}$ exposure-mortality relationship. These commenters interpreted these studies as raising fundamental questions regarding the EPA's determination that a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality. In addition to the commenters mentioned above, all of the authors of the publications by Janes *et al.* (2007) and Greven *et al.* (2011) (i.e., Francesca Dominici, Scott Zeger, Holly Janes, and Sonja Greven) submitted a joint comment to the public docket in order to clarify specific points regarding these two studies (Dominici *et al.,* 2012).

The first study, Janes *et al.* (2007), was evaluated in the Integrated Science Assessment (U.S. EPA, 2009a, p. 7–88). The second study, Greven *et al.* (2011), an extension of the Janes *et al.* (2007) study adding three more years of data, is a ''new'' study discussed in the Provisional Science Assessment (U.S. EPA, 2012). Both studies used nationwide Medicare mortality data to examine the association between monthly average $PM_{2.5}$ concentrations over the preceding 12 months and monthly mortality rates in 113 U.S. counties and examined whether community-specific trends in monthly $PM_{2.5}$ concentrations and mortality declined at the same rate as the national rate. The investigators examined this by decomposing the association between $PM_{2.5}$ and mortality into two components: (1) National trends, defined as the association between the national average trend in monthly $PM_{2.5}$ concentrations averaged over the previous 12 months and the national average trend in monthly mortality rates, and (2) local trends, defined as county-specific deviations in monthly $PM_{2.5}$ concentrations and monthly mortality rates from national trends.

The EPA does not question the results of the national trends analyses conducted by Janes *et al.* (2007) and Greven *et al.* (2011).[55] Both Janes *et al.* (2007) and Greven *et al.* (2011) observed positive and statistically significant associations between long-term exposure to $PM_{2.5}$ and mortality in their national analyses. However, Janes *et al.* (2007) and Greven *et al.* (2011) eliminated all of the spatial variation in air pollution and mortality in their data set when estimating the national effect, focusing instead on both chronic (yearly) and sub-chronic (monthly) temporal differences in the data (Dominici *et al.* 2012). Janes *et al.* (2007) (Table 1) highlighted that over 90 percent of the variance in the data set used for the analyses conducted by both Janes *et al.* (2007) and Greven *et al.* (2011) was attributable to spatial variability, which the authors chose to discard. As noted above, the focus of the analyses by Janes *et al.* (2007) and Greven *et al.* (2011) was on two components: (1) A temporal or time component, i.e., the ''national'' trends analysis, which examined the association between the national average trend in monthly $PM_{2.5}$ concentrations averaged over the previous 12 months and the national average trend in monthly mortality rates and (2) a space-by-time component, i.e., the ''local'' trends analysis, which examined county-specific deviations in monthly $PM_{2.5}$ concentrations and monthly mortality rates from national trends. These two components combined comprised less than 10 percent of the variance in the data set. The authors included a focus on the space-by-time component, which represented approximately 5 percent of the variance in the data set, in an attempt to identify, absent confounding, if $PM_{2.5}$ was associated with mortality at this unique exposure window. Thus, these studies are not directly comparable to other cohort studies investigating the relationship between long-term exposure to $PM_{2.5}$ and mortality, which make use of spatial variability in air pollution and mortality data.[56] This point was highlighted by the study authors who stated that ''when one considers that this wealth of information is not accounted for in [Janes 2007], it is not as surprising that * * * vastly different estimates of the $PM_{2.5}$/mortality relationship [were observed] than in other studies that do exploit that variability'' (Dominici *et al.,* 2012, p. 2).

The EPA notes that the results of the local trends analyses conducted by Janes *et al.* (2007) and Greven *et al.* (2011) are limited by the monthly timescale used in these analyses. This view is consistent with comments on the Janes *et al.* (2007) study articulated in Pope and Burnett (2007),[57] which noted that an important limitation of the local scale analysis conducted by Janes *et al.* (2007) and subsequently by Greven *et al.* (2011) was the subchronic exposure window considered in these analyses. Both studies used annual average $PM_{2.5}$ concentrations to characterize long-term national trends which was consistent with exposure windows considered in other studies of long-term exposure to $PM_{2.5}$ and mortality.[58] However, the local scale analyses used monthly average $PM_{2.5}$ concentrations to characterize county-specific deviations from national trends (the local scale). The use of monthly average data likely does not provide

[55] In its evaluation of Janes et al. (2007) in the Integrated Science Assessment, the EPA did not identify limitations in the statistical methods used *per se* (U.S. EPA, 2009a, p. 7–88) and included the results of the national-scale analyses in that study in the body of evidence that supported the determination that there is a causal relationship between long-term $PM_{2.5}$ exposure and mortality.

[56] Though not directly comparable, the national effect estimates for mortality reported by Janes *et al.* (2007) and Greven *et al.* (2011) are coincidentally similar in magnitude to those previously reported. It is important to note that previous cohort studies have focused on identifying spatial differences in $PM_{2.5}$ concentrations between cities, while Janes *et al.* (2007) and Greven *et al.* (2011) focus primarily on temporal differences in $PM_{2.5}$ concentrations. In fact, Greven *et al.* (2011) state ''We do not focus here on a third type [of statistical approach] used in cohort studies, measuring the association between average $PM_{2.5}$ levels and average age-adjusted mortality rates across cities (purely spatial or cross-sectional association).''

[57] Some commenters argued that there were flaws in the criticisms offered by Pope and Burnett (2007) on the paper by Janes *et al.* (2007) (UARG, 2012, Attachment A, pp. 19 to 23). The EPA responds to each of these specific comments in the Response to Comments document.

[58] As noted above, however, Janes *et al.* (2007) and Greven *et al.* (2011) focused on temporal variability and other studies of long-term exposure to $PM_{2.5}$ and mortality focus on spatial variability.

enough exposure contrast to observe temporal changes in mortality at the local scale. It also represents a different exposure window than considered in the large body of evidence of health effects related to short-term (from less than one day to up to several days) and chronic (one or more years) measures of $PM_{2.5}$.

Furthermore, the EPA disagrees with commenters that studies by Janes *et al.* (2007) and Greven *et al.* (2011) provide evidence that other studies of long-term exposure to $PM_{2.5}$ and mortality are affected by unmeasured confounding. As noted above, the design of the studies conducted by Janes *et al.* (2007) and Greven *et al.* (2011) are fundamentally different than those used in other studies of long-term exposure to $PM_{2.5}$ and mortality, including the ACS cohort and the Harvard Six Cities study. Studies, such as the ACS and Harvard Six Cities studies, used the spatial variation between cities to measure the effect of long-term (annual) exposures to $PM_{2.5}$ on mortality risk, and did not conduct any analyses relying on the temporal variation in $PM_{2.5}$. The opposite is true of the Janes *et al.* (2007) and Greven *et al.* (2011) studies which first removed the spatial variability in $PM_{2.5}$ and then examined the temporal variation at both the national and local scale to measure the effects of temporal differences in $PM_{2.5}$ on mortality risk. Janes *et al.* (2007) and Greven *et al.* (2011) focus on changes in $PM_{2.5}$ concentrations over time and, therefore, control for confounders would be based on including variables that vary over time rather than over space. As a result, any evidence of potential confounding of the $PM_{2.5}$-mortality risk relationship derived from Janes *et al.* (2007) and Greven *et al.* (2011) cannot be extrapolated to draw conclusions related to potential spatial confounding in studies based on the spatial variation in $PM_{2.5}$ concentrations.

As detailed in the Integrated Science Assessment (U.S. EPA, 2009a, section 7.6), and recognized by the authors of Janes *et al.* (2007) and Greven *et al.* (2011), the cohort studies that informed the causality determination for long-term $PM_{2.5}$ exposure and mortality ''have developed approaches to adjust for measured and unmeasured confounders'' (Dominici *et al.,* 2012, p. 2). These approaches were specifically designed to adjust for spatial confounding. The hypothesis that the authors of Janes *et al.* (2007) and Greven *et al.* (2011) chose to examine was that differences in the local and national effects indicated unmeasured temporal confounding in either the local or national effect estimate. This hypothesis was specific to these two studies that examined temporal variability in exposure to air pollution and did not include known potential confounders at either the national or local scale as time-varying covariates in the statistical model. The authors acknowledged that the interpretation of either the national or local estimates needs to occur with an appreciation of the potential confounding effects of national and local scale covariates that were omitted from the model (Dominici *et al.,* 2012).

It is important to recognize that because Janes *et al.* (2007) and Greven *et al.* (2011) focused on variations in $PM_{2.5}$ over time and not space, the results from these two studies do not provide any indication that other studies of long-term exposure to $PM_{2.5}$ and mortality exhibit spatial confounding, or that $PM_{2.5}$ does not cause mortality.[59] The authors of Janes *et al.* (2007) and Greven *et al.* (2011) recognized that ''it is entirely possible that these papers are looking for an association at a timescale for which no association truly exists'' (Dominici *et al.,* 2012, p. 3). Furthermore, as highlighted in the Integrated Science Assessment and discussed by Pope and Burnett (2007), the conclusions of Janes *et al.* (2007) ''are overstated * * * [T]heir analysis tells us little or nothing about unmeasured confounding in those and related studies because the methodology of Janes *et al.* largely excludes the sources of variability that are exploited in those other studies. By using monthly mortality counts and lagged 12-month average pollution concentrations, the authors eliminate the opportunity to exploit short-term or day-to-day variability.''

In conclusion, the EPA interprets the results of the analyses conducted by Janes *et al.* (2007) and Greven *et al.* (2011) as being consistent with prior knowledge of examining associations with long-term exposure to $PM_{2.5}$ at the national scale using long-term average $PM_{2.5}$ concentrations. For the reasons presented above and discussed in more detail in the Response to Comments document, the Agency disagrees with the commenters' assumption that the results of Janes *et al.* (2007) and Greven *et al.* (2011) indicate unmeasured confounding in the results of other cohort studies of long-term exposure to $PM_{2.5}$ and mortality. Therefore, the EPA concludes that these studies do not invalidate the large body of epidemiological evidence that supports the EPA's determination that a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality.[60]

(b) Heterogeneity in Risk Estimates

Some commenters argued that the heterogeneity in risk estimates observed in multi-city epidemiological studies and the lack of statistical significance in many regional or seasonal estimates highlights a potential bias associated with combined multi-city epidemiological study results (e.g., API, 2012, Attachment 1, pp. 15 to 19). These commenters further argued that more refined intra-urban exposure estimates conducted for two of the largest cities included in the ACS study, Los Angeles and New York City, based on land-use regression models and/or kriging methods (Krewski *et al.,* 2009) ''underscore the importance of considering city-specific health estimates, which may account for heterogeneity in $PM_{2.5}$ concentrations or other differences among cities, rather than relying on pooled nationwide results from multi-city studies'' (API, 2012, Attachment 1, p. 17).

With respect to understanding the nature and magnitude of $PM_{2.5}$-related risks, the EPA agrees that epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in responses between cities and effect estimates across geographic regions of the U.S. (U.S. EPA, 2009a, sections 6.2.12.1, 6.3.8.1, 6.5.2, and 7.6.1; U.S. EPA, 2011a, p. 2–25). For example, when focusing on short-term $PM_{2.5}$ exposure, the Integrated Science Assessment found that multi-city studies that examined associations with mortality and cardiovascular and respiratory hospital admissions and emergency department visits demonstrated greater cardiovascular effects in the eastern versus the western U.S. (Dominici, *et al.,* 2006a; Bell *et al.,* 2008; Franklin *et al.* (2007, 2008)).

In addition, the Integrated Science Assessment evaluated studies that provided some evidence for seasonal differences in $PM_{2.5}$ risk estimates, specifically in the northeast. The Integrated Science Assessment found evidence indicating that individuals may be at greater risk of dying from higher exposures to $PM_{2.5}$ in the warmer months, and at greater risk of $PM_{2.5}$ associated hospitalization for

[59] Further, the EPA notes that Janes *et al.* (2007) and Greven *et al.* (2011) provide no information relevant to examining confounding in studies of short-term exposure to $PM_{2.5}$.

[60] The EPA notes that the EPA's conclusion with regard to interpretation of the results from Janes *et al.* (2007) and Greven *et al.* (2012) is supported by the study authors' conclusion that ''*[o]ur results do not invalidate previous epidemiological studies*'' (Dominici, 2012, p. 1 (emphasis original)).

cardiovascular and respiratory diseases during colder months of the year. The limited influence of seasonality on PM risk estimates in other regions of the U.S. may be due to a number of factors including varying PM composition by season, exposure misclassification due to regional tendencies to spend more or less time outdoors and air conditioning usage, and the prevalence of infectious diseases during the winter months (U.S. EPA, 2009a, p. 3–182).

Overall, the EPA took note in the proposal that uncertainties still remain regarding various factors that contribute to heterogeneity observed in epidemiological studies (77 FR 38909/3). Nonetheless, the EPA recognizes that this heterogeneity could be attributed, at least in part, to differences in $PM_{2.5}$ composition across the U.S., as well as to exposure differences that vary regionally such as personal activity patterns, microenvironmental characteristics, and the spatial variability of $PM_{2.5}$ concentrations in urban areas (U.S. EPA, 2009a, section 2.3.2; 77 FR 38910).

As recognized in the Policy Assessment, the current epidemiological evidence and the limited amount of city-specific speciated $PM_{2.5}$ data do not allow conclusions to be drawn that specifically differentiate effects of $PM_{2.5}$ in different locations (U.S. EPA, 2011a, p. 2–25). Furthermore, the Integrated Science Assessment concluded ''that many constituents of $PM_{2.5}$ can be linked with multiple health effects, and the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes'' (U.S. EPA, 2009a, p. 2–17). CASAC thoroughly reviewed the EPA's presentation of the scientific evidence indicating heterogeneity in $PM_{2.5}$ effect estimates in epidemiological studies and concurred with the overall conclusions presented in the Integrated Science Assessment.

(c) Exposure Measurement Error

Some commenters argued that the EPA did not adequately consider exposure measurement error, which they asserted is an important source of bias in epidemiological studies that can bias effect estimates in either direction (e.g., API, 2012, Attachment 1, pp. 19 to 20).

The EPA agrees that exposure measurement error is an important source of uncertainty and that the variability in risk estimates observed in multi-city studies could be attributed, in part, to exposure error due to measurement-related issues (77 FR 38910). However, the Agency disagrees with the commenters' assertion that exposure measurement error was not adequately considered in this review. The Integrated Science Assessment included an extensive discussion that addresses issues of exposure measurement error (U.S. EPA, 2009a, sections 2.3.2 and 3.8.6). Exposure measurement error may lead to bias in effect estimates in epidemiological studies. A number of studies evaluated in the last review (U.S. EPA, 2004, section 8.4.5) and in the current review (U.S. EPA, 2009a, section 3.8.6) have discussed the direction and magnitude of bias resulting from specified patterns of exposure measurement error (Armstrong 1998; Thomas *et al.* 1993; Carroll *et al.* 1995) and have generally concluded ''classical'' (i.e., random, within-person) exposure measurement error can bias effect estimates towards the null. Therefore, consistent with conclusions reached in the last review, the Integrated Science Assessment concluded ''in most circumstances, exposure error tends to bias a health effect estimate *downward*'' (U.S. EPA, 2009a, sections 2.3.2 and 3.8.6) (emphasis added). Thus, the EPA has both considered and accounted for the possibility of exposure measurement error, and the possible bias would make it more difficult to detect true associations, not less difficult.

(d) Model Specification

Commenters contended that the EPA did not account for the fact that ''selecting an appropriate statistical model for epidemiologic studies of air pollution involves several choices that involve much ambiguity, scant biological evidence, and a profound impact on analytic results, given that many estimated associations are weak'' (ACC, 2012, p. 5). For short-term exposure studies, the EPA recognizes, as summarized in the HEI review panel commentary that selecting a level of control to adjust for time-varying factors, such as temperature, in time-series epidemiological studies involves a trade-off (HEI, 2003). For example, if the model does not sufficiently adjust for the relationship between the health outcome and temperature, some effects of temperature could be falsely ascribed to the pollution variable. Conversely, if an overly aggressive approach is used to control for temperature, the result would possibly underestimate the pollution-related effect and compromise the ability to detect a small but true pollution effect (U.S. EPA, 2004, p. 8–236; HEI, 2003, p. 266). The selection of approaches to address such variables depends in part on prior knowledge and judgments made by the investigators, for example, about weather patterns in the study area and expected relationships between weather and other time-varying factors and health outcomes considered in the study. As demonstrated in section 6.5 of the Integrated Science Assessment, the EPA thoroughly considered each of these issues and the overall effect of different model specifications on the association between short-term $PM_{2.5}$ exposure and mortality. Regardless of the model employed, consistent positive associations were observed across studies that controlled for the potential confounding effects of time and weather using different approaches (U.S. EPA 2009a, Figure 6–27). The EPA also considered the influence of model specification in the examination of long-term $PM_{2.5}$ exposure studies. For example, in section 7.6 of the Integrated Science Assessment, Figures 7–6 and 7–7 summarize the collective evidence that evaluated the association between long-term $PM_{2.5}$ exposure and mortality. Regardless of the model used, these studies collectively found evidence of consistent positive associations between long-term $PM_{2.5}$ exposure and mortality.

The EPA, therefore, disagrees with commenters that model specification was not considered when evaluating the epidemiological evidence used to form causality determinations. The EPA specifically points out that the process of assessing the scientific quality and relevance of epidemiological studies includes examining ''important methodological issues (e.g., lag or time period between exposure and effects, model specifications, thresholds, mortality displacement) related to interpretation of the health evidence (U.S. EPA, 2009, p. 1–9).'' Consistent with the conclusions of the 2004 PM Air Quality Criteria Document, the EPA recognizes that there is still no clear consensus at this time as to what constitutes appropriate control of weather and temporal trends in short-term exposure studies, and that no single statistical modeling approach is likely to be most appropriate in all cases (U.S. EPA, 2004, p. 8–238). However, the EPA believes that the available evidence interpreted in light of these remaining uncertainties does provide increased confidence relative to the last review in the reported associations between short- and long-term $PM_{2.5}$ exposures and mortality and morbidity effects, alone and in combination with other pollutants.

(e) Concentration-Response Relationship

Additionally, commenters questioned the interpretation of the shape of the concentration-response relationship, specifically stating that multiple studies have demonstrated that there is a threshold in the PM-health effect relationship and that the log-linear model is not biologically plausible (API, 2012, Attachment 9; ACC, 2012, Appendix A, pp. 7 to 8). The EPA disagrees with this assertion due to the number of studies evaluated in the Integrated Science Assessment that continue to support the use of a no-threshold, log-linear model to most appropriately represent the PM concentration-response relationship (U.S. EPA, 2009a, section 2.4.3). While recognizing that uncertainties remain, the EPA believes that our understanding of this issue for both long- and short-term exposure studies has advanced since the last review. As discussed in the Integrated Science Assessment, both long- and short-term exposure studies have employed a variety of statistical approaches to examine the shape of the concentration-response function and whether a threshold exists. While the EPA recognizes that there likely are individual biological thresholds for specific health responses, the Integrated Science Assessment concluded the overall evidence from existing epidemiological studies does not support the existence of thresholds at the population level, for effects associated with either long-term or short-term PM exposures within the ranges of air quality observed in these studies (U.S. EPA, 2009a, section 2.4.3).[61] The Integrated Science Assessment concluded that this evidence collectively supported the conclusion that a no-threshold, log-linear model is most appropriate (U.S. EPA, 2009a, sections 6.2.10.10, 6.5.2.7, and 7.6.4). CASAC likewise advised that ''[a]lthough there is increasing uncertainty at lower levels, there is no evidence of a threshold'' (Samet, 2010d, p. ii).

The EPA recognizes that some short-term exposure studies have examined the $PM_{2.5}$ concentration-response relationship in individual cities or on a city-to-city basis and observed heterogeneity in the shape of the concentration-response curve across cities. As discussed in (b) above, these findings are a source of uncertainty that the EPA agrees requires further investigation. Nonetheless, the Integrated Science Assessment concluded that ''the studies evaluated further support the use of a no-threshold, log-linear model, but additional issues such as the influence of heterogeneity in estimates between cities and the effects of seasonal and regional differences in PM on the concentration-response-relationship still require further investigation'' (U.S. EPA, 2009a, p. 2–25).

(f) Relative Toxicity of $PM_{2.5}$ Components

Some commenters highlighted uncertainties in understanding the role of individual constituents within the mix of fine particles. These commenters asserted that a mass-based standard may not be appropriate due to the growing body of evidence indicating that certain $PM_{2.5}$ components may be more closely related to specific health outcomes (e.g., EC and OC) (EPRI, 2012, p. 2).

With regard to questions about the role of individual constituents within the mix of fine particles, as a general matter, the EPA recognizes that although new research directed toward this question has been conducted since the last review, important questions remain and the issue remains an important element in the Agency's ongoing research program. At the time of the last review, the Agency determined that it was appropriate to continue to control fine particles as a group, as opposed to singling out any particular component or class of fine particles (71 FR 61162 to 61164, October 17, 2006). This distinction was based largely on epidemiological evidence of health effects using various indicators of fine particles in a large number of areas that had significant contributions of differing components or sources of fine particles, together with some limited experimental studies that provided some evidence suggestive of health effects associated with high concentrations of numerous fine particle components.

In this review, as discussed in the proposal (77 FR 38922 to 38923) and in section III.E.1 below, while most epidemiological studies continue to be indexed by $PM_{2.5}$ mass, several recent epidemiological studies included in the Integrated Science Assessment have used $PM_{2.5}$ speciation data to evaluate health effects associated with fine particle exposures. In the Integrated Science Assessment, the EPA thoroughly evaluated the scientific evidence that examined the effect of different $PM_{2.5}$ components and sources on a variety of health outcomes (U.S. EPA, 2009a, section 6.6) and observed that the available information continues to suggest that many different chemical components of fine particles and a variety of different types of source categories are all associated with, and probably contribute to, effects associated with $PM_{2.5}$. The Integrated Science Assessment concluded that the current body of scientific evidence indicated that ''many constituents of PM can be linked with differing health effects and the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes'' (U.S. EPA, 2009a, p. 2–26 and 6–212). Furthermore, the Policy Assessment concluded that the evidence is not sufficient to support eliminating any component or group of components associated with any specific source categories from the mix of fine particles included in the $PM_{2.5}$ indicator (U.S. EPA, 2009a, p. 2–56). CASAC agreed that it was reasonable to retain $PM_{2.5}$ as an indicator for fine particles in this review as ''[t]here was insufficient peer-reviewed literature to support any other indicator at this time'' (Samet, 2010c, p. 12).

This information is relevant to the Agency's decision to retain $PM_{2.5}$ as the indicator for fine particles as discussed in section III.E.1 below. The EPA also believes that it is relevant to the Agency's conclusion as to whether revision of the suite of primary $PM_{2.5}$ standards is appropriate. While there remain uncertainties about the role and relative toxicity of various components of fine PM, the current evidence continues to support the view that fine particles should be addressed as a group for purposes of public health protection.

In summary, in considering the above issues related to uncertainties in the underlying health science, on balance, the EPA believes that the available evidence interpreted in light of these remaining uncertainties does provide increased confidence relative to the last review in the reported associations between long- and short-term $PM_{2.5}$ exposures and mortality and morbidity effects, alone and in combination with other pollutants, and supports stronger inferences as to the causal nature of the associations. The EPA also believes that this increased confidence, when taken in context of the entire body of available health effects evidence and in light of the evidence from epidemiological studies of associations observed in areas meeting the current primary $PM_{2.5}$ standards, specifically in areas meeting the current primary annual $PM_{2.5}$ standard, adds support to its conclusion that the current suite of $PM_{2.5}$ standards needs to be revised to provide increased public health protection.

(4) In asserting that there is no evidence of greater risk since the 2006

[61] While epidemiological analyses have not identified a population threshold in the range of air quality concentrations evaluated in these studies, the EPA recognizes that it is possible that such thresholds exist towards the lower end of these ranges (or below these ranges).

review to justify lowering the current annual $PM_{2.5}$ standard, some commenters argued that, ''if the current primary $PM_{2.5}$ annual standard of 15 µg/m³ was considered to be adequately protective of public health in 2006, given relative risk estimates that EPA was using at that time, then that standard would surely still be adequately protective of the public health if relative risk estimates remain at the same level (or lower)'' (UARG, 2012, Attachment 1, p. 24). These commenters compared risk coefficients used for mortality in the EPA's risk assessment done in the last review with those from the Agency's core risk assessment done as part of this review, and they concluded that ''the entire range of the core relative risk for long-term mortality is lower now than it was in the prior review'' (UARG, 2012, Attachment 1, p. 24). These commenters used this conclusion as the basis for a claim that there is no reason to revise the current annual $PM_{2.5}$ standard.

The EPA believes that this claim is fundamentally flawed. In comparing the scientific understanding of the risk presented by exposure to $PM_{2.5}$ between the last and current reviews, one must examine not only the quantitative estimate of risk from those exposures (e.g., the numbers of premature deaths or increased hospital admissions at various concentrations), but also the degree of confidence that the Agency has that the observed health effects are causally linked to $PM_{2.5}$ exposure at those concentrations. As documented in the Integrated Science Assessment and in the recommendations and conclusions of CASAC, the EPA recognizes significant advances in our understanding of the health effects of $PM_{2.5}$, based on evidence that is stronger than in the last review. As a result of these advances, the EPA is now more certain that fine particles, alone or in combination with other pollutants, present a significant risk to public health at concentrations allowed by the current primary $PM_{2.5}$ standards. From this more comprehensive perspective, since the risks presented by $PM_{2.5}$ are more certain, similar or even somewhat lower relative risk estimates would not be a basis to conclude that no revision to the suite of $PM_{2.5}$ standards is ''requisite'' to protect public health with an adequate margin of safety. This also ignores that the relative risk estimate is only one factor considered by the Administrator, e.g. it ignores that epidemiological studies since the last review indicate associations between $PM_{2.5}$ and mortality and morbidity in areas meeting the current annual standard.

In any case, the commenters' reliance on the flawed 2006 review is misplaced. As discussed in section III.A.2 above, the D.C. Circuit remanded Administrator Johnson's 2006 decision to retain the primary annual $PM_{2.5}$ standard because the Agency failed to adequately explain why the annual standard provided the requisite protection from both short- and long-term exposure to fine particles including protection for at-risk populations. The 2006 standard was also at sharp odds with CASAC advice and recommendations as to the requisite level of protection (Henderson, 2006a,b). In other words, the 2006 primary annual $PM_{2.5}$ standard is not an appropriate benchmark for comparison.

(5) Some of these commenters also identified ''new'' as well as older studies that had been included in prior reviews as providing additional evidence that the causality determinations presented in the Integrated Science Assessment did not consider the totality of the scientific literature, further supporting their view that a revision of the $PM_{2.5}$ is unwarranted. As discussed in section II.B.3 above, the EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the Integrated Science Assessment that have undergone CASAC and public review, and will consider newly published studies for purposes of decisionmaking in the next PM NAAQS review. In provisionally evaluating commenters' arguments (see Response to Comments document), the EPA notes that its provisional assessment of ''new'' science found that such studies did not materially change the conclusions reached in the Integrated Science Assessment (U.S. EPA, 2012b).

3. Administrator's Final Conclusions Concerning the Adequacy of the Current Primary $PM_{2.5}$ Standards

Having carefully considered the public comments, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of $PM_{2.5}$ reached in the Integrated Science Assessment, and discussed in the Policy Assessment, are valid. In considering whether the suite of primary $PM_{2.5}$ standards should be revised, the Administrator places primary consideration on the evidence obtained from the epidemiological studies. The Administrator believes that this literature, combined with the other scientific evidence discussed in the Integrated Science Assessment, collectively represents a strong and generally robust body of evidence of serious health effects associated with both long- and short-term exposures to $PM_{2.5}$. As discussed in the Integrated Science Assessment and Policy Assessment, the EPA believes that much progress has been made since the last review in reducing some of the major uncertainties that were important considerations in establishing the current suite of $PM_{2.5}$ standards. In that context, the Administrator finds the evidence of serious health effects reported in exposure studies conducted in areas with long-term mean concentrations ranging from approximately at or above the level of the annual standard to long-term mean concentrations significantly below the level of the annual standard to be compelling, especially in light of the extent to which such studies are part of an overall pattern of positive and frequently statistically significant associations across a broad range of studies. The information in the quantitative risk assessment lends support to this conclusion.

There has been extensive critical review of this body of evidence, the quantitative risk assessment, and related uncertainties, including review by CASAC and the public. The public comments on the basis for the EPA's proposed decision to revise the suite of primary $PM_{2.5}$ standards have identified a number of issues about which different parties disagree including issues for which additional research is warranted. Having weighed all comments and the advice of CASAC, the Administrator believes that since the last review the overall uncertainty about the public health risks associated with both long- and short-term exposure to $PM_{2.5}$ has been diminished to an important degree. The remaining uncertainties in the available evidence do not diminish confidence in the associations between exposure to fine particles and mortality and serious morbidity effects. Based on her increased confidence in the association between exposure to $PM_{2.5}$ and serious public health effects, combined with evidence of such an association in areas that would meet the current standards, the Administrator agrees with CASAC that revision of the current suite of $PM_{2.5}$ standards to provide increased public health protection is necessary. Based on these considerations, the Administrator concludes that the current suite of primary $PM_{2.5}$ standards is not sufficient, and thus not requisite, to protect public health with an adequate margin of safety, and that revision is needed to increase public health protection.

It is important to note that this conclusion, and the reasoning on which it is based, do not resolve the question of what specific revisions are appropriate. That requires looking specifically at the current 24-hour and annual $PM_{2.5}$ standards, including their indicator, averaging times, forms, and levels, and evaluating the scientific evidence and other information relevant to determining the appropriate revision of the suite of standards.

E. Conclusions on the Elements of the Primary Fine Particle Standards

1. Indicator

In initially setting standards for fine particles in 1997, the EPA concluded it was appropriate to control fine particles as a group, rather than singling out any particular component or class of fine particles. The EPA noted that community health studies had found significant associations between various indicators of fine particles, and that health effects in a large number of areas had significant mass contributions of differing components or sources of fine particles. In addition, a number of toxicological and controlled human exposure studies had reported health effects associations with high concentrations of numerous fine particle components. It was also not possible to rule out any component within the mix of fine particles as not contributing to the fine particle effects found in the epidemiologic studies (62 FR 38667, July 18, 1977). In establishing a size-based indicator in 1977 to distinguish fine particles from particles in the coarse mode, the EPA noted that the available epidemiological studies of fine particles were based largely on $PM_{2.5}$ and also considered monitoring technology that was generally available. The selection of a 2.5 µm size cut reflected the regulatory importance of defining an indicator that would more completely capture fine particles under all conditions likely to be encountered across the U.S., especially when fine particle concentrations and humidity are likely to be high, while recognizing that some small coarse particles would also be captured by current methods to monitor $PM_{2.5}$ (62 FR 38666 to 38668, July 18, 1997). In the last review, based on the same considerations, the EPA again recognized that the available information supported retaining the $PM_{2.5}$ indicator and remained too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components associated with any source categories of fine particles (71 FR 61162 to 61164, October 17, 2006).

In this current review, the same considerations continue to apply for selection of an appropriate indicator for fine particles. As an initial matter, the Policy Assessment recognizes that the available epidemiological studies linking mortality and morbidity effects with long- and short-term exposures to fine particles continue to be largely indexed by $PM_{2.5}$. For the same reasons discussed in the last two reviews, the Policy Assessment concluded that it was appropriate to consider retaining a $PM_{2.5}$ indicator to provide protection from effects associated with long- and short-term fine particle exposures (U.S. EPA, 2011a, p. 2–50).

The Policy Assessment also considered the expanded body of evidence available in this review to consider whether there was sufficient evidence to support a separate standard for ultrafine particles [62] or whether there was sufficient evidence to establish distinct standards focused on regulating specific $PM_{2.5}$ components or a group of components associated with any source categories of fine particles (U.S. EPA, 2011a, section 2.3.1).

A number of studies available in this review have evaluated potential health effects associated with short-term exposures to ultrafine particles. As noted in the Integrated Science Assessment, the enormous number and larger, collective surface area of ultrafine particles are important considerations for focusing on this particle size fraction in assessing potential public health impacts (U.S. EPA, 2009a, p. 6–83). Per unit mass, ultrafine particles may have more opportunity to interact with cell surfaces due to their greater surface area and their greater particle number compared with larger particles (U.S. EPA, 2009a, p. 5–3). Greater surface area also increases the potential for soluble components (e.g., transition metals, organics) to adsorb to ultrafine particles and potentially cross cell membranes and epithelial barriers (U.S. EPA, 2009a, p. 6–83). In addition, evidence available in this review suggests that the ability of particles to enhance allergic sensitization is associated more strongly with particle number and surface area than with particle mass (U.S. EPA, 2009a, p. 6–127).

New evidence, primarily from controlled human exposure and toxicological studies, expands our understanding of cardiovascular and respiratory effects related to short-term ultrafine particle exposures. However, the Policy Assessment concluded that this evidence was still very limited and largely focused on exposure to diesel exhaust, for which the Integrated Science Assessment concluded it was unclear whether the effects observed are due to ultrafine particles, larger particles within the $PM_{2.5}$ mixture, or the gaseous components of diesel exhaust (U.S. EPA, 2009a, p. 2–22). In addition, the Integrated Science Assessment noted uncertainties associated with the controlled human exposure studies using concentrated ambient particle systems which have been shown to modify the composition of ultrafine particles (U.S. EPA, 2009a, p. 2–22, see also section 1.5.3).

The Policy Assessment recognized that there are relatively few epidemiological studies that have examined potential cardiovascular and respiratory effects associated with short-term exposures to ultrafine particles (U.S. EPA, 2011a, p. 2–51). These studies have reported inconsistent and mixed results (U.S. EPA, 2009a, section 2.3.5).

Collectively, in considering the body of scientific evidence available in this review, the Integrated Science Assessment concluded that the currently available evidence was suggestive of a causal relationship between short-term exposures to ultrafine particles and cardiovascular and respiratory effects. Furthermore, the Integrated Science Assessment concluded that evidence was inadequate to infer a causal relationship between short-term exposure to ultrafine particles and mortality as well as long-term exposure to ultrafine particles and all outcomes evaluated (U.S. EPA, 2009a, sections 2.3.5, 6.2.12.3, 6.3.10.3, 6.5.3.3, 7.2.11.3, 7.3.9, 7.4.3.3, 7.5.4.3, and 7.6.5.3; Table 2–6).

With respect to our understanding of ambient ultrafine particle concentrations, at present, there is no national network of ultrafine particle samplers; thus, only episodic and/or site-specific data sets exist (U.S. EPA, 2009a, p. 2–2). Therefore, the Policy Assessment recognized a national characterization of concentrations, temporal and spatial patterns, and trends was not possible at this time, and the availability of ambient ultrafine measurements to support health studies was extremely limited (U.S. EPA, 2011a, p. 2–51). In general, measurements of ultrafine particles are highly dependent on monitor location and, therefore, more subject to exposure error than

[62] Ultrafine particles, generally including particles with a mobility diameter less than or equal to 0.1 µm, are emitted directly to the atmosphere or are formed by nucleation of gaseous constituents in the atmosphere (U.S. EPA, 2009a, p. 3–3).

accumulation mode particles (U.S. EPA, 2009a, p. 2–22). Furthermore, the number of ultrafine particles generally decreases sharply downwind from sources, as ultrafine particles may grow into the accumulation mode by coagulation or condensation (U.S. EPA, 2009a, p. 3–89). Limited studies of ambient ultrafine particle measurements have suggested that these particles exhibit a high degree of spatial and temporal heterogeneity driven primarily by differences in nearby source characteristics (U.S. EPA, 2009a, p. 3–84). Internal combustion engines and, therefore, roadways are a notable source of ultrafine particles, so concentrations of these particles near roadways are generally expected to be elevated (U.S. EPA, 2009a, p. 2–3). Concentrations of ultrafine particles have been reported to drop off much more quickly with distance from roadways than fine particles (U.S. EPA, 2009a, p. 3–84).

In considering both the currently available health effects evidence and the air quality data, the Policy Assessment concluded that this information was still too limited to provide support for consideration of a distinct PM standard for ultrafine particles (U.S. EPA, 2011a, p. 2–52).

In addressing the issue of particle composition, the Integrated Science Assessment concluded that, ''[f]rom a mechanistic perspective, it is highly plausible that the chemical composition of PM would be a better predictor of health effects than particle size'' (U.S. EPA, 2009a, p. 6–202). Heterogeneity of ambient concentrations of $PM_{2.5}$ constituents (e.g., elemental carbon, organic carbon, sulfates, nitrates) observed in different geographical regions as well as regional heterogeneity in $PM_{2.5}$-related health effects reported in a number of epidemiological studies are consistent with this hypothesis (U.S. EPA, 2009a, section 6.6).

With respect to the availability of ambient measurement data for fine particle components in this review, the Policy Assessment noted that there were now more extensive ambient $PM_{2.5}$ speciation measurement data available through the Chemical Speciation Network (CSN) than in previous reviews (U.S. EPA, 2011a, section 1.3.2 and Appendix B, section B.1.3). The Integrated Science Assessment observed that data from the CSN provided further evidence of spatial and seasonal variation in both $PM_{2.5}$ mass and composition among cities and geographic regions (U.S. EPA, 2009a, pp. 3–50 to 3–60; Figures 3–12 to 3–18; Figure 3–47). Some of this variation may be related to regional differences in meteorology, sources, and topography (U.S. EPA, 2009a, p. 2–3).

The currently available epidemiological, toxicological, and controlled human exposure studies evaluated in the Integrated Science Assessment on the health effects associated with ambient $PM_{2.5}$ constituents and categories of fine particle sources used a variety of quantitative methods applied to a broad set of $PM_{2.5}$ constituents, rather than selecting a few constituents a priori (U.S. EPA, 2009a, p. 2–26). Epidemiological studies have used measured ambient $PM_{2.5}$ speciation data, including monitoring data from the CSN, while all of the controlled human exposure and most of the toxicological studies have used concentrated ambient particles and analyzed the constituents therein (U.S. EPA, 2009a, p. 6–203).[63] The CSN provides $PM_{2.5}$ speciation measurements generally on a one-in-three or one-in-six day sampling schedule and, thus, does not capture data every day at most sites.[64]

The Policy Assessment recognized that several new multi-city studies evaluating short-term exposures to fine particle constituents are now available. These studies continued to show an association between mortality and cardiovascular and/or respiratory morbidity effects and short-term exposures to various $PM_{2.5}$ components including nickel, vanadium, elemental carbon, organic carbon, nitrates, and sulfates (U.S. EPA, 2011a, section 2.3.1; U.S. EPA, 2009a, sections 6.5.2.5 and 6.6).

Limited evidence is available to evaluate the health effects associated with long-term exposures to $PM_{2.5}$ components (U.S. EPA, 2009a, section 7.6.2). The Policy Assessment noted the most significant new evidence was provided by a study that evaluated multiple $PM_{2.5}$ components and an indicator of traffic density in an assessment of health effects related to long-term exposure to $PM_{2.5}$ (Lipfert *et al.,* 2006a). Using health data from a cohort of U.S. military veterans and $PM_{2.5}$ measurement data from the CSN, Lipfert *et al.* (2006a) reported positive associations between mortality and long-term exposures to nitrates, elemental carbon, nickel, and vanadium as well as traffic density and peak ozone concentrations (U.S. EPA, 2011a, p. 2–54; U.S. EPA, 2009a, pp. 7–89 to 7–90).

With respect to source categories of fine particles potentially associated with a range of health endpoints, the Integrated Science Assessment reported that the currently available evidence suggests associations between cardiovascular effects and a number of specific $PM_{2.5}$-related source categories, including oil combustion, wood or biomass burning, motor vehicle emissions, and crustal or road dust sources (U.S. EPA, 2009a, section 6.6; Table 6–18). In addition, a few studies have evaluated associations between $PM_{2.5}$-related source categories and mortality. For example, one study reported an association between mortality and a $PM_{2.5}$ coal combustion factor (Laden *et al.,* 2000), while other studies linked mortality to a secondary sulfate long-range transport $PM_{2.5}$ source (Ito *et al.,* 2006; Mar *et al.,* 2006) (U.S. EPA, 2009a, section 6.6.2.1). Other studies have looked at different components of particulate matter. There was less consistency in associations observed between selected sources of fine particles and respiratory health endpoints, which may be partially due to the fact that fewer studies have evaluated respiratory-related outcomes and measures. However, there was some evidence for $PM_{2.5}$-related associations with secondary sulfate and decrements in lung function in asthmatic and healthy adults (U.S. EPA, 2009a, p. 6–211; Gong *et al.,* 2005; Lanki *et al.,* 2006). A couple of studies have observed an association between respiratory endpoints in children and adults with asthma and surrogates for the crustal/soil/road dust and traffic sources of PM (U.S. EPA, 2009a, p. 6–205; Gent *et al.,* 2009; Penttinen *et al.,* 2006).

Recent studies have shown that source apportionment methods have the potential to add useful insights into which sources and/or PM constituents may contribute to different health effects. Of particular interest are several epidemiological studies that compared source apportionment methods and reported consistent results across research groups (U.S. EPA, 2009a, p. 6–211; Hopke *et al.,* 2006; Ito *et al.,* 2006; Mar *et al.,* 2006; Thurston *et al.,* 2005).

[63] Most studies considered between 7 to 20 ambient $PM_{2.5}$ constituents, with elemental carbon, organic carbon, sulfates, nitrates, and metals most commonly measured. Many of the studies grouped the constituents with various factorization or source apportionment techniques to examine the relationship between the grouped constituents and various health effects. However, not all studies labeled the constituent groupings according to their presumed source and a small number of controlled human exposure and toxicological studies did not use any constituent grouping. These differences across studies substantially limit any integrative interpretation of these studies (U.S. EPA, 2009a, p. 6–203).

[64] To expand our understanding of the role of specific $PM_{2.5}$ components and sources with respect to the observed health effects, researchers have expressed a strong interest in having access to $PM_{2.5}$ speciation measurements collected more frequently (U.S. EPA, 2011a, p. 2–53, including footnote 47).

These studies reported associations between total mortality and secondary sulfate in two cities for two different lag times. The sulfate effect was stronger for total mortality in Washington, DC and for cardiovascular-related mortality in Phoenix (U.S. EPA, 2009a, p. 6–204). These studies also found some evidence for associations with mortality and a number of source categories (e.g., biomass/wood combustion, traffic, copper smelter, coal combustion, sea salt) at various lag times (U.S. EPA, 2009a, p. 6–204). Sarnat *et al.* (2008) compared three different source apportionment methods and reported consistent associations between emergency department visits for cardiovascular diseases with mobile sources and biomass combustion as well as increased respiratory-related emergency department visits associated with secondary sulfate (U.S. EPA, 2009a, pp. 6–204 and 6–211).

Collectively, in considering the currently available evidence for health effects associated with specific $PM_{2.5}$ components or groups of components associated with any source categories of fine particles as presented in the Integrated Science Assessment, the Policy Assessment concluded that additional information available in this review continues to provide evidence that many different constituents of the fine particle mixture as well as groups of components associated with specific source categories of fine particles are linked to adverse health effects (U.S. EPA, 2011a, p. 2–55). However, as noted in the Integrated Science Assessment, while ''[t]here is some evidence for trends and patterns that link particular ambient PM constituents or sources with specific health outcomes * * * there is insufficient evidence to determine whether these patterns are consistent or robust'' (U.S. EPA, 2009a, p. 6–210). Assessing this information, the Integrated Science Assessment concluded that ''the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes'' (U.S. EPA, 2009a, pp. 2–26 and 6–212). Therefore, the Policy Assessment concluded that the currently available evidence is not sufficient to support consideration of a separate indicator for a specific $PM_{2.5}$ component or group of components associated with any source category of fine particles. Furthermore, the Policy Assessment concluded that the evidence is not sufficient to support eliminating any component or group of components associated with any source categories of fine particles from the mix of fine particles included in the $PM_{2.5}$ indicator (U.S. EPA, 2011a, p. 2–56).

The CASAC agreed with the EPA staff conclusions presented in the Policy Assessment and concluded that it is appropriate to consider retaining $PM_{2.5}$ as the indicator for fine particles and further asserted, ''There [is] insufficient peer-reviewed literature to support any other indicator at this time'' (Samet, 2010c, p. 12). CASAC expressed a strong desire for the EPA to ''look ahead to future review cycles and reinvigorate support for the development of evidence that might lead to newer indicators that may correlate better with the health effects associated with ambient air concentrations of PM * * *'' (Samet, 2010c, p 2).

Consistent with the staff conclusions presented in the Policy Assessment and CASAC advice, the Administrator proposed to retain $PM_{2.5}$ as the indicator for fine particles. Further, the Administrator provisionally concluded that currently available scientific information does not provide a sufficient basis for supplementing mass-based, primary fine particle standards with standards using a separate indicator for ultrafine particles or a separate indicator for a specific $PM_{2.5}$ component or group of components associated with any source categories of fine particles. In addition, the Administrator also provisionally concluded that the currently available scientific information did not provide a sufficient basis for eliminating any individual component or group of components associated with any source categories from the mix of fine particles included in the $PM_{2.5}$ mass-based indicator.

The EPA received comparatively few public comments on issues related to the indicator for fine particles.[65] Some commenters emphasized the need to conduct additional research to more fully understand the effect of specific $PM_{2.5}$ components and/or sources on public health. These commenters expressed views about the importance of evaluating health effect associations with various fine particle components and types of source categories as a basis for focusing ongoing and future research to reduce uncertainties in this area and for considering whether alternative indicator(s) may be appropriate to consider in future PM NAAQS reviews for standards intended to protect against the array of health effects that have been associated with fine particles as indexed by $PM_{2.5}$. For example, the PSR encouraged more research and monitoring related to $PM_{2.5}$ components and noted the importance of components associated with coal combustion (PSR, 2012, pp. 5 to 6). EPRI asserted that ''new'' studies support focusing on EC and OC and encouraged the EPA to seriously consider the mass-based approach (EPRI, 2012, p. 2). Likewise, Georgia Mining Association supported additional monitoring and research efforts related to $PM_{2.5}$ composition and specifically encouraged the evaluation of using particle number (e.g., particle count) (GMA, 2012, pp. 2 to 3).

The Administrator agrees with CASAC as well as these commenters that the results of additional research and monitoring efforts will be helpful for informing future PM NAAQS reviews. Information from such studies could also help inform the development of strategies that emphasize control of specific types of emission sources so as to address particles of greatest concern to public health. However, based upon the scientific information considered in the Integrated Science Assessment as well as the public comments summarized above, the Administrator continues to take note there is evidence that many different constituents of the fine particle mixture as well as groups of components associated with specific sources of fine particles are linked to adverse health effects. Furthermore, she recognizes that the evidence is not yet sufficient to differentiate those constituents or sources that are most closely related to specific health outcomes nor to exclude any $PM_{2.5}$ components or sources of fine particles from the mix of particles included in the $PM_{2.5}$ indicator.

Having considered the public comments on this issue, the Administrator concurs with the Policy Assessment conclusions and CASAC recommendations and concludes that it is appropriate to retain $PM_{2.5}$ as the indicator for fine particles.

2. Averaging Time

In 1997, the EPA initially set both an annual standard, to provide protection from health effects associated with both long- and short-term exposures to $PM_{2.5}$, and a 24-hour standard to supplement the protection afforded by the annual standard (62 FR 38667 to 38668, July, 18, 1997). In the last review, the EPA retained both annual and 24-hour averaging times (71 FR 61164, October 17, 2006). These decisions were based, in part, on evidence of health effects related to both long-term (from a year to several years) and short-term (from less than one day to up to several days) measures of $PM_{2.5}$.

[65] No public comments were submitted regarding the use of a different size cut for fine particles.

The overwhelming majority of studies conducted since the last review continue to utilize annual (or multi-year) and 24-hour averaging times, reflecting the averaging times of the current $PM_{2.5}$ standards. These studies continue to provide evidence that health effects are associated with annual and 24-hour averaging times. Therefore, the Policy Assessment concluded it is appropriate to retain the current annual and 24-hour averaging times to provide protection from effects associated with both long- and short-term $PM_{2.5}$ exposures (U.S. EPA, 2011a, p. 2–57).

In considering whether the information available in this review supports consideration of different averaging times for $PM_{2.5}$ standards specifically with regard to considering a standard with an averaging time less than 24 hours to address health effects associated with sub-daily $PM_{2.5}$ exposures, the Policy Assessment noted there continues to be a growing body of studies that provide additional evidence of effects associated with exposure periods less than 24-hours (U.S. EPA, 2011a, p. 2–57). Relative to information available in the last review, recent studies provide additional evidence for cardiovascular effects associated with sub-daily (e.g., one to several hours) exposure to PM, especially effects related to cardiac ischemia, vasomotor function, and more subtle changes in markers of systemic inflammation, hemostasis, thrombosis and coagulation (U.S. EPA, 2009a, section 6.2). Because these studies have used different indicators (e.g., $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$, ultrafine particles), averaging times (e.g., 1, 2, and 4 hours), and health outcomes, it is difficult to draw conclusions about cardiovascular effects associated specifically with sub-daily exposures to $PM_{2.5}$.

With regard to respiratory effects associated with sub-daily $PM_{2.5}$ exposures, the currently available evidence was much sparser than for cardiovascular effects and continues to be very limited. The Integrated Science Assessment concluded that for several studies of hospital admissions or medical visits for respiratory diseases, the strongest associations were observed with 24-hour average or longer exposures, not with less than 24-hour exposures (U.S. EPA, 2009a, section 6.3).

Collectively, the Policy Assessment concluded that this information, when viewed as a whole, is too unclear, with respect to the indicator, averaging time and health outcome, to serve as a basis for consideration of establishing a primary $PM_{2.5}$ standard with an averaging time shorter than 24-hours at this time (U.S. EPA, 2011a, p. 2–57).

With regard to health effects associated with $PM_{2.5}$ exposure across varying seasons in this review, Bell *et al.* (2008) reported higher $PM_{2.5}$ risk estimates for hospitalization for cardiovascular and respiratory diseases in the winter compared to other seasons. In comparison to the winter season, smaller statistically significant associations were also reported between $PM_{2.5}$ and cardiovascular morbidity for spring and autumn, and a positive, but statistically non-significant association was observed for the summer months. In the case of mortality, Zanobetti and Schwartz (2009) reported a 4-fold higher effect estimate for $PM_{2.5}$-associated mortality for the spring as compared to the winter. Taken together, these results provided emerging but limited evidence that individuals may be at greater risk of dying from higher exposures to $PM_{2.5}$ in the warmer months and may be at greater risk of $PM_{2.5}$-associated hospitalization for cardiovascular and respiratory diseases during colder months of the year (U.S. EPA, 2011a, p. 2–58).

Overall, the Policy Assessment observed that there are few studies presently available to deduce a general pattern in $PM_{2.5}$-related risk across seasons. In addition, these studies utilized 24-hour exposure periods within each season to assess the $PM_{2.5}$-associated health effects and do not provide information on health effects associated with a season-long exposure to $PM_{2.5}$. Due to these limitations in the currently available evidence, the Policy Assessment concluded that there was no basis to consider a seasonal averaging time separate from a 24-hour averaging time.

Based on the above considerations, the Policy Assessment concluded that the currently available information provided strong support for consideration of retaining the current annual and 24-hour averaging times but does not provide support for considering alternative averaging times (U.S. EPA, 2011a, p. 2–58). In addition, CASAC considered it appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$ standards (Samet, 2010c, pp. 2 to 3). At the time of the proposal, the Administrator concurred with the staff conclusions and CASAC advice and proposed that the averaging times for the primary $PM_{2.5}$ standards should continue to include annual and 24-hour averages to protect against health effects associated with long- and short-term exposures. Furthermore, the Administrator provisionally concluded, consistent with conclusions reached in the Policy Assessment and by CASAC, that the currently available information was too limited to support consideration of alternative averaging times to establish a national standard with a shorter-than 24-hour averaging time or with a seasonal averaging time.

The EPA received no significant public comments on the issue of averaging time for the $PM_{2.5}$ primary standards. The Administrator concurs with recommendations made by CASAC and the staff conclusions presented in the Policy Assessment and concludes, as proposed, that it is appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$ standards to protect against health effects associated with long- and short-term exposure periods.

3. Form

The ''form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard. In this review, the EPA considers whether currently available information supports retaining or revising the forms for the annual or 24-hour $PM_{2.5}$ standards.

a. Annual Standard

In 1997, the EPA established the form of the annual $PM_{2.5}$ standard as an annual arithmetic mean, averaged over 3 years, from single or multiple community-oriented monitors. This form was intended to represent a relatively stable measure of air quality and to characterize longer-term area-wide $PM_{2.5}$ concentrations, in conjunction with a 24-hour standard designed to provide adequate protection against localized peak or seasonal $PM_{2.5}$ concentrations. The level of the standard was to be compared to measurements made at each community-oriented monitoring site, or, if specific criteria were met, measurements from multiple community-oriented monitoring sites could be averaged (i.e., spatial averaging)[66] (62 FR 38671 to 38672, July 18, 1997). The constraints were intended to ensure that spatial averaging would not result in inequities in the level of protection provided by the standard (62 FR 38672, July 18, 1997). This approach was consistent with the epidemiological studies on which the $PM_{2.5}$ standard was primarily based, in which air quality data were generally averaged across multiple monitors in an

[66] Spatial averaging as part of the form of the annual $PM_{2.5}$ standard is unique to this standard and is not used with other PM standards nor with other NAAQS.

area or were taken from a single monitor that was selected to represent community-wide exposures.

In the last review, the EPA tightened the criteria for use of spatial averaging to provide increased protection for vulnerable populations exposed to $PM_{2.5}$. This change was based in part on an analysis of the potential for disproportionate impacts on potentially at-risk populations, which found that the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding population is more likely to have lower education and income levels and higher percentages of minority populations (71 FR 61166/2, October 17, 2006; U.S. EPA, 2005, section 5.3.6.1).

In this review, as outlined in section III.B above and discussed more fully in section III.B.3 of the proposal, there now exist more health data such that the Integrated Science Assessment has identified persons from lower socioeconomic strata as an at-risk population (U.S. EPA, 2009a, section 8.1.7; U.S. EPA, 2011a, section 2.2.1). Moreover, there now exist more years of $PM_{2.5}$ air quality data than were available in the last review. Consideration in the Policy Assessment of the spatial variability across urban areas that was revealed by this expanded data base has raised questions as to whether an annual standard that allows for spatial averaging, even within specified constraints as narrowed in 2006 (71 FR 61165 to 61167, October 17, 2006), would provide appropriate public health protection.

In considering the potential for disproportionate impacts on at-risk populations, the Policy Assessment considered an update of an air quality analysis conducted for the last review (U.S. EPA, 2011a, pp. 2–59 to 60; Schmidt, 2011, Analysis A). This analysis focused on determining whether the spatial averaging provisions, as modified in 2006, could introduce inequities in protection for at-risk populations exposed to $PM_{2.5}$. Specifically, the Policy Assessment considered whether persons of lower socioeconomic status, minority groups, or different age groups (i.e., children or older adults) are more likely than the general population to live in areas in which the monitors recording the highest air quality values in an area are located. Data used in this analysis included demographic parameters measured at the Census Block or Census Block Group level, including percent minority population, percent minority subgroup population, percent of persons living below the poverty level, percent of persons 18 years of age or older, and percent of persons 65 years of age and older. In each candidate geographic area, data from the Census Block(s) or Census Block Group(s) surrounding the location of the monitoring site (as delineated by radii buffers of 0.5, 1.0, 2.0, and 3.0 miles) in which the highest air quality value was monitored were compared to the average of monitored values in the area. This analysis looked beyond areas that would meet the current spatial averaging criteria and considered all urban areas (i.e., Core Based Statistical Areas or CBSAs) with at least two valid annual design value monitors (Schmidt, 2011, Analysis A). Recognizing the limitations of such cross-sectional analyses, the Policy Assessment observed that the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding populations are more likely to live below the poverty line and to have higher percentage of minorities (U.S. EPA, 2011a, p. 2–60).

Based upon the analysis described above, the Policy Assessment concluded that the existing constraints on spatial averaging, as modified in 2006, may be inadequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on at-risk populations of persons with lower SES levels as well as minorities. Therefore, the Policy Assessment concluded that it was appropriate to consider revising the form of the annual $PM_{2.5}$ standard such that it did not allow for the use of spatial averaging across monitors. In doing so, the level of the annual $PM_{2.5}$ standard would be compared to measurements made at the monitoring site that represents area-wide air quality recording the highest $PM_{2.5}$ concentrations[67] (U.S. EPA, 2011a, p. 2–60).

The CASAC agreed with staff conclusions that it was ''reasonable'' for the EPA to eliminate the spatial averaging provisions (Samet, 2010d, p. 2). Further, in CASAC's comments on the first draft Policy Assessment, it noted, ''Given mounting evidence showing that persons with lower SES levels are a susceptible group for PM-related health risks, CASAC recommends that the provisions that allow for spatial averaging across monitors be eliminated for the reasons cited in the (first draft) Policy Assessment'' (Samet, 2010c, p. 13). In its review of the second draft Policy Assessment, CASAC recognized ''although much of the epidemiological research has been conducted using community-wide averages, several key studies reference the nearest measurement site, so that some risk estimates are not necessarily biased by the averaging process. Further, the number of such studies is likely to expand in the future'' (Samet, 2010d, pp. 1 to 2).

Only two areas in the country used the initial spatial averaging provisions for demonstrating attainment with the primary annual $PM_{2.5}$ standard set in 1997 (70 FR 19847, April 14, 2005; U.S. EPA, 2006c). Since these provisions were tightened in 2006, no area has used spatial averaging to demonstrate attainment. No areas in the country are currently using the spatial averaging provisions to demonstrate attainment with the current primary annual $PM_{2.5}$ standard.

In considering the Policy Assessment's conclusions based on the results of the analysis discussed above and concern over the evidence of potential disproportionate impacts on at-risk populations as well as CASAC advice, the Administrator proposed to revise the form of the annual $PM_{2.5}$ standard to eliminate the use of spatial averaging. Thus, the Administrator proposed revising the form of the annual $PM_{2.5}$ standard to compare the level of the standard with measurements from each ''appropriate'' monitor in an area[68] with no allowance for spatial averaging. Thus, for an area with multiple monitors, the appropriate reporting monitor with the highest design value would determine the attainment status for that area.

Of the commenters noted in section III.D.2 above who supported a more stringent annual $PM_{2.5}$ standard, those who commented on the form of the annual $PM_{2.5}$ standard supported the EPA's proposal to eliminate the spatial averaging provisions. These commenters contended that the EPA's analyses of the potential impacts of spatial averaging, discussed above and in the proposal (77 FR 38924), demonstrated that the current form results in uneven public health protection leading to disproportionate impacts on at-risk populations. Specifically, the ALA and other environmental and public health commenters contended that ''spatial averaging allows exposure of people to unhealthy levels of pollution at specific locales even within an area meeting the standard'' (ALA *et al.,* 2012, p. 23).

[67] As discussed in section VIII.B.1 below, the EPA is revising several terms associated with $PM_{2.5}$ monitor placement. Specifically, the EPA is revoking the term ''community-oriented'' and replacing it with the term ''area-wide'' monitoring.

[68] As discussed in section VIII.B.2.b below, the EPA concludes that $PM_{2.5}$ monitoring sites at micro- and middle-scale locations are comparable to the annual standard if the monitoring site has been approved by the Regional Administrator as representing an area-wide location.

These commenters particularly focused on the importance for low-income and minority populations of eliminating the spatial averaging provisions. They concluded that spatial averaging ''is an environmental justice concern because poor people are more likely to live near roads, depots, factories, ports, and other pollution sources.'' *Id.* p. 24.

Other commenters (e.g., AAM, 2012; Dow, 2012) also supported the elimination of spatial averaging in order to ''avoid potential disproportionate impacts on at-risk populations'' and to maximize ''the benefits to public health of reducing the annual $PM_{2.5}$ standard.'' However, these groups expressed concern that the elimination of spatial averaging, in combination with the requirement for near road monitors (as discussed in section VIII.B.3.b.i of the proposal), would effectively and inappropriately increase the stringency of the annual $PM_{2.5}$ standard.

This concern was also shared by other commenters who disagreed with the elimination of spatial averaging. For example, the Class of '85 RRG emphasized concerns about increasing the stringency of the standard while providing few health benefits if spatial averaging is eliminated, particularly in combination with the requirement for near-road monitors. These commenters contended that ''[b]ecause EPA proposes to use the readings from the highest single worst case monitor (rather than the average of all community area monitors), and since roadway monitoring locations will likely be worst case monitors, the proposed NAAQS will become more stringent without targeting the $PM_{2.5}$ species most harmful to human health'' (Class of '85 RRG, 2012, p. 6).

Several commenters also maintained that because spatial averaging is consistent with how air quality data are considered in the underlying epidemiological studies, such averaging should not be eliminated. Specifically, commenters including NAM *et al.,* AFPM, and ACC pointed out that $PM_{2.5}$ epidemiological studies use spatially averaged multi-monitor concentrations, rather than the single highest monitor, when evaluating health effects. Therefore, these commenters contended that allowing spatial averaging would make the $PM_{2.5}$ standard more consistent with the approaches used in the epidemiological studies upon which the standard is based. In addition, some commenters also contended that the EPA failed to consider whether modifying, rather than eliminating, the constraints on spatial averaging would have been sufficient to protect the public health. If so, these commenters argued that ''elimination of spatial averaging would go beyond what is requisite to protect the public health'' (NAM *et al.,* 2012, p. 20).

In considering the public comments on the form of the annual standard, the EPA recognizes a number of commenters agreed with the basis for the EPA's proposal to eliminate spatial averaging. While other commenters expressed disagreement or concern with the proposed decision to eliminate the spatial averaging provisions, the Agency notes that these commenters did not challenge the analyses or considerations that provided the fundamental basis for the Administrator's proposed decision. Rather, these commenters generally raised concerns that eliminating the option for spatial averaging would increase the stringency of the standard, especially in light of additional monitoring sites in near-road environments (as discussed in section VIII.B.3.b.1 below).

The EPA does not agree with the comment that siting some monitors in near roadway environments makes the standard more stringent or impermissibly more stringent. As discussed in section VIII.B.3.b.i below, a significant fraction of the population lives in proximity to major roads, and these exposures occur in locations that represent ambient air. Monitoring in such areas does not make the standard more stringent than warranted, but rather affords the intended protection to the exposed populations, among them at-risk populations, exposed to fine particles in these areas. Thus, in cases where monitors in near roadway environments are deemed to be representative of area-wide air quality they would be compared to the annual standard (as discussed more fully in section VIII below). The 24-hour and annual NAAQS are designed to protect the public with an adequate margin of safety, and this siting provision is fully consistent with providing the protection the standard is designed to provide and does not make the standard more stringent or more stringent than necessary.

Monitors that are representative of area-wide air quality may be compared to the annual standard. This is consistent with the use of monitoring data in the epidemiological studies that provide the primary basis for determining the level of the annual standard. In addition, the EPA notes that the annual standard is designed to protect against both long- and short-term exposures through controlling the broad distribution of air quality across an area over time.[69] It is fully consistent with the protection the standard is designed to provide for near road monitors to be compared to the annual standard if the monitor is representative of area-wide air quality. This does not make the standard either more stringent or impermissibly more stringent.

In further considering these comments, the EPA notes that the stringency or level of protection provided by each NAAQS is not based solely on the form of the standard; rather, the four elements of the standard that together serve to define each standard (i.e., indicator, averaging time, form, and level) must be considered collectively in evaluating the protection afforded by each standard. Therefore, the EPA considers these comments are also appropriate to discuss collectively with other issues related to the appropriate level for annual standard, and are discussed below in sections III.E.4.c–d.

In reaching a final decision on the form of the annual standard, the Administrator considers the available analyses, CASAC advice, and public comments on form as discussed above. She also considers related issues in the public comments on the level of the annual standard as discussed in section III.E.4.c below. She notes that even when the annual $PM_{2.5}$ standard was first set in 1997, the spatial averaging provisions included constraints intended to ensure that inequities in the level of protection would not result. These constraints on spatial averaging were tightened in the last review, based on an analysis showing the potential for spatial averaging to allow higher $PM_{2.5}$ concentrations in locations where subgroups within the general population were potentially disproportionately exposed and hence, at disproportionate risk (e.g., low income and minority communities). The Administrator notes that in proposing to eliminate spatial averaging altogether in this review, she has relied on further analyses in the current review (Schmidt, 2011, Analysis A). As discussed above and in the proposal (77 FR 38924), these analyses showed that the current constraints on spatial averaging may be inadequate in some areas to avoid substantially greater exposures for people living near monitors recording the highest $PM_{2.5}$ concentrations. Such exposures could result in

[69] This is in contrast to the 24-hour standard which is designed to provide supplemental protection, addressing peak exposures that might not otherwise be addressed by the annual standard. Consistent with this, monitors are not required to be representative of area-wide air quality to be compared to the 24-hour standard.

disproportionate impacts to at-risk populations, including low-income populations as well as minority groups.

On this basis, the Administrator concludes that public health would not be protected with an adequate margin of safety in all locations, as required by law, if disproportionately higher exposure concentrations in at-risk populations such as low income communities as well as minority communities were averaged together with lower concentrations measured at other sites in a large urban area. See *ALA* v. *EPA,* 134 F. 3d 388, 389 (D.C. Cir., 1998) (''this court has held that 'NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children,' and 'if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard''') and *Coalition of Battery Recyclers Association* v. *EPA,* 604 F 3d. 613, 617 (D.C. Cir., 2010) (''Petitioners' assertion that the revised lead NAAQS is overprotective because it is more stringent than necessary to protect the entire population of young U.S. children ignores that the Clean Air Act allows protection of sensitive subpopulations.'') In reaching this conclusion, the Administrator further notes that her concern over possible disproportionate $PM_{2.5}$-related health impacts in at-risk populations extends to populations living near important sources of $PM_{2.5}$, including the large populations that live near major roadways.[70]

In light of all of the above considerations, including consideration of available analyses, CASAC advice, and public comments, the Administrator concludes that the current form of the annual $PM_{2.5}$ standard should be revised to eliminate spatial averaging provisions. Thus, the level of the revised annual $PM_{2.5}$ standard established with this rule will be compared with measurements from each appropriate monitor in an area, with no allowance for spatial averaging. The Administrator's conclusions with regard to the appropriate level of the annual $PM_{2.5}$ standard to set in conjunction with this form are discussed below in section III.E.4.d.

b. 24-Hour Standard

In 1997, the EPA established the form of the 24-hour $PM_{2.5}$ standard as the 98th percentile of 24-hour concentrations at each population-oriented monitor within an area, averaged over three years (62 FR at 38671 to 38674, July 18, 1997). The Agency selected the 98th percentile as an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability which, when averaged over 3 years, facilitated effective health protection through the development of more stable implementation programs. By basing the form of the standard on concentrations measured at population-oriented monitoring sites, the EPA intended to provide protection for people residing in or near localized areas of elevated concentrations. In the last review, in conjunction with lowering the level of the 24-hour standard, the EPA retained this form based in part on a comparison with the 99th percentile form.[71]

In revisiting the stability of a 98th versus 99th percentile form for a 24-hour standard intended to provide supplemental protection for a generally controlling annual standard, an analysis presented in the Policy Assessment considered air quality data reported in 2000 to 2008 to update our understanding of the ratio between peak-to-mean $PM_{2.5}$ concentrations. This analysis provided evidence that the 98th percentile value was a more stable metric than the 99th percentile (U.S. EPA, 2011a, Figure 2–2, p. 2–62).

At the time of the proposal, the Agency recognized that the selection of the appropriate form of the 24-hour standard includes maintaining adequate protection against peak 24-hour concentrations while also providing a stable target for risk management programs, which serves to provide for the most effective public health protection in the long run.[72] As in previous reviews, the EPA recognized that a concentration-based form, compared to an exceedance-based form, was more reflective of the health risks posed by elevated pollutant concentrations because such a form gives proportionally greater weight to days when concentrations are well above the level of the standard than to days when the concentrations are just above the level of the standard. Further, the Agency provisionally concluded that a concentration-based form, when averaged over three years, provided an appropriate balance between limiting peak pollutant concentrations and providing a stable regulatory target, thus facilitating the development of more stable implementation programs.

In considering the information provided in the Policy Assessment and recognizing that the degree of public health protection likely to be afforded by a standard is a result of the combination of the form and the level of the standard, the Administrator proposed to retain the 98th percentile form of the 24-hour standard. The Administrator provisionally concluded that the 98th percentile form represents an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability relative to an alternative 99th percentile form.

Few public commenters commented specifically on the form of the 24-hour standard. None of the public commenters raised objections to continuing the use of a concentration-based form for the 24-hour standard. Many of the individuals and groups who supported a more stringent 24-hour $PM_{2.5}$ standard noted in section III.D.2 above, however, recommended a more restrictive concentration-based percentile form, specifically a 99th percentile form. The limited number of these commenters who provided a specific rationale for this recommendation generally expressed their concern that the 98th percentile form could allow too many days where concentrations exceeded the level of the standard, and thus fail to adequately protect public health. Other public commenters representing state and local air agencies and industry groups generally supported retaining the current 98th percentile form. In most cases, these groups expressed the overall view that the current 24-hour $PM_{2.5}$ standard, including the form of the current standard, should be retained.

The EPA notes that the viewpoints represented in this review are similar to comments submitted in the last review and through various NAAQS reviews. The EPA recognizes that the selection of the appropriate form includes maintaining adequate protection against peak 24-hour values while also providing a stable target for risk management programs, which serves to provide for the most effective public

[70] Section VIII.B.3.b.i below discusses public comments specifically related to the proposed requirement for near-road monitors.

[71] In reaching this final decision, the EPA recognized a technical problem associated with a potential bias in the method used to calculate the 98th percentile concentration for this form. The EPA adjusted the sampling frequency requirement in order to reduce this bias. Accordingly, the Agency modified the final monitoring requirements such that areas that are within 5 percent of the standards are required to increase the sampling frequency to every day (71 FR 61164 to 61165, October 17, 2006).

[72] See *ATA III,* 283 F.3d at 374–376 which concludes that it is legitimate for the EPA to consider overall stability of the standard and its resulting promotion of overall effectiveness of NAAQS control programs in setting a standard that is requisite to protect the public health.

health protection in the long run.[73] Nothing in the commenters' views has provided a reason to change the Administrator's previous conclusion regarding the appropriate balance represented in the proposed form of the 24-hour $PM_{2.5}$ standard. Therefore, the Administrator concurs with staff conclusions presented in the Policy Assessment and CASAC recommendations and concludes that it is appropriate to retain the 98th percentile form for the 24-hour $PM_{2.5}$ standard.

4. Level

In the last review, the EPA selected levels for the annual and the 24-hour $PM_{2.5}$ standards using evidence of effects associated with periods of exposure that were most closely matched to the averaging time of each standard. Thus, as discussed in section III.A.1, the EPA relied upon evidence from long-term exposure studies as the principal basis for selecting the level of the annual $PM_{2.5}$ standard that would protect against effects associated with long-term exposures. The EPA relied upon evidence from the short-term exposure studies as the principal basis for selecting the level of the 24-hour $PM_{2.5}$ standard that would protect against effects associated with short-term exposures. As summarized in section III.A.2 above, the 2006 decision to retain the level of the annual $PM_{2.5}$ standard at 15 μg/m³ [74] was challenged and on judicial review, the DC Circuit remanded the primary annual $PM_{2.5}$ standard to the EPA, finding that EPA's explanation for its approach to setting the level of the annual standard was inadequate.

a. General Approach for Considering Standard Levels

Building upon the lessons learned in the previous PM NAAQS reviews, in considering alternative standard levels supported by the currently available scientific information, the Policy Assessment used an approach that integrated evidence-based and risk-based considerations, took into account CASAC advice, and considered the issues raised by the court in remanding the primary annual $PM_{2.5}$ standard. Following the general approach outlined in section III.A.3 above, for the reasons discussed below, the Policy Assessment concluded it was appropriate to consider the protection afforded by the annual and 24-hour standards taken together against mortality and morbidity effects associated with both long- and short-term $PM_{2.5}$ exposures. This was consistent with the approach taken in the review completed in 1997 rather than considering each standard separately, as was done in the review completed in 2006.

Beyond looking directly at the relevant epidemiologic evidence, the Policy Assessment considered the extent to which specific alternative $PM_{2.5}$ standard levels were likely to reduce the nature and magnitude of both long-term exposure-related mortality risk and short-term exposure-related mortality and morbidity risk (U.S. EPA, 2011a, section 2.3.4.2; U.S.EPA, 2010a, section 4.2.2). As noted in section III.C above, patterns of increasing estimated risk reductions were generally observed as either the annual or 24-hour standard, or both, were reduced below the level of the current standards (U.S. 2011a, Figures 2–11 and 2–12; U.S. EPA, 2010a, sections 4.2.2, 5.2.2, and 5.2.3).

Based on the quantitative risk assessment, the Policy Assessment observed, as discussed in section III.A.3, that analyses conducted for this and previous reviews demonstrated that much, if not most, of the aggregate risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low-to mid-range, below the peak 24-hour concentrations (U.S. EPA, 2011a, p. 2–9). Furthermore, as discussed in section III.C above and in section III.C.3 of the proposal, the Risk Assessment observed that alternative annual standard levels, when controlling, resulted in more consistent risk reductions across urban study areas, thereby potentially providing a more consistent degree of public health protection (U.S. EPA, 2010a, pp. 5–15 to 5–16). In contrast, the Risk Assessment noted that the results of simulating alternative suites of $PM_{2.5}$ standards including different combinations of alternative annual and 24-hour standard levels suggested that an alternative 24-hour standard level can produce additional estimated risk reductions beyond that provided by an alternative annual standard alone. However, the degree of estimated risk reduction provided by alternative 24-hour standard levels was highly variable, in part due to the choice of rollback approached used (U.S. EPA, 2010a, p. 5–17).

Based on its review of the second draft Policy Assessment, CASAC agreed with the EPA staff's general approach for translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on alternative standards for consideration. Furthermore, CASAC agreed ''that it is appropriate to return to the strategy used in 1997 that considers the annual and the short-term standards together, with the annual standard as the controlling standard, and the short-term standard supplementing the protection afforded by the annual standard'' and ''considers it appropriate to place the greatest emphasis'' on health effects judged to have evidence supportive of a causal or likely causal relationship as presented in the Integrated Science Assessment (Samet, 2010d, p. 1).

Therefore, the Policy Assessment concluded, consistent with specific CASAC advice, that it was appropriate to set a ''generally controlling'' annual standard that will lower a wide range of ambient 24-hour concentrations. The Policy Assessment concluded this approach would likely reduce aggregate risks associated with both long- and short-term exposures with more consistency than a generally controlling 24-hour standard and would be the most effective and efficient way to reduce total $PM_{2.5}$-related population risk and so provide appropriate protection. The staff believed this approach, in contrast to one focusing on a generally controlling 24-hour standard, would likely reduce aggregate risks associated with both long- and short-term exposures with more consistency and would likely avoid setting national standards that could result in relatively uneven protection across the country due to setting standards that were either more or less stringent than necessary in different geographical areas.

The Policy Assessment recognized that an annual standard intended to serve as the primary means for providing protection against effects associated with both long- and short-term $PM_{2.5}$ exposures cannot be expected to offer an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures. As a result, in conjunction with a generally controlling annual standard, the Policy Assessment concluded it was appropriate to

[73] As just noted above, it is legitimate for the EPA to consider promotion of overall effectiveness of risk management programs designed to attain the NAAQS, including their overall stability, in setting a standard that is requisite to protect the public health. The context for the court's discussion in *ATA III* is identical to that here; whether to adopt a 98th percentile form for a 24-hour standard intended to provide supplemental protection for a generally controlling annual standard.

[74] Throughout this section, the annual standard levels are denoted as integer values for simplicity, although, as noted above in section II.B.1, Table 1, the annual standard level is defined to one decimal place, such that the current annual standard level is 15.0 μg/m³. Alternative annual standard levels discussed in this section are similarly defined to one decimal place.

consider setting a 24-hour standard to provide supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods.

At the time of the proposal, the Administrator agreed with the approach discussed in the Policy Assessment as summarized in section III.A.3 above, and supported by CASAC, of considering the protection afforded by the annual and 24-hour standards taken together for mortality and morbidity effects associated with both long- and short-term exposures to $PM_{2.5}$. Furthermore, based on the evidence and quantitative risk assessment, the Administrator provisionally concluded it was appropriate to set a ''generally controlling'' annual standard that will lower a wide range of ambient 24-hour concentrations, with a 24-hour standard focused on providing supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods. The Administrator provisionally concluded this approach would likely reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and would be the most effective and efficient way to reduce total PM_{2-5}-related population risk.

The Administrator is mindful that considering what standards are requisite to protect public health with an adequate margin of safety requires public health policy judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. At the time of the proposal, in considering how to translate the available information into appropriate standard levels, the Administrator weighed the available scientific information and associated uncertainties and limitations. For the purpose of determining what standard levels were appropriate to propose, the Administrator recognized, as did the EPA staff in the Policy Assessment, that there was no single factor or criterion that comprised the ''correct'' approach to weighing the various types of available evidence and information, but rather there were various approaches that were appropriate to consider. The Administrator further recognized that different evaluations of the evidence and other information before the Administrator could reflect placing different weight on the relative strengths and limitations of the scientific information, and different judgments could be made as to how such information should appropriately be used in making public health policy decisions on standard levels. This recognition led the Administrator to consider various approaches to weighing the evidence so as to identify appropriate standard levels to propose. In so doing, the Administrator encouraged extensive public comment on alternative approaches to weighing the evidence and other information so as to inform her public health policy judgments before reaching final decisions on appropriate standard levels.

b. Proposed Decisions on Standard Levels

i. Consideration of the Alternative Standard Levels in the Policy Assessment

In recognizing the absence of a discernible population threshold below which effects would not occur, the Policy Assessment's general approach for identifying alternative annual standard levels that were appropriate to consider focused on characterizing the part of the distribution of $PM_{2.5}$ concentrations in which we had the most confidence in the associations reported in the epidemiological studies and conversely where our confidence in the association became appreciably lower. The most direct approach to address this issue, consistent with CASAC advice (Samet, 2010c, p. 10), was to consider epidemiological studies reporting confidence intervals around concentration-response relationships (U.S. EPA, 2011a, p. 2–63). Based on a thorough search of the available evidence, the Policy Assessment identified only one study (Schwartz *et al.,* 2008) that conducted a multi-model analysis to characterize confidence intervals around the estimated concentration-response relationship. The Policy Assessment concluded that this single relevant analysis was too limited to serve as the principal basis for identifying alternative standard levels in this review (U.S. EPA, 2011a, p. 2–70).

The Policy Assessment explored other approaches to characterize the part of the distributions of long-term mean $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in long- and short-term epidemiological studies, and placed greatest weight on those studies that reported positive and statistically significant associations (U.S. EPA, 2011a, p. 2–63). First, as discussed in section III.A.3 above, the Policy Assessment considered the statistical metric used in previous reviews. This approach recognized the EPA's views that the strongest evidence of associations occurs at concentrations around the long-term mean concentration. Thus, in earlier reviews, the EPA focused on identifying standard levels that were somewhat below the long-term mean concentrations reported in $PM_{2.5}$ epidemiological studies. The long-term mean concentrations represented air quality data typically used in epidemiological analyses and provided a direct link between $PM_{2.5}$ concentrations and the observed health effects. Further, these data were available for all long- and short-term exposure studies analyzed and, therefore, represented the data set available for the broadest set of epidemiological studies.

However, consistent with CASAC's comments on the second draft Policy Assessment [75] (Samet, 2010d, p. 2), in preparing the final Policy Assessment, the EPA staff explored ways to take into account additional information from epidemiological studies, when available (Rajan *et al.,* 2011). These analyses focused on evaluating different statistical metrics, beyond the long-term mean concentration, to characterize the part of the distribution of $PM_{2.5}$ concentrations in which staff continued to have confidence in the associations observed in epidemiological studies and below which there was a comparative lack of data such that the staff's confidence in the relationship was appreciably less. This would also be the part of the distribution of $PM_{2.5}$ concentrations which had the most influence on generating the health effect estimates reported in epidemiological studies. As discussed in section III.A.3 above, the Policy Assessment recognized there was no one percentile value within a given distribution that was the most appropriate or ''correct'' way to characterize where our confidence in the associations becomes appreciably lower. The Policy Assessment concluded that focusing on concentrations within the lower quartile of a distribution, such as the range from the 25th to the 10th percentile, was reasonable to consider as a region within which we begin to have appreciably less confidence in the associations observed in epidemiological studies.[76] In the EPA staff's view, considering lower $PM_{2.5}$ concentrations, down to the lowest concentration observed in a study, would be a highly uncertain basis for selecting alternative standard levels (U.S. EPA, 2009a, p. 2–71).

As outlined in section III.A.3 above, the Policy Assessment recognized that there were two types of population-level information to consider in identifying the range of $PM_{2.5}$ concentrations which have the most influence on generating the health effect estimates reported in epidemiological studies. The most relevant information to consider was the number of health events (e.g., deaths, hospitalizations) occurring within a study population in relation to the distribution of $PM_{2.5}$ concentrations likely experienced by study participants. However, in recognizing that access to health event data may be restricted, and consistent with advice from CASAC (Samet 2010d, p. 2), EPA staff also considered the number of participants within each study area, in relation to the distribution of $PM_{2.5}$ concentrations (i.e., study population data), as a surrogate for health event data.

In applying this approach, the Policy Assessment focused on identifying the part of the distribution of $PM_{2.5}$ concentrations which had the most influence on generating health effect estimates in epidemiological studies, as discussed in section III.A.3 above. As discussed below, in working with study investigators, the EPA staff was able to obtain health event data for three large multi-city studies (Krewski *et al.,* 2009; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008) and population data for the same three studies and one additional long-term exposure study (Miller *et al.,* 2007), as documented in a staff memorandum (Rajan *et al.,* 2011).[77] For the three studies for which both health event and study population data were available, the EPA staff analyzed the reliability of using study population data as a surrogate for health event data. Based on these analyses, the EPA staff recognized that the 10th and 25th percentiles of the health event and study population distributions are nearly identical and concluded that the distribution of population data can be a useful surrogate for event data, providing support for consideration of the study population data for Miller *et al.* (2007), for which health event data were not available (Rajan *et al.,* 2011, Analysis 1 and Analysis 2, in particular, Table 1 and Figures 1 and 2).

With regard to the long-term mean $PM_{2.5}$ concentrations which are relevant to the first approach, Figures 1 through 3 (U.S. EPA, 2011a, Figures 2–4, 2–5, 2–6, and 2–8) summarize data available for multi-city, long- and short-term exposure studies that evaluated endpoints classified in the Integrated Science Assessment as having evidence of a causal or likely causal relationship or evidence suggestive of a causal relationship, showing the studies with long-term mean $PM_{2.5}$ concentrations below 17 μg/m^3.[78] As discussed in more detail in section III.E.4.b of the proposal, Figures 1 and 3 summarize the health outcomes evaluated, relative risk estimates, air quality data, and geographic scope for long- and short-term exposure studies, respectively, that evaluated mortality (evidence of a causal relationship); cardiovascular effects (evidence of a causal relationship); and respiratory effects (evidence of a likely causal relationship) in the general population, as well as in older adults, an at-risk population. Figure 2 provides this same summary information for long-term exposure studies that evaluated respiratory effects (evidence of a likely causal relationship) in children, an at-risk population, as well as developmental effects (evidence suggestive of a causal relationship).

[75] While CASAC expressed the view that it would be most desirable to have information on concentration-response relationships, they recognized that it would also be ''preferable to have information on the concentrations that were most influential in generating the health effect estimates in individual studies'' (Samet, 2010d, p. 2).

[76] In the last review, staff believed it was appropriate to consider a level for an annual $PM_{2.5}$ standard that was somewhat below the averages of the long-term concentrations across the cities in each of the key long-term exposures studies, recognizing that the evidence of an association in any such study was strongest at and around the long-term average where the data in the study are most concentrated. For example, the interquartile range of long-term average concentrations within a study and a range within one standard deviation around the study mean were considered reasonable approaches for characterizing the range over which the evidence of association is strongest (U.S. EPA, 2005, pp. 5–22 to 5–23). In this review, the Policy Assessment noted the interrelatedness of the distributional statistics and a range of one standard deviation around the mean which contains approximately 68 percent of normally distributed data, in that one standard deviation below the mean falls between the 25th and 10th percentiles (U.S. EPA, 2011a, p. 2–71).

[77] The distributional statistical analysis of population-level data built upon an earlier analysis that evaluated the distributions of air quality and associated population data for three long-term exposure studies and three short-term exposure studies (Schmidt *et al.,* 2010, Analysis 2).

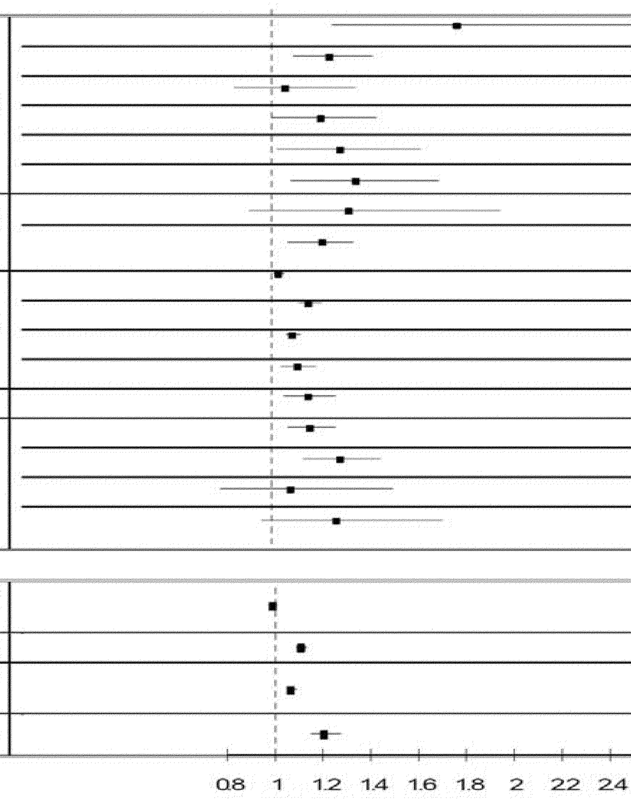
[78] Additional studies presented and assessed in the Integrated Science Assessment report effects at higher long-term mean $PM_{2.5}$ concentrations (e.g., U.S. EPA, 2009a, Figures 2–1, 2–2, 7–6, and 7–7).

[79] The long-term mean $PM_{2.5}$ concentrations reported by the study authors for the Miller *et al.* (2007) and Lipfert *et al.* (2006a) studies are discussed more fully in the Response to Comments document (U.S. EPA, 2012a).

Figure 1. Summary of Effect Estimates (per 10 μg/m^3) and Air Quality Distributions for Multi-City, Long-term $PM_{2.5}$ Exposure Studies of the General Population and Older Adults[79]

Study	Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (μg/m³) Author Reported Data: 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

Effect Estimate (95% CI)



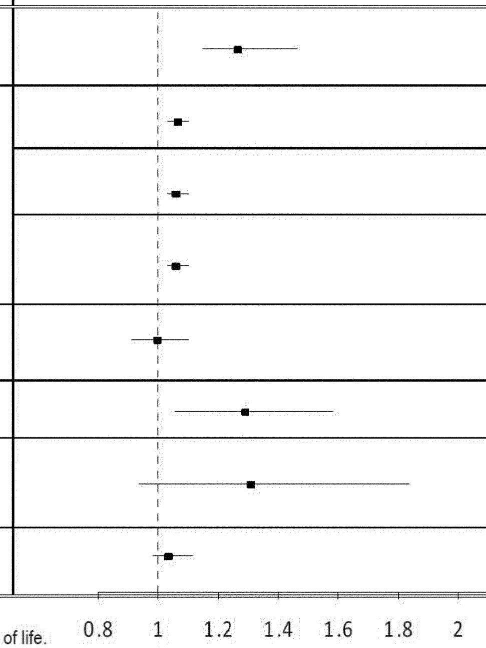
[a]Update of Miller et al. (2007) $PM_{2.5}$ data included in Curl, 2009
[b]Cohort included persons with cystic fibrosis age 6 and older, mean age: 18.4 yrs
[c]Estimated from data provided by study author (Laden, 2009)
[d]Median (IQR: Interquartile range); overall US reported median (IQR) of 13.2 μg/m³ (11.1-14.9)

Source: U.S. EPA, 2011a, Figure 2-4

Figure 2. Summary of Effect Estimates (per 10 µg/m³) 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/m³) Mean	Mean – 1SD	Range	Effect Estimate (95% CI)
	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 -1[nd] trimester	12.2	-	6.3-15	
				IUGR -2[nd] trimester				
				IUGR – 3[rd] 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/m³. Exposure period was first 2 months of life.

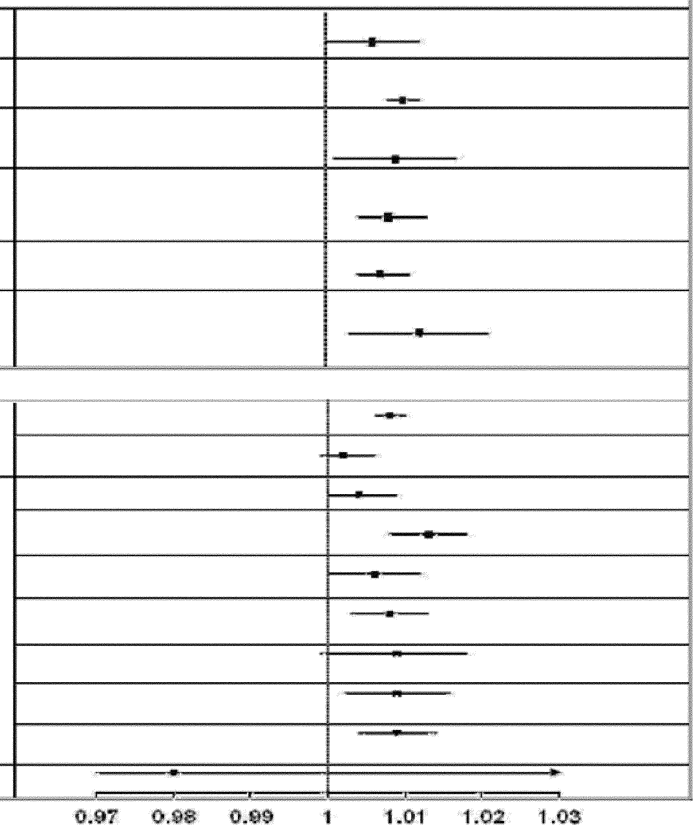
Source: U.S. EPA, 2011a, Figure 2-5

With regard to consideration of additional information from epidemiological studies which was relevant to the second approach, the EPA staff compiled a summary of the range of $PM_{2.5}$ concentrations

Figure 3. Summary of Effect Estimates (per 10 µg/m³) 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/m³) Author Reported Data: 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]

Effect Estimate (95% CI)



[a]Estimated from data provided by study author or published study
[b]Estimated from coefficient of variation reported in original study by Burnett et al. (2000)
[c]Mean value not reported in study, median presented from original study by Schwartz et al. (1996)
[d]MCAPS cohort included adults ≥ 65 yrs; O'Connor (2008) cohort included children, mean age: 7.7 yrs
IQR: interquartile range

Source: U.S. EPA, 2011a, Figure 2-6

corresponding with the 25th to 10th percentiles of health event or study population data from the four multi-city studies, for which distributional statistics are available [80] (U.S. EPA, 2011a, Figure 2–7; Rajan *et al.,* 2011, Table 1). By considering this approach, one could focus on the range of $PM_{2.5}$ concentrations below the long-term mean ambient concentrations over which we continue to have confidence in the associations observed in epidemiological studies (e.g., above the 25th percentile) where commensurate public health protection could be obtained for $PM_{2.5}$-related effects and, conversely, identify the range in the distribution below which our confidence in the associations is appreciably less, to identify alternative annual standard levels.

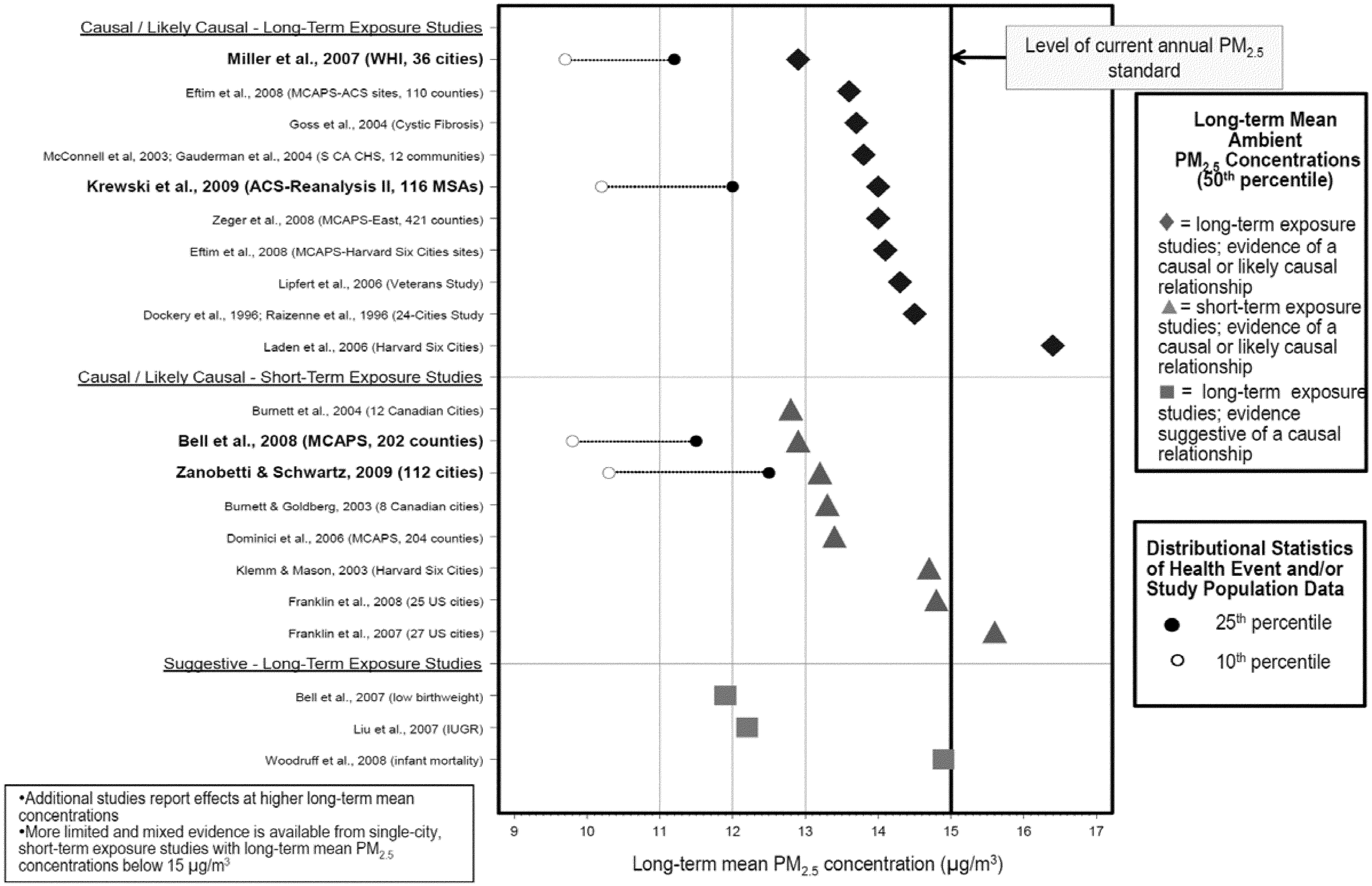
The mean $PM_{2.5}$ concentrations associated with the studies summarized in Figures 1, 2, and 3 and with the distributional statistics analyses (Rajan *et al.,* 2011) are based on concentrations averaged across ambient monitors within each area included in a given study and then averaged across study areas to calculate an overall study mean concentration, as discussed above. Figure 4, discussed in more detail in section III.E.4.a of the proposal, summarizes statistical metrics for those key studies [81] included in Figures 1, 2, and 3 that provide evidence of positive and generally statistically significant $PM_{2.5}$-related effects, which are relevant to the two approaches for translating epidemiological evidence into potential standard levels as discussed above. The top of Figure 4 includes information for *long-term* exposure studies evaluating health outcomes classified as having evidence of a *causal* or *likely causal relationship* with $PM_{2.5}$ exposures (long-term mean $PM_{2.5}$ concentrations indicated by diamond symbols). The middle of Figure 4 includes information for *short-term* exposure studies evaluating health outcomes classified as having evidence of a *causal* or *likely causal* relationship with $PM_{2.5}$ exposures (long-term mean $PM_{2.5}$ concentrations indicated by triangle symbols). The bottom of Figure 4 includes information for *long-term* exposures studies evaluating health outcomes classified as having evidence *suggestive of a causal relationship* (long-term mean $PM_{2.5}$ concentrations indicated by square symbols). Figure 4 also summarizes the range of $PM_{2.5}$ concentrations corresponding with the 25th (indicated by solid circles) to 10th (indicated by open circles) percentiles of the health event or study population data from the four multi-city studies (highlighted in bold text) for which distributional statistics are available.

[80] The EPA staff obtained health event data (e.g., number of deaths, hospitalizations) occurring in a study population for three multi-city studies (Krewski *et al.,* 2009; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008) and study population data were obtained for the same three studies and one additional study (Miller *et al.,* 2007) (U.S. EPA, 2011a, p. 2–71). If health event or study population data were available for additional studies, the EPA could employ distributional statistics to identify the broader range of $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in those studies.

[81] Long- and short-term exposure studies considered ''key'' studies for consideration are summarized in Figure 4 and include those studies observing effects for which the evidence supported a causal or likely causal association. This figure represents the subset of multi-city studies included in Figures 1 through 3 that provided evidence of positive and generally statistically significant effects associated in whole or in part with more recent air quality data, generally representing health effects associated with lower $PM_{2.5}$ concentrations than had previously been considered in the last review. The EPA notes that many of these studies evaluated multiple health endpoints, and not all of the effects evaluated provided evidence of positive and statistically significant effects. For purposes of informing the Administrator's decision on the appropriate standard levels, the Agency considers the full body of scientific evidence and focuses on those aspects of the key studies that provided evidence of positive and generally statistically significant effects.

[82] The long-term mean $PM_{2.5}$ concentrations reported by the study authors for the Miller *et al.* (2007) and Lipfert *et al.* (2006a) studies are discussed more fully in the Response to Comments document (U.S. EPA, 2012a).

Figure 4. Translating Epidemiological Evidence from Multi-City Exposure Studies into an Annual $PM_{2.5}$ Standard[82]



Source: U.S. EPA, 2011a, Figure 2-8

In considering the evidence, the Policy Assessment recognized that NAAQS are standards set so as to provide requisite protection, neither more nor less stringent than necessary to protect public health, with an adequate margin of safety. This judgment, ultimately made by the Administrator, involves weighing the strength of the evidence and the inherent uncertainties and limitations of that evidence. Therefore, depending on the weight placed on different aspects of the evidence and inherent uncertainties, consideration of different alternative standard levels could be supported.

Given the currently available evidence discussed in more detail in section III.E.4.b of the proposal and considering the various approaches discussed above, the Policy Assessment concluded it was appropriate to focus on an annual standard level within a range of about 12 to 11 μg/m³ (U.S. EPA, 2011a, pp. 2–82, 2–101, and 2–106). As illustrated in Figure 4, the Policy Assessment recognized that a standard level of 12 μg/m³, at the upper end of this range, was somewhat below the long-term mean $PM_{2.5}$ concentrations reported in all the multi-city, long- and short-term exposure studies that provided evidence of positive and statistically significant associations with health effects classified as having evidence of a causal or likely causal relationship, including premature mortality and hospitalizations and emergency department visits for cardiovascular and respiratory effects as well as respiratory effects in children. Further, a level of 12 μg/m³ would reflect consideration of additional population-level information from such epidemiological studies in that it generally corresponded with approximately the 25th percentile of the available distributions of health events data in the studies for which population-level information was available. In addition, a level of 12 μg/m³ would reflect some consideration of studies that provided more limited evidence of reproductive and developmental effects, which were suggestive of a causal relationship, in that it was about at the same level as the lowest long-term mean $PM_{2.5}$ concentrations reported in such studies (see Figure 4).

Alternatively the Policy Assessment recognized that an annual standard level of 11 μg/m³, at the lower end of this range, was well below the lowest long-term mean $PM_{2.5}$ concentrations reported in all multi-city long- and short-term exposure studies that provide evidence of positive and statistically significant associations with health effects classified as having evidence of a causal or likely causal relationship. A level of 11 μg/m³ would reflect placing more weight on the distributions of health event and population data, in that this level was within the range of $PM_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of all the available distributions of such data. In addition, a level of 11 μg/m³ was somewhat below the lowest long-term mean $PM_{2.5}$ concentrations reported in reproductive and developmental effects studies that are suggestive of a causal relationship. Thus, a level of 11 μg/m³ would reflect an approach to translating the available evidence that places relatively more emphasis on margin of safety considerations and less certain causal relationships than would a standard set at a higher level. Such a policy approach would tend to weigh uncertainties in the evidence in such a way as to avoid potentially underestimating $PM_{2.5}$-related risks to public health. Further, recognizing the uncertainties inherent in identifying any particular point at which our confidence in reported associations becomes appreciably less, the Policy Assessment concluded that the available evidence did not provide a sufficient basis to consider alternative annual standard levels below 11 μg/m³ (U.S. EPA, 2011a, p. 2–81).

The Policy Assessment also considered the extent to which the available evidence provided a basis for considering alternative annual standard levels above 12 μg/m³. As discussed below, the Policy Assessment concluded that it could be reasonable to consider a standard level up to 13 μg/m³ based on a policy approach that weighed uncertainties in the evidence in such a way as to avoid potentially overestimating $PM_{2.5}$-related risks to public health, especially to the extent that primary emphasis was placed on long-term exposure studies as a basis for an annual standard level. A level of 13 μg/m³ was somewhat below the long-term mean $PM_{2.5}$ concentrations reported in all but one of the long-term exposure studies providing evidence of positive and statistically significant associations with $PM_{2.5}$-related health effects classified as having a causal or likely causal relationship. As shown in Figure 4, the one long-term exposure study with a long-term mean $PM_{2.5}$ concentration just below 13 μg/m³ was the Miller *et al.,* (2007) study. However, as noted in section III.D.1.a of the proposal and discussed in more detail in the Response to Comments document, the Policy Assessment observed that in comparison to other long-term exposure studies, the Miller *et al.* study was more limited in that it was based on only one year of air quality data and the one year was after the health outcomes were reported (U.S. EPA, 2011a, pp. 2–81 to 2–82). Thus, to the extent that less weight was placed on the Miller *et al.* study than on other long-term exposure studies with more robust air quality data, a level of 13 μg/m³ could be considered as being protective of long-term exposure related effects classified as having a causal or likely causal relationship. In also considering short-term exposure studies, however, the Policy Assessment noted that a level of 13 μg/m³ was below the long-term mean $PM_{2.5}$ concentrations reported in most but not all such studies. In particular, two studies—Burnett *et al.* (2004) and Bell *et al.* (2008)—reported long-term mean $PM_{2.5}$ concentrations of 12.8 and 12.9 μg/m³, respectively. In considering these studies, the Policy Assessment found no basis to conclude that these two studies were any more limited or uncertain than the other short-term exposure studies shown in Figures 3 and 4 (U.S. EPA, 2011a, p. 2–82). On this basis, as discussed below, the Policy Assessment concluded that consideration of an annual standard level of 13 μg/m³ would have implications for the degree of protection that would need to be provided by the 24-hour standard, in order that the suite of $PM_{2.5}$ standards, taken together, would provide appropriate protection from effects on public health related to short-term exposure to $PM_{2.5}$ (U.S. EPA, 2011a, p. 2–82).

The Policy Assessment also noted that a standard level of 13 μg/m³ would reflect a judgment that the uncertainties in the epidemiological evidence as summarized in section III.B above and discussed in more detail in section III.B.2 of the proposal, including uncertainties related to the heterogeneity observed in the epidemiological studies in the eastern versus western parts of the U.S., the relative toxicity of $PM_{2.5}$ components, and the potential role of co-pollutants, are too great to warrant placing any weight on the distributions of health event and population data that extend down below the long-term mean concentrations into the lower quartile of the data. This level would also reflect a judgment that the evidence from reproductive and developmental effects studies that is suggestive of a causal relationship was too uncertain to support consideration of any lower level.

Beyond evidence-based considerations, the Policy Assessment also considered the extent to which the quantitative risk assessment supported consideration of these alternative standard levels or provided support for lower levels. In considering simulations of just meeting alternative annual standard levels within the range of 13 to 11 μg/m³ (in conjunction with the current 24-hour standard level of 35 μg/m³), the Policy Assessment concluded that important public health improvements are associated with risk reductions estimated for standard levels of 13 and 12 μg/m³ and noted that the level of 11 μg/m³ was not included in the quantitative risk assessment. The Policy Assessment noted that the overall confidence in the quantitative risk estimates varied for the different alternative standard levels evaluated and was stronger for the higher levels and substantially lower for the lowest level evaluated (i.e., 10 μg/m³). Based on the above considerations, the Policy Assessment concluded that the quantitative risk assessment provided support for considering alternative annual standard levels within a range of 13 to 11 μg/m³, but did not provide strong support for considering lower alternative standard levels (U.S. EPA, 2011a, pp. 2–102 to 2–103).

Taken together, the Policy Assessment concluded that consideration of alternative annual standard levels in the range of 13 to 11 μg/m³ may be appropriate. Furthermore, the Policy Assessment concluded that the currently available evidence most strongly supported consideration of an alternative annual standard level in the range of 12 to 11 μg/m³ (U.S. EPA, 2011a, p. 2–82). The Policy Assessment concluded that an alternative level within the range of 12 to 11 μg/m³ would more fully take into consideration the available information from all long- and short-term $PM_{2.5}$ exposure studies, including studies of at-risk populations, than would a higher level. This range also reflected placing weight on information from studies that helped to characterize the range of $PM_{2.5}$ concentrations over which we continue to have confidence in the associations observed in epidemiological studies, as well as the extent to which our confidence in the associations was appreciably less at lower concentrations.

As recognized in sections III.A.3 and III.E.4.a above, an annual standard intended to serve as the primary means for providing protection from effects associated with both long- and short-term $PM_{2.5}$ exposures is not expected to provide appropriate protection against the effects of all short-term $PM_{2.5}$ exposures (unless established at a level so low as to undoubtedly provide more protection than necessary for long-term exposures). Of particular concern are areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods. As a result, the Policy Assessment concluded that it was appropriate to consider alternative 24-hour $PM_{2.5}$ standard levels that would supplement the protection provided by an annual standard.

As outlined in section III.A.3 above, the Policy Assessment considered the available evidence from short-term $PM_{2.5}$ exposure studies, as well as the uncertainties and limitations in that evidence, to assess the degree to which alternative annual and 24-hour $PM_{2.5}$ standards can be expected to reduce the estimated risks attributed to short-term fine particle exposures. In considering the available epidemiological evidence, the Policy Assessment took into account information from multi-city studies as well as single-city studies. The Policy Assessment considered the distributions of 24-hour $PM_{2.5}$ concentrations reported in short-term exposure studies, focusing on the 98th percentile concentrations to match the form of the 24-hour standard as discussed in section III.E.3.b above. In recognizing that the annual and 24-hour standards work together to provide protection from effects associated with short-term $PM_{2.5}$ exposures, the Policy Assessment also considered information on the long-term mean $PM_{2.5}$ concentrations from these studies.

In addition to considering the epidemiological evidence, the Policy Assessment considered air quality information, specifically peak-to-mean ratios using county-level 24-hour and annual design values, to characterize air quality patterns in areas possibly associated with strong local or seasonal sources. These patterns helped in understanding the extent to which different combinations of annual and 24-hour standards would be consistent with the policy goal of setting a generally controlling annual standard with a 24-hour standard that provides supplemental protection especially for areas with high peak-to-mean ratios (U.S. EPA, 2011a, p. 2–14).

In considering the information provided by the short-term exposure studies, the Policy Assessment recognized that to the extent these studies were conducted in areas that likely did not meet one or both of the current standards, such studies did not help inform the characterization of the potential public health improvements of alternative standards set at lower levels. Therefore, in considering the short-term exposure studies to inform staff conclusions regarding levels of the 24-hour standard that are appropriate to consider, the Policy Assessment placed greatest weight on studies conducted in areas that likely met both the current annual and 24-hour standards.

With regard to multi-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures, as summarized in Figure 3 above and discussed in more detail in section III.E.4.c of the proposal, the Policy Assessment noted that, to the extent air quality distributions were reduced to reflect just meeting the current 24-hour standard, additional protection would be anticipated for the effects observed in the three multi-city studies with 98th percentile values greater than 35 μg/m³ (Burnett *et al.,* 2004; Burnett and Goldberg, 2003; Franklin *et al.,* 2008). In the three additional studies with 98th percentile values below 35 μg/m³, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 μg/m³, the Policy Assessment noted that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 μg/m³, respectively (Bell *et al.,* 2008; Zanobetti and Schwartz, 2009; Dominici *et al.,* 2006a). To the extent that consideration was given to revising the level of the annual standard, as discussed in section III.E.4.b of the proposal, the Policy Assessment recognized that potential changes associated with meeting such an alternative annual standard would result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures. Consequently, in considering a 24-hour standard that would operate in conjunction with an annual standard to provide appropriate public health protection, the Policy Assessment noted that to the extent that the level of the annual standard was revised to within a range of 13 to 11 μg/m³, in particular in the range of 12 to 11 μg/m³, additional protection would be provided for the long-term effects observed in these multi-city studies (U.S. EPA, 2011a, p. 2–84).

Based on this information, the Policy Assessment concluded that the multi-city, short-term exposure studies generally provided support for retaining the 24-hour standard level at 35 μg/m³ so long as the standard is in conjunction with an annual standard level revised to within a range of 12 to 11 μg/m³ (U.S. EPA, 2011a, p. 2–84). Alternatively, in conjunction with an annual standard level of 13 μg/m³, the Policy Assessment concluded that the multi-city studies provided limited support for revising the 24-hour standard level somewhat below 35 μg/m³, such as down to 30 μg/m³, based on one study (Bell *et al.,* 2008) that reported positive and statistically significant effects with an overall 98th percentile value below the level of the current 24-hour standard and an overall long-term mean concentration slightly less than 13 μg/m³ (Figure 3; U.S. EPA, 2011a, p. 2–84).

In reaching staff conclusions regarding alternative 24-hour standard levels that were appropriate to consider, the Policy Assessment also took into account relevant information from single-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures. The Policy Assessment recognized that these studies may provide additional insights regarding impacts on at-risk populations and/or on areas with isolated peak concentrations.

As discussed in more detail in section III.E.4.c of the proposal, although a number of single-city studies reported effects at appreciably lower $PM_{2.5}$ concentrations than multi-city short-term exposure studies, the uncertainties and limitations associated with the single-city studies were considerably greater than those associated with the multi-city studies and, thus, the Policy Assessment concluded there was less confidence in using these studies as a basis for setting the level of a standard. Therefore, the Policy Assessment concluded that the multi-city short-term exposure studies provided the strongest evidence to inform decisions on the level of the 24-hour standard, and the single-city studies did not warrant consideration of 24-hour standard levels different from those supported by the multi-city studies (U.S. EPA, 2011a, p. 2–88).

In addition to considering the epidemiological evidence, the Policy Assessment took into account air quality information based on county-level 24-hour and annual design values to understand the public health implications of the alternative standard levels supported by the currently available scientific evidence, as discussed in this section. Consistent with the general approach discussed in section III.A.3 above, the Policy Assessment considered the extent to which different combinations of alternative annual and 24-hour standard levels based on the evidence would support the policy goal of lowering annual and 24-hour air quality distributions by using the annual standard to be the ''generally controlling'' standard in conjunction with setting the 24-hour standard to provide supplemental protection (U.S. EPA, 2011a, pp 2–88 to 2–91, Figure 2–10).

Using information on the relationship of the 24-hour and annual design values, the Policy Assessment examined the implications of three alternative suites of $PM_{2.5}$ standards identified as appropriate to consider based on the currently available scientific evidence, as discussed above. The Policy Assessment concluded that an alternative suite of $PM_{2.5}$ standards that would include an annual standard level of 11 or 12 μg/m³ and a 24-hour standard with a level of 35 μg/m³ (i.e., 11/35 or 12/35) would result in the annual standard being the generally controlling standard in most areas although the 24-hour standard would continue to be the generally controlling standard in the Northwest (U.S. EPA, 2011a, pp. 2–89 to 2–91 and Figure 2–10). These Northwest counties generally represented areas where the annual mean $PM_{2.5}$ concentrations have historically been low but where relatively high 24-hour concentrations occur, often related to seasonal wood smoke emissions. Alternatively, combining an alternative annual standard of 13 μg/m³ with a 24-hour standard of 30 μg/m³ would result in many more areas across the country in which the 24-hour standard would likely become the controlling standard (the standard driving air quality distributions lower) than if an alternative annual standard of 12 or 11 μg/m³ were paired with the current level of the 24-hour standard (i.e., 35 μg/m³).

The Policy Assessment concluded that consideration of retaining the 24-hour standard level at 35 μg/m³ would reflect placing greatest weight on evidence from multi-city studies that reported positive and statistically significant associations with health effects classified as having a causal or likely causal relationship. In conjunction with lowering the annual standard level, especially within a range of 12 to 11 μg/m³, this alternative recognized additional public health protection against effects associated with short-term $PM_{2.5}$ exposures which would be provided by lowering the annual standard such that revision to the 24-hour standard would not be warranted (U.S. EPA, 2011a, p. 2–91).

Beyond evidence-based considerations, the Policy Assessment also considered the extent to which the quantitative risk assessment supported consideration of retaining the current 24-hour standard level or provided support for lower standard levels. In considering simulations of just meeting the current 24-hour standard level of 35 μg/m³ or alternative levels of 30 or 25 μg/m³ (in conjunction with alternative annual standard levels within a range of 13 to 11 μg/m³), the Policy Assessment noted that the overall confidence in the quantitative risk estimates varied for the different standard levels evaluated and was stronger for the higher levels and substantially lower for the lowest level evaluated (i.e., 25 μg/m³). Based on this information, the Policy Assessment concluded that the quantitative risk assessment provided support for considering a 24-hour standard level of 35 or 30 μg/m³ (in conjunction with an alternative standard level within a range of 13 to 11 μg/m³) but did not provide strong support for considering lower alternative 24-hour standard levels (U.S. EPA, 2011a, pp. 2–102 to 2–103).

Taken together, the Policy Assessment concluded that while it was appropriate to consider an alternative 24-hour standard level within a range of 35 to 30 μg/m³, the currently available evidence most strongly supported consideration for retaining the current 24-hour standard level at 35 μg/m³ in conjunction with lowering the level of the annual standard within a range of 12 to 11 μg/m³ (U.S. EPA, 2011a, p. 2–92).

ii. CASAC Advice

Based on its review of the second draft Policy Assessment, CASAC agreed with the general approach for translating the available epidemiological evidence, risk information, and air quality information into the basis for reaching conclusions on alternative standards for consideration. Furthermore, CASAC agreed ''that it is appropriate to return to the strategy used in 1997 that considers the annual and the short-term standards together, with the annual standard as the controlling standard, and the short-term standard supplementing the protection afforded by the annual standard'' and ''considers it appropriate to place the greatest emphasis'' on health effects judged to have evidence supportive of a causal or likely causal relationship as presented in the Integrated Science Assessment (Samet, 2010d, p. 1).

CASAC concluded that the range of levels presented in the second draft Policy Assessment (i.e., alternative annual standard levels within a range of 13 to 11 μg/m³ and alternative 24-hour standard levels within a range of 35 to 30 μg/m³) ''are supported by the epidemiological and toxicological evidence, as well as by the risk and air quality information compiled'' in the Integrated Science Assessment, Risk Assessment, and second draft Policy Assessment. CASAC further noted that ''[a]lthough there is increasing uncertainty at lower levels, there is no evidence of a threshold (i.e., a level below which there is no risk for adverse health effects)'' (Samet, 2010d, p. ii).

Although CASAC supported the alternative standard level ranges presented in the second draft Policy Assessment, it did not express support for any specific levels or combinations of standards. Rather, CASAC encouraged the EPA to develop a clearer rationale in the final Policy Assessment for staff conclusions regarding annual and 24-hour standards that were appropriate to consider, including consideration of the combination of these standards supported by the available information (Samet, 2010d, p. ii). Specifically, in commenting on a distributional statistical analysis of air quality and associated population data presented in the second draft Policy Assessment, CASAC encouraged staff to focus on information related to the concentrations that were most influential in generating the health effect estimates in individual studies to inform alternative standard levels. CASAC urged that the EPA redo that analysis using health event or study population data (Samet, 2010d, p. 2). CASAC also commented that the approach presented in the second draft Policy Assessment to identify alternative 24-hour standard levels which focused on peak-to-mean ratios was not relevant for informing the actual level (Samet 2010d, p. 4). Further, they expressed the concern that the combinations of annual and 24-hour standard levels discussed in the second draft Policy Assessment (i.e., in the range of 13 to 11 μg/m³ for the annual standard, in conjunction with retaining the current 24-hour $PM_{2.5}$ standard level of 35 μg/m³; alternatively, revising the level of the 24-hour standard to 30 μg/m³ in conjunction with an annual standard level of 11 μg/m³) ''may not be adequately inclusive'' and ''[i]t was not clear why, for example a daily standard of 30 μg/m³ should only be considered in combination with an annual level of 11 μg/m³'' (Samet, 2010d, p. ii). CASAC encouraged the EPA to more clearly explain its rationale for identifying the 24-hour/annual combinations that are appropriate for consideration (Samet 2010d, p. ii).

In considering CASAC's advice as well as public comment on the second draft Policy Assessment, the EPA staff conducted additional analyses and modified their conclusions regarding alternative standard levels that were appropriate to consider. The staff conclusions in the final Policy Assessment (U.S. EPA, 2011a, section 2.3.4.4) differed somewhat from the alternative standard levels discussed in the second draft Policy Assessment (U.S. EPA, 2010f, section 2.3.4.3), upon which CASAC based its advice. Changes made in the final Policy Assessment were primarily focused on improving and clarifying the approach for translating the epidemiological evidence into a basis for staff conclusions on the broadest range of alternative standard levels supported by the available scientific information and more clearly articulating the rationale for the staff's conclusions (Wegman, 2011, pp. 1 to 2). Consistent with CASAC's advice to consider more information from epidemiological studies, as discussed in section III.E.4.b.1 above, the EPA analyzed additional population-level data obtained from several study authors (Rajan *et al.,* 2011). In transmitting the final Policy Assessment to CASAC, the Agency notified CASAC that the final staff conclusions reflected consideration of CASAC's advice and that those staff conclusions were based, in part, on the specific distributional analysis that CASAC had urged the EPA to conduct (Wegman, 2011, p.2). Thus, CASAC had an opportunity to comment on the final Policy Assessment, but chose not to provide any additional comments or advice after receiving it.

iii. Administrator's Proposed Decisions on the Primary $PM_{2.5}$ Standard Levels

In reaching her conclusions regarding appropriate alternative standard levels to consider, the Administrator considered the epidemiological and other scientific evidence, estimates of risk reductions associated with just meeting alternative annual and/or 24-hour standards, air quality analyses, related limitations and uncertainties, staff conclusions as presented in the Policy Assessment, and the advice of CASAC. As an initial matter, the Administrator agreed with the general approach discussed in the Policy Assessment as summarized in sections III.A.3 and III.E.4.a above, and supported by CASAC, of considering the protection afforded by the annual and 24-hour standards taken together for mortality and morbidity effects associated with both long- and short-term exposures to $PM_{2.5}$ (77 FR 38939). Furthermore, based on the evidence and quantitative risk assessment, the Administrator provisionally concluded it is appropriate to set a ''generally controlling'' annual standard that will lower a wide range of ambient 24-hour concentrations, with a 24-hour standard focused on providing supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods. The Administrator provisionally concluded this approach would likely reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and would be the most effective and efficient way to reduce total $PM_{2.5}$-related population risk. *Id.*

In reaching decisions on alternative standard levels to propose, the Administrator judged that it was most appropriate to examine where the evidence of associations observed in the epidemiological studies was strongest and, conversely, where she had appreciably less confidence in the associations observed in the epidemiological studies. Based on the characterization and assessment of the epidemiological and other studies presented and assessed in the Integrated Science Assessment and the Policy Assessment, the Administrator recognized the substantial increase in the number and diversity of studies available in this review including extended analyses of the seminal studies of long-term $PM_{2.5}$ exposures (i.e., ACS and Harvard Six Cities studies) as well as important new long-term exposure studies (as summarized in Figures 1 and 2). Collectively, the Administrator noted that these studies, along with evidence available in the last review, provided consistent and stronger evidence of an association with premature mortality, with the strongest evidence related to cardiovascular-related mortality, at lower ambient concentrations than previously observed. The Administrator also recognized the availability of stronger evidence of morbidity effects associated with long-term $PM_{2.5}$ exposures, including evidence of cardiovascular effects from the WHI study and respiratory effects, including decreased lung function growth, from the extended analyses for the Southern California Children's Health Study. Furthermore, the Administrator recognized new U.S. multi-city studies that greatly expanded and reinforced our understanding of mortality and morbidity effects associated with short-term $PM_{2.5}$ exposures, providing stronger evidence of associations at ambient concentrations similar to those previously observed (as summarized in Figure 3). *Id.* at 38939–40.

The newly available scientific evidence built upon the previous scientific data base to provide evidence of generally robust associations and to provide a basis for greater confidence in the reported associations than in the last review. The Administrator recognized that the weight of evidence, as evaluated in the Integrated Science Assessment, was strongest for health endpoints classified as having evidence of a causal relationship. These relationships included those between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects. She recognized that the weight of evidence was also strong for health endpoints classified as having evidence of a likely causal relationship, which included those between long- and short-term $PM_{2.5}$ exposures and respiratory effects. In addition, the Administrator made note of the much more limited evidence for health endpoints classified as having evidence suggestive of a causal relationship, including developmental, reproductive and carcinogenic effects. *Id.* at 38940.

Based on information discussed and presented in the Integrated Science Assessment, the Administrator recognized that health effects may occur over the full range of concentrations observed in the long- and short-term epidemiological studies and that no discernible threshold for any effects can be identified based on the currently available evidence (U.S. EPA, 2009a, section 2.4.3). She also recognized, in taking note of CASAC advice and the distributional statistics analysis discussed in section III.E.4.b.i above and in the Policy Assessment, that there was significantly greater confidence in observed associations over certain parts of the air quality distributions in the studies, and conversely, that there was significantly diminished confidence in ascribing effects to concentrations toward the lower part of the distributions.

Consistent with the general approach summarized in section III.A.3 above, and supported by CASAC as discussed in section III.E.4.a above, the Administrator generally agreed that it was appropriate to consider a level for an annual standard that was somewhat below the long-term mean $PM_{2.5}$ concentrations reported in long- and short-term exposure studies. In recognizing that the evidence of an association in any such study was strongest at and around the long-term average where the data in the study are most concentrated, she understood that this approach did not provide a bright line for reaching decisions about appropriate standard levels. The Administrator noted that long-term mean $PM_{2.5}$ concentrations were available for each study considered and, therefore, represented the most robust data set to inform her decisions on appropriate annual standard levels. She also noted that the overall study mean $PM_{2.5}$ concentrations were generally calculated based on monitored concentrations averaged across monitors in each study area with multiple monitors, referred to as a composite monitor concentration, in contrast to the highest concentration monitored in each study area, referred to as a maximum monitor concentration, which are used to determine whether an area meets a given standard. In considering such long-term mean concentrations, the Administrator understood that it was appropriate to consider the weight of evidence for the health endpoints evaluated in such studies in giving weight to this information. *Id.*

Based on the information summarized in Figure 4 above and presented in more detail in the Policy Assessment (U.S. EPA, 2011a, chapter 2) for effects classified in the Integrated Science Assessment as having a causal or likely causal relationship with $PM_{2.5}$ exposures, the Administrator observed an overall pattern of statistically significant associations reported in studies of long-term $PM_{2.5}$ exposures with long-term mean concentrations ranging from somewhat above the current standard level of 15 μg/m³ down to the lowest mean concentration in such studies of 12.9 μg/m³ (in Miller *et al.,* 2007).[83] She observed a similar pattern of statistically significant associations in studies of short-term $PM_{2.5}$ exposures with long-term mean concentrations ranging from around 15 μg/m³ down to 12.8 μg/m³ (in Burnett *et al.,* 2004). With regard to effects classified as providing evidence suggestive of a causal relationship, the Administrator observed a small number of long-term exposure studies related to developmental and reproductive effects that reported statistically significant associations with overall study mean $PM_{2.5}$ concentrations down to 11.9 μg/m³ (in Bell *et al.,* 2007).[84] *Id.*

The Administrator also considered additional information from epidemiological studies, consistent with CASAC advice, to take into account the broader distribution of $PM_{2.5}$ concentrations and the degree of confidence in the observed associations over the broader air quality distribution. In considering this additional information, she understood that the Policy Assessment presented information on the 25th and 10th percentiles of the distributions of $PM_{2.5}$ concentrations available from four multi-city studies to provide a general frame of reference as to the part of the distribution in which the data become appreciably more sparse and, thus, where her confidence in the associations observed in epidemiological studies would become appreciably less.

As summarized in Figure 4 above, the Administrator took note of additional population-level data that were available for four studies (Krewski *et al.,* 2009; Miller *et al.,* 2007; Bell *et al.,* 2008; Zanobetti and Schwartz, 2009), each of which reported statistically significant associations with health endpoints classified as having evidence of a causal relationship. In considering the long-term $PM_{2.5}$ concentrations associated with the 25th percentile values of the population-level data for these four studies, she observed that these values ranged from somewhat above to somewhat below 12 μg/m³. The Administrator recognized that these studies include some of the strongest evidence available within the overall body of scientific evidence and noted that three of these studies (Krewski *et al.,* 2009; Bell *et al.,* 2008; Zanobetti and Schwartz, 2009) were used as the basis for concentration-response functions used in the quantitative risk assessment (U.S. EPA, 2010a, section 3.3.3).

In considering this information, the Administrator noted that CASAC advised that information about the long-term $PM_{2.5}$ concentrations that were most influential in generating the health effect estimates in epidemiological studies can help to inform selection of an appropriate annual standard level. However, the Administrator also recognized that additional population-level data were available for only these four studies and, therefore, she believed that these studies comprised a more limited data set than one based on long-term mean $PM_{2.5}$ concentrations for which data were available for all studies considered, as discussed above.

The Administrator recognized, as summarized in section III.B above, that important uncertainties remain in the evidence and information considered in this review of the primary fine particle standards. These uncertainties are generally related to understanding the relative toxicity of the different components in the fine particle mixture, the role of $PM_{2.5}$ in the complex ambient mixture, exposure measurement errors inherent in epidemiological studies based on concentrations measured at

[83] The EPA notes that the Miller *et al.,* (2007) study provides strong evidence of cardiovascular related effects associated with long-term $PM_{2.5}$ exposures. At the time of the proposal, the EPA recognized the limited nature of the air quality data considered in this study (77 FR 38918, fn. 62). The EPA has reviewed those limitations, in conjunction with consideration of public comments received on the proposal as discussed in section III.E.4.c, in conjunction with reaching a final decision on the level of the annual standard.

[84] With respect to suggestive evidence related to cancer, mutagenic, and genotoxic effects, the $PM_{2.5}$ concentrations reported in studies generally included ambient concentrations that are equal to or greater than ambient concentrations observed in studies that reported mortality and cardiovascular and respiratory effects (U.S. EPA, 2009a, section 7.5), such that in selecting alternative standard levels that provide protection from mortality and cardiovascular and respiratory effects, it is reasonable to anticipate that protection will also be provided for carcinogenic effects.

fixed monitor sites, and the nature, magnitude, and confidence in estimated risks related to increasingly lower ambient $PM_{2.5}$ concentrations. Furthermore, the Administrator noted that epidemiological studies have reported heterogeneity in responses both within and between cities and geographic regions across the U.S. She recognized that this heterogeneity may be attributed, in part, to differences in fine particle composition in different regions and cities. The Administrator also recognized that there are additional limitations associated with evidence for reproductive and developmental effects, identified as being suggestive of a causal relationship with long-term $PM_{2.5}$ exposures, including: the limited number of studies evaluating such effects; uncertainties related to identifying the relevant exposure time periods of concern; and limited toxicological evidence providing little information on the mode of action(s) or biological plausibility for an association between long-term $PM_{2.5}$ exposures and adverse birth outcomes. *Id.* at 38941.

The Administrator was mindful that considering what standards were requisite to protect public health with an adequate margin of safety required public health policy judgments that neither overstated nor understated the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. In considering how to translate the available information into appropriate standard levels, the Administrator weighed the available scientific information and associated uncertainties and limitations. For the purpose of determining what standard levels were appropriate to propose, the Administrator recognized, as did EPA staff in the Policy Assessment, that there was no single factor or criterion that comprised the sole ''correct'' approach to weighing the various types of available evidence and information, but rather there were various approaches that are appropriate to consider. The Administrator further recognized that different evaluations of the evidence and other information before the Administrator could reflect placing different weight on the relative strengths and limitations of the scientific information, and different judgments could be made as to how such information should appropriately be used in making public health policy decisions on standard levels. This recognition led the Administrator to consider various approaches to weighing the evidence so as to identify appropriate standard levels to propose. In so doing, the Administrator encouraged extensive public comment on alternative approaches to weighing the evidence and other information so as to inform her public health policy judgments before reaching final decisions on appropriate standard levels.

In considering the available information, the Administrator noted the advice of CASAC that the currently available scientific information, including epidemiological and toxicological evidence as well as risk and air quality information, provided support for considering an annual standard level within a range of 13 to 11 μg/m³ and a 24-hour standard level within a range of 35 to 30 μg/m³. In addition, the Administrator recognized that the Policy Assessment concluded that the available evidence and risk-based information support consideration of annual standard levels in the range of 13 to 11 μg/m³, and that the Policy Assessment also concluded that the evidence most strongly supported consideration of an annual standard level in the range of 12 to 11 μg/m³. In considering how the annual and 24-hour standards work together to provide appropriate public health protection, the Administrator observed that CASAC did not express support for any specific levels or combinations of standards within these ranges. Nor did CASAC choose to comment on additional information and analyses presented in the final Policy Assessment prepared in response to CASAC's recommendations on the second draft Policy Assessment (Wegman, 2011).

In considering the extent to which the currently available evidence and information provided support for specific standard levels within the ranges identified by CASAC and the Policy Assessment as appropriate for consideration, the Administrator initially considered standard levels within the range of 13 to 11 μg/m³ for the annual standard. In so doing, the Administrator first considered the long-term mean $PM_{2.5}$ concentrations reported in studies of effects classified as having evidence of a causal or likely causal relationship, as summarized in Figure 4 above and discussed more broadly above. She noted that a level at the upper end of this range would be below most but not all the overall study mean concentrations from the multi-city studies of long- and short-term exposures, whereas somewhat lower levels within this range would be below all such overall study mean concentrations. In considering the appropriate weight to place on this information, the Administrator again noted that the evidence of an association in any such study was strongest at and around the long-term average where the data in the study are most concentrated, and that long-term mean $PM_{2.5}$ concentrations were available for each study considered and, therefore, represented the most robust data set to inform her decisions on appropriate annual standard levels. Further, she was mindful that this approach did not provide a bright line for reaching decisions about appropriate standard levels. *Id.*

In considering the long-term mean $PM_{2.5}$ concentrations reported in studies of effects classified as having evidence suggestive of a causal relationship, as summarized in Figure 4 for reproductive and developmental effects, the Administrator noted that a level at the upper end of this range would be below the overall study mean concentration in one of the three studies, while levels in the mid- to lower part of this range would be below the overall study mean concentrations in two or three of these studies. In considering the appropriate weight to place on this information, the Administrator noted the very limited nature of this evidence of such effects and the additional uncertainties in these epidemiological studies relative to the studies that provide evidence of causal or likely causal relationships.

The Administrator also considered the distributional analyses of population-level information that were available from four of the epidemiological studies that provide evidence of effects identified as having a causal relationship with long- or short-term $PM_{2.5}$ concentrations for annual standard levels within the same range of 13 to 11 μg/m³. In so doing, the Administrator first noted that a level in the mid-part of this range generally corresponds with approximately the 25th percentile of the distributions of health events data available in three of these studies. The Administrator also noted that standard levels toward the upper part of this range would reflect placing substantially less weight on this information, whereas standard levels toward the lower part of this range would reflect placing substantially more weight on this information. In considering this information, the Administrator noted that there was no bright line that delineates the part of the distribution of $PM_{2.5}$ concentrations within which the data become appreciably more sparse and, thus, where her confidence in the associations observed in epidemiological studies became appreciably less.

In considering mean $PM_{2.5}$ concentrations and distributional analyses from the various sets of epidemiological studies noted above, the Administrator was mindful, as noted above, that such studies typically report concentrations based on composite monitor distributions, in which concentrations may be averaged across multiple ambient monitors that may be present within each area included in a given study. Thus, a policy approach that used data based on composite monitors to identify potential alternative standard levels would inherently build in a margin of safety of some degree relative to an alternative standard level based on measurements at the monitor within an area that records the highest concentration, or the maximum monitor, since once a standard was set, concentrations at appropriate maximum monitors within an area were generally used to determine whether an area meets a given standard.

The Administrator also recognized that judgments about the appropriate weight to place on any of the factors discussed above should reflect consideration not only of the relative strength of the evidence but also on the important uncertainties that remained in the evidence and information being considered in this review. The Administrator noted that the extent to which these uncertainties influenced judgments about appropriate annual standard levels within the range of 13 to 11 μg/m³ would likely be greater for standard levels in the lower part of this range which would necessarily be based on fewer available studies than would higher levels within this range.

Based on the above considerations, the Administrator concluded that it was appropriate to propose to set a level for the primary annual $PM_{2.5}$ standard within the range of 12 to 13 μg/m³. The Administrator provisionally concluded that a standard set within this range would reflect alternative approaches to appropriately placing the most weight on the strongest available evidence, while placing less weight on much more limited evidence and on more uncertain analyses of information available from a relatively small number of studies. Further, she provisionally concluded that a standard level within this range would reflect alternative approaches to appropriately providing an adequate margin of safety for the populations at risk for the serious health effects classified as having evidence of a causal or likely causal relationship, depending in part on the emphasis placed on margin of safety considerations. The Administrator recognized that setting an annual standard level at the lower end of this range would reflect an approach that placed more emphasis on the entire body of the evidence, including the analysis of the distribution of air quality concentrations most influential in generating health effect estimates in the studies, and on margin of safety considerations, than would setting a level at the upper end of the range. Conversely, an approach that would support a level at the upper end of this range would generally support a view that the uncertainties remaining in the evidence are such that the evidence does not warrant setting a lower annual standard level. *Id.* at 38942.

At the time of the proposal, while the Administrator recognized that CASAC advised, and the Policy Assessment concluded, that the available scientific information provided support for considering a range that extended down to 11 μg/m³, she concluded that proposing such an extended range would reflect a public health policy approach that placed more weight on relatively limited evidence and more uncertain information and analyses than she considered appropriate at this time. Nonetheless, the Administrator solicited comment on a level down to 11 μg/m³ as well as on approaches for translating scientific evidence and rationales that would support such a level. Such an approach might reflect a view that the uncertainties associated with the available scientific information warrant a highly precautionary public health policy response that would incorporate a large margin of safety.

The Administrator recognized that potential air quality changes associated with meeting an annual standard set at a level within the range of 12 to 13 μg/m³ will result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures. However, the Administrator recognized that such an annual standard intended to serve as the primary means for providing protection from effects associated with both long- and short-term $PM_{2.5}$ exposures would not by itself be expected to offer requisite protection with an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures. As a result, in conjunction with proposing an annual standard level in the range of 12 to 13 μg/m³, the Administrator provisionally concluded that it was appropriate to continue to provide supplemental protection by means of a 24-hour standard set at the appropriate level, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or for $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods.

Based on the approach discussed in section III.A.3 above, at the time of the proposal the Administrator relied upon evidence from the short-term exposure studies as the principal basis for selecting the level of the 24-hour standard. In considering these studies as a basis for the level of a 24-hour standard, and having selected a 98th percentile form for the standard, the Administrator agreed with the focus in the Policy Assessment of looking at the 98th percentile values, as well as at the long-term mean $PM_{2.5}$ concentrations in these studies.

In considering the information provided by the short-term exposure studies, the Administrator recognized that to the extent these studies were conducted in areas that likely did not meet one or both of the current standards, such studies did not help inform the characterization of the potential public health improvements of alternative standards set at lower levels. By reducing the $PM_{2.5}$ concentrations in such areas to just meet the current standards, the Administrator anticipated that additional public health protection would occur. Therefore, the Administrator focused on studies that reported positive and statistically significant associations in areas that would likely have met both the current 24-hour and annual standards. She also considered whether or not these studies were conducted in areas that would likely have met an annual standard level of 12 to 13 μg/m³ to inform her decision regarding an appropriate 24-hour standard level. As discussed in section III.E.4.a, consistent with the Policy Assessment, the Administrator concluded that multi-city, short-term exposure studies provided the strongest data set for informing her decisions on appropriate 24-hour standard levels. The Administrator viewed the single-city, short-term exposure studies as a much more limited data set providing mixed results and, therefore, she had less confidence in using those studies as a basis for setting the level of a 24-hour standard. With regard to the limited number of single-city studies that reported positive and statistically significant associations for a range of health endpoints related to short-term $PM_{2.5}$ concentrations in areas that would likely have met the current suite of $PM_{2.5}$ standards, the Administrator recognized that many of those studies had significant limitations (e.g., limited statistical power, limited exposure data) or equivocal results (mixed results within the same study area) that made them unsuitable to form the basis for setting the level of a 24-hour standard.

With regard to multi-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures, the Administrator observed an overall pattern of positive and statistically significant associations in studies with 98th percentile values averaged across study areas in the range of 45.8 to 34.2 μg/m³ (Burnett *et al.,* 2004; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008; Dominici *et al.,* 2006a, Burnett and Goldberg, 2003; Franklin *et al.,* 2008). The Administrator noted that, to the extent air quality distributions were reduced to reflect just meeting the current 24-hour standard, additional protection would be anticipated for the effects observed in the three multi-city studies with 98th percentile values greater than 35 μg/m³ (Burnett *et al.,* 2004; Burnett and Goldberg, 2003; Franklin *et al.,* 2008). In the three additional studies with 98th percentile values below 35 μg/m³, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 μg/m³, the Administrator noted that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 μg/m³, respectively (Bell *et al.,* 2008; Zanobetti and Schwartz, 2009; Dominici *et al.,* 2006a).

In proposing to revise the level of the annual standard to within the range of 12 to 13 μg/m³, as discussed above, the Administrator recognized that additional protection would be provided for the short-term effects observed in these multi-city studies in conjunction with an annual standard level of 12 μg/m³, and in two of these three studies in conjunction with an annual standard level of 13 μg/m³. She noted that the study-wide mean concentrations were based on averaging across monitors within study areas and that compliance with the standard would be based on concentrations measured at the monitor reporting the highest concentration within each area. The Administrator believed it would be reasonable to conclude that revision to the 24-hour standard would not be appropriate in conjunction with an annual standard within this range. Based on the above considerations related to the epidemiological evidence, the Administrator provisionally concluded that it was appropriate to retain the level of the 24-hour standard at 35 μg/m³, in conjunction with a revised annual standard level in the proposed range of 12 to 13 μg/m³.

In addition to considering the epidemiological evidence, the Administrator also took into account air quality information based on county-level 24-hour and annual design values to understand the public health implications of retaining the 24-hour standard level at 35 μg/m³ in conjunction with an annual standard level within the proposed range of 12 to 13 μg/m³. She considered whether these suites of standards would meet a public health policy goal which included setting the annual standard to be the ''generally controlling'' standard in conjunction with setting the 24-hour standard to provide supplemental protection to the extent that additional protection is warranted. As discussed above, the Administrator provisionally concluded that this approach was the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures, resulting in more uniform protection across the U.S. than the alternative of setting the 24-hour standard to be the controlling standard.

In considering the air quality information, the Administrator first recognized that there was no annual standard within the proposed range of levels, when combined with a 24-hour standard at the proposed level of 35 μg/m³, for which the annual standard would be the generally controlling standard in all areas of the country. She further observed that such a suite of $PM_{2.5}$ standards with an annual standard level of 12 μg/m³ would result in the annual standard as the generally controlling standard in most regions across the country, except for certain areas in the Northwest, where the annual mean $PM_{2.5}$ concentrations have historically been low but where relatively high 24-hour concentrations occur, often related to seasonal wood smoke emissions (U.S. EPA, 2011a, pp. 2–89 to 2–91, Figure 2–10). Although not explicitly delineated on Figure 2–10 in the Policy Assessment, an annual standard of 13 μg/m³ would be somewhat less likely to be the generally controlling standard in some regions of the U.S. outside the Northwest in conjunction with a 24-hour standard level of 35 μg/m³.

Taking the above considerations into account, the Administrator proposed to revise the level of the primary annual $PM_{2.5}$ standard from 15.0 μg/m³ to within the range of 12.0 to 13.0 μg/m³ and to retain the 24-hour standard level at 35 μg/m³. In the Administrator's judgment, such a suite of primary $PM_{2.5}$ standards and the rationale supporting such levels could reasonably be judged to reflect alternative approaches to the appropriate consideration of the strength of the available evidence and other information and their associated uncertainties and the advice of CASAC.

The Administrator recognized that the final suite of standards selected from within the proposed range of annual standard levels, or the broader range of annual standard levels on which public comment was solicited, must be clearly responsive to the issues raised by the DC Circuit's remand of the 2006 primary annual $PM_{2.5}$ standard. Furthermore, at the time of the proposal, she recognized that the final suite of standards will reflect her ultimate judgment in the final rulemaking as to the suite of primary $PM_{2.5}$ standards that would be requisite to protect the public health with an adequate margin of safety from effects associated with fine particle exposures. The final judgment to be made by the Administrator will appropriately consider the requirement for a standard that is neither more nor less stringent than necessary and will recognize that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

At the time of the proposal, having reached her provisional judgment to propose revising the annual standard level from 15.0 to within a range of 12.0 to 13.0 μg/m³ and to propose retaining the 24-hour standard level at 35 μg/m³, the Administrator solicited public comment on this range of levels and on approaches to considering the available evidence and information that would support the choice of levels within this range. The Administrator also solicited public comment on alternative annual standard levels down to 11 μg/m³ and on the combination of annual and 24-hour standards that commenters may believe is appropriate, along with the approaches and rationales used to support such levels. In addition, given the importance the evidence from epidemiologic studies played in considering the appropriate annual and 24-hour levels, the Administrator solicited public comment on issues related to translating epidemiological evidence into standards, including approaches for addressing the uncertainties and limitations associated with this evidence.

c. Comments on Standard Levels

This section addresses comments that relate to consideration of the appropriate levels of the primary annual and 24-hour $PM_{2.5}$ standards, including comments on the general approach used by the EPA to translate the available scientific information into standard levels and how specific $PM_{2.5}$ exposure studies should be considered as a basis for the standard levels. These comments on standard levels expand upon the more general comments that either supported or opposed any change to the current suite of primary $PM_{2.5}$

standards, which are addressed above in section III.D.2.[85] As explained there, one group of commenters generally opposed any change to the current primary $PM_{2.5}$ standards and more specifically disagreed with the basis for the EPA's proposal to revise the annual standard level. Another group of commenters supported revising the current suite of primary $PM_{2.5}$ standards to provide increased public health protection. Some commenters in this second group argued that both the annual and 24-hour standard levels should be lowered while other commenters in this group agreed with the EPA's proposal to retain the level of the 24-hour standard in conjunction with revising the level of the annual standard. While generally supporting the EPA's proposal to lower the level of the annual standard, many commenters in this group disagreed that a level within the EPA's proposed range was adequately protective and supported a level of 11 µg/m³ or below.

i. Annual Standard Level

The group of commenters opposed to any change to the current suite of primary $PM_{2.5}$ standards generally raised questions regarding the underlying scientific evidence, including the causal determinations reached in the Integrated Science Assessment, and focused strongly on the uncertainties they saw in the scientific evidence as a basis for their conclusion that no changes to the current standard levels were warranted. In commenting on the proposed standard levels, these commenters typically relied on the arguments summarized and addressed above in section III.D.2 as to why they believed it was inappropriate for the EPA to make any revisions to the suite of primary $PM_{2.5}$ standards. That is, they asserted that the EPA's causal determinations were not adequately supported by the underlying scientific information; the biological plausibility of health effects observed in epidemiological studies has not been demonstrated in controlled human exposure and toxicological studies; uncertainties in the underlying health science are as great or greater than in 2006; there is no evidence of greater risk since the last review to justify tightening the current annual $PM_{2.5}$ standard; and ''new'' studies not included in the Integrated Science Assessment continue to increase uncertainty about possible health risks associated with exposure to $PM_{2.5}$.

With regard to the level of the annual standard, these commenters strongly disagreed with the Agency's proposed decision to revise the level to within a range of 12 to 13 µg/m³ and argued that the current standard level of 15 µg/m³ should be retained. For example, UARG, API, and other commenters in this group raised a number of issues that they asserted called into question the EPA's interpretation of the epidemiological evidence to support revising the annual standard level. These commenters raised specific questions related to the general approach used by the EPA to translate the air quality and other information from specific epidemiological studies into standard levels, including: (1) The EPA's approach for using composite monitor air quality distributions reported in epidemiological studies to select a standard level that would be compared to measurements at the monitor recording the highest value in an area to determine compliance with the standard; (2) the appropriate exposure period for effects observed in long-term exposure mortality studies; and (3) the use of the EPA's analysis of distributions of underlying population-level data (i.e., health event and study population data) for those epidemiological studies for which such information was available. These commenters also raised questions regarding the EPA's consideration of specific scientific evidence as a basis for setting a standard level, including: (4) evidence of respiratory morbidity effects in long-term exposure studies and (5) more limited evidence of health effects which have been categorized in the Integrated Science Assessment as *suggestive* of a causal relationship (i.e., developmental and reproductive outcomes). These comments are discussed in turn below.

(1) Some commenters in this group argued that one reason why they believe there is no basis for setting a standard level below 15 µg/m³ is that the air quality metric from epidemiological studies that the EPA relied on in the proposal is not the same metric that will be compared to the level of the standard to determine compliance with the standard. That is, commenters noted that the long-term mean $PM_{2.5}$ concentrations that the EPA considered, shown in Figure 4 above, are *composite monitor* mean concentrations (i.e., concentrations averaged across multiple monitors within areas with more than one monitor), whereas the $PM_{2.5}$ concentrations that will be compared to the level of the standard are *maximum monitor* concentrations (i.e., the concentration measured by the monitor within an area reporting the highest concentration). This comment was presented most specifically in UARG's comments (UARG, 2012, Attachment 1, pp. 2 to 6), which raised two overarching issues as discussed below.

First, the commenter noted that the EPA's approach of considering composite monitor mean $PM_{2.5}$ concentrations in selecting a standard level, and then comparing the maximum monitor mean $PM_{2.5}$ concentration in each area to the standard level when the standard is implemented, was characterized in the proposal as inherently having the potential to build in a margin of safety (UARG, 2012, Attachment 1, p. 4, citing 77 FR 38905). The commenter asserted that the Administrator is ignoring this distinction between composite and maximum monitor concentrations, and that this approach creates an unwarranted case for lowering the standard level, since in the commenter's view, it would result in a margin of safety that would be arbitrary, not based on evidence, and unquantified (UARG, 2012, Attachment 1, p. 4). In support of this view, the commenter asserted that there is a significant difference between composite monitor mean $PM_{2.5}$ concentrations and maximum monitor mean $PM_{2.5}$ concentrations. The commenter asserted that the maximum monitor value will always be higher than the composite monitor value (except in areas that contain only a single monitor), such that when an area just attains the NAAQS, that area's composite monitor long-term mean $PM_{2.5}$ concentration will be lower than the level of the standard (UARG, 2012, Attachment 1, p. 3).

Second, the commenter asserted that a more ''reasoned and consistent approach would be to decide on a mean composite monitor $PM_{2.5}$ level that should be achieved and then identify the maximum monitor level that would result in that composite value'' (UARG, 2012, Attachment 1, p. 4). The commenter conducted an analysis of maximum monitor versus composite monitor annual mean $PM_{2.5}$ concentrations using monitoring data[86] from 2006 to 2008 and presented results averaged across areas within two groups (i.e., those with design values[87] above the current standard level and those with design values just below the

[85] Specific comments on the forms of the annual and 24-hour standards are addressed in section III.E.3.a and III.E.3.b, respectively.

[86] The commenter indicated that this analysis was based on monitoring data for every core based statistical area (CBSA) in the EPA's Air Quality System (AQS) database.

[87] The design value is the air quality statistic that is compared to the level of the NAAQS to determine the attainment status of a given area.

current standard level) to illustrate their suggested alternative approach. The commenter interpreted this analysis as showing that the composite monitor long-term mean $PM_{2.5}$ concentrations from the subset of the epidemiological studies shown in Figure 4 (of the proposal and above) that the commenter considered to be an appropriate focus for this analysis would be achieved across the U.S. if the current annual NAAQS of 15 μg/m³ is retained and attained. The commenter considered the subset of epidemiological studies that included only long-term exposures studies of effects for which the evidence is categorized as causal or likely causal, but did not consider short-term exposure studies. On this basis, the commenter asserted that attaining the current annual $PM_{2.5}$ standard would result in composite monitor long-term mean concentrations in all areas that would be generally within or below the range of the composite monitor long-term mean concentrations from such studies and, as a result, there is no reason to lower the level of the current annual NAAQS.

In considering the first issue related to the EPA's approach, the EPA notes that in proposing to revise both the form and level of the annual standard, the Administrator clearly took into account the distinction between the composite monitor long-term mean $PM_{2.5}$ concentrations from the epidemiological studies, considered as a basis for selecting an annual standard level, and maximum monitor long-term mean $PM_{2.5}$ concentrations. In deciding to focus on the composite monitor long-term mean concentrations in selecting the standard level, and on the maximum monitor concentrations in selecting the form of the standard (i.e., consistent with proposing to eliminate the option for spatial averaging across monitors within an area when implementing the standard [88]), the Administrator reasonably considered the distinction between these metrics in a manner that was consistent with advice from CASAC (Samet *et al.,* 2010d, pp. 2 to 3).

As noted above in section III.A.3, the EPA recognizes that a statistical metric (e.g., the mean of a distribution) based on maximum monitor concentrations may be identical to or above the same statistical metric based on composite monitor concentrations. More specifically, many areas have only one monitor, in which case the composite and maximum monitor concentrations are identical. Based on the most recent data from the EPA's AQS from 2009 to 2011 in the 331 CBSAs in which valid $PM_{2.5}$ data are available, as discussed in Frank (2012a, Table 5), there were 208 such areas (with design values ranging up to about 15 μg/m³). Frank (2012a) also observed that other areas have multiple monitors with composite and maximum monitor mean $PM_{2.5}$ concentrations that were the same or relatively close, with 57 areas in which the maximum monitor mean concentration was no more than 0.5 μg/m³ higher than the composite monitor mean concentration and 56 areas in which the difference was between 0.6 and 2 μg/m³. Further, there were only a few other areas in which the maximum monitor mean concentration was appreciably higher than the composite monitor mean concentration, such as areas in which some monitors may be separately impacted by local sources. There were only 10 such areas in the country in which the maximum monitor mean concentration was between 2 to 6 μg/m³ higher than the composite monitor concentration (Frank, 2012a, Table 4).[89] Thus, the EPA does not agree that there is a significant difference between composite monitor mean $PM_{2.5}$ concentrations and maximum monitor mean $PM_{2.5}$ concentrations in the large majority of areas across the country.

In proposing to revise the form of the annual $PM_{2.5}$ standard, as discussed above in section III.E.3.a, the EPA noted that when an annual $PM_{2.5}$ standard was first set in 1997, the form of the standard included the option for averaging across measurements at appropriate monitoring sites within an area, generally consistent with the composite monitor approach used in epidemiological studies, with some constraints intended to ensure that spatial averaging would not result in inequities in the level of protection for communities within large metropolitan areas. In the last review the EPA tightened the constraints on spatial averaging, and in this review has eliminated the option altogether, on the basis of analyses in each review that showed that such constraints may be inadequate to avoid substantially greater exposures for people living in locations around the monitors recording the highest $PM_{2.5}$ concentrations in some areas, potentially resulting in disproportionate impacts on at-risk populations of persons with lower SES levels as well as minorities. In light of these analyses, and consistent with the Administrator's decision to revise the form of the annual $PM_{2.5}$ standard by eliminating the option for spatial averaging, the EPA continues to conclude that a standard level based on consideration of long-term mean concentrations from composite monitors, and applied at each monitor within an area including the monitor measuring the highest concentration, is the appropriate approach to use in setting a standard that will protect public health, including the health of at-risk populations, with an adequate margin of safety, as required by the CAA.

The EPA acknowledges that at proposal, the Agency characterized the approach of using maximum monitor concentrations to determine compliance with the standard, while selecting the standard level based on consideration of composite monitor concentrations, as one that inherently had the potential to build in a margin of safety (77 FR 38905), and CASAC reiterated that view in supporting the EPA's approach (Samet, 2010d, p. 3). Nonetheless, in light of the discussion above, the EPA more specifically recognizes that this approach does not build in any margin of safety in the large number of areas across the country with only one monitor. Further, based on the analyses done to inform consideration of the form of the standard (Schmidt, 2011, Analysis A), the EPA concludes that this approach does not provide a margin of safety for the at-risk populations that live around the monitor measuring the highest concentration, such as in those few areas in which the maximum monitor concentration is appreciably higher than the composite monitor concentration. Rather, this approach properly treats those at-risk populations the same way it does the broader populations that live in areas with only one monitor, by providing the same degree of protection for those at-risk populations that would otherwise be disproportionately impacted as it does for the broader populations in other areas, While the EPA recognizes that this approach can result in some additional margin of safety for the subset of areas with multiple monitors in which at-risk populations may not be disproportionately represented in areas around the maximum monitor, which may be the case in areas with relatively small differences between the maximum and composite monitor concentrations, the EPA notes that this margin would be relatively small in such areas.

Based on the above considerations, the EPA does not agree that the Agency's approach of using maximum monitor concentrations to determine compliance with the standard, while

[88] As discussed above in section III.E.3.a.

[89] The average difference between the maximum and composite design value among the 123 CBSAs with two or more monitors is 0.8 μg/m³ and the median difference is 0.6 μg/m³. The 25th and 75th percentiles are 0.3 and 1.0 μg/m³, respectively (Frank, 2012a, p. 4).

selecting the standard level based on consideration of composite monitor concentrations creates an unwarranted case for lowering the standard level based on a margin of safety that would be arbitrary, not based on evidence, or lack quantification. The EPA recognizes that setting a standard to protect public health, including the health of at-risk populations, with an adequate margin of safety, depends upon selecting a standard level sufficiently below where the EPA has found the strongest evidence of health effects so as to provide such protection, and that the EPA's approach regarding consideration of composite and maximum monitor concentrations is intended to, and does, serve to address this requirement as part of and not separate from the selection of an appropriate standard level based on the health effects evidence.

In considering the second issue related to the commenter's suggested alternative approach, the EPA strongly disagrees with the commenter's view that a more ''reasoned and consistent approach would be to decide on a mean composite monitor $PM_{2.5}$ level that should be achieved and then identify the maximum monitor level that would result in that composite value'' (UARG, 2012, Attachment 1, p. 4). As discussed above, the EPA notes that for areas with only one monitor, or with multiple monitors that measure concentrations that are very close in magnitude, the maximum monitor level that would limit the composite monitor $PM_{2.5}$ level to be no greater than the level that should be achieved to protect public health with an adequate margin of safety, would essentially be the same as that composite monitor level. Further, as discussed above, even for areas in which the maximum monitor concentration is appreciably higher than other monitor concentrations within the same area, public health would not be protected with an adequate margin of safety if the disproportionately higher exposures of at-risk, susceptible populations around the monitor measuring the highest concentration were in essence averaged away with measurements from monitors in other locations within large urban areas. Further, the commenter's suggested approach would be based on annual average $PM_{2.5}$ concentrations that have been measured over some past time period. Such an approach would reflect the air quality that existed in the past, but it would not necessarily provide appropriate constraints on the range of concentrations that would be allowed by such a standard in the future, when relationships between maximum and composite monitor concentrations in areas across the country may be different. For these reasons, the EPA fundamentally rejects the commenter's suggested approach because in the EPA's view it would not protect public health, including providing protection for at-risk populations, with an adequate margin of safety in areas across the country.

More specifically, in further considering the commenter's analysis of design values based on maximum versus composite monitor annual mean $PM_{2.5}$ concentrations using monitoring data from 2006 to 2008 which they assert supports retaining the current standard level of 15 μg/m^3, the EPA finds flaws with the numerical results and the scope of the analysis, as well as flaws in the commenter's translation of the analysis results into the basis for selecting an annual standard level.

In considering the commenter's analysis, the EPA notes that the analysis compared maximum versus composite monitor annual mean $PM_{2.5}$ concentrations, averaged over 3 years, for two groups of areas: (1) Areas with design values that exceed the current annual standard level (i.e., greater than 15.0 μg/m^3) and (2) areas with design values that are just attaining the current annual standard (i.e., between 14.5 and 15.0 μg/m^3).[90] The commenter indicated that they used the full body of $PM_{2.5}$ monitoring data from the EPA's AQS database (UARG, 2012, Attachment 1, p. 4), In attempting to reproduce the commenter's results, the EPA repeated the calculations using only valid air quality data (i.e., data that meet data completeness and monitor siting criteria) from the AQS database for the same time period (Frank, 2012a).[91] Based on this corrected analysis, the EPA finds that the composite monitor concentrations averaged across the areas within each group are somewhat higher than those calculated by the commenter, and the average differences between the maximum and composite monitor concentrations are somewhat smaller (Frank, 2012a, Table 3).[92] Notably, the difference between the maximum and composite monitor average concentrations for the second group of areas is substantially reduced in the corrected analysis, such that the difference (averaged across the 10 areas with valid data in the second group) is approximately 0.5 μg/m^3, not 1.2 μg/m^3 as in the commenter's analysis. In addition, the commenter's analysis compared the average of the composite monitors to the average of the maximum monitors for each subset of areas. This comparison of averages across all the areas in each subset masks the fact that the large majority of areas across the country have only one monitor, with the composite monitor and maximum monitor values the same for such areas, and many other areas have a maximum monitor value that is close to the composite monitor value. As discussed above, these circumstances have a major impact on the protection that would be achieved by the approach suggested by the commenter.

With regard to the scope of the commenter's analysis, the EPA finds that by limiting the scope to a small subset of areas with design values above or just below the current annual standard level of 15 μg/m^3, the analysis ignores the large number of areas across the country with lower design values that are relevant to consider in light of the epidemiological evidence of serious health effects at lower concentrations, well below the level of the current standard.

In translating the analysis results into the basis for selecting an annual standard level, the commenter's translation is premised on the view that the ''natural focal point'' for setting an annual $PM_{2.5}$ standard level should be somewhere within the range of the long-term mean $PM_{2.5}$ concentrations from the subset of epidemiological studies that included only long-term exposure studies of effects for which the evidence is categorized as causal or likely causal, but not for effects categorized as suggestive of causality, nor did it

[90] For the first group of areas (which included 33 areas), this analysis calculated an average across the areas of maximum monitor annual mean $PM_{2.5}$ concentrations, averaged over 3 years, of 17.2 μg/m^3 compared to an average of composite monitor concentrations of 14.3 μg/m^3. For the second group of areas (which included 11 areas), this analysis calculated an average across the areas of maximum monitor annual mean concentrations, averaged over 3 years, of 14.8 μg/m^3 compared to an average of composite monitor concentrations of 13.6 μg/m^3 (UARG, 2012, Attachment 1, Table 1).

[91] The EPA notes that the Frank (2012a) analysis is similar to an earlier EPA staff analysis (Hassett-Sipple et al., 2010), which used air quality data from EPA's AQS database to compare maximum versus composite monitor long-term mean $PM_{2.5}$ concentrations across the study areas in six selected multi-city epidemiological studies.

[92] The EPA's analysis was intended to repeat the commenter's analysis, but using only valid air quality data (from 2006 to 2008). For the first group of areas (which included 21 areas with valid data), the EPA's analysis calculated an average across the areas of maximum monitor annual mean concentrations, averaged of 3 years, of 16.8 μg/m^3 compared to an average of composite monitor concentrations of 14.8 μg/m^3. For the second group of areas (which included 10 areas with valid data), the EPA's analysis calculated an average across the areas of maximum monitor annual mean concentrations, averaged over 3 years, of 14.8 μg/m^3 compared to an average of composite monitor concentrations of 14.2 μg/m^3 (Frank, 2012a, Table 3).

include short-term exposure studies (which are included in Figure 4 of the proposal notice and above). Such a view is not consistent with setting a standard that would provide sufficient protection from the serious health effects reported even in the limited subset of studies considered by the commenter, including protecting public health with an adequate margin of safety. As discussed below, the EPA does not agree with the commenter's view as to the appropriate focal point for selecting the level of an annual $PM_{2.5}$ standard, or with the limited set of studies considered by the commenter as a basis for selecting the level of the annual $PM_{2.5}$ standard.

Regarding an appropriate focal point for selecting the level of the annual standard, as discussed in the proposal and as advised by CASAC, the EPA has focused on $PM_{2.5}$ concentrations somewhat *below* the lowest long-term mean concentrations from *each* of the key studies of both long- and short-term exposures of effects for which the evidence is causal or likely causal, as considered by the EPA (i.e., the first two sets of studies shown in Figure 4). If the level of the annual standard was set just somewhere *within* the range of the long-term mean concentrations from the various long-term exposure studies, then one or more of the studies would have a long-term mean concentration below the selected level of the standard. Absent some reason to ignore or discount these studies, which the commenter does not provide (and of which the EPA is unaware), setting such a standard would allow that level of air quality, where the evidence of health effects is strongest, and its associated risk of $PM_{2.5}$-related mortality and/or morbidity effects to continue. Selecting such a standard level could not be considered sufficient to protect the public health with an adequate margin of safety.

Further, focusing on just the long-term *mean* $PM_{2.5}$ concentrations in the key epidemiological studies—even the lowest long-term mean concentration from the set of key studies—is not appropriate. Concentrations at and around the long-term mean concentrations represent the part of the air quality distribution where the data in any given study are most concentrated and, thus, where the confidence in the magnitude and significance of an association in such study is strongest. However, the evidence of an association with adverse health effects in the studies is not limited to the $PM_{2.5}$ concentrations just at and around the long-term mean, but rather extends more broadly to a lower part of the distribution, recognizing that no discernible population-level threshold for any such effects can be identified based on the available evidence. This broader region of the distribution of $PM_{2.5}$ concentrations should be considered to the extent relevant information is available, recognizing that the degree of confidence in the association identified in a study would become lower as one moves below concentrations at and around the long-term mean concentration in any given study. The commenter's approach ignores this fundamental consideration.

Regarding the set of studies that is appropriate to inform the selection of the level of the annual $PM_{2.5}$ standard, the EPA finds that limiting consideration only to the *long-term exposure* studies, as this commenter suggests, would be tantamount to ignoring the *short-term exposure* studies,[93] which provide some of the strongest evidence from the entire body of epidemiological studies. Thus, selecting an annual standard level using the limited set of studies suggested by the commenter would fail to provide a degree of protection that would be sufficient to protect public health with an adequate margin of safety.

For all the reasons discussed above, the EPA finds the commenter's concerns with the EPA's approach to considering composite and maximum monitor $PM_{2.5}$ concentrations in selecting the level of the annual $PM_{2.5}$ standard to be without merit. Further, the EPA finds no support in the commenter's analysis for their suggested alternative approach.

(2) With respect to the appropriate exposure period for mortality effects observed in long-term exposure studies, some commenters in this group generally expressed views consistent with comments from UARG that argued that these studies ''are most likely detecting health risk from earlier, higher $PM_{2.5}$ levels and misattributing those risks to more recent, lower $PM_{2.5}$ levels'' (UARG, 2012, Attachment 1, p 7). Further, this commenter asserted that ''there is no knowledge or evidence indicating whether premature deaths are the result of $PM_{2.5}$ exposures in the most recent year; or due to physical damages incurred from $PM_{2.5}$ exposures much earlier in life (with the impact on lifespan only emerging later in life); or due to total accumulated $PM_{2.5}$ exposure over many years.'' *Id.* In addition, the commenter asserted that the long-term exposure studies of mortality are central to the EPA's basis for proposing to set a lower annual standard level, since most of the estimated benefits associated with a lower annual $PM_{2.5}$ standard are based on reductions in mortality related to long-term exposures to $PM_{2.5}$.

As an initial matter, the EPA has recognized the challenge in distinguishing between $PM_{2.5}$-associated effects due to past and recent long-term exposures, and in identifying the relevant latency period for long-term exposure to PM and resultant health effects (U.S. EPA, 2009a, section 7.6.4; 77 FR 38941/1). While the EPA has acknowledged that there remain important uncertainties related to characterizing the most relevant exposure periods in long-term exposure studies, the assertion that there is ''no knowledge or evidence'' that helps to inform this issue is not correct, as discussed below.

Both in the last review and in the current review, the EPA has assessed studies that used different air quality periods for estimating long-term exposure and tested associations with mortality for the different exposure periods (U.S. EPA, 2004, section 8.2.3.5; U.S. EPA 2009a, section 7.6.4). In this review, the Integrated Science Assessment discussed studies available since the last review that have assessed the relationship between long-term exposure to $PM_{2.5}$ and mortality to explore the issue of the latency period between exposure to $PM_{2.5}$ and death (U.S. EPA, 2009a, section 7.6.4).

Notably, in a recent analysis of the extended Harvard Six Cities Study, Schwartz *et al.* (2008) used model averaging (i.e., multiple models were averaged and weighted by probability of accuracy) to assess exposure periods prospectively (77 FR 38907/1–2). The exposure periods were estimated across a range of unconstrained distributed lag models (i.e., same year, one year prior, two years prior to death). In comparing lags, the authors reported that the effects of changes in exposure to $PM_{2.5}$ on mortality were strongest within a 2-year period prior to death (U.S. EPA, 2009a, p. 7–92, Figure 7–9). Similarly, a large

[93] The commenter suggests that the EPA should not place significant reliance on the long-term mean concentrations from short-term exposure studies because ''[T]he short-term studies did not use the annual average of $PM_{2.5}$ to develop their associations; they used the daily 24-hour averages of $PM_{2.5}$. Thus, short-term studies do not provide a natural indicator for the appropriate level of an annual standard * * *.'' (UARG, 2012, Attachment 1, p. 3). The EPA finds this argument unpersuasive. Quite simply, effects were observed in these studies with an air quality distribution that can meaningfully be characterized by these long-term mean concentrations. Indeed, in remanding the 2006 standard, the D.C. Circuit discussed at length the interrelationship of the long- and short-term standards and studies, and remanded the 2006 standard to the EPA, in part, for ignoring those relationships without adequate explanation. *American Farm Bureau Federation* v. *EPA. 559* F. 3d at 522–24.

multi-city study of the elderly found that the mortality risk associated with long-term exposure to PM_{10} reported cumulative effects that extended over the years that deaths were observed in the study population (i.e., the follow-up period) and for the 3-year period prior to death (Zanobetti *et al.,* 2008).

Further, in a study of two locations that experienced an abrupt decline in $PM_{2.5}$ concentrations (i.e., Utah Steel Strike, coal ban in Ireland), Röösli *et al.* (2005) reported that approximately 75 percent of health benefits were observed in the first 5 years (U.S. EPA, 2009a, Table 7–9). Schwartz *et al.* (2008) and Puett *et al.* (2008) found, in a comparison of exposure periods ranging from 1 month to 48 months prior to death, that exposure to PM_{10} 24 months prior to death exhibited the strongest association, and the weakest association was reported for exposure in the time period of 1 month prior to death.

Overall, the EPA notes that the available evidence for determining the exposure period that is causally related to the mortality effects of long-term $PM_{2.5}$ exposures, as discussed above, cannot specifically disentangle the effects observed in long-term exposure studies associated with more recent air quality measurements from effects that may have been associated with earlier, and most likely higher, $PM_{2.5}$ exposures. While the evidence suggests that a latency period of up to five years would account for the majority of deaths, it does not provide a basis for concluding that it is solely recent $PM_{2.5}$ concentrations that account for the mortality risk observed in such studies. Nonetheless, the more recent air quality data does well at explaining the relationships observed between long-term exposures to $PM_{2.5}$ and mortality, with the strongest association observed in the two years prior to death. Further, the EPA recognizes that there is no discernible population-level threshold below which effects would not occur, such that it is reasonable to consider that health effects may occur over the full range of concentrations observed in the epidemiological studies, including the lower concentrations in the latter years.

In light of this evidence and these considerations, the EPA concludes that it is appropriate to consider air quality concentrations that are generally contemporaneous with the collection of health event data (i.e., collected over the same time period) as being causally associated with at least some proportion of the deaths assessed in a long-term exposure study. This would include long-term mean $PM_{2.5}$ concentrations from most of the key long-term exposure studies of effects with causal or likely causal evidence shown in Figure 4 above, which reported long-term mean $PM_{2.5}$ concentrations ranging from 13.6 μg/m^3 to 14.3 μg/m^3. These studies include studies of mortality by Eftim *et al.* (2008), which separately analyzed the ACS and Harvard Six City sites, Zeger *et al.* (2008), and Lipfert *et al.* (2006a), as well as studies of morbidity endpoints by Goss *et al.* (2004), McConnell *et al.* (2003) and Gauderman *et al.* (2004), and Dockery *et al.* (1996) and Razienne *et al.* (1996). The EPA acknowledges that uncertainty in the relevant exposure period is most notable in two other long-term exposure studies of mortality. The Miller *et al.* (2007) reported a long-term mean $PM_{2.5}$ concentration for a 1-year exposure period that post-dated the follow-up period in which health event data were collected by two years. Also, the Krewski *et al.* (2009) study reported a long-term mean $PM_{2.5}$ concentration for an exposure period that included only the last two years of the 18-year follow-up period. Based on these considerations, the EPA does not now consider it appropriate to put weight on the reported long-term mean concentrations from these two studies for the purpose of translating the information from the long-term mortality studies into a basis for selecting the level of the annual $PM_{2.5}$ standard.[94]

In addition, the EPA acknowledges that exposure periods that extend at least a couple years prior to the follow-up period in which health event data were collected would likely more fully capture the PM-related deaths in such studies. To explore how much higher the long-term mean $PM_{2.5}$ concentrations would likely have been had air quality data prior to the follow-up years of the studies been included, the EPA conducted a sensitivity analysis of long-term mean $PM_{2.5}$ concentrations (Schmidt, 2012a) particularly considering studies that only included deaths from a relatively recent follow-up period. As examples of such studies, this analysis considered the Eftim *et al.* (2008) study of mortality in the ACS sites and the Harvard Six Cities sites, as well as sites in the eastern region in the Zeger *et al.* (2008) study. Using data from the EPA's AQS database, the analysis added the two years of air quality data just prior to the follow-up period in each study, which was 2000 to 2002 in Eftim *et al.* (2008) and 2000 to 2005 in Zeger *et al.* (2008). The analysis then calculated the extended long-term mean $PM_{2.5}$ concentration for each study. As discussed in Schmidt (2012a), in each case the long-term mean $PM_{2.5}$ concentration averaged over the extended exposure period was less than 0.4 μg/m^3 higher than the long-term mean $PM_{2.5}$ concentration averaged over the follow-up period. The EPA finds it reasonable to conclude that such a relatively small difference in long-term mean $PM_{2.5}$ concentrations would likely apply for other long-term exposure studies that used similarly recent follow-up periods as well (e.g., Goss *et al.,* 2004; Lipfert *et al.,* 2006a).

Based on the above considerations, the EPA concludes that it is appropriate to consider the available air quality information from the long-term exposure studies, while taking into account the uncertainties in the relevant long-term exposure periods in weighing the information from these studies. The EPA recognizes that considering such information in selecting an appropriate annual standard level has the potential to build in some margin of safety. The EPA further concludes that it is appropriate to consider the air quality information from the set of long-term exposure studies discussed above in the context of the broader array of epidemiological studies that inform the EPA's consideration of the level of the annual $PM_{2.5}$ standard.

The EPA also notes that while the long-term exposure studies are an important component of the epidemiological evidence that informs the Agency's consideration of the level of the annual standard, they do not provide the only relevant information, nor are they the set of studies for which the relevant long-term mean $PM_{2.5}$ concentrations are the lowest. As discussed in the proposal, the EPA also considers the long-term mean $PM_{2.5}$ concentrations from the short-term mortality and morbidity studies as providing important information in considering the level of the annual standard. As discussed above, a large proportion of the aggregate risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range of the concentrations observed in the studies. Thus, setting the level of the annual standard based on long-term mean concentrations, as well as the distribution of concentrations below the mean, in the short-term exposure studies is the most effective and efficient way to reduce total $PM_{2.5}$-

[94] Nonetheless, the EPA notes that the Krewski et al. (2009) and Miller et al. (2007) studies provide strong evidence of mortality and cardiovascular-related effects associated with long-term $PM_{2.5}$ exposures to inform causality determinations reached in the Integrated Science Assessment (U.S. EPA, 2009a, sections 7.2.11 and 7.6).

related risk from the broad array of mortality and morbidity effects associated with short-term exposures.

Further, the EPA notes that the relevant exposure period for the short-term exposure studies is the period contemporaneous with the collection of health event data, and that this exposure period is not subject to the uncertainties discussed above related to the long-term exposure studies. Recognizing that the long-term mean $PM_{2.5}$ concentrations from several of the multi-city short-term exposure studies shown in Figure 4 are below the long-term mean $PM_{2.5}$ concentrations from the long-term exposure studies (with the exception of Miller *et al.,* 2007).[95] It is reasonable that in selecting the level of the annual standard primary consideration should be given to the information from this set of short-term exposure studies. There is no reasonable basis to discount the long-term mean concentrations of the short-term exposure studies for purposes of setting the level of the annual standard. Thus, the commenter is incorrect in asserting that the long-term exposure studies, not the short-term exposure studies, would be central in the Administrator's decision on the level of the annual standard. The standard is ultimately intended to protect not just against the single type of effect that contributes the most to quantitative estimates of risk to public health, but rather to the broad array of effects, including mortality and morbidity effects from long- and short-term exposures across the range of at-risk populations impacted by $PM_{2.5}$-related effects.

(3) With regard to the EPA's analysis of distributions of underlying population-level data (i.e., health event and study population data) and corresponding air quality data from each study area in certain key multi-city epidemiological studies (Rajan *et al.,* 2011), some commenters in this group raised a number of issues related to this analysis (API, 2012, Attachment 1 pp. 5 to 6; McClellan, 2012, pp.2 to 4). Some commenters noted the limited number of studies for which health event and study population data were available, and questioned whether these distributions would apply to other studies. Commenters expressed concerns that this analysis had not been formally reviewed by CASAC and was not published in the peer-review literature. Based on such concerns, some commenters asserted that the EPA should not consider this information as a basis for selecting a standard level.

As an initial matter, as discussed in section III.E.4.b above, the EPA agrees with CASAC's advice that it is appropriate to consider additional data beyond the mean $PM_{2.5}$ concentrations in key multi-city studies to help inform selection of the level of the annual $PM_{2.5}$ standard. As both the EPA and CASAC recognize, in the absence of a discernible threshold, health effects may occur over the full range of concentrations observed in the epidemiological studies. Nonetheless, the EPA recognizes that confidence in the magnitude and significance of an association is highest at and around the long-term mean $PM_{2.5}$ concentrations reported in the studies and the degree of confidence becomes lower at lower concentrations within any given study. Following CASAC's advice (Samet, 2010d, p.2), the EPA used additional population-level and air quality data made available by study authors to conduct an analysis of the distributions of such data, to help inform consideration of how the degree of confidence in the magnitude and significance of observed associations varies across the range of long-term mean $PM_{2.5}$ concentrations in study areas within key multi-city epidemiological studies. In the EPA's view, such consideration is important in selecting a level for an annual standard that will protect public health with an adequate margin of safety.

With regard to the number of multi-city studies for which an analysis of the distributions of population-level data across the study areas and the corresponding annual mean $PM_{2.5}$ concentrations was done, the EPA noted at proposal that data for such an analysis were made available from study authors for four studies, including two long-term exposure studies and two short-term exposure studies.[96] The EPA recognized that access to health event data can be restricted due to confidentiality issues, such that it is not reasonable to expect that such information could be made available from all studies. In considering the information from these four studies, the EPA has further taken into consideration uncertainties discussed in response to the above comment related to the appropriate exposure period for long-term exposure studies. Based on these considerations, as noted above, the EPA concludes that such uncertainties are an important factor in evaluating the usefulness of the air quality information from the two long-term exposure studies in this analysis (Krewski *et al.,* 2009; Miller *et al.,* 2007) and that it would not be appropriate to place weight on the distributional analysis of health event and air quality data from these two studies specifically for the purpose of translating the information from the long-term mortality studies into a basis for selecting the level of the annual $PM_{2.5}$ standard. Such uncertainties are not relevant to the short-term exposure studies, and thus, the Agency focuses on the two short-term exposure studies in this analysis (Bell *et al.,* 2008; Zanobetti and Schwartz, (2009).

In focusing on these two short-term exposure studies, the EPA first notes that these studies are key multi-city studies that reported positive and statistically significant associations between mortality and cardiovascular-related hospital admissions across a large number of areas throughout the U.S. (112 U.S. cities in Zanobetti and Schwartz, 2009; 202 U.S. counties in Bell *et al.,* 2008) using relatively recent air quality and health event data (i.e., 1999 through 2005 in both studies). The EPA considers this to be a modest but important data set to use for this distributional analysis to help inform consideration of how much below the long-term mean $PM_{2.5}$ concentrations in key multi-city long- and short-term exposure studies the annual $PM_{2.5}$ standard level should be set. While the EPA acknowledges that having such data available from more studies would have been useful, the Agency finds the information from this limited set of studies to be an important consideration in selecting an annual standard level, consistent with CASAC advice to consider such information.

In considering the results of this distributional analysis, as discussed more fully in the Response to Comments document, the EPA considers $PM_{2.5}$ concentrations between the 25th and 10th percentiles of the distribution of health events to be a reasonable range for providing a general frame of reference for that part of the distribution in which confidence in the magnitude and significance of the association may be appreciably lower than confidence at and around the long-term mean concentration. For the two short-term exposure studies included in this analysis, the EPA notes that the $PM_{2.5}$ concentrations corresponding to the 25th percentiles of the distributions of

[95] As noted above, the EPA is not placing weight on the reported long-term mean concentrations from the Miller et al. (2007) study for the purpose of translating the information from the long-term mortality studies into a basis for selecting the level of the annual $PM_{2.5}$ standard.

[96] Health event data and study population data were available from two short-term exposure studies (Bell *et al.* 2008; Zanobetti and Schwartz, 2009) and one long-term exposure study (Krewski *et al.,* 2009). Only study population data were available from another long-term exposure study (Miller *et al.,* 2007).

health events were 12.5 μg/m³ and 11.5 μg/m³, respectively, for Zanobetti and Schwartz (2009) and for Bell *et al.* (2008), with the 10th percentiles being lower by approximately 2 μg/m³ in each study (Rajan *et al.,* 2011, Table 1). In considering this information, the EPA recognizes, however, that there is no clear dividing line or single percentile within a given distribution (including both above and below the 25th percentile) provided by the scientific evidence that is most appropriate or 'correct' to use to characterize where the degree of confidence in the associations warrants setting the annual standard level. The decision as to the appropriate standard level below the long-term mean concentrations of the key studies is largely a public health policy judgment to be made by the Administrator, taking into account all of the evidence and its related uncertainties, as discussed in section III.E.4.d below.

In response to concerns that this analysis was not reviewed by CASAC nor published in the peer-reviewed literature, the EPA notes that this analysis was conducted to directly respond to advice from CASAC, as discussed in section III.E.4.b.i above, in conjunction with their review of the Policy Assessment. The EPA notes that the same type of distributional analysis was presented in the second draft Policy Assessment based on air quality data, as well as population-weighted air quality data, rather than health event or study population data. In considering that distributional information, CASAC urged that the EPA redo the analysis using health event or study population data, which is exactly what the EPA did and presented in the final Policy Assessment. The EPA provided CASAC with the final Policy Assessment and communicated how the final staff conclusions reflected consideration of its advice and that those staff conclusions were based in part on the specific distributional analysis that CASAC had urged the EPA to conduct (Wegman, 2011, Attachment p. 2). CASAC did not choose to provide any additional comments or advice after receiving the final Policy Assessment. The EPA considers this distributional analysis to be the product of the peer review conducted by CASAC of the Policy Assessment, and thus does not agree with commenters' characterization that the analysis lacked appropriate peer review. The EPA's final analysis was based on the comments provided by CASAC, the peer review committee established pursuant to the CAA, on the draft analysis, such that the final analysis stems directly from CASAC's advice and the EPA's response to its comments.

Based on the above considerations, the EPA continues to conclude that its analysis of distributions of health event and air quality data from two key multi-city epidemiological studies provides important information related to understanding the associations between health events observed in each city (e.g., deaths, hospitalizations) and the corresponding long-term mean $PM_{2.5}$ concentrations observed in the studies. While recognizing that this is a relatively modest data set, the EPA further concludes that such information can appropriately help to inform the selection of the level of an annual standard that will protect public health with an adequate margin of safety from these types of health effects which are causally related to long- and short-term exposures to $PM_{2.5}$.

(4) Some commenters in this group asserted there were limitations in the long-term exposure studies of morbidity, including studies evaluating respiratory effects in children. For example, one commenter (UARG, 2012, p. 12, Attachment 1, pp. 14 to 16) asserted there were serious limitations in the long-term exposure studies of respiratory morbidity in each of the studies considered by the EPA (including McConnell *et al.,* 2003; Gauderman *et al.,* 2004; Dockery *et al.,* 1996; Raizenne *et al.,* 1996; and Goss *et al.,* 2004) and argued that this evidence provides only a ''weak association'' with $PM_{2.5}$ exposures. This commenter asserted that many of these long-term exposure studies evaluating respiratory effects were considered at the time the EPA reaffirmed the current annual standard level of 15 μg/m³ in 2006, that the Administrator in the last review determined that the information they provided ''was too limited to serve as the basis for setting a level of a national standard,'' and that they should be given little weight in setting the level of the annual standard in this review (UARG, 2012, Attachment 1, p. 14).

More specifically, this commenter asserted that the McConnell *et al.* (2003) and Gauderman *et al.* (2004) studies reported mixed results for associations with $PM_{2.5}$ and stronger associations with NO_2 (API, 2012, Attachment 1, pp. 14 to 15). Similarly, this commenter argued that the Dockery *et al.* (1996) and Raizenne *et al.* (1996) studies showed stronger associations with acidity than with fine particles (measured as $PM_{2.1}$). *Id.* pp. 15 to 16. With regard to the cystic fibrosis study, this commenter noted that the association between pulmonary exacerbations and $PM_{2.5}$ in this study was no longer statistically significant when the model adjusted for each individual's baseline lung function. The commenters referred to the data on lung function as an ''important explanatory variable,'' and suggested that the EPA should rely on results from the model that included individual baseline lung function information. *Id.* p. 16. For the reasons discussed below and in more detail in the Response to Comments document, the EPA disagrees with the commenters' interpretation of these studies.

As an initial matter, the EPA notes that three of these studies (McConnell *et al.,* 2003; Dockery *et al.,* 1996; Raizenne *et al.,* 1996) as well as the initial studies from the Southern California Children's Health Study (Peters *et al.,* 1999; McConnell *et al.,* 1999; Gauderman *et al.,* 2000, 2002; Avol *et al.,* 2001) were discussed and considered in the 2004 Air Quality Criteria Document (U.S. EPA, 2004) and, thus, considered within the air quality criteria supporting the EPA's final decisions in the review completed in 2006. Two additional studies (Gauderman *et al.,* 2004; Goss *et al.,* 2004) were discussed and considered in the provisional science assessment conducted for the last review (U.S. EPA, 2006a). The EPA concluded that ''new'' studies considered in the provisional assessment completed in 2006 did not materially change any of the broad scientific conclusions regarding the health effects of PM exposure made in the Criteria Document (71 FR 61148 to 61149, October 17, 2006). All of these studies were considered in the Integrated Science Assessment that informs the current review (U.S. EPA, 2009a).

With regard to the Southern California Children's Health Study, extended analyses considered in the Integrated Science Assessment provided evidence that clinically important deficits in lung function [97] associated with long-term exposure to $PM_{2.5}$ persist into early adulthood (U.S. EPA, 2009a, p. 7–27; Gauderman *et al.,* 2004). These effects remained positive in copollutant models.[98] Additional analyses of the

[97] Clinical significance was defined as an FEV_1 below 80 percent of the predicted value, a criterion commonly used in clinical settings to identify persons at increased risk for adverse respiratory conditions (U.S. EPA, 2009a, p. 7–29 to 7–30). The primary NAAQS for sulfur dioxide (SO_2) also included this interpretation for FEV_1 (75 FR 35525, June 22, 2010).

[98] Gauderman *et al.* (2004) clearly stated throughout their analysis that NO_2 was one component of a highly correlated mixture that contains $PM_{2.5}$. Gauderman *et al.* (2004) did not present the results from copollutants models but stated ''two-pollutant models for any pair of

Southern California Children's Health Study cohort reported an association between long-term $PM_{2.5}$ exposure and bronchitic symptoms (U.S. EPA, 2009a, p. 7–23 to 7–24; McConnell *et al.,* 2003, long-term mean concentration of 13.8 µg/m³) that remained positive in co-pollutant models, with the $PM_{2.5}$ effect estimates increasing in magnitude in some models and decreasing in others, and a strong modifying effect of $PM_{2.5}$ on the association between lung function and asthma incidence (U.S. EPA, 2009a, 7–24; Islam *et al.,* 2007). The outcomes observed in the more recent reports from the Southern California Children's Health Study, including evaluation of a broader range of endpoints and longer follow-up periods, were larger in magnitude and more precise than reported in the initial version of the study. Supporting these results were new longitudinal cohort studies conducted by other researchers in varying locations using different methods (U.S. EPA, 2009a, section 7.3.9.1). The EPA, therefore, disagrees with the commenters that the studies by McConnell *et al.* (2003) and Gauderman *et al.* (2004) are flawed and should not be used in the PM NAAQS review process.

The 24-City study [99] by Dockery *et al.* (1996) (long-term mean concentration of 14.5 µg/m³) was considered in the current as well as two previous reviews (U.S. EPA, 2009a; U.S. EPA, 2004; U.S. EPA, 1996). This study observed that PM, specifically ''particle strong acidity'' and sulfate particles (indicators of fine particles), were associated with reports of bronchitis in the previous year. Similarly, the magnitude of the associations between bronchitis and PM_{10} and $PM_{2.1}$ were similar to those for acidic aerosols and sulfate particles, though the confidence intervals for the PM_{10} and $PM_{2.1}$ associations were slightly wider and the associations were not statistically significant. Acid aerosols, sulfate, and fine particles are formed in secondary reactions of the emissions from incomplete combustion and these pollutants have similar regional and temporal distributions. As noted by the study authors, ''the strong correlations of several pollutants in this study, especially particle strong acidity with sulfate (r=0.90) and $PM_{2.1}$ (r=0.82), make it difficult to distinguish the agent of interest'' (Dockery *et al.,* 1996, p. 505). Overall, Dockery *et al.* (1996) (and, similarly, Raizenne *et al.,* 1996) observed similar associations between respiratory health effects and acid aerosols, sulfate, PM_{10} and $PM_{2.1}$ concentrations. The commenters noted that the associations with particle acidity were sensitive to the inclusion of the six Canadian sites. The EPA notes that none of these Canadian cities were in the ''sulfate belt'' where particle strong acidity was highest. Thus, the change in the effect estimate when the six Canadian cities were excluded from the analysis is likely due to the lower prevalence of bronchitis and the lower concentrations of acid aerosols in these cities, and not due to some difference in susceptibility to bronchitis between the U.S. and Canadian populations that is not due to air pollution, as suggested by the commenters (UARG, 2012, Attachment 1, p. 15). In fact, contrary to the statements made by the commenters, the authors did not observe any subgroups that appeared to be markedly more susceptible to the risk of bronchitis.

The Goss *et al.* (2004) study considered a U.S. cohort of cystic fibrosis patients and provided evidence of association between long-term $PM_{2.5}$ exposures and exacerbations of respiratory symptoms resulting in hospital admissions or use of home intravenous antibiotics (U.S. EPA, 2009a, p. 7–25; long-term mean concentration of 13.7 µg/m³). The commenters noted that the association between pulmonary exacerbations and $PM_{2.5}$ in this study was no longer statistically significant when the model adjusted for each individual's baseline lung function. The commenters referred to the data on lung function as an ''important explanatory variable,'' and suggested that the EPA should rely on results from the model that included individual baseline lung function information. The EPA disagrees with the commenters' interpretation of this study. The Agency concludes it is unlikely that lung function is a potential confounder or an important explanatory variable in this study. In fact, the authors noted that ''it is more likely that lung function decline may be intimately associated with chronic exposure to air pollutants and may be part of the causal pathway in worsening prognosis in CF [cystic fibrosis]; in support of this explanation, we found both cross-sectional and longitudinal strong inverse relationships between FEV_1 and PM levels'' (Goss *et al.,* 2004, p. 819). The EPA notes that adjusting for a variable that is on the causal pathway can lead to overadjustment bias, which is likely to attenuate the association (Schisterman *et al.* 2009); this is likely what was observed by the authors. Thus, the EPA continues to believe it is appropriate to focus on the results reported in Goss *et al.* (2004) that did not include individual baseline lung function in the model.

In addition, the EPA disagrees with commenters' reliance solely on statistical significance when interpreting the study results from individual study results and the collective evidence across studies. As discussed in section III.D.2 above, statistical significance of individual study findings has played an important role in the EPA's evaluation of the study's results and the EPA has placed greater emphasis on studies reporting statistically significant results. However, in the broader evaluation of the evidence from many epidemiological studies, and subsequently during the process of forming causality determinations in the Integrated Science Assessment by integrating evidence from across epidemiological, controlled human exposure, and toxicological studies, the EPA has emphasized the *pattern of results* across epidemiological studies and whether the effects observed were *coherent* across the scientific disciplines for drawing conclusions on the relationship between $PM_{2.5}$ and different health outcomes.

As noted in section III.B.1.a of the proposal, with regard to respiratory effects, the Integrated Science Assessment concluded that extended analyses of studies available in the last review as well as new epidemiological studies conducted in the U.S. and abroad provided stronger evidence of respiratory-related morbidity associated with long-term $PM_{2.5}$ exposure (77 FR 38918). The strongest evidence for respiratory-related effects available in this review was from epidemiological studies that evaluated decrements in lung function growth in children and increased respiratory symptoms and disease incidence in adults (U.S. EPA, 2009a, sections 2.3.1.2, 7.3.1.1, and 7.3.2.1).

In considering the collective evidence from epidemiological, toxicological, and controlled human exposure studies, including the studies discussed above, the EPA recognizes that the Integrated Science Assessment concluded that a causal relationship is likely to exist between long-term $PM_{2.5}$ exposures and respiratory effects (U.S. EPA, 2009a, p. 2–12, pp. 7–42 to 7–43). CASAC concurred with this causality determination (Samet, 2009f, p.9).

pollutants did not provide a significantly better fit to the data than the corresponding single-pollutant models.''

[99] The 24-City study conducted by Dockery *et al.* (1996) included 18 sites in the U.S. and 6 sites in Canada. The Raizenne *et al.* (1996) study considered 22 of these 24 study areas. Athens, OH and South Brunswick, NJ were not included in this study.

The commenter's assertion that the EPA should adhere to its assessment of these studies as it did in the review completed in 2006 is significantly mistaken. Most obviously, the EPA's final decision in the last review was held to be deficient by the DC Circuit in remanding the 2006 primary annual $PM_{2.5}$ standard. As discussed in section III.A.2 above, the DC Circuit specifically held that the EPA did not provide a reasonable explanation of why certain morbidity studies, including an earlier study from the Southern California Children's Health Study (Gauderman *et al.,* 2000, long-term mean $PM_{2.5}$ concentration approximately 15 μg/m^3) and the 24-Cities Study (Raizenne *et al.,* 1996, long-term mean concentrations approximately 14.5 μg/m^3) did not warrant a more stringent annual $PM_{2.5}$ standard when the long-term mean $PM_{2.5}$ concentrations reported in those studies were at or lower than the level of the annual standard. *American Farm Bureau Federation* v. *EPA.* 559 F. 3d at 525. Indeed, the court found that, viewed together, the Gauderman *et al.* (2000) and Raizenne *et al.,* (1996) studies ''are related and together indicate a significant public health risk * * * On this record, therefore, it appears the EPA too hastily discounted the Gauderman and 24-Cities studies as lacking in significance.'' *Id.*

In this review, the EPA recognizes a significant amount of evidence beyond these two studies that expands our understanding of respiratory effects associated with long-term $PM_{2.5}$ exposures. This body of scientific evidence includes an extended and new analyses from the Southern California Children's Health Study (Gauderman *et al.,* 2004; Islam *et al.,* 2007; Stanojevic *et al.,* 2008) as well as additional studies that examined these health effects (Kim *et al.,* 2004; Goss *et al.,* 2004). Thus, even more so than in the last review, the evidence indicates a ''significant public health risk'' to children from long-term $PM_{2.5}$ exposures at concentrations below the level of the current annual standard. A standard that does not reflect appropriate consideration of this evidence would not be requisite to protect public health with an adequate margin of safety.

(5) With regard to the use of studies of health effects for which the EPA finds the evidence to be ''suggestive'' of a causal relationship, some commenters argued that such studies ''do not merit any weight in the setting of the annual NAAQS'' (e.g., UARG, 2012, Appendix 1, p. 3).

The EPA disagrees with the commenter's view that studies of health effects for which the evidence is suggestive of a causal relationship, rather than studies of health effects for which the evidence supports a causal or likely causal relationship, merit no weight at all in setting the NAAQS. To place no weight at all on such evidence would in essence treat such evidence as though it had been categorized as ''not likely to be a causal relationship.'' To do so would ignore the important distinctions in the nature of the evidence supporting these different causality determinations in the Integrated Science Assessment. It would also ignore the CAA requirement that primary standards are to be set to provide protection with an adequate margin of safety, including providing protection for at-risk populations. Thus, ignoring this information in making decisions on the appropriate standard level would not be appropriate.[100] Nonetheless, in considering studies of health effects for which the evidence is suggestive of a causal relationship, the EPA does believe that it is appropriate to place less weight on such studies than on studies of health effects for which there is evidence of a causal or likely causal relationship.

A second group of commenters supported revising the suite of primary $PM_{2.5}$ standards to provide increased public health protection. These commenters found the available scientific information and technical analyses to be stronger and more compelling than in the last review. These commenters generally placed substantial weight on CASAC advice and on the EPA staff analyses presented in the final Policy Assessment, which concluded that the evidence most strongly supported an annual standard level within a range of 11 to 12 μg/m^3 (U.S. EPA, 2011a, p. 2–206). While some of these commenters felt that the level should be set within the proposed range (12 to 13 μg/m^3), most of these commenters advocated a level of 11 μg/m^3.[101] For example, ALA *et al.,* asserted:

> The EPA's proposed $PM_{2.5}$ standards, while a step in the right direction are insufficient to protect public health, including the health of susceptible populations, with an adequate margin of safety as required by the Clean Air Act * * *we will discuss the enormous gap in public health protection afforded by an annual standard of 13 μg/m^3, at the upper end of the proposed range, compared to the more protective 11 μg/m^3, as advocated by our organizations (ALA *et al.,* 2012, p. 6).

In general, these commenters expressed the view that given the strength of the available scientific evidence, the serious nature of the health effects associated with $PM_{2.5}$ exposures, the large size of the at-risk populations, the risks associated with long- and short-term $PM_{2.5}$ exposures, and the important uncertainties inherently present in the evidence, the EPA should follow a highly precautionary policy response by selecting an annual standard level that incorporates a large margin of safety.

More specifically, these commenters offered a range of comments related to the general approach used by the EPA to select standard levels, including: (1) The EPA's approach for setting a generally controlling annual standard; (2) the importance of the greatly expanded and stronger overall scientific data base; (3) consideration of the distributional statistical analysis conducted by the EPA and other approaches for translating the air quality information from specific epidemiological studies into standard levels; and (4) the significance of the $PM_{2.5}$-related public health impacts, especially potential impacts on at-risk populations, including children, in reaching judgments on setting standards that provide protection with an adequate margin of safety. These comments are discussed in turn below.

(1) Some of these commenters disagreed with the EPA's approach for setting a ''generally controlling'' annual standard in conjunction with a 24-hour standard providing supplemental protection particularly for areas with high peak-to-mean ratios. These commenters argued this approach would lead to ''regional inequities'' as demonstrated in the EPA's analyses contained in Appendix C of the Policy Assessment (ALA *et al.,* pp. 26 to 27). Specifically, these commenters argued:

> There is no basis in the Clean Air Act for such a determination. The Clean Air Act requires only that the NAAQS achieve public health protection with an adequate margin of safety. It is well-documented that both long- and short-term exposures to $PM_{2.5}$ have serious and sometimes irreversible health impacts. There is no health protection reason to argue that one standard should be ''controlling'' as a matter of policy without regard to the health consequences of such a policy. To adopt such a policy ignores the obligation to provide equal protection under

[100] As discussed in section II.A above, the requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. I was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. This certainly encompasses consideration of effects for which there is evidence suggestive of a causal relationship.

[101] As discussed in section III.E.4.c.ii, many of these commenters also supported lowering the level of the primary 24-hour $PM_{2.5}$ standard.

the law to all Americans because it would result in uneven protection from air pollution in different localities and regions of the country (ALA *et al.,* 2012, p. 26).

The EPA believes these commenters misunderstood the basis for the EPA's policy goal of setting a ''generally controlling'' annual standard. This approach relates exclusively to setting standards that will provide requisite protection against effects associated with both long- and short-term $PM_{2.5}$ exposures. It does so by lowering the overall air quality distributions across an area, recognizing that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in lower annual mean $PM_{2.5}$ concentrations but also in fewer and lower peak 24-hour $PM_{2.5}$ concentrations. As discussed in section III.A.3 in the proposal and above, the EPA recognizes that there are various ways to combine the two primary $PM_{2.5}$ standards to achieve an appropriate degree of public health protection. Furthermore, the extent to which these two standards are interrelated in any given area depends in large part on the relative levels of the standards, the peak-to-mean ratios that characterize air quality patterns in an area, and whether changes in air quality designed to meet a given suite of standards are likely to be of a more regional or more localized nature.

In focusing on an approach of setting a generally controlling annual standard, the EPA's intent is in fact to avoid the potential ''regional inequities'' that are of concern to the commenters. The EPA judges that the most appropriate way to set standards that provide more consistent public health protection is by using the approach of setting a generally controlling annual standard. This judgment builds upon information presented in the Policy Assessment as discussed in section III.A.3 above. More specifically, the Policy Assessment recognized that the short-term exposure studies primarily evaluated daily variations in health effects with monitor(s) that measured the variation in daily $PM_{2.5}$ concentrations over the course of several years. The strength of the associations observed in these epidemiological studies was demonstrably in the numerous ''typical'' days within the air quality distribution, not in the peak days (U.S. EPA, 2011a, p. 2–9). In addition, the quantitative risk assessments conducted for this and previous reviews demonstrated the same point, that is, much, if not most, of the aggregate risk associated with short-term $PM_{2.5}$ exposures results from the large number of days during which the 24-hour average concentrations are in the low-to mid-range, below the peak 24-hour concentrations (U.S. EPA, 2011a, section 2.2.2; U.S. EPA, 2010a, section 3.1.2.2). In addition, there was no evidence suggesting that risks associated with long-term exposures were likely to be disproportionately driven by peak 24-hour concentrations.[102]

For these reasons, the Policy Assessment concluded that strategies that focused primarily on reducing peak days were less likely to achieve reductions in the $PM_{2.5}$ concentrations that were most strongly associated with the observed health effects. Furthermore, the Policy Assessment concluded that an approach that focused on reducing peak exposures would most likely result in more uneven public health protection across the U.S. by either providing inadequate protection in some areas or overprotecting in other areas (U.S. EPA, 2011a, p. 2–9; U.S. EPA, 2010a, section 5.2.3). This is because reductions based on control of peak days are less likely to control the bulk of the air quality distribution.

As a result, the EPA believes an approach that focuses on a generally controlling annual standard would likely reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and, therefore, would be the most effective and efficient way to reduce total $PM_{2.5}$-related population risk. The CASAC agreed with this approach and considered it was ''appropriate to return to the strategy used in 1997 that considers the annual and the short-term standards together, with the annual standard as the controlling standard, and the short-term standard supplementing the protection afforded by the annual standard'' (Samet, 2010d, p. 1). For the reasons discussed above, the EPA disagrees with the comments that this approach will result in the concerns raised by the commenters; rather the EPA concludes that this approach will help to address these concerns.

(2) Many of these commenters asserted that the currently available scientific information is greatly expanded and stronger compared to the last review. Some of these commenters highlighted the availability of multiple, multi-city long- and short-term exposure studies providing ''repeated, consistent evidence of effects below the current annual standard level'' (ALA *et al.,* 2012, pp. 39 to 49) and, more specifically, ''significant evidence of harm with strong confidence well below EPA's proposed annual standard range of 12–13 μg/m³'' (AHA *et al.,* 2012, pp. 10 to 12).

The EPA recognizes that in setting standards that are requisite to protect public health with an adequate margin of safety, the Administrator must weigh the various types of available scientific information in reaching public health policy judgments that neither overstate nor understate the strength and limitations of this information or the appropriate inferences to be drawn from the available science.

In general, the EPA agrees with these commenters' views that the currently available scientific evidence is stronger ''because of its breadth and the substantiation of previously observed health effects'' (77 FR 38906/2) and provides ''greater confidence in the reported associations than in the last review'' (77 FR 38940/1). The EPA also agrees with the commenters' position that it is appropriate to consider the regions within the broader air quality distributions where we have the strongest confidence in the associations reported in epidemiological studies in setting the level of the annual standard. However, as discussed in section III.E.4.d below, in weighing the available evidence and technical analyses, as well as the associated uncertainties and limitations in that information, the EPA disagrees with the commenters' views regarding the extent to which the available scientific information provides support for considering an annual standard level below the proposed range (i.e., below 12 to 13 μg/m³). In particular, the EPA disagrees with the degree to which these commenters place more weight on the relatively more uncertain evidence that is suggestive of a causal relationship (e.g., low birth weight). Consistent with CASAC advice (Samet, 2010d, p. 1), the Agency concludes it is appropriate and reasonable to place the greatest emphasis on health effects for which the Integrated Science Assessment concluded there is evidence of a causal or likely causal relationship and to place less weight on the health effects that provide evidence that is only suggestive of a causal relationship.

(3) With regard to using the air quality information from epidemiological studies to inform decisions on standard levels, commenters in this group generally supported the EPA's efforts to explore different statistical metrics from

[102] In confirmation, a number of studies have presented analyses excluding higher PM concentration days and reported a limited effect on the magnitude of the effect estimates or statistical significance of the association (e.g., Dominici, 2006b; Schwartz *et al.,* 1996; Pope and Dockery, 1992).

epidemiological studies to inform the Administrator's decisions. These commenters argued that by considering different analytic measures—either concentrations one standard deviation below the long-term means reported in the epidemiological studies or the EPA's distributional statistical analysis of population-level data that extends the approach used in previous PM NAAQS reviews to consider information beyond a single statistical metric—''the annual standard must be significantly lower than EPA has proposed'' (ALA *et al.,* 2012, pp. 50 to 61). Furthermore, with regard to characterizing the $PM_{2.5}$ air quality at which associations have been observed, some of these commenters highlighted CASAC's recommendation that ''[f]urther consideration should be given to using the 10th percentile as a level for assessing various scenarios of levels for the PM NAAQS'' (Samet, 2010c, p. 11) (ALA *et al.,* 2012, p. 55). Other commenters urged that the EPA extend the distributional analysis to include additional studies. For example, CHPAC urged the EPA to also conduct distributional analysis for children's health studies to better inform standards that would protect both children and adults from adverse health outcomes (CHPAC, 2012, p. 3).

The EPA agrees with these commenters' views that it is appropriate to take into account different statistical metrics from epidemiological studies to inform the decisions on standard levels that are appropriate to consider in setting a standard that will protect public health with an adequate margin of safety. In the development of the Policy Assessment, the EPA staff explored various approaches for using information from epidemiological studies in setting the standards. The general approach used in the final Policy Assessment, discussed in sections III.A.3 and III.E.4.a above, reflects consideration of CASAC advice (Samet, 2010c, d) and public comments on multiple drafts of the Policy Assessment.

With regard to using the distributional statistical analysis to characterize the confidence in the associations, the EPA emphasizes that there is no clear dividing line provided by the scientific evidence, and that choosing how far below the long-term mean concentrations from the epidemiological studies is appropriate to identify a standard level that will provide protection for the public health with an adequate margin of safety is largely a public health policy judgment. The EPA considers the region from approximately the 25th to 10th percentiles to be a reasonable range for providing a general frame of reference as to the part of the distribution over which our confidence in the magnitude and significance of the associations observed in epidemiological studies is appreciably lower. Based on these considerations, the EPA concludes that it is not appropriate to place as much confidence in the magnitude and significance of the associations over the lower percentiles of the distributions in each study as at and around the long-term mean concentrations. Thus, the EPA disagrees with the commenters' views that this analysis compels placing more emphasis on the lower part of this range in selecting a level for an annual standard that will protect public health with an adequate margin of safety. The EPA recognizes that this information comes primarily from two short-term exposure studies, a relatively modest data set. In light of the limited nature of this information, and in recognition of more general uncertainties inherent in the epidemiological evidence, the Administrator deems it reasonable not to place more emphasis on concentrations in the lower part of this range, as discussed below in section III.E.4.d.

With regard to the scope of the distributional statistical analysis, the EPA requested additional population-level data from the study authors for a group of six multi-city studies for which previous air quality analyses had been conducted (Hassett-Sipple *et al.,* 2010; Schmidt *et al.,* 2010, Analysis 2). These six studies were originally selected because they considered multiple locations representing varying geographic regions across multiple years. Thus, these studies provided evidence on the influence of different particle mixtures on health effects associated with long- and short-term $PM_{2.5}$ exposures. In addition, these multi-city studies considered relatively more recent health events and air quality conditions (1999 to 2005). As discussed in section III.E.4.b.i above, the EPA received and analyzed population-level data for four of the six studies (Rajan *et al.,* 2011). Three of these four studies (Krewski *et al.,* 2009; Bell *et al.,* 2008; Zanobetti and Schwartz, 2009) served as the basis for the concentration-response functions used to develop the core risk estimates (U.S. EPA, 2010a, section 3.3.3). While, the EPA agrees that it would be useful to have such data from more studies, the Agency believes that the additional data that was requested and received from study authors provide useful information to help inform the Administrator's selection of the annual standard level.

(4) Many commenters in this group highlighted $PM_{2.5}$-related impacts on at-risk populations, including potential impacts on children, older adults, persons with pre-existing heart and lung disease, and low-income populations, to support their views that the annual standard should be revised to a level of 11 $\mu g/m^3$ or lower (CHPAC, 2012; AHA *et al.,* 2012; ALA, 2012, pp. 29 to 38; Rom *et al.,* 2012; Air Alliance Houston, *et al.,* 2012). These commenters urged the EPA to adopt a policy approach that placed less weight on the remaining uncertainties and limitations in the evidence and placed more emphasis on margin of safety considerations, including providing protection against effects for which there is more limited scientific evidence. For example, CHPAC urged the EPA ''to place the same weight on studies examining impacts on children's health as that of adult studies. * * * The fact that there may be stronger evidence from adult studies does not mean that standards based on adult studies will be protective for children and consequently will meet the standard requisite to protect public health with an adequate margin of safety'' (CHPAC, 2012 p. 3). Furthermore, with regard to the EPA's approach for weighing uncertainties, some of these commenters stated that ''we find no justification in the preamble for an annual standard level as high as 13 $\mu g/m^3$, other than the vague assertion that uncertainties increase at lower concentrations. Further, the final proposal completely failed to address the Policy Assessment recommendations that if 13 $\mu g/m^3$ was proposed, the 24-hour standard should be strengthened as well'' (ALA *et al.,* p. 7).

The EPA has carefully evaluated and considered evidence of effects in at-risk populations. With regard to effects classified as having evidence of a causal or likely causal relationship with long- or short-term $PM_{2.5}$ exposures (i.e., premature mortality, cardiovascular effects, and respiratory effects), the Agency takes note that it considered the full range of studies evaluating these effects, including studies of at-risk populations, to inform its review of the primary $PM_{2.5}$ standards. Specific multi-city studies summarized in Figures 1, 2, and 3 above highlight evidence of effects observed in two different lifestages—children and older adults—that have been identified as at-risk populations. Thus, the EPA places as much weight on studies that explored effects in children for which the evidence is causal or likely causal in nature as on studies of such effects in adults, including older adults. As discussed above in responses to commenters supporting the retention of the current standards, in setting the standard, the EPA has focused on considering $PM_{2.5}$ concentrations somewhat *below* the lowest long-term mean concentrations from *each* of the key studies of both long- and short-term exposures of effects for which the evidence supports a causal or likely causal relationship (i.e., the first two sets of studies shown in Figure 4). Absent some reason to ignore or discount these studies, which the commenter does not provide (and of which the EPA is unaware), the EPA considers the available evidence of effects in children as well as other at-risk populations.

With respect to the EPA's consideration of more limited studies providing evidence suggestive of a causal relationship (e.g., developmental and reproductive effects), as noted above in responding to comments from the first group of commenters, the Agency agrees that it is important to place some weight on this body of evidence in setting standards that provide protection for at-risk populations, as required by the CAA. However, the Agency does not agree that the same weight must be placed on this information as on the body of scientific information for which there is evidence of a causal or likely causal relationship. To do so would ignore the difference in the breadth and strength of the evidence supporting the different causality determinations reached in the Integrated Science Assessment.

With regard to weighing the uncertainties and limitations remaining in the evidence and technical analyses, as discussed in section II.A above, the EPA recognizes that in setting a primary NAAQS that provides an adequate margin of safety, the Administrator must consider a number of factors including the nature and severity of the health effects involved, the size of sensitive population(s) at risk, and the kind and degree of the uncertainties that remain. As discussed in section III.E.4.d below, the Agency agrees with these commenters that, in weighing the available evidence and technical analyses including the uncertainties and limitations in this scientific information, there is no justification for setting a primary $PM_{2.5}$ annual standard level as high as 13 µg/m³.

Finally, some commenters in both groups also identified ''new'' studies that were not included in the Integrated Science Assessment as providing further support for their views on the level of the annual standard. As discussed in section II.B.3 above, the EPA completed a provisional review and assessment of ''new'' studies published since the close of the Integrated Science Assessment, including ''new'' studies submitted by commenters (U.S. EPA, 2012b). The provisional assessment found that the ''new'' studies expand the scientific information considered in the Integrated Science Assessment and provide important insights on the relationship between $PM_{2.5}$ exposure and health effects of PM (U.S. EPA, 2012b). However, the EPA notes that the provisional assessment found that the ''new'' science did not materially change the conclusions reached in the Integrated Science Assessment. The EPA notes that, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the Integrated Science Assessment that have undergone CASAC and public review, and will consider newly published studies for purposes of decision making in the next PM NAAQS review.

ii. 24-Hour Standard Level

With respect to the level of the 24-hour standard, the EPA received comments on the proposal from two distinct groups of commenters. One group that included virtually all commenters representing industry associations, businesses, and many States agreed with the Agency's proposed decision to retain the level of the 24-hour $PM_{2.5}$ standard. The other group of commenters included many medical groups, numerous physicians and academic researchers, many public health organizations, some State and local agencies, five State Attorneys General, and a large number of individual commenters. These commenters disagreed with the Agency's proposed decision and argued that EPA should lower the level of the 24-hour standard to 30 or 25 µg/m³. Comments from these groups on the level of the 24-hour $PM_{2.5}$ standard are addressed below and in the Response to Comments Document.

As noted above, of the public commenters who addressed the level of the 24-hour $PM_{2.5}$ standard, all industry commenters and most State and local commenters supported the proposed decision to retain the current level of 35 µg/m³. In many cases, these groups agreed with the rationale supporting the Administrator's proposed decision to retain the current 24-hour $PM_{2.5}$ standard, including her emphasis on the annual standard as the generally controlling standard with the 24-hour standard providing supplementary protection, and her conclusion that multi-city, short-term exposure studies provide the strongest data set for informing decisions on the appropriate 24-hour standard level. Many of these commenters agreed with the Administrator's view that the single-city, short-term studies provided a much more limited data set (e.g., limited statistical power, limited exposure data) and more equivocal results (e.g., mixed results within the same study area), making them an unsuitable basis for setting the level of the 24-hour standard.

While these commenters agreed with the EPA's proposed decision to retain the current 24-hour $PM_{2.5}$ standard, some did not agree with the EPA's approach to considering the evidence from short-term multi-city studies. For example, a commenter representing UARG pointed out that the 98th percentile concentrations reported in the proposal for multi-city studies reflect the averages of 98th percentile concentrations across the cities included in those studies (UARG, 2012; Attachment 1; p. 25). This commenter contended that such averaged 98th percentile $PM_{2.5}$ concentrations do not provide information that can appropriately inform a decision on the adequacy of the public health protection provided by the current or alternative 24-hour standards.

While the EPA agrees that there is uncertainty in linking effects reported in multi-city studies to specific air quality concentrations (U.S. EPA, 2011a, section 2.3.4.1), the EPA disagrees with this commenter's view that such uncertainty precludes the use of averaged 98th percentile $PM_{2.5}$ concentrations to inform a decision on the appropriateness of the protection provided by the 24-hour $PM_{2.5}$ standard. In particular, the EPA notes that averaged 98th percentile concentrations do provide information on the extent to which study cities contributing to reported associations would likely have met or violated the current 24-hour $PM_{2.5}$ standard during the study period. As evidence of this, the EPA notes the three multi-city studies specifically highlighted by this commenter as having averaged 98th percentile 24-hour $PM_{2.5}$ concentrations below 35 µg/m³ (Dominici *et al.,* 2006a; Bell *et al.,* 2008; Zanobetti and Schwartz, 2009). Based on the 98th percentiles of 24-hour $PM_{2.5}$ concentrations in the individual cities evaluated in these studies, the EPA notes that the majority of these study cities would likely have met the current standard during the study periods (Hassett-Sipple *et al.,* 2010). Therefore, regardless of whether the averaged 98th percentile concentrations or the 98th percentile concentrations in each city are considered, these studies provide evidence for associations between short-term $PM_{2.5}$ and mortality or morbidity across a large number of U.S. cities, the majority of which would likely have met the current 24-hour $PM_{2.5}$ standard during study periods. In their review of the PM Policy Assessment, CASAC endorsed the conclusions drawn from analyses of averaged 98th percentile 24-hour $PM_{2.5}$ concentrations, and the EPA continues to conclude that this type of information can appropriately inform the Administrator's decision on the current 24-hour $PM_{2.5}$ standard.[103]

Another group of commenters argued that the 24-hour standard level should be lowered. Many of these commenters supported setting the level of the 24-hour $PM_{2.5}$ standard at either 25 or 30 μg/m³. In support of their position, the ALA *et. al.,* AHA *et al.,* five state Attorneys General, and a number of additional groups pointed to 98th percentile $PM_{2.5}$ concentrations in locations of multi-city and single-city epidemiological studies. For example, the ALA and others pointed to multi-city studies by Dominici *et al.* (2006a), Zanobetti and Schwartz (2009), Burnett *et al.* (2000), and Bell *et al.* (2008) as providing evidence for associations with mortality and morbidity in study locations with averaged (i.e., averaged across cities) 98th percentile 24-hour $PM_{2.5}$ concentrations below 35 μg/m³. These commenters also pointed to several single-city and panel studies reporting associations between short-term $PM_{2.5}$ and mortality or morbidity in locations with relatively low 24-hour $PM_{2.5}$ concentrations. Because some of these multi- and single-city studies have reported associations with health effects in locations with 98th percentile $PM_{2.5}$ concentrations below 35 μg/m³, commenters maintained that the current 24-hour $PM_{2.5}$ standard (i.e., with its level of 35 μg/m³) does not provide an appropriate degree of protection in all areas.

In further support of their position that the level of the current 24-hour standard should be lowered, these commenters pointed out the variability across the U.S. in ratios of 24-hour to annual $PM_{2.5}$ concentrations. They noted that some locations, including parts of the northwestern U.S., experience relatively low annual $PM_{2.5}$ concentrations but can experience relatively high 24-hour concentrations at certain times of the year. In order to provide protection against effects associated with short-term $PM_{2.5}$ exposures, especially in locations with high ratios of 24-hour to annual $PM_{2.5}$ concentrations, these commenters advocated setting a lower level for the 24-hour standard.

The EPA agrees with these commenters that it is appropriate to maintain a 24-hour $PM_{2.5}$ standard in order to supplement the protection provided by the revised annual standard, particularly in locations with relatively high ratios of 24-hour to annual $PM_{2.5}$ concentrations. However, in highlighting 98th percentile $PM_{2.5}$ concentrations in study locations without also considering the impact of a revised annual standard on short-term concentrations, these commenters ignore the fact that many areas would be expected to experience decreasing short- and long-term $PM_{2.5}$ concentrations in response to a revised annual standard.

In considering the specific multi-city studies highlighted by public commenters who advocated a more stringent 24-hour standard, the EPA notes that such studies have reported consistently positive and statistically significant associations with short-term $PM_{2.5}$ exposures in locations with averaged 98th percentile $PM_{2.5}$ concentrations ranging from 45.8 to 34.2 μg/m³ and long-term mean $PM_{2.5}$ concentrations ranging from 13.4 to 12.9 (Burnett and Goldberg, 2003; Burnett *et al.,* 2004; Dominici *et al.,* 2006a; Bell *et al.,* 2008; Franklin *et al.,* 2008; Zanobetti and Schwartz, 2009).[104] The EPA notes that to the extent air quality distributions are reduced to meet the current 24-hour standard with its level of 35 μg/m³ and/or the revised annual standard with its level of 12 μg/m³, additional protection would be anticipated against the effects reported in these short-term, multi-city studies. Put another way, to attain an annual standard with a level below the long-term means in the locations of these short-term studies (as EPA is adopting here), the overall air quality distributions in the majority of study cities will necessarily be reduced, resulting in lower daily $PM_{2.5}$ ambient concentrations. We therefore expect that the revised annual standard will result in 98th percentile $PM_{2.5}$ concentrations in these cities that are lower than those measured in the studies, and that the overall distributions of $PM_{2.5}$ concentrations will be lower than those reported to be associated with health effects. Thus, even for effects reported in multi-city studies with averaged 98th percentile concentrations below 35 μg/m³, additional protection from the risks associated with short-term exposures is anticipated from the revised annual standard, without revising the 24-hour standard, because long-term average $PM_{2.5}$ concentrations in multi-city study locations were above the level of the revised annual standard (i.e., 12 μg/m³).[105] As discussed above, reducing the annual standard is the most efficient way to reduce the risks from short-term exposures identified in these studies, as the bulk of the risk comes from the large number of days across the bulk of the air quality distribution, not the relatively small number of days with peak concentrations.

In considering the single-city studies highlighted by public commenters who advocated a more stringent 24-hour standard, the EPA first notes that, overall, these single-city studies reported mixed results. Specifically, some studies reported positive and statistically significant associations with $PM_{2.5}$, some studies reported positive but non-significant associations, and several studies reported negative associations or a mix of positive and negative associations with $PM_{2.5}$. In light of these inconsistent results, the proposal noted that the overall body of evidence from single-city studies is mixed, particularly in locations with 98th percentiles of 24-hour concentrations below 35 μg/m³. Therefore, although some single-city

[103] This is not to say that the EPA's decision on whether to revise the 24-hour $PM_{2.5}$ standard should be based on or only be informed by considerations of whether studies reported associations with mortality or morbidity in areas with averaged 98th percentile $PM_{2.5}$ concentrations less than 35 mg/m³. As discussed below, in reaching a decision in this final notice on the most appropriate approach to strengthen the suite of $PM_{2.5}$ standards, the Administrator considers the degree of public health protection provided by the combination of the annual and 24-hour standards together.

[104] Commenters also highlighted associations with short-term $PM_{2.5}$ concentrations reported in sub-analyses restricted to days with 24-hour concentrations at or below 35 μg/m³ (Dominici, 2006b). These sub-analyses were not included in the original publication by Dominici *et al.* (2006a). Authors provided results of sub-analyses for the Administrator's consideration in a letter to the docket following publication of the proposed rule in January 2006 (personal communication with Dr. Francesca Dominici, 2006b). As noted in section III.A.3, these sub-analyses are part of the basis for the conclusion that there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations. Because the sub-analyses did not present long-term average $PM_{2.5}$ concentrations, it is not clear whether they reflected $PM_{2.5}$ air quality that would have been allowed by the revised annual $PM_{2.5}$ standard being established in this rule.

[105] It is also the case that additional protection is anticipated in locations with 98th percentile 24-hour $PM_{2.5}$ concentrations above 35 μg/m³, even if long-term concentrations are below 12 μg/m³. As noted in the proposal and in the Policy Assessment (U.S. EPA, 2011a, Figure 2–10), parts of the northwestern U.S. are more likely than other parts of the country to violate the 24-hour standard and meet the revised annual standard.

studies reported effects at appreciably lower $PM_{2.5}$ concentrations than short-term multi-city studies, the uncertainties and limitations associated with the single-city studies were noted to be greater. In light of these greater uncertainties and limitations, the Administrator concluded in the proposal that she had less confidence in using these studies as a basis for setting the level of the standard (77 FR 38943).

Given the considerations and conclusions noted above, in the proposal the Administrator concluded that the short-term multi-city studies provide the strongest evidence to inform decisions on the level of the 24-hour standard. Further, she viewed single-city, short-term exposure studies as a much more limited data set providing mixed results, and she had less confidence in using these studies as a basis for setting the level of a 24-hour standard (77 FR 38942). In highlighting specific single-city studies, public health, environmental, and State and local commenters appear to have selectively focused on studies reporting associations with $PM_{2.5}$ and to have overlooked studies that reported more equivocal results (e.g., Ostro *et al.,* 2003; Rabinovitch *et al.,* 2004; Slaughter *et al.,* 2005; Villeneuve *et al.,* 2006) (U.S. EPA, 2011, Figure 2–9). As such, these commenters have not presented new information that causes the EPA to reconsider its decision to emphasize multi-city studies over single-city studies when identifying the appropriate level of the 24-hour $PM_{2.5}$ standard.

In further considering the single-city studies highlighted by public commenters, the EPA notes that some commenters advocating for a lower level for the 24-hour $PM_{2.5}$ standard also discussed short-term studies that have been published since the close of the Integrated Science Assessment. These recent studies were conducted in single cities or in small panels of volunteers. As in prior NAAQS reviews and as discussed above in more detail (section II.B.3), the EPA is basing its decisions in this review on studies and related information assessed in the Integrated Science Assessment. The studies assessed in the Integrated Science Assessment, and the conclusions based on those studies, have undergone extensive critical review by the EPA, CASAC, and the public. The rigor of that review makes the studies assessed in the Integrated Science Assessment, and the conclusions based on those studies, the most reliable source of scientific information on which to base decisions on the NAAQS.

However, as discussed above (section II.B.3), the EPA recognizes that ‘‘new studies’’ may sometimes be of such significance that it is appropriate to delay a decision on revision of a NAAQS and to supplement the pertinent air quality criteria so the studies can be taken into account. In the present case, the EPA's provisional consideration of ‘‘new studies’’ concludes that, taken in context, the ‘‘new’’ information and findings do not materially change any of the broad scientific conclusions made in the air quality criteria regarding the health effects of $PM_{2.5}$ (U.S. EPA, 2012b).

For this reason, reopening the air quality criteria review would not be warranted, even if there were time to do so under the court order governing the schedule for completing this review. Accordingly, the EPA is basing its final decisions in this review on the studies and related information included in the PM Integrated Science Assessment (i.e., the air quality criteria) that has undergone CASAC and public review. The EPA will consider the ‘‘new studies’’ in the next periodic review of the PM NAAQS, which will provide an opportunity to fully assess these studies through a more rigorous review process involving the EPA, CASAC, and the public.

Some public health, medical, and environmental commenters also criticized the EPA's interpretation of $PM_{2.5}$ risk results. These commenters presented risk estimates for combinations of annual and 24-hour standards using more recent air quality data than that used in the EPA's Risk Assessment (U.S. EPA, 2010a). Based on these additional risk analyses, the ALA and other commenters contended that public health benefits could continue to increase as annual and 24-hour standard levels decrease below 13 $\mu g/m^3$ and 35 $\mu g/m^3$, respectively.

The EPA agrees with commenters that important public health benefits are expected as a result of revising the level of the annual standard to 12 $\mu g/m^3$, as is done in this rule, rather than 13 $\mu g/m^3$. The Agency also acknowledges that estimated $PM_{2.5}$-associated health risks continue to decrease with annual standard levels below 12 $\mu g/m^3$ and/or with 24-hour standard levels below 35 $\mu g/m^3$. However, the EPA disagrees with the commenters' views regarding the extent to which risk estimates support setting standard levels below 12 $\mu g/m^3$ (annual standard) and 35 $\mu g/m^3$ (24-hour standard).[106]

The CAA charges the Administrator with setting NAAQS that are ‘‘requisite’’ (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. In setting such standards the Administrator must weigh the available scientific evidence and information, including associated uncertainties and limitations. As described above, in reaching her proposed decisions on the $PM_{2.5}$ standards that would provide ‘‘requisite’’ protection, the Administrator carefully considered the available scientific evidence and risk information, making public health policy judgments that, in her view, neither overstated nor understated the strengths and limitations of that evidence and information. In contrast, as discussed more fully above, public health, medical, and environmental commenters who recommended levels below 35 $\mu g/m^3$ for the 24-hour $PM_{2.5}$ standard have not provided new information or analyses to suggest that such standard levels are appropriate, given the uncertainties and limitations in the available health evidence, particularly uncertainties in studies conducted in locations with 98th percentile 24-hour $PM_{2.5}$ concentrations below 35 $\mu g/m^3$ and long-term average concentrations below 12 $\mu g/m^3$.

d. Administrator's Final Conclusions on the Primary $PM_{2.5}$ Standard Levels

In reaching her conclusions regarding appropriate standard levels, the Administrator has considered the epidemiological and other scientific evidence, estimates of risk reductions associated with just meeting alternative annual and/or 24-hour standards, air quality analyses, related limitations and uncertainties, the advice of CASAC, and extensive public comments on the proposal. After careful consideration of all of these, the Administrator has decided to revise the level of the primary annual $PM_{2.5}$ standard from 15.0 $\mu g/m^3$ to 12.0 $\mu g/m^3$ and to retain the level of the primary 24-hour standard at 35 $\mu g/m^3$.

As an initial matter, the Administrator agrees with the approach supported by CASAC and discussed in the Policy Assessment as summarized in sections III.A.3 and III.E.4.a above, of considering the annual and 24-hour standards together in determining the protection afforded against mortality and morbidity effects associated with both long- and short-term exposures to $PM_{2.5}$. This approach is consistent with the approach taken in the review

[106] This section focuses on the 24-hour standard. Section III.E.4.c.i above also discusses these commenters' recommendations within the context of the annual $PM_{2.5}$ standard.

completed in 1997, in contrast to the approach used in the review completed in 2006 where each standard was considered independently of the other (i.e., only data from long-term exposure studies were used to inform the level of the annual standard and only data from short-term exposure studies were used to inform the level of the 24-hour standard).[107]

Based on the evidence and quantitative risk assessment, the Administrator concludes that it is appropriate to set an annual standard that is generally controlling, which will lower the broad distribution of 24-hour average concentrations in an area as well as the annual average concentration, so as to provide protection from both long- and short-term $PM_{2.5}$ exposures. In conjunction with this, it is appropriate to set a 24-hour standard focused on providing supplemental protection, particularly for areas with high peak-to-mean ratios of 24-hour concentrations, possibly associated with strong local or seasonal sources, and for $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods. The Administrator concludes this approach will reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and is the most effective and efficient way to reduce total $PM_{2.5}$-related population risk and to protect public health with an adequate margin of safety.

In selecting the level of the annual $PM_{2.5}$ standard, based on the characterization and assessment of the epidemiological and other studies presented and assessed in the Integrated Science Assessment and the Policy Assessment, the Administrator recognizes the substantial increase in the number and diversity of studies available in this review. This expanded body of evidence includes extended analyses of the seminal studies of long-term $PM_{2.5}$ exposures (i.e., ACS and Harvard Six Cities studies) as well as important new long-term exposure studies (as summarized in Figures 1 and 2). Collectively, the Administrator notes that these studies, along with evidence available in the last review, provide consistent and stronger evidence than previously observed of an association between long-term $PM_{2.5}$ exposures and premature mortality in areas with lower long-term ambient concentrations than previously observed, with the strongest evidence related to cardiovascular-related mortality. The Administrator also recognizes the availability of stronger evidence of morbidity effects associated with long-term $PM_{2.5}$ exposures, including evidence of respiratory effects such as decreased lung function growth, from the extended analyses for the Southern California Children's Health Study and evidence of cardiovascular effects from the WHI study. Furthermore, the Administrator recognizes new U.S. multi-city studies that greatly expand and reinforce our understanding of mortality and morbidity effects associated with short-term $PM_{2.5}$ exposures, providing stronger evidence of associations in areas with ambient concentrations similar to those previously observed in short-term exposure studies considered in the previous review (as summarized in Figure 3).

The Administrator recognizes the strength of the scientific evidence for evaluating health effects associated with fine particles, noting that the newly available scientific evidence builds upon the previous scientific data base to provide evidence of generally robust associations and a basis for greater confidence in the reported associations than in the last review. She notes the conclusion of the Integrated Science Assessment that this body of evidence supports a causal relationship between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects and a likely causal relationship between long- and short-term $PM_{2.5}$ exposures and respiratory effects. In addition, the Administrator notes additional, but more limited evidence, for a broader range of health endpoints including evidence suggestive of a causal relationship for developmental and reproductive effects as well as for carcinogenic effects.

Based on information discussed and presented in the Integrated Science Assessment, the Administrator recognizes that health effects may occur over the full range of concentrations observed in the epidemiological studies of both long-term and short-term exposures, since no discernible population-level threshold for any such effects can be identified based on the currently available evidence (U.S. EPA, 2009a, section 2.4.3). To inform her decisions on an appropriate level for the annual standard that will protect public health with an adequate margin of safety, in the absence of any discernible population-level thresholds, the Administrator judges that it is appropriate to consider the relative degree of confidence in the magnitude and significance of the associations observed in epidemiological studies across the range of long-term $PM_{2.5}$ concentrations in such studies. Further, she recognizes, in taking note of CASAC advice and the distributional statistics analysis discussed in the Policy Assessment and in section III.E.4.a above, that there is significantly greater confidence in the magnitude and significance of observed associations for the part of the air quality distribution corresponding to where the bulk of the health events evaluated in each study have been observed, generally at and around the long-term mean concentrations. Conversely, she also recognizes that there is significantly diminished confidence in the magnitude and significance of observed associations in the lower part of the air quality distribution corresponding to where a relatively small proportion of the health events were observed. Further, the Administrator recognizes that the long-term mean concentrations, or any other specific point in the air quality distribution of each study, do not represent a ''bright line'' at and above which effects have been observed and below which effects have not been observed.

In considering the long-term mean concentrations reported in epidemiological studies, the Administrator recognizes that in selecting a level of the annual standard that will protect public health with an adequate margin of safety, it is not sufficient to focus on a concentration generally somewhere within the range of long-term mean concentrations from the key long-term and short-term exposure studies that reported lower concentrations than had been observed in earlier reviews. These key studies provide information for various types of serious health endpoints (including mortality and morbidity effects), different study populations (which may include at-risk populations such as children and older adults), and different air quality distributions that are specific to each study. A level somewhere within the range of long-term mean concentrations of the full set of key studies would be higher than the long-term mean of at least one of the studies being considered and therefore would not provide a sufficient degree of protection against the health effects observed in that study. Absent some reasoned basis to place less weight on the evidence in the epidemiological study with the lowest long-term mean concentration among these key studies, this approach would not be consistent with the requirement to set a standard that will protect public health with an

[107] See 71 FR 61148 and 61168, October 17, 2006.

adequate margin of safety.[108] Thus, the Administrator recognizes it is important to protect against the serious effects observed in *each* of these studies so as to protect public health with an adequate margin of safety. In so doing, she looks to identify the study with the lowest long-term mean concentration within the *full* set of key studies to help inform her decision of the appropriate standard level which will provide protection for the broad array of health outcomes observed in *all* of the studies, including effects observed in at-risk populations.

Further, consistent with the general approach summarized in section III.E.4.a above and supported by CASAC as discussed in section III.E.4.b.ii above, the Administrator recognizes that it is appropriate to consider a level for an annual standard that is not just at but rather is somewhat below the long-term mean $PM_{2.5}$ concentrations reported in each of the key long- and short-term exposure studies. In so doing, she focuses especially on multi-city studies that evaluated health endpoints for which the associations are causal or likely causal (i.e., mortality and cardiovascular and respiratory effects associated with both long- and short-term $PM_{2.5}$ exposures). As discussed above, the importance of considering a level somewhat below the lowest long-term mean concentrations in this set of key studies is to establish a standard that would be protective against the observed effects in *all* of the studies, and that takes into account the relative degree of confidence in the magnitude and significance of observed associations across the air quality distributions in these studies.

The Administrator recognizes that there is no clear way to identify how much below the long-term mean concentrations of key studies to set a standard that would provide requisite protection with an adequate margin of safety. She therefore must use her judgment to weigh the available scientific and technical information, and associated uncertainties, to reach a final decision on the appropriate standard level. In considering the information in Figures 1–4 for effects classified as having evidence of a causal or likely causal relationship with long- or short-term $PM_{2.5}$ exposures, she observes a cluster of short-term exposure studies with long-term mean concentrations within a range of 13.4 μg/m³ down to 12.8 μg/m³ (Dominici *et al.,* 2006a; Burnett and Goldberg, 2003; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008; Burnett *et al.,* 2004). She also observes a cluster of long-term exposure studies with long-term mean concentrations within a range of 14.5 μg/m³ to 13.6 μg/m³ (Dockery *et al.,* 1996; Lipfert *et al.,* 2006a; Zeger *et al.,* 2008; McConnell *et al.,* 2003; Goss *et al.,* 2004; Eftim *et al.,* 2008). For the reasons discussed in response to public comments in section III.E.4.c above, the Administrator is less influenced by the long-term mean $PM_{2.5}$ concentrations from the Miller *et al.* (2007) and Krewski *et al.* (2009) studies with reported long-term mean $PM_{2.5}$ concentrations of 12.9 and 14.0 μg/m³, respectively. In each case, the most relevant exposure periods would likely have had higher mean $PM_{2.5}$ concentrations than those reported in the studies.[109] Thus, the Administrator considers the long-term mean $PM_{2.5}$ concentrations from these two studies to be a highly uncertain basis for informing her selection of the annual standard level.[110]

To help guide her judgment of the appropriate level below the long-term mean concentrations in the epidemiological studies at which to set the standard, the Administrator considered additional information from epidemiological studies concerning the broader distribution of $PM_{2.5}$ concentrations which correspond to the health events observed in these studies (e.g., deaths, hospitalizations). The Administrator observes that the development and use of this information in considering standard levels is consistent with CASAC's advice, as discussed in section III.E.4.b.ii above, to focus on understanding the concentrations that were most influential in generating the health effect estimates in individual studies (Samet, 2010d, p. 2).

In considering this additional population-level information, the Administrator recognizes that, in general, the confidence in the magnitude and significance of an association identified in a study is strongest at and around the long-term mean concentration for the air quality distribution, as this represents the part of the distribution in which the data in any given study are generally most concentrated. She also recognizes that the degree of confidence decreases as one moves towards the lower part of the distribution. Consistent with the approach used in the Policy Assessment, the Administrator believes that the range from approximately the 25th to 10th percentiles is a reasonable range for providing a general frame of reference as to the part of the distribution in which her confidence in the associations observed in epidemiological studies is appreciably lower. However, as noted above, it is important to emphasize that there is no clear dividing line or single percentile within a given distribution provided by the scientific evidence that is most appropriate or 'correct' to use to characterize where the degree of confidence in the associations warrants setting the annual standard level. The decision of the appropriate standard level below the long-term mean concentrations of the key studies, which in conjunction with the other elements of the standard would protect public health with an adequate margin of safety, is largely a public health policy judgment, taking into account all of the evidence and its related uncertainties.

As discussed in section III.E.4.b, the Administrator takes note of additional population-level data that were made available to the EPA by study authors.[111] In considering this information, the Administrator particularly focuses on the analysis of the distributions of the health event data for each area within these studies and the corresponding air quality data for the two short-term exposure studies (Zanobetti and Schwartz, 2009; Bell *et al.,* 2008). These short-term exposure studies evaluate the relationship between daily changes (one or more days) in $PM_{2.5}$ concentrations and daily changes in health events (e.g., deaths, hospitalizations), such that the air quality concentrations that comprise the most relevant exposure periods in these

[108] See *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512, 525–26 (D.C. Cir. 2009).

[109] In the case of Miller *et al.* (2007), the mean concentration is based on a single year of air quality data which post-dated by two years the period for which the health events data were collected. In the case of Krewski *et al.* (2009), the air quality data were based on the last two years of the 18-year period for which the health event data were collected.

[110] Nonetheless, as noted above, the EPA notes that the Krewski *et al.* (2009) and Miller *et al.* (2007) studies provide strong evidence of mortality and cardiovascular-related effects associated with long-term $PM_{2.5}$ exposures to inform causality determinations reached in the Integrated Science Assessment (U.S. EPA, 2009a, sections 7.2.11 and 7.6).

[111] As summarized in section III.E.4.a, population-level data were provided to the EPA for four studies. These four studies represent some of the strongest evidence showing associations between health effects and $PM_{2.5}$ within the overall body of scientific evidence and include three studies (Krewski *et al.,* 2009; Bell *et al.,* 2008; and Zanobetti and Schwartz, 2009) that were used as the basis for concentration-response functions in the quantitative risk assessment (U.S. EPA, 2010a, section 3.3.3). The Administrator recognizes that the additional population-level data available for these four multi-city studies represents a more limited data set compared to the set of long-term mean $PM_{2.5}$ concentrations which were available in the published literature for all studies considered in the Integrated Science Assessment.

studies are contemporaneous with the health event data. In addition, these studies considered more recent air quality data, representing generally lower $PM_{2.5}$ concentrations, in a large number of study areas across the U.S. Thus, such studies provide the most useful evidence for an analysis evaluating the distribution of health event data and the corresponding long-term mean $PM_{2.5}$ concentrations across the areas included in each multi-city study.

The Administrator also considered the additional population-level data that were made available to EPA for two long-term exposure studies (Krewski *et al.,* 2009; Miller *et al.,* 2007). She recognizes that in long-term exposure studies investigators follow a specific group of study participants (i.e., cohort) over time and across urban study areas, and evaluate how $PM_{2.5}$ concentrations averaged over a period of years are associated with specific health endpoints (e.g., deaths) across cities. As discussed in response to public comments in section III.E.4.c, disentangling the effects observed in long-term exposure studies associated with more recent air quality measurements from effects that may have been associated with earlier, and most likely higher, $PM_{2.5}$ exposures introduces some uncertainty with regard to understanding the appropriate exposure window associated with the observed effects. This is in contrast to the short-term exposure studies where the relevant exposure period is contemporaneous to the period for which the health data were collected. In light of these considerations, as noted above, the Administrator considers the analysis of air quality concentrations that correspond to the distribution of population-level data in these two studies to be a highly uncertain basis for informing her selection of the annual standard level.

Based on the above considerations, the Administrator views the additional population-level data for the two short-term exposure studies as appropriate to help inform her judgment of how much below the long-term mean concentrations to set the level of the annual standard. The Administrator notes that the long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25th percentiles of the distribution of deaths and cardiovascular-related hospitalizations in these two short-term exposure studies were 12.5 μg/m³ and 11.5 μg/m³, respectively, for Zanobetti and Schwartz (2009) and for Bell *et al.* (2008), with the 10th percentiles being lower by approximately 2 μg/m³ in each study.

The Administrator recognizes, as summarized in section III.B above and discussed more fully in section III.B.2 of the proposal, that important uncertainties remain in the evidence and information considered in this review of the primary fine particle standards. These uncertainties are generally related to understanding the relative toxicity of the different components in the fine particle mixture, the role of $PM_{2.5}$ in the complex ambient mixture, exposure measurement errors, and the nature and magnitude of estimated risks related to increasingly lower ambient $PM_{2.5}$ concentrations. Furthermore, the Administrator notes that epidemiological studies have reported heterogeneity in responses both within and between cities and geographic regions across the U.S. She recognizes that this heterogeneity may be attributed, in part, to differences in fine particle composition in different regions and cities.[112]

With regard to evidence for reproductive and developmental effects identified as being suggestive of a causal relationship with long-term $PM_{2.5}$ exposures, the Administrator recognizes that there are a number of limitations associated with this body of evidence including: the limited number of studies evaluating such effects; uncertainties related to identifying the relevant exposure time periods of concern; and limited toxicological evidence providing little information on the mode of action(s) or biological plausibility for an association between long-term $PM_{2.5}$ exposures and adverse birth outcomes. Nonetheless, the Administrator believes that this more limited body of evidence provides some support for considering that serious effects may be occurring in a susceptible population at concentrations lower than those associated with effects classified as having a causal or likely causal relationship with long-term $PM_{2.5}$ exposures (i.e., mortality, cardiovascular, and respiratory effects).

Overall, the Administrator believes that the available evidence interpreted in light of the remaining uncertainties, as summarized above and discussed more fully in the Integrated Science Assessment and the Policy Assessment, provides increased confidence relative to information available in the last review and provides a strong basis for informing her final decisions in the current review. The Administrator is mindful that considering what standards are requisite to protect public health with an adequate margin of safety requires public health policy judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. In considering how to translate the available information into appropriate standard levels, the Administrator weighs the available scientific information and associated uncertainties and limitations. For the purpose of determining what annual standard level is appropriate the Administrator recognizes that there is no single factor or criterion that comprises the ''correct'' approach to weighing the various types of available evidence and information.

In considering this information, the Administrator notes the advice of CASAC that ''there are significant public health consequences at the current levels of the standards that justify consideration of lowering the $PM_{2.5}$ NAAQS further'' (Samet, 2010c, p. 12). In addition, she recognizes that CASAC concluded, ''although there is increasing uncertainty at lower levels, there is no evidence of a threshold (i.e., a level below which there is no risk for adverse effects)'' (Samet, 2010d, p.ii) and that the final decisions on standard levels must reflect a judgment of the available scientific information with respect to her interpretation of the CAA's requirement to set primary standards that provide requisite protection to public health with an adequate margin of safety (Samet, 2010d, p. 4). The Administrator recognizes CASAC's advice that the currently available scientific information provided support for considering an annual standard level within a range of 13 to 11 μg/m³ and a 24-hour standard level within a range of 35 to 30 μg/m³. In considering how the annual and 24-hour standards work together to provide appropriate public health protection, the Administrator observes that CASAC did not express support for any specific levels or combinations of standards within these ranges. She also notes that CASAC encouraged the EPA staff to consider additional data from epidemiological studies to help quantify the characterization of the $PM_{2.5}$ concentrations that were most influential in generating the health

[112] Nonetheless, as explained in section III.E.1, the currently available evidence is not sufficient to support replacing or supplementing the $PM_{2.5}$ indicator with any other indicator defined in terms of a specific fine particle component or group of components associated with any source categories of fine particles. Furthermore, the evidence is not sufficient to support eliminating any component or group of components associated with any source categories of fine particles from the mix of fine particles included in the $PM_{2.5}$ indicator.

effect estimates in these studies (Samet, 2010d, p. 2).

In response to CASAC's advice, the Administrator recognizes that the EPA staff acquired additional data from authors of key epidemiological studies and analyzed these data to characterize the distribution of $PM_{2.5}$ concentrations in relation to health events data to better understand the degree of confidence in the associations observed in the studies as discussed above. The Administrator recognizes that the final Policy Assessment included consideration of these additional analyses in reaching final staff conclusions with regard to the broadest range of alternative standard levels supported by the science. She takes note that the final Policy Assessment concluded that while alternative standard levels within the range of 13 to 11 μg/m³ were appropriate to consider, the evidence most strongly supported consideration of an annual standard level in the range of 12 to 11 μg/m³. The Administrator is aware that, in transmitting the final Policy Assessment to CASAC, the Agency notified CASAC that the final staff conclusions reflected consideration of CASAC's advice and that those staff conclusions were based, in part, on the specific distributional analysis that CASAC had urged the EPA to conduct (Wegman, 2011). Thus, CASAC had an opportunity to comment on the final Policy Assessment, but chose not to provide any additional comments or advice after receiving it.

In selecting the annual standard level, the Administrator has considered many factors including the nature and severity of the health effects involved, the strength of the overall body of scientific evidence as considered in reaching causality determinations, the size of the at-risk populations, and the estimated public health impacts. She has also considered the kind and degree of the uncertainties that remain in the available scientific information. She recognizes that the association between $PM_{2.5}$ and serious health effects is well established, including at concentrations below those allowed by the current standard. Further, she recognizes the CAA requirement that requires primary standards to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information as well as to provide a reasonable degree of protection against hazards that research has not yet identified. In considering the currently available evidence, as summarized and discussed more broadly above, the information on risk, CASAC advice, the conclusions of the Policy Assessment, and public comments on the proposal, the Administrator strongly believes that a lower annual standard level is needed to protect public health with an adequate margin of safety.

In reaching her final decision on the appropriate annual standard level to set, the Administrator is mindful that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health, including the health of at-risk populations, with an adequate margin of safety. On balance, the Administrator concludes that an annual standard level of 12 μg/m³ would be requisite to protect the public health with an adequate margin of safety from effects associated with long- and short-term $PM_{2.5}$ exposures, while still recognizing that uncertainties remain in the scientific information.

In the Administrator's judgment, an annual standard of 12 μg/m³ appropriately reflects placing greatest weight on evidence of effects for which the Integrated Science Assessment determined there is a causal or likely causal relationship with long- and short-term $PM_{2.5}$ exposures. An annual standard level of 12 μg/m³ is below the long-term mean $PM_{2.5}$ concentrations reported in *each* of the key multi-city, long- and short-term exposures studies providing evidence of an array of serious health effects (e.g., premature mortality, increased hospitalization for cardiovascular and respiratory effects). As noted above, the importance of considering a level somewhat below the lowest long-term mean concentration in the full set of studies considered is to set a standard that would provide appropriate protection against the observed effects in *all* such studies.

In reaching her decision, the Administrator has taken into account that at and around the mean $PM_{2.5}$ concentration in any given study represents a part of the air quality distribution in which the health event data in that study are generally most concentrated. Furthermore, in identifying an appropriate annual standard level below the long-term mean concentrations, she recognizes that there is no evidence to support the existence of any discernible threshold, and, therefore, she has a high degree of confidence that the observed effects are associated with concentrations not just at but extending somewhat below the long-term mean concentration. To further inform her judgment in setting the annual standard level so as to protect public health with an adequate margin of safety, the Administrator has placed weight on additional population-level information available from a subset of these epidemiological studies, consistent with CASAC advice. In particular, she has drawn from two short-term exposure studies, which provide the most relevant information for evaluating the distribution of health events and corresponding long-term $PM_{2.5}$ concentrations. As explained above, this helps inform her judgment as to the degree of confidence in the observed associations in the epidemiological studies. In this regard, the Administrator generally judges the region around the 25th percentile as a reasonable part of the distribution to help guide her decision on the appropriate standard level. Since this evidence comes primarily from two studies, a relatively modest data set, the Administrator deems it reasonable not to draw further inferences from air quality and health event data in the lower part of the distribution for the purpose of setting a standard level. The Administrator notes that the long-term mean $PM_{2.5}$ concentrations around the 25th percentile of the distributions of deaths and cardiovascular-related hospitalizations were approximately around 12 μg/m³ in these two studies. The Administrator views this information as helpful in guiding her determination as to where her confidence in the magnitude and significance of the associations is reduced to such a degree that a standard set at a lower level would not be warranted to provide requisite protection that is neither more nor less than needed to provide an adequate margin of safety.

The Administrator also recognizes that a level of 12 μg/m³ places some weight on studies which provide evidence of reproductive and developmental effects (e.g., infant mortality, low birth weight). These studies were identified in the Integrated Science Assessment as having evidence suggestive of a causal relationship with long-term $PM_{2.5}$ concentrations. A level of 12 μg/m³ is approximately the same level as the lowest long-term mean concentration reported in such studies (Figures 2 and 4; 11.9 μg/m³ for Bell *et al.,* 2007).[113] While the Administrator

[113] With respect to cancer, mutagenic, and genotoxic effects, the Administrator observes that the $PM_{2.5}$ concentrations reported in studies evaluating these effects generally included ambient concentrations that are equal to or greater than ambient concentrations observed in studies that reported mortality and cardiovascular and respiratory effects (U.S. EPA, 2009a, section 7.5). Therefore, the Administrator concludes that in selecting alternative standard levels that provide protection from mortality and cardiovascular and respiratory effects, it is reasonable to anticipate that

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acknowledges that this evidence is limited, she believes it is appropriate to place some weight on these studies in order to set a standard that provides protection with an adequate margin of safety, including providing protection for at-risk populations, as required by the CAA. Due to the limited nature of this evidence, she has determined it is not necessary to set a standard below the lowest long-term mean concentration in these studies.

In reflecting on extensive public comments received on the proposal as discussed in section III.E.4.c above, the Administrator recognizes that some commenters have offered different evaluations of the evidence and other information available in this review and would make different judgments about the weight to place on the relative strengths and limitations of the scientific information and about how such information could be used in making public health policy decisions on the annual standard level. One group of such commenters who supported a higher annual standard level (e.g., above 13 μg/m^3) would place greater weight on the remaining uncertainties in the evidence as a basis for supporting a higher standard level than the Administrator judges to be appropriate. Such an approach is based on these commenters' judgment that the uncertainties remaining in the evidence are too great to warrant setting an annual standard below the current level. The Administrator does not agree.

As an initial matter, an annual standard level of 13 μg/m^3 or higher would be above the long-term mean concentrations reported in two well-conducted, multi-city short-term exposure studies reporting positive and statistically significant associations of serious effects (Burnett *et al.,* 2004 and Bell *et al.,* 2008). These important studies are fully consistent with the pattern of evidence presented by the large body of evidence in this review. As the Administrator recognized in the proposal, and as advised by CASAC, the appropriate focus for selecting the level of the annual $PM_{2.5}$ standard is on concentrations somewhat *below* the lowest long-term mean concentrations from the set of key studies of both long-term and short-term $PM_{2.5}$ exposures considered by the EPA (i.e., as shown in Figure 4). Thus, a standard level set at 13 μg/m^3 or higher would clearly not provide protection for the effects observed in the full set epidemiological studies and, therefore, this standard level could not be judged to be requisite with an adequate margin of safety.[114]

In addition, as noted above, in recognizing that there is no evidence to support the existence of a discernible threshold below which an effect would not occur, the Administrator is mindful that effects occur around and below the long-term mean concentrations reported in both the short-term and long-term the epidemiological studies. A standard level of 13 μg/m^3 or higher would not appropriately take into account evidence from the two well-conducted, multi-city, short-term exposure studies reporting serious effects with long-term mean concentrations below 13 μg/m^3 noted above (Burnett *et al,* 2004; Bell *et al.,* 2008). Such a standard level would also not appropriately take into account additional population-level data from a limited number of epidemiological studies. This approach would ignore CASAC's advice to consider such information in order to better understand the concentrations over which there is a high degree of confidence regarding the magnitude and significance of the associations observed in individual epidemiological studies and where there is appreciably less confidence.

Furthermore, a standard level of 13 μg/m^3 or higher would not appropriately take into account the more limited evidence of effects in some at-risk populations (e.g., low birth weight). In the Administrator's view, a standard set at this level would not provide protection with an adequate margin of safety, including providing protection for at-risk populations. The Administrator is mindful that the CAA requirement that primary standards provide an adequate margin of safety, discussed in section II.A above, was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting as well as to provide a reasonable degree of protection against hazards that research has not yet identified.

In light of the entire body of evidence as discussed above, the Administrator judges that an annual standard level set above 12 μg/m^3 would not be sufficient to protect public health with an adequate margin of safety from the serious health effects associated with long- and short-term exposure to $PM_{2.5}$.

The Administrator also recognizes that a second group of commenters supported a lower annual standard level (e.g., no higher than 11 μg/m^3). Such a standard level would reflect placing essentially as much weight on the relatively more limited data providing evidence suggestive of a causal relationship for effects observed in some at-risk populations (e.g., low birth weight) as on more certain evidence of effects classified as having a causal or likely causal relationship with $PM_{2.5}$ exposures. In the Administrator's view, while it is important to place some weight on such suggestive evidence, it would not be appropriate to place as much weight on it as the commenters would do.

An annual standard level of 11 μg/m^3 would also reflect these commenters' judgment that it is appropriate to focus on a lower part of the distributions of health event data from the small number of epidemiological studies for which this information was made available than the Administrator believes is warranted. In the Administrator's view, using this type of information to set a standard level of 11 μg/m^3 or below would assume too high a degree of confidence in the magnitude and significance of the associations observed in the lower part of the distributions of health events observed in these studies. Given the uncertainties in the evidence and the limited set of studies for which the EPA has information on the distribution of health event data and corresponding air quality data, the Administrator believes it is not appropriate to focus on the lower part of the distributions of health events data.

On balance, the Administrator finds that the available evidence interpreted in light of the remaining uncertainties does not justify a standard level set below 12 μg/m^3 as necessary to protect public health with an adequate margin of safety.

After carefully considering the above considerations and the public comments summarized in section III.E.4.c above, the Administrator has decided to set the level of the primary annual $PM_{2.5}$ standard at 12 μg/m^3. In her judgment, a standard set at this level provides the requisite degree of public health protection, including the health of at-risk populations, with an adequate margin of safety and is neither more nor less stringent than necessary for this purpose.

protection will also be provided for carcinogenic effects.

[114] The Administrator is mindful that, in reviewing the 2006 final PM NAAQS decisions, the D.C. Circuit Court of Appeals concluded that the EPA failed to adequately explain why that annual standard provided requisite protection from effects associated with both long- and short-term exposures or from morbidity effects in children and other at-risk populations when long-term means of important short-term studies were below the level the Administrator selected for the annual standard. See *American Farm Bureau* v. *EPA.* 559 F. 3d 512, 524–26. There is no reasonable basis to discount these two studies for purposes of setting the level of the annual standard.

As discussed above, the Administrator concludes that an approach that focuses on setting a generally controlling annual standard is the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures. Such an approach would result in more uniform protection across the U.S. than the alternative of setting the levels of the 24-hour and annual standard such that the 24-hour standard would generally be the controlling standard in areas across the country (see section III.A.3).

The Administrator recognizes that potential air quality changes associated with meeting an annual standard level of 12.μg/m³ will result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures by lowering the overall air quality distribution. However, the Administrator recognizes that such an annual standard alone would not be expected to offer sufficient protection with an adequate margin of safety against the effects of short-term $PM_{2.5}$ exposures in all parts of the country. As a result, in conjunction with an annual standard level of 12 μg/m³, the Administrator concludes that it is appropriate to continue to provide supplemental protection by means of a 24-hour standard set at the appropriate level, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources and for areas with $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods.

In selecting the level of a 24-hour standard meant to provide such supplemental protection, the Administrator relies upon evidence and air quality information from key short-term exposure studies. In considering these studies, the Administrator notes that to the extent air quality distributions in the study areas considered are reduced to meet the current 24-hour standard (at a level of 35 μg/m³) or to meet the revised annual standard discussed above (at a level of 12 μg/m³), additional protection would be anticipated against the effects observed in these studies. In light of this, when selecting the appropriate level for the 24-hour standard, the Administrator considers both the 98th percentiles of 24-hour $PM_{2.5}$ concentrations and the long-term mean $PM_{2.5}$ concentrations in the locations of the short-term exposure studies. She notes that such consideration of both short- and long-term $PM_{2.5}$ concentrations can inform her decision on the extent to which a given 24-hour standard, in combination with the revised annual standard established in this rule, would provide protection against the health effects reported in short-term studies.

As discussed in section III.E.4.a above, the Administrator concludes that multi-city short-term exposure studies provide the strongest data set for informing her decisions on appropriate 24-hour standard levels. With regard to the limited number of single-city studies that reported positive and statistically significant associations for a range of health endpoints related to short-term $PM_{2.5}$ concentrations in areas that would likely have met the current suite of $PM_{2.5}$ standards, the Administrator recognizes that many of these studies had significant limitations (e.g., limited statistical power, limited exposure data) or equivocal results (mixed results within the same study area) that make them unsuitable to form the basis for setting the level of a 24-hour standard.

With regard to multi-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures, the Administrator observes an overall pattern of positive and statistically significant associations in studies with 98th percentile 24-hour values averaged across study areas within the range of 45.8 to 34.2 μg/m³ (Burnett *et al.,* 2004; Zanobetti and Schwartz, 2009; Bell *et al.,* 2008; Dominici *et al.,* 2006a, Burnett and Goldberg, 2003; Franklin *et al.,* 2008). The Administrator notes that, to the extent air quality distributions are reduced to reflect just meeting the current 24-hour standard, additional protection would be provided for the effects observed in the three multi-city studies with 98th percentile values greater than 35 μg/m³ (Burnett *et al.,* 2004; Burnett and Goldberg, 2003; Franklin *et al.,* 2008). In the three additional multi-city studies with 98th percentile values below 35 μg/m³, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 μg/m³, the Administrator notes that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 μg/m³, respectively (Bell *et al.,* 2008; Zanobetti and Schwartz, 2009; Dominici *et al.,* 2006a). In revising the level of the annual standard to 12 μg/m³, as discussed above, the Administrator recognizes that additional protection would be provided for the short-term effects observed in these multi-city studies such that revision to the 24-hour standard would not be warranted. That is, by lowering the level of the annual standard to 12 μg/m³, the 98th percentile of the distribution would be lowered as well such that additional protection from effects associated with short-term exposures would be afforded. Therefore, the epidemiological evidence supports a conclusion that it is appropriate to retain the level of the 24-hour standard at 35 μg/m³, in conjunction with a revised annual standard level of 12 μg/m³.

In addition to considering the epidemiological evidence, the Administrator also has taken into account air quality information based on county-level 24-hour and annual design values to understand the implications of revising the annual standard level from 15 to 12 μg/m³ in conjunction with retaining the 24-hour standard level at 35 μg/m³. She has considered this information to evaluate the public health protection provided by the two standards in combination and to evaluate the most appropriate means of developing a suite of standards providing requisite public health protection with an adequate margin of safety.

In considering the air quality information, the Administrator observes that a suite of $PM_{2.5}$ standards that includes an annual standard level of 12 μg/m³ and a 24-hour standard level of 35 μg/m³ would result in the annual standard as the generally controlling standard in most regions across the country, except for certain areas in the Northwest, where the annual mean $PM_{2.5}$ concentrations have historically been low but where relatively high 24-hour concentrations occur, often related to seasonal wood smoke emissions (U.S. EPA, 2011a, pp. 2–89 to 2–91, Figure 2–10). In fact, these are the type of areas for which the supplemental protection afforded by the 24-hour standard is intended, such that the two standards together provide the requisite degree of protection. The Administrator concludes the current 24-hour standard at a level of 35 μg/m³, in conjunction with a revised annual standard level of 12 μg/m³, will provide appropriate protection from effects observed in studies in such areas in which the long-term mean concentrations were below 12 μg/m³ and the 98th percentile 24-hour concentrations were above 35 μg/m³ (e.g., areas in the Northwest U.S.).

After carefully taking the public comments and above considerations into account, the Administrator has decided to retain the current level of the primary $PM_{2.5}$ 24-hour standard at 35 μg/m³ in conjunction with revising the annual standard level from 15.0 μg/m³ to 12.0 μg/m³.[115] In the Administrator's

[115] As noted in section II.B.1, Table 1 and section III.E.4.a above, the annual standard level is defined to one decimal place. Throughout this section, the annual standard levels discussed have been

Continued

judgment, this suite of primary $PM_{2.5}$ standards and the rationale supporting these levels appropriately reflects consideration of the strength of the available evidence and other information and its associated uncertainties as well as the advice of CASAC and consideration of public comments. In the Administrator's judgment, this suite of primary $PM_{2.5}$ standards is sufficient but not more protective than necessary to protect the public health, including at-risk populations, with an adequate margin of safety from effects associated with long- and short-term exposures to fine particles. This suite of standards will provide significant protection from serious health effects including premature mortality and cardiovascular and respiratory morbidity effects that are causally or likely causally related to long- and short-term $PM_{2.5}$ exposures. These standards will also provide an appropriate degree of protection against other health effects for which there is more limited evidence of effects and causality, such as reproductive and developmental effects. This judgment by the Administrator appropriately considers the requirement for a standard that is requisite to protect public health but is neither more nor less stringent than necessary.[116]

D. Administrator's Final Decisions on Primary $PM_{2.5}$ Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Integrated Science Assessment, Risk Assessment, and Policy Assessment, the advice and recommendations of CASAC, and public comments to date, the Administrator revises the current suite of primary $PM_{2.5}$ standards. Specifically, the Administrator revises: (1) The level of the primary annual $PM_{2.5}$ standard to 12.0 μg/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 option for spatial averaging. In conjunction with revising the primary annual $PM_{2.5}$ standard to provide protection from effects associated with long- and short-term $PM_{2.5}$ exposures, the Administrator retains the level of 35 μg/m^3 and the 98th percentile form of the primary 24-hour $PM_{2.5}$ standard to continue to provide supplemental protection for areas with high peak $PM_{2.5}$ concentrations. The Administrator is not revising the current $PM_{2.5}$ indicator or the annual and 24-hour averaging times for the primary $PM_{2.5}$ standards. The Administrator concludes that this suite of standards would be requisite to protect public health with an adequate margin of safety against health effects potentially associated with long- and short-term $PM_{2.5}$ exposures.

IV. Rationale for Final Decision on Primary PM_{10} Standard

This section presents the rationale for the Administrator's final decision to retain the current 24-hour primary PM_{10} standard in order to continue to provide public health protection against short-term exposures to inhalable particles in the size range of 2.5 to 10 μm (i.e., $PM_{10\text{-}2.5}$ or thoracic coarse particles). These are particles capable of reaching the most sensitive areas of the lung, including the trachea, bronchi, and deep lungs. The current standard uses PM_{10} as the indicator for thoracic coarse particles, and thus is referred to as a PM_{10} standard.[117]

As discussed more fully in the proposal and below, this rationale is based on a thorough review of the latest scientific evidence, published through mid-2009 and assessed in the Integrated Science Assessment (U.S. EPA, 2009a), evaluating human health effects associated with long- and short-term exposures to thoracic coarse particles. The Administrator's final decision also takes into account: (1) The EPA staff analyses of air quality information and health evidence and staff conclusions regarding the current and potential alternative standards, as presented in the Policy Assessment for the PM NAAQS (U.S. EPA, 2011a); (2) CASAC advice and recommendations, as reflected in discussions at public meetings of drafts of the Integrated Science Assessment and Policy Assessment, and in CASAC's letters to the Administrator; (3) the multiple rounds of public comments received during the development of the Integrated Science Assessment and Policy Assessment, both in connection with CASAC meetings and separately; and (4) public comments (including testimony at the public hearings) received on the proposal.

In presenting the rationale for the final decision to retain the current primary PM_{10} standard, this section discusses the EPA's past reviews of the PM NAAQS and the general approach taken to review the current standard (section IV.A), the health effects associated with exposures to ambient $PM_{10\text{-}2.5}$ (section IV.B), the consideration of the current and potential alternative standards in the Policy Assessment (section IV.C), CASAC recommendations regarding the current and potential alternative standards (section IV.D), the Administrator's proposed decision to retain the current primary PM_{10} standard (section IV.E), public comments received in response to the Administrator's proposed decision (section IV.F), and the Administrator's final decision to retain the current primary PM_{10} standard (section IV.G).

A. Background

The following sections discuss previous reviews of the PM NAAQS (section IV.A.1), the litigation of the EPA's 2006 decision on the PM_{10} standards (section IV.A.2), and the general approach taken to review the primary PM_{10} standard in the current review (section IV.A.3).

1. Previous Reviews of the PM NAAQS

a. Reviews Completed in 1987 and 1997

The PM NAAQS have always included some type of a primary standard to protect against effects associated with exposures to thoracic coarse particles. In 1987, when the EPA first revised the PM NAAQS, the EPA changed the indicator for PM from TSP to focus on inhalable particles, those which can penetrate into the trachea, bronchi, and deep lungs (52 FR 24634, July 1, 1987). In that review, the EPA changed the PM indicator to PM_{10} based on evidence that the risk of adverse health effects associated with particles with a nominal mean aerodynamic diameter less than or equal to 10 μm was significantly greater than risks associated with larger particles (52 FR 24639, July 1, 1987).

In the 1997 review, in conjunction with establishing new fine particle (i.e., $PM_{2.5}$) standards (discussed above in sections II.B.1 and III.A.1), the EPA concluded that continued protection was warranted against potential effects associated with thoracic coarse particles in the size range of 2.5 to 10 μm. This conclusion was based on particle dosimetry, toxicological information, and on limited epidemiological evidence from studies that measured PM_{10} in areas where the coarse fraction was likely to dominate PM_{10} mass (62 FR 38677, July 18, 1997). The EPA concluded there that a PM_{10} standard could provide requisite protection against effects associated with particles

denoted as integer values (e.g., 12 μg/m^3) for simplicity.

[116] The Administrator also judges that this suite of standards addresses the issues raised by the D.C. Circuit's remand of the 2006 primary annual $PM_{2.5}$ standard by appropriately revising that standard.

[117] Throughout this section of the preamble, we are using the terms ''thoracic coarse particles'', ''inhalable coarse particles'', and ''$PM_{10\text{-}2.5}$'' synonymously.

in the size range of 2.5 to 10 µm.[118] Although the EPA considered a more narrowly defined indicator for thoracic coarse particles in that review (i.e., $PM_{10-2.5}$), the EPA concluded that it was more appropriate, based on existing evidence, to continue to use PM_{10} as the indicator. This decision was based, in part, on the recognition that the only studies of clear quantitative relevance to health effects most likely associated with thoracic coarse particles used PM_{10}. These were two studies conducted in areas where the coarse fraction was the dominant fraction of PM_{10}, and which substantially exceeded the 24-hour PM_{10} standard (62 FR 38679). In addition, there were only very limited ambient air quality data then available specifically for $PM_{10-2.5}$, in contrast to the extensive monitoring network already in place for PM_{10}. Therefore, the EPA considered it more administratively feasible to use PM_{10} as an indicator. The EPA also stated that the PM_{10} standards would work in conjunction with the $PM_{2.5}$ standards by regulating the portion of particulate pollution not regulated by the then newly adopted $PM_{2.5}$ standards.

In May 1998, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit found ''ample support'' for the EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that the EPA had failed to adequately explain its choice of PM_{10} as the indicator for thoracic coarse particles *American Trucking Associations* v. *EPA,* 175 F. 3d 1027, 1054–56 (D.C. Cir. 1999). In particular, the court held that the EPA had not explained the use of an indicator under which the allowable level of coarse particles varied according to the amount of $PM_{2.5}$ present, and which, moreover, potentially double regulated $PM_{2.5}$. The court also rejected considerations of administrative feasibility as justification for use of PM_{10} as the indicator for thoracic coarse PM, since NAAQS (and their elements) are to be based exclusively on health and welfare considerations. *Id.* at 1054. Pursuant to the court's decision, the EPA removed the vacated 1997 PM_{10} standards from the CFR (69 FR 45592, July 30, 2004) and deleted the regulatory provision (at 40 CFR 50.6(d)) that controlled the transition from the pre-existing 1987 PM_{10} standards to the 1997 PM_{10} standards (65 FR 80776, December 22, 2000). The pre-existing 1987 PM_{10} standards thus remained in place. Id. at 80777.

b. Review Completed in 2006

In the review of the PM NAAQS that concluded in 2006, the EPA considered the growing, but still limited, body of evidence supporting associations between health effects and thoracic coarse particles measured as $PM_{10-2.5}$.[119] The new studies available in the 2006 review included epidemiological studies that reported associations with health effects using direct measurements of $PM_{10-2.5}$, as well as dosimetric and toxicological studies. In considering this growing body of $PM_{10-2.5}$ evidence, as well as evidence from studies that measured PM_{10} in locations where the majority of PM_{10} was in the $PM_{10-2.5}$ fraction (U.S. EPA, 2005, section 5.4.1), staff concluded that the level of protection afforded by the existing 1987 PM_{10} standard remained appropriate (U.S. EPA, 2005, p. 5–67) but recommended that the indicator for the standard be revised. Specifically, staff recommended replacing the PM_{10} indicator with an indicator of urban thoracic coarse particles in the size range of 10–2.5 µm (U.S. EPA, 2005, pp. 5–70 to 5–71). The agency proposed to retain a standard for a subset of thoracic coarse particles, proposing a qualified $PM_{10-2.5}$ indicator to focus on the mix of thoracic coarse particles generally present in urban environments. More specifically, the proposed revised thoracic coarse particle standard would have applied only to an ambient mix of $PM_{10-2.5}$ dominated by resuspended dust from high-density traffic on paved roads and/or by industrial and construction sources. The proposed revised standard would not have applied to any ambient mix of $PM_{10-2.5}$ dominated by rural windblown dust and soils. In addition, agricultural sources, mining sources, and other similar sources of crustal material would not have been subject to control in meeting the standard (71 FR 2667 to 2668, January 17, 2006).

The Agency received a large number of comments overwhelmingly and persuasively opposed to the proposed qualified $PM_{10-2.5}$ indicator (71 FR 61188 to 61197, October 17, 2006). After careful consideration of the scientific evidence and the recommendations contained in the 2005 Staff Paper, the advice and recommendations from CASAC, and the public comments received regarding the appropriate indicator for coarse particles, and after extensive evaluation of the alternatives available to the Agency, the Administrator decided it would not be appropriate to adopt the proposed qualified $PM_{10-2.5}$ indicator, or any qualified indicator. Underlying this determination was the Administrator's decision that it was requisite to provide protection from exposure to *all* thoracic coarse PM, regardless of its origin. The Administrator thus rejected arguments that there are no health effects from community-level exposures to coarse PM in non-urban areas (71 FR 61189). The EPA concluded that dosimetric, toxicological, occupational and epidemiological evidence supported retention of a primary standard for short-term exposures that included all thoracic coarse particles (i.e., particles of both urban and non-urban origin), consistent with the Act's requirement that primary NAAQS must be requisite to protect the public health and provide an adequate margin of safety. At the same time, the Agency concluded that the standard should target protection toward urban areas, where the evidence of health effects from exposure to $PM_{10-2.5}$ was strongest (71 FR at 61193, 61197). The proposed indicator was not suitable for that purpose. Not only did it inappropriately provide no protection at all to many areas, but it failed to identify many areas where the ambient particle mix was dominated by coarse particles contaminated with urban/industrial types of coarse particles for which evidence of health effects was strongest (71 FR 61193).

The Agency ultimately concluded that the existing indicator, PM_{10}, was most consistent with the evidence. Although PM_{10} includes both coarse and fine PM, the Agency concluded that it remained an appropriate indicator for thoracic coarse particles because, as discussed in the PM Staff Paper (U.S. EPA, 2005, p. 2–54, Figures 2–23 and 2–24), fine particle levels are generally higher in urban areas and, therefore, a PM_{10} standard set at a single unvarying level will generally result in lower allowable concentrations of thoracic coarse particles in urban areas than in non-urban areas (71 FR 61195–96). The EPA considered this to be an appropriate targeting of protection given that the strongest evidence for effects associated with thoracic coarse particles came from epidemiological studies conducted in urban areas and that elevated fine particle concentrations in urban areas could result in increased contamination of coarse fraction particles by $PM_{2.5}$,

[118] With regard to the 24-hour PM_{10} standard, the EPA retained the indicator, averaging time, and level (150 µg/m³), but revised the form (i.e., from one-expected-exceedance to the 99th percentile).

[119] The PM Staff Paper (U.S. EPA, 2005) also presented results of a quantitative assessment of health risks for $PM_{10-2.5}$. However, staff concluded that the nature and magnitude of the uncertainties and concerns associated with this risk assessment weighed against its use as a basis for recommending specific levels for a thoracic coarse particle standard (U.S. EPA, 2005, p. 5–69).

potentially increasing the toxicity of thoracic coarse particles in urban areas (*id.*). Given the evidence that the existing (i.e., 1987) PM_{10} standard was established at a level and form which afforded requisite protection with an adequate margin of safety, the Agency retained the level and form of the 24-hour PM_{10} standard.[120]

The Agency also revoked the annual PM_{10} standard, in light of the conclusion in the PM Criteria Document (U.S. EPA, 2004, p. 9–79) that the available evidence does not suggest an association with long-term exposure to $PM_{10-2.5}$ and the conclusion in the Staff Paper (U.S. EPA, 2005, p. 5–61) that there is no quantitative evidence that directly supports retention of an annual standard. This decision was consistent with CASAC advice and recommendations (Henderson, 2005a,b).

In the same rulemaking, the EPA also included a new FRM for the measurement of $PM_{10-2.5}$ 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 NAAQS (71 FR 61202/3, October 17, 2006).[121]

2. Litigation Related to the 2006 Primary PM_{10} Standards

A number of groups filed suit in response to the final decisions made in the 2006 review. *See American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir. 2009). Among the petitions for review were challenges from industry groups on the decision to retain the PM_{10} indicator and the level of the PM_{10} standard and from environmental and public health groups on the decision to revoke the annual PM_{10} standard. The court upheld both the decision to retain the 24-hour PM_{10} standard and the decision to revoke the annual standard.

First, the court upheld the EPA's decision for a standard to encompass all thoracic coarse PM, both of urban and non-urban origin. The court rejected arguments that the evidence showed there are no risks from exposure to non-urban coarse PM. The court further found that the EPA had a reasonable basis not to set separate standards for urban and non-urban coarse PM, namely the inability to reasonably define what ambient mixes would be included under either 'urban' or 'non-urban;' and the evidence in the record that supported the EPA's appropriately cautious decision to provide ''some protection from exposure to thoracic coarse particles * * * in all areas.'' 559 F. 3d at 532–33. Specifically, the court stated,

> Although the evidence of danger from coarse PM is, as EPA recognizes, ''inconclusive,'' (71 FR 61193, October 17, 2006), the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health. The evidence in the record supports the EPA's cautious decision that ''some protection from exposure to thoracic coarse particles is warranted in all areas.'' *Id.* As the court has consistently reaffirmed, the CAA permits the Administrator to ''err on the side of caution'' in setting NAAQS. 559 F. 3d at 533.

The court also upheld the EPA's decision to retain the level of the standard at 150 μg/m³ and to use PM_{10} as the indicator for thoracic coarse particles. In upholding the level of the standard, the court referred to the conclusion in the Staff Paper that there is ''little basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times.'' 559 F. 3d at 534. The court also rejected arguments that a PM_{10} standard established at an unvarying level will result in arbitrarily varying levels of protection given that the level of coarse PM would vary based on the amount of fine PM present. The court agreed that the variation in allowable coarse PM was in accord with the strength of the evidence: Typically less coarse PM would be allowed in urban areas (where levels of fine PM are typically higher), in accord with the strongest evidence of health effects from coarse particles. 559 F. 3d at 535–36. In addition, such regulation would not impermissibly double regulate fine particles, since any additional control of fine particles (beyond that afforded by the primary $PM_{2.5}$ standard) would be for a different purpose: To prevent contamination of coarse particles by fine particles. 559 F. 3d at 535, 536. These same explanations justified the choice of PM_{10} as an indicator and provided the reasoned explanation for that choice lacking in the record for the 1997 standard. 559 F. 3d at 536.

With regard to the challenge from environmental and public health groups, the court upheld the EPA's decision to revoke the annual PM_{10} standard. The court rejected the argument that the EPA is required by law to have an annual PM_{10} standard, holding that section 109(d)(1) of the Act allows the EPA to revoke a standard no longer warranted by the current scientific understanding. 559 F. 3d at 538. The court further held that the EPA's decision to revoke the annual standard was supported by the science:

> The EPA reasonably decided that an annual coarse PM standard is not necessary because, as the Criteria Document and the Staff Paper make clear, the latest scientific data do not indicate that long-term exposure to coarse particles poses a health risk. The CASAC also agreed that an annual coarse PM standard is unnecessary. 559 F. 3d at 538–39.

3. General Approach Used in the Current Review

The approach taken to considering the existing and potential alternative primary PM_{10} standards in the current review builds upon the approaches used in previous PM NAAQS reviews. This approach is based most fundamentally on using information from epidemiological studies and air quality analyses to inform the identification of a range of policy options for consideration by the Administrator. The Administrator considers the appropriateness of the current and potential alternative standards, taking into account the four elements of the NAAQS: Indicator, averaging time, form, and level.

Evidence-based approaches to using information from epidemiological studies to inform decisions on PM standards are complicated by the recognition that no population threshold, below which it can be concluded with confidence that PM-related effects do not occur, can be discerned from the available evidence (U.S. EPA, 2009a, sections 2.4.3 and 6.5.2.7).[122] As a result, any approach to

[120] Thus, the standard is met when a 24-hour average PM_{10} concentration of 150 μg/m³ is not exceeded more than one day per year, on average over a three-year period. As noted above, the 1987 PM_{10} standard was not adopted solely to control thoracic coarse particles. However, when reviewing this standard in the 2006 review, EPA determined that the level and form of the standard being reviewed (i.e., the 1987 PM_{10} standard) provided requisite protection with an adequate margin of safety from short-term exposures to thoracic coarse particles.

[121] As noted below, however, with this rule the EPA is revoking the requirement for $PM_{10-2.5}$ speciation at NCore monitoring sites due to technical issues related to the development of appropriate monitoring methods (section VIII.B.3.c). The requirement for $PM_{10-2.5}$ mass measurements at NCore sites is being retained.

[122] Studies that have characterized the concentration-response relationships for PM exposures have evaluated PM_{10}, which includes

reaching decisions on what standards are appropriate requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards, which includes consideration of how to weigh the uncertainties in reported associations across the distributions of PM concentrations in the studies. The approach taken to informing these decisions in the current review recognizes that the available health effects evidence reflects a continuum consisting of ambient levels at which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. Such an approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

Because the purpose of the PM_{10} standard is to protect against exposures to $PM_{10-2.5}$, it is most appropriate to focus on $PM_{10-2.5}$ health studies when considering the degree of public health protection provided by the current PM_{10} standard. Compared to health studies of PM_{10}, studies that evaluate associations with $PM_{10-2.5}$ provide clearer evidence for health effects following exposures to thoracic coarse particles. In contrast, it is difficult to interpret PM_{10} studies within the context of a standard meant to protect against exposures to $PM_{10-2.5}$ 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). Therefore, the extent to which PM_{10} effect estimates reflect associations with $PM_{10-2.5}$ versus $PM_{2.5}$ can be highly uncertain. In light of this uncertainty, it is preferable to consider $PM_{10-2.5}$ studies when such studies are available. Given the availability in this review of a number of studies that evaluated associations with $PM_{10-2.5}$, and given that the Integrated Science Assessment weight-of-evidence conclusions for thoracic coarse particles were based on studies of $PM_{10-2.5}$, in this review the EPA focuses primarily on studies that have specifically evaluated $PM_{10-2.5}$.[123]

As discussed in more detail in the Risk Assessment (U.S. EPA, 2010a, Appendix H), the EPA did not conduct a quantitative assessment of health risks associated with $PM_{10-2.5}$. 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). This decision does not indicate that health effects are not associated with exposure to thoracic coarse particles. Rather, as noted above, it reflects the conclusion that limitations in the available health studies and air quality information would introduce significant uncertainty into a quantitative assessment of $PM_{10-2.5}$ risks such that the risk estimates generated would be of limited value in informing review of the standard.

both coarse and fine particles, and $PM_{2.5}$ (U.S. EPA, 2009a, sections 2.4.3 and 6.5.2.7).

[123] It should also be noted that CASAC endorsed the approach adopted in the Integrated Science Assessment, which draws weight-of-evidence conclusions for $PM_{2.5}$ and $PM_{10-2.5}$, but not for PM_{10} (Samet, 2009f).

B. Health Effects Related to Exposure to Thoracic Coarse Particles

This section briefly outlines the key information presented in section IV.B of the proposal (77 FR 38947 to 38951, June 29, 2012), and discussed more fully in the Integrated Science Assessment (U.S. EPA, 2009a, Chapters 2, 4, 5, 6, 7, and 8) and the Policy Assessment (U.S. EPA, 2011a, Chapter 3), related to health effects associated with thoracic coarse particle exposures. In looking across the new scientific evidence available in this review, our overall understanding of health effects associated with thoracic coarse particle exposures has been expanded, though important uncertainties remain. Some highlights of the key policy-relevant scientific evidence available in this review include the following:

(1) A number of multi-city and single-city epidemiological studies have evaluated associations between short-term $PM_{10-2.5}$ and mortality, cardiovascular effects (e.g., including hospital admissions and emergency department visits), and/or respiratory effects. Despite differences in the approaches used to estimate ambient $PM_{10-2.5}$ concentrations, the majority of these studies have reported positive, though often not statistically significant, associations with short-term $PM_{10-2.5}$ concentrations. Most $PM_{10-2.5}$ effect estimates remained positive in co-pollutant models that included either gaseous or particulate co-pollutants. In U.S. study locations likely to have met the current PM_{10} standard during the study period, a few $PM_{10-2.5}$ effect estimates were statistically significant and remained so in co-pollutant models.[124]

[124] The statistical significance of effect estimates provides important information on their statistical precision. However, when a group of studies report effect estimates that are similar in direction and magnitude, such a pattern of results warrants consideration of those studies even if not all reported statistically significant associations in single- or co-pollutant models (section III.D.2, above). In considering the $PM_{10-2.5}$ epidemiologic studies below, the Administrator considers both the pattern of results across studies and the statistical significance of those results.

(2) A small number of controlled human exposure studies have reported alterations in heart rate variability or increased pulmonary inflammation following short-term exposure to $PM_{10-2.5}$, providing some support for the associations reported in epidemiological studies. Toxicological studies that have examined the effects of $PM_{10-2.5}$ have used intratracheal instillation and, because these studies do not directly mirror any real-world mode of exposure, they provide only limited evidence for the biological plausibility of $PM_{10-2.5}$-induced effects.

(3) Using a more formal framework for reaching causal determinations than used in previous reviews, the Integrated Science Assessment concluded that the existing evidence is ''suggestive'' of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects (U.S. EPA, 2009a, section 2.3.3).[125] In contrast, the Integrated Science Assessment concluded that available evidence is ''inadequate'' to infer a causal relationship between long-term $PM_{10-2.5}$ exposures and various health effects.

(4) There are several at-risk populations that may be especially susceptible or vulnerable to PM-related effects, including effects associated with exposures to coarse particles. These groups include those with preexisting heart and lung diseases, specific genetic differences, and lower socioeconomic status as well as the lifestages of childhood and older adulthood. Evidence for PM-related effects in these at-risk populations has expanded and is stronger than previously observed. There is emerging, though still limited, evidence for additional potentially at-risk populations, such as those with diabetes, people who are obese, pregnant women, and the developing fetus.

(5) The Integrated Science Assessment concludes that currently available evidence is insufficient to draw distinctions in particle toxicity based on composition and notes that recent studies have reported that PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from a variety of sources,

[125] The causal framework draws upon the assessment and integration of evidence from across epidemiological, controlled human exposure, and toxicological studies, and the related uncertainties that ultimately influence our understanding of the evidence. This framework employs a five-level hierarchy that classifies the overall weight-of-evidence using the following categorizations: Causal relationship, likely to be causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (U.S. EPA, 2009a, Table 1–3). In the case of a ''suggestive'' determination, ''the evidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out. For example, at least one high-quality epidemiologic study shows an association with a given health outcome but the results of other studies are inconsistent'' (U.S. EPA, 2009a, Table 1–3).

including sources likely to be present in urban and non-urban locations, is associated with adverse health effects.

Although new $PM_{10-2.5}$ scientific studies have become available since the last review and have expanded our understanding of the association between $PM_{10-2.5}$ and adverse health effects (see above and U.S. EPA, 2009a, Chapter 6), important uncertainties remain. These uncertainties, and their implications for interpreting the scientific evidence, include the following:

(1) The potential for confounding by co-occurring pollutants, especially $PM_{2.5}$, has been addressed with co-pollutant models in only a relatively small number of $PM_{10-2.5}$ epidemiological studies (U.S. EPA, 2009a, section 2.3.3). This is a particularly important limitation given the relatively small body of experimental evidence (i.e., controlled human exposure and animal toxicological studies) available to support the associations between $PM_{10-2.5}$ and adverse health effects. The net impact of such limitations is to increase uncertainty in characterizations of the extent to which $PM_{10-2.5}$ itself, rather than one or more co-occurring pollutants, is responsible for the mortality and morbidity effects reported in epidemiological studies.

(2) There is greater spatial variability in $PM_{10-2.5}$ concentrations than $PM_{2.5}$ concentrations, resulting in increased exposure error for $PM_{10-2.5}$ (U.S. EPA, 2009a, p. 2–8). Available measurements do not provide sufficient information to adequately characterize the spatial distribution of $PM_{10-2.5}$ concentrations (U.S. EPA, 2009a, section 3.5.1.1). The net effect of these uncertainties on $PM_{10-2.5}$ epidemiological studies is to bias the results of such studies toward the null hypothesis. That is, as noted in the Integrated Science Assessment, these limitations in estimates of ambient $PM_{10-2.5}$ concentrations ''would tend to increase uncertainty and make it more difficult to detect effects of $PM_{10-2.5}$ in epidemiologic studies'' (U.S. EPA, 2009a, p. 2–21).

(3) Only a relatively small number of $PM_{10-2.5}$ monitoring sites are currently operating and such sites have been in operation for a relatively short period of time, limiting the spatial and temporal coverage for routine measurement of $PM_{10-2.5}$ concentrations. Given these limitations in routine monitoring, epidemiological studies have employed different approaches for estimating $PM_{10-2.5}$ concentrations. Given the relatively small number of $PM_{10-2.5}$ monitoring sites, the relatively large spatial variability in ambient $PM_{10-2.5}$ concentrations (see above), the use of different approaches to estimating ambient $PM_{10-2.5}$ concentrations across epidemiological studies, and the limitations inherent in such estimates, the distributions of thoracic coarse particle concentrations over which reported health outcomes occur remain highly uncertain (U.S. EPA, 2009a, sections 2.2.3, 2.3.3, 2.3.4, and 3.5.1.1).

(4) There is relatively little information on the chemical and biological composition of $PM_{10-2.5}$ and the effects associated with the various components (U.S. EPA, 2009a, section 2.3.4). Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations with health effects across locations is difficult to characterize (U.S. EPA, 2009a, section 6.5.2.3).

(5) One of the implications of the uncertainties and limitations discussed above is that the Risk Assessment concluded it would not be appropriate to conduct a quantitative assessment of health risks associated with $PM_{10-2.5}$. The lack of a quantitative $PM_{10-2.5}$ risk assessment in the current review adds to the uncertainty in any conclusions about the extent to which revision of the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard.[126]

C. Consideration of the Current and Potential Alternative Standards in the Policy Assessment

The following sections discuss the Policy Assessment's consideration of the current and potential alternative standards to protect against exposures to thoracic coarse particles (U.S. EPA, 2011a, chapter 3). Section IV.C.1 discusses the consideration of the current standard while section IV.C.2 discusses the consideration of potential alternative standards in terms of the basic elements of a standard: Indicator, averaging time, form, and level.

1. Consideration of the Current Standard in the Policy Assessment

As discussed above the 24-hour PM_{10} standard is meant to protect the public health against exposures to thoracic coarse particles (i.e., $PM_{10-2.5}$). In considering the adequacy of the current PM_{10} standard, the Policy Assessment considered the health effects evidence linking short-term $PM_{10-2.5}$ exposures with mortality and morbidity (U.S. EPA, 2009a, chapters 2 and 6), the ambient PM_{10} concentrations in $PM_{10-2.5}$ study locations (U.S. EPA, 2011a, section 3.2.1), the uncertainties and limitations associated with this health evidence (U.S. EPA, 2011a, section 3.2.1), and the consideration of these uncertainties and limitations as part of the weight of evidence conclusions in the Integrated Science Assessment (U.S. EPA, 2009a).

In considering the health evidence, air quality information, and associated uncertainties as they relate to the current PM_{10} standard, the Policy Assessment noted that a decision on the adequacy of the public health protection provided by that standard is a public health policy judgment in which the Administrator weighs the evidence and information, as well as its uncertainties. Therefore, depending on the emphasis placed on different aspects of the evidence, information, and uncertainties, consideration of different conclusions on the adequacy of the current standard could be supported. For example, the Policy Assessment noted that one approach to considering the evidence, information, and its associated uncertainties would be to place emphasis on the following (U.S. EPA, 2011a, section 3.2.3):

(1) While most of $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were positive, many were not statistically significant, even in single-pollutant models. This includes effect estimates reported in study locations with PM_{10} concentrations above those allowed by the current 24-hour PM_{10} standard.

(2) The number of epidemiological studies that have employed co-pollutant models to address the potential for confounding, particularly by $PM_{2.5}$, remains limited. Therefore, the extent to which $PM_{10-2.5}$ itself, rather than one or more co-pollutants, contributes to reported health effects remains uncertain.

(3) Only a limited number of experimental studies provide support for the associations reported in epidemiological studies, resulting in further uncertainty regarding the plausibility of a causal link between $PM_{10-2.5}$ and mortality and morbidity.

(4) Limitations in $PM_{10-2.5}$ monitoring and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiological studies result in uncertainty as to the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur.

(5) The chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components, remains uncertain. Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across locations is difficult to interpret.

(6) In considering the available evidence and its associated uncertainties, the Integrated Science Assessment concluded that the evidence is ''suggestive'' of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. These weight-of-evidence conclusions contrast with those for the relationships between $PM_{2.5}$ exposures and adverse health effects, which were judged in the Integrated Science Assessment to be either ''causal'' or ''likely causal'' for mortality, cardiovascular effects, and respiratory effects.

The Policy Assessment concluded that, to the extent a decision on the adequacy of the current 24-hour PM_{10} standard were to place emphasis on the considerations noted above, it could be judged that, although it remains appropriate to maintain a standard to protect against short-term exposures to

[126] As noted above, the EPA's decision not to conduct a quantitative risk assessment reflects uncertainty regarding the value of such an assessment, but does not indicate that health effects are not associated with exposure to thoracic coarse particles.

thoracic coarse particles, the available evidence suggests that the current 24-hour PM_{10} standard appropriately protects public health and provides an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$ exposures. Although such an approach to considering the adequacy of the current standard would recognize the positive, and in some cases statistically significant, associations between all types of $PM_{10-2.5}$ and mortality and morbidity, it would place relatively greater emphasis on the limitations and uncertainties noted above, which tend to complicate the interpretation of that evidence.

In addition, the Policy Assessment noted the judgment that, given the uncertainties and limitations in the $PM_{10-2.5}$ health evidence and air quality information, it would not have been appropriate to conduct a quantitative assessment of health risks associated with $PM_{10-2.5}$ (U.S. EPA, 2011a, p. 3–6; U.S. EPA, 2010a, pp. 2–6 to 2–7, Appendix H). As discussed above, the lack of a quantitative $PM_{10-2.5}$ risk assessment adds to the uncertainty associated with any characterization of potential public health improvements that would be realized with a revised standard.

The Policy Assessment also noted an alternative approach to considering the evidence and its uncertainties would place emphasis on the following (U.S. EPA, 2011a, section 3.2.3):

(1) Several multi-city epidemiological studies conducted in the U.S., Canada, and Europe, as well as a number of single-city studies, have reported generally positive, and in some cases statistically significant, associations between short-term $PM_{10-2.5}$ concentrations and adverse health endpoints including mortality and cardiovascular-related and respiratory-related hospital admissions and emergency department visits.

(2) Both single-city and multi-city analyses, using different approaches to estimate ambient $PM_{10-2.5}$ concentrations, have reported positive $PM_{10-2.5}$ effect estimates in locations that would likely have met the current 24-hour PM_{10} standard. In a few cases, these $PM_{10-2.5}$ effect estimates were statistically significant.

(3) While limited in number, studies that have evaluated co-pollutant models have generally reported that $PM_{10-2.5}$ effect estimates remain positive, and in a few cases statistically significant, when these models include gaseous pollutants or fine particles.

(4) Support for the plausibility of the associations reported in epidemiological studies is provided by a small number of controlled human exposure studies reporting that short-term (i.e., 2-hour) exposures to $PM_{10-2.5}$ decrease heart rate variability and increase markers of pulmonary inflammation.

This approach to considering the health evidence, air quality information, and the associated uncertainties would place substantial weight on the generally positive $PM_{10-2.5}$ effect estimates that have been reported for mortality and morbidity, even those effect estimates that are not statistically significant. The Policy Assessment concluded that this could be judged appropriate given that consistent results have been reported across multiple studies using different approaches to estimate ambient $PM_{10-2.5}$ concentrations and that exposure measurement error, which is likely to be larger for $PM_{10-2.5}$ than for $PM_{2.5}$, tends to bias the results of epidemiological studies toward the null hypothesis, making it less likely that associations will be detected. Such an approach would place less weight on the uncertainties and limitations in the evidence that resulted in the Integrated Science Assessment conclusions that the evidence is only suggestive of a causal relationship.

Given all of the above, the Policy Assessment concluded that it would be appropriate to consider either retaining or revising the current 24-hour PM_{10} standard, depending on the approach taken to considering the available evidence, air quality information, and the uncertainties and limitations associated with that evidence and information (U.S. EPA, 2011a, section 3.2.3).

2. Consideration of Potential Alternative Standards in the Policy Assessment

Given the conclusion that it would be appropriate to consider either retaining or revising the current PM_{10} standard, the Policy Assessment also considered what potential alternative standards, if any, could be supported by the available scientific evidence in order to increase public health protection against exposures to $PM_{10-2.5}$. The Policy Assessment considered such potential alternative standards defined in terms of the elements of a standard (i.e., indicator, averaging time, form, and level). Key conclusions from the Policy Assessment regarding indicator, averaging time, and form included the following:

(1) A PM_{10} indicator would continue to appropriately target protection against thoracic coarse particle exposures to those locations where the evidence is strongest for associations with adverse health effects (i.e., urban areas).

(2) The available evidence supports the importance of maintaining a standard that protects against short-term exposures to all thoracic coarse particles. Given that the majority of this evidence is based on 24-hour average thoracic coarse particle concentrations, consideration of a 24-hour averaging time remains appropriate.

(3) Given the limited body of evidence supporting $PM_{10-2.5}$-related effects following long-term exposures, which resulted in the Integrated Science Assessment conclusion that the available evidence is ''inadequate'' to infer a causal relationship between long-term $PM_{10-2.5}$ exposures and a variety of health effects, consideration of an annual thoracic coarse particle standard is not supported at this time.

(4) To the extent it is judged appropriate to revise the current 24-hour PM_{10} standard, it would be appropriate to consider revising the form to the 3-year average of the 98th percentile of the annual distribution of 24-hour PM_{10} concentrations.

In considering the available evidence and air quality information within the context of identifying potential alternative standard levels for consideration (assuming a decision were made that it is appropriate to amend the standard), the Policy Assessment first noted that a standard level as high as about 85 μg/m³, for a 24-hour PM_{10} standard with a 98th percentile form, could be supported. Based on considering air quality concentrations in study locations, the Policy Assessment noted that such a standard level would be expected to maintain PM_{10} and $PM_{10-2.5}$ concentrations below those present in U.S. locations of single-city studies where $PM_{10-2.5}$ effect estimates have been reported to be positive and statistically significant and below those present in some locations where single-city studies reported $PM_{10-2.5}$ effect estimates that were positive, but not statistically significant. These include some locations likely to have met the current PM_{10} standard during the study periods (U.S. EPA, 2011a, section 3.3.4).

The Policy Assessment also noted that, based on analysis of the number of people living in counties that could violate the current and potential alternative PM_{10} standards, a 24-hour PM_{10} standard with a 98th percentile form and a level between 75 and 80 μg/m³ would provide a level of public health protection that is generally equivalent, across the U.S., to that provided by the current standard. Given this, the Policy Assessment concluded that it would be appropriate to consider standard levels in the range of approximately 75 to 80 μg/m³ (with a 98th percentile form), to the extent population counts were emphasized in comparing the public health protection provided by the current and potential alternative standards and to the extent it was judged appropriate to set a revised standard providing at least the level of public health protection that is provided by the current standard, based on such population counts (U.S. EPA, 2011a, section 3.3.4).

The Policy Assessment also concluded that alternative approaches to considering the evidence could lead to consideration of standard levels below 75 µg/m³ for a standard with a 98th percentile form. For example, a number of single-city epidemiological studies have reported positive, though not statistically significant, $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations below 75 µg/m³. Given that exposure error is particularly important for $PM_{10-2.5}$ epidemiological studies and can bias the results of these studies toward the null hypothesis (see section IV.B above), the Policy Assessment noted that it could be judged appropriate to place more weight on positive associations reported in these epidemiological studies, even when those associations are not statistically significant. In addition, the Policy Assessment noted that multi-city averages of 98th percentile PM_{10} concentrations in the locations evaluated by U.S. multi-city studies of thoracic coarse particles (Zanobetti and Schwartz, 2009; Peng et al., 2008) were near or below 75 ppb. Despite uncertainties in the extent to which effects reported in multi-city studies are associated with the short-term air quality in any particular location, the Policy Assessment noted that emphasis could be placed on these multi-city averaged concentrations. The Policy Assessment concluded that, to the extent more weight is placed on single-city studies reporting positive, but not statistically significant, $PM_{10-2.5}$ effect estimates and on multi-city studies, it could be appropriate to consider standard levels as low as 65 µg/m³ with a 98th percentile form (U.S. EPA, 2011a, section 3.3.4).

In considering potential alternative standard levels below 65 µg/m³, the Policy Assessment noted that the overall body of $PM_{10-2.5}$ health evidence is relatively uncertain, with somewhat stronger support in U.S. studies for associations with $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations above 85 µg/m³ than in locations with 98th percentile PM_{10} concentrations below 65 µg/m³. In light of the limitations in the evidence for a relationship between $PM_{10-2.5}$ and adverse health effects in locations with relatively low PM_{10} concentrations, along with the overall uncertainties in the body of $PM_{10-2.5}$ health evidence as described above and in the Integrated Science Assessment, the Policy Assessment concluded that consideration of standard levels below 65 µg/m³ was not appropriate (U.S. EPA, 2011a, section 3.3.4).

D. CASAC Advice

Following their review of the first and second draft Policy Assessments, CASAC provided advice and recommendations regarding the current and potential alternative standards for thoracic coarse particles (Samet, 2010c,d). With regard to the existing PM_{10} standard, CASAC concluded that ''the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard'' (Samet, 2010d, p. 7). In drawing this conclusion, CASAC noted the positive associations in multi-city and single-city studies, including in locations with PM_{10} concentrations below those allowed by the current standard. In addition, CASAC gave ''significant weight to studies that have generally reported that $PM_{10-2.5}$ effect estimates remain positive when evaluated in co-pollutant models'' and concluded that ''controlled human exposure $PM_{10-2.5}$ studies showing decreases in heart rate variability and increases in markers of pulmonary inflammation are deemed adequate to support the plausibility of the associations reported in epidemiologic studies'' (Samet, 2010d, p. 7).[127] Given all of the above conclusions CASAC recommended that ''the primary standard for PM_{10} should be revised'' (Samet, 2010d, p. ii and p. 7). In discussing potential revisions, while CASAC noted that the scientific evidence supports adoption of a standard at least as stringent as the current standard, they recommended revising the current standard in order to increase public health protection. In considering potential alternative standards, CASAC drew conclusions and made recommendations in terms of the major elements of a standard: indicator, averaging time, form, and level.

The CASAC agreed with the EPA staff's conclusions that the available evidence supports consideration in the current review of retaining the current PM_{10} indicator and the current 24-hour averaging time (Samet, 2010c, Samet, 2010d). Specifically, with regard to indicator, CASAC concluded that ''[w]hile it would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles'' (Samet, 2010d, p. ii). In addition, CASAC ''vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles'' (Samet, 2010d, p. 7).

The CASAC also agreed that the evidence supports consideration of a potential alternative form. Specifically, CASAC ''felt strongly that it is appropriate to change the statistical form of the PM_{10} standard to a 98th percentile'' (Samet, 2010d, p.7). In reaching this conclusion, CASAC noted that ''[p]ublished work has shown that the percentile form has greater power to identify non-attainment and a smaller probability of misclassification relative to the expected exceedance form of the standard'' (Samet, 2010d. p. 7).

With regard to standard level, in conjunction with a 98th percentile form, CASAC concluded that ''alternative standard levels of 85 and 65 µg/m³ (based on consideration of 98th percentile PM_{10} concentration) could be justified'' (Samet, 2010d, p.8). However, in considering the evidence and uncertainties, CASAC recommended a standard level from the lower part of the range discussed in the Policy Assessment, recommending a level ''somewhere in the range of 75 to 65 µg/m³'' (Samet, 2010d, p. ii).

In making this recommendation, CASAC noted that the number of people living in counties with air quality not meeting the current standard is approximately equal to the number living in counties that would not meet a 98th percentile standard with a level between 75 and 80 µg/m³. CASAC used this information as the basis for their conclusion that a 98th percentile standard between 75 and 80 µg/m³ would be ''comparable to the degree of protection afforded to the current PM_{10} standard'' (Samet, 2010d, p. ii). Given this conclusion regarding the comparability of the current and potential alternative standards, as well as their conclusion on the public health protection provided by the current standard (i.e., that available evidence is sufficient to call it into question), CASAC recommended a level within a range of 75 to 65 µg/m³ in order to increase public health protection, relative to that provided by the current standard (Samet 2010d, p. ii).

[127] Nonetheless, CASAC endorsed the Integrated Science Assessment weight of evidence conclusions for $PM_{10-2.5}$ (i.e., that the evidence is only ''suggestive'' of a causal relationship between short-term exposures and mortality, respiratory effects, and cardiovascular effects) (Samet, 2009e; Samet, 2009f).

E. Administrator's Proposed Conclusions Concerning the Adequacy of the Current Primary PM_{10} Standard

In considering the evidence and information as they relate to the adequacy of the current 24-hour PM_{10} standard, the Administrator first noted in the proposal that this standard is meant to protect the public health against effects associated with short-term exposures to $PM_{10-2.5}$. In the last review, it was judged appropriate to maintain such a standard given the ''growing body of evidence suggesting causal associations between short-term exposure to thoracic coarse particles and morbidity effects, such as respiratory symptoms and hospital admissions for respiratory diseases, and possibly mortality'' (71 FR 61185, October 17, 2006). Given the continued expansion in the body of scientific evidence linking short-term $PM_{10-2.5}$ to health outcomes such as premature death and hospital visits, discussed in detail in the Integrated Science Assessment (U.S. EPA, 2009a, Chapter 6) and summarized in the proposal, the Administrator provisionally concluded that the available evidence continued to support the appropriateness of maintaining a standard to protect the public health against effects associated with short-term (e.g., 24-hour) exposures to all $PM_{10-2.5}$. In drawing provisional conclusions in the proposal as to whether the current PM_{10} standard remains requisite (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety against such exposures, the Administrator considered the following:

(1) The extent to which it is appropriate to maintain a standard that provides some measure of protection against all $PM_{10-2.5}$, regardless of composition or source of origin;

(2) The extent to which it is appropriate to retain a PM_{10} indicator for a standard meant to protect against exposures to ambient $PM_{10-2.5}$; and

(3) The extent to which the current PM_{10} standard provides an appropriate degree of public health protection.

With regard to the first point, the proposal noted the conclusion from the last review that dosimetric, toxicological, occupational, and epidemiological evidence supported retention of a primary standard to provide some measure of protection against short-term exposures to all thoracic coarse particles, regardless of their source of origin or location, consistent with the Act's requirement that primary NAAQS provide requisite protection with an adequate margin of safety (71 FR 61197). In that review, the EPA concluded that PM from a number of source types, including motor vehicle emissions, coal combustion, oil burning, and vegetative burning, are associated with health effects (U.S. EPA, 2004). This information formed part of the basis for the D.C. Circuit's holding that it was appropriate for the thoracic coarse particle standard to provide ''some protection from exposure to thoracic coarse particles * * * in all areas'' (*American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 532–33).

In considering this issue in the proposal, the Administrator judged that the expanded body of scientific evidence in this review provides even more support for a standard that protects against exposures to all thoracic coarse particles, regardless of their location or source of origin. Specifically, the Administrator noted that epidemiological studies have reported positive associations between $PM_{10-2.5}$ and mortality or morbidity in a large number of cities across North America, Europe, and Asia, encompassing a variety of environments where $PM_{10-2.5}$ sources and composition are expected to vary widely. See 77 FR 38959. In considering this evidence, the Integrated Science Assessment concluded that ''many constituents of PM can be linked with differing health effects'' (U.S. EPA, 2009a, p. 2–26). While $PM_{10-2.5}$ in most of these study areas is of largely urban origin, the Administrator noted that some recent studies have also linked mortality and morbidity with relatively high ambient concentrations of thoracic coarse particles of non-urban crustal origin. In considering these studies, she noted the Integrated Science Assessment's conclusion that ''PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from crustal, soil or road dust sources or PM tracers linked to these sources are associated with cardiovascular effects'' (U.S. EPA, 2009a, p. 2–26).

In light of this body of available evidence reporting $PM_{10-2.5}$-associated health effects across different locations with a variety of sources, as well as the Integrated Science Assessment's conclusions regarding the links between adverse health effects and PM sources and composition, the Administrator provisionally concluded in the proposal that it is appropriate to maintain a standard that provides some measure of protection against exposures to all thoracic coarse particles, regardless of their location, source of origin, or composition (77 FR 38959–60).

With regard to the second point, in considering the appropriateness of a PM_{10} indicator for a standard meant to provide such public health protection, the Administrator noted that the rationale used in the last review to support the unqualified PM_{10} indicator (see above) remains relevant in the current review. Specifically, as an initial consideration, she noted that PM_{10} mass includes both coarse PM ($PM_{10-2.5}$) and fine PM ($PM_{2.5}$). As a result, the concentration of $PM_{10-2.5}$ allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. At the same time, the Administrator noted that $PM_{2.5}$ concentrations tend to be higher in urban areas than in rural areas (U.S. EPA, 2005, p. 2–54, and Figures 2–23 and 2–24) and, therefore, a PM_{10} standard will generally allow lower $PM_{10-2.5}$ concentrations in urban areas than in rural areas. 77 FR 38960.

In considering the appropriateness of this variation in allowable $PM_{10-2.5}$ concentrations, the Administrator considered the relative strength of the evidence for health effects associated with $PM_{10-2.5}$ of urban origin versus non-urban origin. She specifically noted that, as described above and similar to the scientific evidence available in the last review, the large majority of the available evidence for thoracic coarse particle health effects comes from studies conducted in locations with sources more typical of urban and industrial areas than of rural areas. Although as just noted, associations with adverse health effects have been reported in some study locations where $PM_{10-2.5}$ is largely non-urban in origin (i.e., in dust storm studies), particle concentrations in these study areas are typically much higher than reported in study locations where the $PM_{10-2.5}$ is of urban origin. Therefore, the Administrator noted that the strongest evidence for a link between $PM_{10-2.5}$ and adverse health impacts, particularly for such a link at relatively low particle concentrations, comes from studies where exposure is to $PM_{10-2.5}$ of urban or industrial origin. 77 FR 38960.

The Administrator also noted that chemical constituents present at higher levels in urban or industrial areas, including byproducts of incomplete combustion (e.g. polycyclic aromatic hydrocarbons) emitted as $PM_{2.5}$ from motor vehicles as well as metals and other contaminants emitted from anthropogenic sources, can contaminate $PM_{10-2.5}$ (U.S. EPA, 2004, p. 8–344; 71 FR 2665). While the Administrator acknowledged the uncertainty expressed in the Integrated Science Assessment regarding the extent to which, based on available evidence, particle composition can be linked to health outcomes, she also considered the possibility that $PM_{10-2.5}$ contaminants typical of urban or industrial areas could increase the toxicity of thoracic coarse particles in urban locations (77 FR 38960).

Given that the large majority of the evidence for $PM_{10-2.5}$ toxicity, particularly at relatively low particle concentrations, comes from study locations where thoracic coarse particles are of urban origin, and given the possibility that $PM_{10-2.5}$ contaminants in urban areas could increase particle toxicity, the Administrator provisionally concluded in the proposal that it remains appropriate to maintain a standard that targets public health protection to urban locations. Specifically, she concluded at proposal that it is appropriate to maintain a standard that allows lower ambient concentrations of $PM_{10-2.5}$ in urban areas, where the evidence is strongest that thoracic coarse particles are linked to mortality and morbidity, and higher concentrations in non-urban areas, where the public health concerns are less certain. *Id.*

Given all of the above considerations and conclusions, the Administrator judged that the available evidence supported retaining a PM_{10} indicator for a standard that is meant to protect against exposure to thoracic coarse particles. In reaching this initial judgment, she noted that, to the extent a PM_{10} indicator results in lower allowable concentrations of thoracic coarse particles in some areas compared to others, lower concentrations will be allowed in those locations (i.e., urban or industrial areas) where the science has shown the strongest evidence of adverse health effects associated with exposure to thoracic coarse particles and where we have the most concern regarding $PM_{10-2.5}$ toxicity. Therefore, the Administrator provisionally concluded that the varying amounts of coarse particles that are allowed in urban vs. non-urban areas under the 24-hour PM_{10} standard, based on the varying levels of $PM_{2.5}$ present, appropriately reflect the differences in the strength of evidence regarding coarse particle effects in urban and non-urban areas (77 FR 38960).

In reaching this provisional conclusion, the Administrator also noted that, in their review of the second draft Policy Assessment, CASAC concluded that ''[w]hile it would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles'' (Samet, 2010d, p. ii). In addition, CASAC ''vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles'' (Samet, 2010d, p. 7). Given this recommendation, the Administrator further judged that, although current evidence is not sufficient to identify a standard based on an alternative indicator that would be requisite to protect public health with an adequate margin of safety across the United States, consideration of alternative indicators (e.g., $PM_{10-2.5}$) in future reviews is desirable and could be informed by additional research, as described in the Policy Assessment (U.S. EPA, 2011a, section 3.5).

With regard to the third point, in evaluating the degree of public health protection provided by the current PM_{10} standard, the Administrator noted that the Policy Assessment discussed two different approaches to considering the scientific evidence and air quality information (U.S. EPA, 2011a, section 3.2.3). These different approaches, which are described above (section IV.C.1), lead to different conclusions regarding the appropriateness of the degree of public health protection provided by the current PM_{10} standard. The Administrator further noted that the primary difference between the two approaches lies in the extent to which weight is placed on the following (U.S. EPA, 2011a, section 3.2.3):

(1) The $PM_{10-2.5}$ weight-of-evidence classifications presented in the Integrated Science Assessment concluding that the existing evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects (a classification supported by CASAC);

(2) Individual $PM_{10-2.5}$ epidemiological studies reporting associations in locations that meet the current PM_{10} standard, including associations that are not statistically significant;

(3) The limited number of $PM_{10-2.5}$ epidemiological studies that have evaluated co-pollutant models;

(4) The limited number of $PM_{10-2.5}$ controlled human exposure studies;

(5) Uncertainties in the $PM_{10-2.5}$ air quality concentrations reported in epidemiological studies, given limitations in $PM_{10-2.5}$ monitoring data and the different approaches used across studies to estimate ambient $PM_{10-2.5}$ concentrations; and

(6) Uncertainties and limitations in the evidence that tend to call into question the presence of a causal relationship between $PM_{10-2.5}$ exposures and mortality/morbidity.

In evaluating the different possible approaches to considering the public health protection provided by the current PM_{10} standard, the Administrator first noted that when the available $PM_{10-2.5}$ scientific evidence and its associated uncertainties are considered, the Integrated Science Assessment concluded that the evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. As discussed in section IV.B.1 above and in more detail in the Integrated Science Assessment (U.S. EPA, 2009a, section 1.5), a suggestive determination is made when the ''[e]vidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out.'' In contrast, the Administrator noted that she proposed to strengthen the annual fine particle standard based on a body of scientific evidence judged sufficient to conclude that a causal relationship exists (i.e., mortality, cardiovascular effects) or is likely to exist (i.e., respiratory effects) (section III.B). 77 FR 38961. The suggestive judgment for $PM_{10-2.5}$ reflects the greater degree of uncertainty associated with this body of evidence, as discussed above (sections IV.B and IV.C) and summarized below.

In the proposal (77 FR 38961), the Administrator noted that the important uncertainties and limitations associated with the scientific evidence and air quality information raise questions as to whether public health benefits would be achieved by revising the existing PM_{10} standard. Such uncertainties and limitations include the following:

(1) While $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were generally positive, most were not statistically significant, even in single-pollutant models. This includes effect estimates reported in some study locations with PM_{10} concentrations above those allowed by the current 24-hour PM_{10} standard.

(2) The number of epidemiological studies that have employed co-pollutant models to address the potential for confounding, particularly by $PM_{2.5}$, remains limited. Therefore, the extent to which $PM_{10-2.5}$ itself, rather than one or more co-pollutants, contributes to reported health effects is less certain.

(3) Only a limited number of experimental studies (i.e., controlled human exposure and animal toxicological) provide support for the associations reported in epidemiological studies, resulting in further uncertainty regarding the plausibility of the associations between $PM_{10-2.5}$ and mortality and morbidity reported in epidemiological studies.

(4) Limitations in $PM_{10-2.5}$ monitoring data and the different approaches used by epidemiological study researchers to estimate $PM_{10-2.5}$ concentrations across epidemiological studies result in uncertainty in the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur, increasing uncertainty in estimates of the extent to

which changes in ambient $PM_{10-2.5}$ concentrations would likely impact public health.

(5) The lack of a quantitative $PM_{10-2.5}$ risk assessment further contributes to uncertainty regarding the extent to which any revisions to the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard (see section III.B.5 above).

(6) The chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components, remains uncertain. Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across locations is difficult to interpret.

In considering these uncertainties and limitations, the Administrator noted in particular the considerable degree of uncertainty in the extent to which health effects reported in epidemiological studies are due to $PM_{10-2.5}$ itself, as opposed to one or more co-occurring pollutants. As discussed above, this uncertainty reflects the fact that there are a relatively small number of $PM_{10-2.5}$ studies that have utilized co-pollutant models, particularly co-pollutant models that have included $PM_{2.5}$, and a very limited body of controlled human exposure evidence supporting the biological plausibility of a causal relationship between $PM_{10-2.5}$ and mortality and morbidity at ambient concentrations. The Administrator noted that these important limitations in the overall body of health evidence introduce uncertainty into the interpretation of individual epidemiological studies, particularly those studies reporting associations with $PM_{10-2.5}$ that are not statistically significant. Given this, the Administrator reached the provisional conclusion in the proposal that it is appropriate to place relatively little weight on epidemiological studies reporting associations with $PM_{10-2.5}$ that are not statistically significant in single-pollutant and/or co-pollutant models. *Id.*

With regard to this provisional conclusion, the Administrator noted that, for single-city mortality studies conducted in the United States where ambient PM_{10} concentration data were available for comparison to the current standard, positive and statistically significant $PM_{10-2.5}$ effect estimates were only reported in study locations that would likely have violated the current PM_{10} standard during the study period (U.S. EPA, 2011a, Figure 3–2). In U.S. study locations that would likely have met the current standard, $PM_{10-2.5}$ effect estimates for mortality were positive, but not statistically significant (U.S. EPA, 2011a, Figure 3–2). In considering U.S. study loc'ations where single-city morbidity studies were conducted, and which would likely have met the current PM_{10} standard during the study period, the Administrator noted that $PM_{10-2.5}$ effect estimates were both positive and negative, with most not statistically significant (U.S. EPA, 2011a, Figure 3–3).

In addition, in considering single-city analyses for the locations evaluated in a large U.S. multi-city mortality study (Zanobetti and Schwartz, 2009), the Administrator noted that associations in most of the study locations were not statistically significant and that this was the only study to estimate ambient $PM_{10-2.5}$ concentrations as the difference between county-wide PM_{10} and $PM_{2.5}$ mass. As discussed in the Policy Assessment and in the proposal, it is not clear how computed $PM_{10-2.5}$ measurements, such as those used by Zanobetti and Schwartz (2009), compare with the $PM_{10-2.5}$ concentrations obtained in other studies either by direct measurement or by calculating the difference using co-located samplers (U.S. EPA, 2009a, section 6.5.2.3). For these reasons, in the proposal the Administrator noted that ''there is considerable uncertainty in interpreting the associations in these single-city analyses'' (77 FR 38961–62).

The Administrator acknowledged that an approach to considering the available scientific evidence and air quality information that emphasizes the above considerations differs from the approach taken by CASAC. Specifically, in its review of the draft Policy Assessment CASAC placed a substantial amount of weight on individual studies, particularly those reporting positive health effects associations for $PM_{10-2.5}$ in locations that met the current PM_{10} standard during the study period. In emphasizing these studies, as well as the limited number of supporting studies that have evaluated co-pollutant models and the small number of supporting experimental studies, CASAC concluded that ''the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard'' (Samet, 2010d, p. 7) and recommended revising the current PM_{10} standard (Samet, 2010d).

The Administrator carefully considered CASAC's advice and recommendations. She noted that in making its recommendation on the current PM_{10} standard, CASAC did not discuss its approach to considering the important uncertainties and limitations in the health evidence, and did not discuss how these uncertainties and limitations were reflected in its recommendation. Nor did CASAC discuss uncertainties in the reported concentrations of $PM_{10-2.5}$ in the epidemiological studies, or how reported concentrations in the various studies relate to one another when differing measurement methodologies are used. As discussed above, such uncertainties and limitations contributed to the conclusions in the Integrated Science Assessment that the $PM_{10-2.5}$ evidence is only suggestive of a causal relationship, a conclusion that CASAC endorsed (Samet, 2009e,f). Given the importance of these uncertainties and limitations to the interpretation of the evidence, as reflected in the weight of evidence conclusions in the Integrated Science Assessment and as discussed above, the Administrator judged it appropriate to consider and account for them when drawing conclusions about the potential implications of individual $PM_{10-2.5}$ health studies for the current standard.

In light of the above approach to considering the scientific evidence, air quality information, and associated uncertainties, the Administrator reached the following provisional conclusions in the proposal:

(1) When viewed as a whole the available evidence and information suggests that the degree of public health protection provided against short-term exposures to $PM_{10-2.5}$ does not need to be increased beyond that provided by the current PM_{10} standard. This provisional conclusion noted the important uncertainties and limitations associated with the overall body of health evidence and air quality information for $PM_{10-2.5}$, as discussed above and as reflected in the Integrated Science Assessment weight-of-evidence conclusions; that $PM_{10-2.5}$ effect estimates for the most serious health effect, mortality, were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers; and that $PM_{10-2.5}$ effect estimates for morbidity endpoints were both positive and negative in locations that met the current standard, with most not statistically significant.

(2) The degree of public health protection provided by the current standard is not greater than warranted. This provisional conclusion noted that positive and statistically significant associations with mortality were reported in single-city U.S. study locations likely to have violated the current PM_{10} standard.[128]

[128] There are similarities with the conclusions drawn by the Administrator in the last review. There, the Administrator concluded that there was no basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour

Continued

In reaching these provisional conclusions, the Administrator noted that the Policy Assessment also discussed the potential for a revised PM_{10} standard (i.e., with a revised form and level) to be ''generally equivalent'' to the current standard, but to better target public health protection to locations where there is greater concern regarding $PM_{10-2.5}$-associated health effects (U.S. EPA, 2011a, sections 3.3.3 and 3.3.4). In considering such a potential revised standard, the Policy Assessment discussed the large amount of variability in PM_{10} air quality correlations across monitoring locations and over time (U.S. EPA, 2011a, Figure 3–7) and the regional variability in the relative degree of public health protection that could be provided by the current and potential alternative standards (U.S. EPA, 2011a, Table 3–2). In light of this variability, the Administrator noted the Policy Assessment conclusion that no single revised PM_{10} standard (i.e., with a revised form and level) would provide public health protection equivalent to that provided by the current standard, consistently over time and across locations (U.S. EPA, 2011a, section 3.3.4). That is, a revised standard, even one that is meant to be ''generally equivalent'' to the current PM_{10} standard, could increase protection in some locations while decreasing protection in others (77 FR 38962).

In considering the appropriateness of revising the current PM_{10} standard in this way, the Administrator noted the following:

(1) Positive $PM_{10-2.5}$ effect estimates for mortality were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers, while positive and statistically significant associations with mortality were reported in locations likely to have violated the current PM_{10} standard.

(2) Effect estimates for morbidity endpoints in locations that met the current standard were both positive and negative, with most not statistically significant.

(3) Important uncertainties and limitations associated with the overall body of health evidence and air quality information for $PM_{10-2.5}$, as discussed above and as reflected in the Integrated Science Assessment weight-of-evidence conclusions, call into question the extent to which the type of quantified and refined targeting of public health protection envisioned under a revised standard could be reliably accomplished.

Given all of the above considerations, the Administrator noted that there is a large amount of uncertainty in the extent to which public health would be improved by changing the locations to which the PM_{10} standard targets protection. Therefore, she reached the provisional conclusion that the current PM_{10} standard should not be revised in order to change that targeting of protection.

In considering all of the above, including the scientific evidence, the air quality information, the associated uncertainties, and CASAC's advice, the Administrator reached the provisional conclusion that the current 24-hour PM_{10} standard is requisite (i.e., neither more protective nor less protective than necessary) to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. In light of this provisional conclusion, the Administrator proposed to retain the current PM_{10} standard in order to protect against health effects associated with short-term exposures to $PM_{10-2.5}$ (77 FR 38963).

The Administrator recognized that her proposed conclusions and decision to retain the current PM_{10} standard differed from CASAC's recommendations, stemming from the differences in how the Administrator and CASAC considered and accounted for the evidence and its limitations and uncertainties. In light of CASAC's views and recommendation to revise the current PM_{10} standard, the Administrator welcomed the public's views on these different approaches to considering and accounting for the evidence and its limitations and uncertainties, as well as on the appropriateness of revising the primary PM_{10} standard, including revising the form and level of the standard. In doing so, the Administrator solicited comment on all aspects of the proposed decision, including her rationale for reaching the provisional conclusion that the current PM_{10} standard is requisite to protect public health with an adequate margin of safety and the provisional conclusion that it is not appropriate to revise the current PM_{10} standard by setting a ''generally equivalent'' standard with the goal of better targeting public health protection.

F. Public Comments on the Administrator's Proposed Decision To Retain the Primary PM_{10} Standard

This section discusses the major public comments received on the Administrator's proposed decision to retain the primary PM_{10} standard. Additional comments are addressed in the Response to Comments Document (U.S. EPA, 2012a).

Many public commenters agreed with the Administrator's proposed decision to retain the current 24-hour primary PM_{10} standard. Among those expressing a position on this proposed decision, industry groups and most State and Local commenters endorsed the Administrator's proposed rationale for retaining the current primary PM_{10} standard, including her consideration of the available scientific evidence and associated uncertainties and her consideration of CASAC recommendations.

Although industry commenters generally agreed with the Administrator's proposed decision to retain the current primary PM_{10} standard, some also contended that the current standard is ''excessively precautionary'' (NMA and NCBA, 2012, p. 4) and a few expressed support for a less stringent standard for coarse particles that are comprised largely of crustal material. For example, the Coarse Particulate Matter Coalition (CPMC) (2012) and several other industry commenters recommended that the final decision allow application of a 98th percentile form for the current standard (i.e. with its level of 150 μg/m^3) in cases where coarse particles consist primarily of crustal material. Such an approach would allow more yearly exceedances of the existing standard level than are allowed with the current one-expected-exceedance form. These industry commenters contended that a 98th percentile form applied in this way would provide appropriate regulatory relief for areas where the evidence for coarse particle-related health effects is relatively uncertain.

In reaching her conclusion that the current primary PM_{10} standard is requisite to protect public health with an adequate margin of safety, the Administrator considered the degree of public health protection provided by the current standard as a whole, including all elements of that standard (i.e., indicator, averaging time, form, level). As discussed above and in the following section, this conclusion reflects the Administrator's judgments that (1) the current standard appropriately provides some measure of protection against exposures to all thoracic coarse

standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times (71 FR 61202). In addition, the Administrator concluded that there was a high degree of uncertainty in the relevant population exposures implied by the morbidity studies suggesting that there is little basis for concluding that a greater degree of protection is warranted. *Id.* The D.C. Circuit in *American Farm Bureau Federation* v *EPA* explicitly endorsed this reasoning. 559 F. 3d at 534.

particles, regardless of their location, source of origin, or composition and (2) the current standard appropriately allows lower ambient concentrations of $PM_{10-2.5}$ in urban areas, where the evidence is strongest that thoracic coarse particles are linked to mortality and morbidity, and higher concentrations in non-urban areas, where the public health concerns are less certain.

Because the considerations that led to these judgments, and to the conclusion that the current primary PM_{10} standard is requisite to protect public health, took into account the degree of public health protection provided by the standard as a whole, it would not be appropriate to consider revising one element of the standard (e.g., the form, as suggested by commenters in this case) without considering the extent to which the other elements of the standard should also be revised. The change in form requested by industry commenters, without also lowering the level of the standard, would markedly reduce the public health protection provided against exposures to thoracic coarse particles.[129] However, industry commenters have not presented new evidence or analyses to support their conclusion that an appropriate degree of public health protection could be achieved by allowing the use of an alternative form (i.e., 98th percentile) for some coarse particles, while retaining the other elements of the current standard. Nor have these commenters presented new evidence or analyses challenging the basis for the conclusion in the proposal that the varying amounts of coarse particles allowed in urban versus non-urban areas under the current 24-hour PM_{10} standard, based on the varying levels of $PM_{2.5}$ present, appropriately reflect the differences in the strength of evidence regarding coarse particle effects in urban and non-urban areas. In light of this, EPA does not believe that a reduction in public health protection, such as that requested by industry commenters, is warranted.

In further considering these comments, it is to be remembered that epidemiologic studies have not demonstrated that coarse particles of non-urban origin do not cause health effects, and commenters have not provided additional evidence on this point. While there are fewer studies of non-urban coarse particles than of urban coarse particles, several studies have reported positive and statistically significant associations between coarse particles of crustal, non-urban origin and mortality or morbidity (Ostro *et al.,* 2003; Bell *et al.,* 2008; Chan *et al.,* 2008; Middleton *et al.,* 2008; Perez *et al.,* 2008). These studies formed part of the basis for the PM Integrated Science Assessment conclusion that ''recent studies have suggested that PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from crustal, soil or road dust sources or PM tracers linked to these sources are associated with cardiovascular effects'' (U.S. EPA, 2009a, p. 2–26). Moreover, crustal coarse particles may be contaminated with toxic trace elements and other components from previously deposited fine PM from ubiquitous sources such as mobile source engine exhaust, as well as by toxic metals from smelters or other industrial activities, animal waste, or pesticides (U.S. EPA, 2004, p. 8–344). In the proposal, the Administrator acknowledged the potential for this type of contamination to increase the toxicity of coarse particles of crustal, non-urban origin (77 FR 38960; see also 71 FR 61190).

In suggesting a change in the form of the current standard, industry commenters also did not address the manifold difficulties noted above, and in the last review, associated with developing an indicator that could reliably identify ambient mixes dominated by particular types of sources of coarse particles. See above and 71 FR 61193. Yet such an indicator would be a prerequisite of the type of standard these commenters request.

For all of the reasons discussed above, the EPA does not agree with industry commenters who recommended allowing the application of a 98th percentile form for the current standard in cases where coarse particles consist primarily of crustal material.

Some industry commenters contended that the uncertainties and limitations that precluded a quantitative risk assessment also preclude revising the PM_{10} standard. Although the EPA agrees that there are important uncertainties and limitations in the extent to which the quantitative relationships between ambient $PM_{10-2.5}$ and health outcomes can be characterized in risk models, the Agency does not agree that such limitations alone preclude the option of revising a NAAQS. As noted above, the lack of a quantitative $PM_{10-2.5}$ risk assessment in the current review adds uncertainty to conclusions about the extent to which revision of the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard. However, the EPA does not agree that such uncertainties necessarily preclude revision of a NAAQS. Indeed, with respect to thoracic coarse particles, the DC Circuit noted that ''[a]lthough the evidence of danger from coarse PM is, as the EPA recognizes, 'inconclusive', the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health.'' 559 F. 3d at 533. Thus, the Administrator's conclusion that the current 24-hour PM_{10} standard provides requisite protection of public health relies on her consideration of the broad body of evidence, rather than solely on the uncertainties that led to the decision not to conduct a quantitative assessment of $PM_{10-2.5}$ health risks.

Commenters representing a number of environmental groups and medical organizations disagreed with the Administrator's proposal to retain the current primary PM_{10} standard. These commenters generally requested that the EPA revise the PM_{10} standard to increase public health protection, consistent with the recommendations from CASAC.

As discussed above and in the proposal, in reaching provisional conclusions in the proposal regarding the current standard, the Administrator carefully considered CASAC's advice and recommendations. She specifically noted that in making its recommendation on the current PM_{10} standard, CASAC did not discuss its approach to considering the important uncertainties and limitations in the health evidence, and did not discuss how these uncertainties and limitations were reflected in its recommendations. Such uncertainties and limitations contributed to the conclusions in the Integrated Science Assessment that the $PM_{10-2.5}$ evidence is only suggestive of a causal relationship, a conclusion that CASAC endorsed (Samet, 2009e,f). These commenters also did not address the important uncertainties in the epidemiologic studies on which their comments are based. Given the importance of these uncertainties and limitations to the interpretation of the

[129] Based on regression analyses presented in the PA (U.S. EPA, 2011a, Figures 3–7 and 3–8), PM_{10} one-expected-exceedance concentration-equivalent design values were between approximately 175 and 300 µg/m^3 at monitoring locations recording 3-year averages of 98th percentile 24-hour PM_{10} concentrations around 150 µg/m^3 (i.e., the level of the current standard). This suggests that, depending on the location, a 24-hour PM_{10} standard with a 98th percentile form in conjunction with the current level (i.e., as recommended by these commenters) could be ''generally equivalent'' to a 24-hour PM_{10} standard with a one-expected-exceedance form and a level as high as approximately 300 µg/m^3. Based on this analysis, a 24-hour PM_{10} standard with a 98th percentile form and a level of 150 µg/m^3 would be markedly less health protective than the current standard.

evidence, as reflected in the weight of evidence conclusions in the Integrated Science Assessment and as discussed in the proposal, the Administrator judges that it is appropriate to consider and account for them when drawing conclusions about the implications of individual $PM_{10\text{-}2.5}$ health studies for the current standard. Commenters have not provided new information that would change the Administrator's views on the evidence and uncertainties.

In recommending that the PM_{10} standard be revised, some commenters supported their conclusions by referencing studies that evaluated PM_{10}, rather than $PM_{10\text{-}2.5}$. These commenters contended that ''[t]he most relevant studies to the setting of a PM_{10} standard are the thousands of studies that have reported adverse effects associated with PM_{10} pollution'' (ALA *et al.,* 2012).

As discussed in the Policy Assessment, the proposal, and above, since the establishment of the primary $PM_{2.5}$ standards, the purpose of the primary PM_{10} standard has been to protect against health effects associated with exposures to $PM_{10\text{-}2.5}$. PM_{10} is the indicator, not the target pollutant. With regard to the appropriateness of considering PM_{10} health studies for the purpose of reaching conclusions on a standard meant to protect against exposures to $PM_{10\text{-}2.5}$, the proposal noted that PM_{10} includes both fine and coarse particles, even in locations with the highest concentrations of $PM_{10\text{-}2.5}$. Therefore, the extent to which PM_{10} effect estimates reflect associations with $PM_{10\text{-}2.5}$ versus $PM_{2.5}$ can be highly uncertain and it is often unclear how PM_{10} health studies should be interpreted when considering a standard meant to protect against exposures to $PM_{10\text{-}2.5}$. Given this uncertainty and the availability of a number of $PM_{10\text{-}2.5}$ health studies in this review, the Integrated Science Assessment considered $PM_{10\text{-}2.5}$ studies, but not PM_{10} studies, when drawing weight-of-evidence conclusions regarding the coarse fraction.[130] In light of the uncertainty in ascribing PM_{10}-related health effects to the coarse or fine fractions, indicating that the best evidence for effects associated with exposures to $PM_{10\text{-}2.5}$ comes from studies evaluating $PM_{10\text{-}2.5}$ itself, and given CASAC's support for the approach adopted in the Integrated Science Assessment, which draws weight-of-evidence conclusions for $PM_{2.5}$ and $PM_{10\text{-}2.5}$ but not for PM_{10} (Samet, 2009f), the EPA continues to conclude that it is appropriate to focus on $PM_{10\text{-}2.5}$ health studies when considering the degree of public health protection provided by the current primary PM_{10} standard, a standard intended exclusively to provide protection against exposures to $PM_{10\text{-}2.5}$.

G. Administrator's Final Decision on the Primary PM_{10} Standard

In reaching a final decision on the primary PM_{10} standard, the Administrator takes into account the available scientific evidence, and the assessment of that evidence, in the Integrated Science Assessment; the analyses and staff conclusions presented in the Policy Assessment; the advice and recommendations of CASAC; and public comments on the proposal. In particular, as in the proposal, the Administrator places emphasis on her consideration of the following issues:

(1) The extent to which it is appropriate to maintain a standard that provides some measure of protection against all $PM_{10\text{-}2.5}$, 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 $PM_{10\text{-}2.5}$; and

(3) The extent to which the current PM_{10} standard provides an appropriate degree of public health protection.

Each of these issues is discussed below.

With regard to the first issue, as in the proposal the Administrator judges that the expanded body of scientific evidence available in this review provides ample support for a standard that protects against exposures to all thoracic coarse particles, regardless of their location or source of origin. There was already ample evidence for this position in the previous review,[131] and that evidence has since increased. Specifically, the Administrator notes that epidemiological studies have reported positive associations between $PM_{10\text{-}2.5}$ and mortality or morbidity in a large number of cities across North America, Europe, and Asia, encompassing a variety of environments where $PM_{10\text{-}2.5}$ sources and composition are expected to vary widely. In considering this evidence, the Integrated Science Assessment concludes that ''many constituents of PM can be linked with differing health effects'' (U.S. EPA, 2009a, p. 2–26). Although $PM_{10\text{-}2.5}$ 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 $PM_{10\text{-}2.5}$) from crustal, soil or road dust sources or PM tracers linked to these sources are associated with cardiovascular effects'' (U.S. EPA, 2009a, p. 2–26). The Administrator likewise notes CASAC's emphatic advice that a standard remains needed for all types of thoracic coarse PM.[132] In light of this body of available evidence reporting $PM_{10\text{-}2.5}$-associated health effects across different locations with a variety of sources, the Integrated Science Assessment's conclusions regarding the links between adverse health effects and PM sources and composition, and CASAC's advice, the Administrator concludes in the current review that it is appropriate to maintain a standard that provides some measure of protection against exposures to all thoracic coarse particles, regardless of their location, source of origin, or composition.

With regard to the second issue, in considering the appropriateness of a PM_{10} indicator for a standard meant to provide such public health protection, the Administrator notes that the rationale used in the last review to support the unqualified PM_{10} indicator remains relevant in the current review. Specifically, as an initial consideration, she notes that PM_{10} mass includes both coarse PM ($PM_{10\text{-}2.5}$) and fine PM ($PM_{2.5}$). As a result, the concentration of $PM_{10\text{-}2.5}$ 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 $PM_{10\text{-}2.5}$ concentrations in urban areas than in rural areas.

In considering the appropriateness of this variation in allowable $PM_{10\text{-}2.5}$ concentrations, the Administrator considers the relative strength of the evidence for health effects associated with $PM_{10\text{-}2.5}$ of urban origin versus non-urban origin. She specifically notes that, as discussed in the proposal, the large majority of the available evidence for

[130] Although EPA relied in the 1997 review on evidence from PM_{10} studies, EPA did so out of necessity (i.e., there were as yet no reliable studies measuring $PM_{10\text{-}2.5}$). In the 2006 review, EPA placed primary reliance on epidemiologic studies measuring or estimating $PM_{10\text{-}2.5}$, although there were comparatively few such studies. In this review, a larger body of $PM_{10\text{-}2.5}$ studies are available. EPA regards these studies as the evidence to be given principal weight in reviewing the adequacy of the PM_{10} standard.

[131] The D.C. Circuit agreed. See 559 F. 3d at 532–33.

[132] Indeed, CASAC recommended making the standard for all types of thoracic coarse PM more stringent (Samet, 2010d).

thoracic coarse particle health effects comes from studies conducted in locations with sources more typical of urban and industrial areas than rural areas. While associations with adverse health effects have been reported in some study locations where $PM_{10-2.5}$ is largely non-urban in origin (i.e., in dust storm studies), particle concentrations in these study areas are typically much higher than reported in study locations where the PM is of urban origin. Therefore, the Administrator notes that the strongest evidence for a link between $PM_{10-2.5}$ and adverse health impacts, particularly for such a link at relatively low particle concentrations, comes from studies of urban or industrial $PM_{10-2.5}$.

The Administrator also notes that chemical constituents present at higher levels in urban or industrial areas, including byproducts of incomplete combustion (e.g. polycyclic aromatic hydrocarbons) emitted as $PM_{2.5}$ from motor vehicles as well as metals and other contaminants emitted from anthropogenic sources, can contaminate $PM_{10-2.5}$ (U.S. EPA, 2004, p. 8–344; 71 FR 2665, January 17, 2006). While the Administrator acknowledges the uncertainty expressed in the Integrated Science Assessment regarding the extent to which particle composition can be linked to health outcomes based on available evidence, she also considers the possibility that $PM_{10-2.5}$ contaminants typical of urban or industrial areas could increase the toxicity of thoracic coarse particles in urban locations.

Given that the large majority of the evidence for $PM_{10-2.5}$ toxicity, particularly at relatively low particle concentrations, comes from study locations where thoracic coarse particles are of urban origin, and given the possibility that $PM_{10-2.5}$ contaminants in urban areas could increase particle toxicity, the Administrator concludes that it remains appropriate to maintain a standard that provides some protection in all areas but targets public health protection to urban locations. Specifically, she concludes that it is appropriate to maintain a standard that allows lower ambient concentrations of $PM_{10-2.5}$ in urban areas, where the evidence is strongest that thoracic coarse particles are linked to mortality and morbidity, and higher concentrations in non-urban areas, where the public health concerns are less certain.

Given all of the above considerations and conclusions, the Administrator judges that the available evidence supports retaining a PM_{10} indicator for a standard that is meant to protect against exposures to thoracic coarse particles. In reaching this judgment, she notes that, to the extent a PM_{10} indicator results in lower allowable concentrations of thoracic coarse particles in some areas compared to others, lower concentrations will be allowed in those locations (i.e., urban or industrial areas) where the science has shown the strongest evidence of adverse health effects associated with exposure to thoracic coarse particles and where we have the most concern regarding $PM_{10-2.5}$ toxicity. Therefore, the Administrator concludes that the varying amounts of coarse particles that are allowed in urban vs. non-urban areas under the 24-hour PM_{10} standard, based on the varying levels of $PM_{2.5}$ present, appropriately reflect the differences in the strength of evidence regarding coarse particle effects in urban and non-urban areas.[133] [134]

In reaching this conclusion, the Administrator also notes that, in their review of the second draft Policy Assessment, CASAC concluded that ''[w]hile it would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles'' (Samet, 2010d, p. ii). Thus, consistent the considerations presented above and with CASAC advice, the Administrator concludes that it is appropriate to retain PM_{10} as the indicator for thoracic coarse particles.[135]

With regard to the third issue, in evaluating the degree of public health protection provided by the current PM_{10} standard, the Administrator first notes that when the available $PM_{10-2.5}$ scientific evidence and its associated uncertainties were considered, the Integrated Science Assessment concluded that the evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. As discussed above and in more detail in the Integrated Science Assessment (U.S. EPA, 2009a, section 1.5), a suggestive determination is made when the ''[e]vidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out.'' In contrast, the Administrator notes that she is strengthening the annual fine particle standard based on a body of scientific evidence judged sufficient to conclude that a causal relationship exists (i.e., mortality, cardiovascular effects) or is likely to exist (i.e., respiratory effects). The suggestive judgment for $PM_{10-2.5}$ reflects the greater degree of uncertainty associated with this body of evidence, as discussed above and in more detail in the proposal, and as summarized below.

The Administrator notes that the important uncertainties and limitations associated with the scientific evidence and air quality information raise questions as to whether public health benefits would be achieved by revising the existing PM_{10} standard. Such uncertainties and limitations include the following:

(1) While $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were generally positive, most were not statistically significant, even in single-pollutant models. This includes effect estimates reported in some study locations with PM_{10} concentrations above those allowed by the current 24-hour PM_{10} standard.

(2) The number of epidemiological studies that have employed co-pollutant models to address the potential for confounding, particularly by $PM_{2.5}$, remains limited. Therefore, the extent to which $PM_{10-2.5}$ itself, rather than one or more co-pollutants, contributes to reported health effects remains uncertain.

(3) Only a limited number of experimental studies provide support for the associations reported in epidemiological studies, resulting in further uncertainty regarding the plausibility of the associations between $PM_{10-2.5}$ and mortality and morbidity reported in epidemiological studies.

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[133] As discussed in the proposal, the Administrator recognizes that this relationship is qualitative. That is, the varying coarse particle concentrations allowed under the PM_{10} standard do not precisely correspond to the variable toxicity of thoracic coarse particles in different areas (insofar as that variability is understood). Although currently available information does not allow any more precise adjustment for relative toxicity, the Administrator believes the standard will generally ensure that the coarse particle levels allowed will be lower in urban areas and higher in non-urban areas. Addressing this qualitative relationship, the DC Circuit held that ''[i]t is true that the EPA relies on a qualitative analysis to describe the protection the coarse PM NAAQS will provide. But the fact that the EPA's analysis is qualitative rather than quantitative does not undermine its validity as an acceptable rationale for the EPA's decision.'' 559 F. 3d at 535.

[134] The D.C. Circuit agreed with similar conclusions in the last review and held that this rationale reasonably supported use of an unqualified PM_{10} indicator for thoracic coarse particles. *American Farm Bureau Federation* v. *EPA,* 559 F. 3d at 535–36.

[135] In addition, CASAC ''vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles'' (Samet, 2010d, p. 7). Consideration of alternative indicators (e.g., $PM_{10-2.5}$) in future reviews could be informed by additional research, as described in the Policy Assessment (U.S. EPA, 2011a, section 3.5).

(4) Limitations in $PM_{10-2.5}$ monitoring data and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiological studies result in uncertainty in the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur, increasing uncertainty in estimates of the extent to which changes in ambient $PM_{10-2.5}$ concentrations would likely impact public health.

(5) The lack of a quantitative $PM_{10-2.5}$ risk assessment further contributes to uncertainty regarding the extent to which any revisions to the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard (see section III.B.5 above).

(6) The chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components, remains uncertain. Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across locations is difficult to characterize.

In considering these uncertainties and limitations, the Administrator notes in particular the considerable degree of uncertainty in the extent to which health effects reported in epidemiological studies are due to $PM_{10-2.5}$ itself, as opposed to one or more co-occurring pollutants. As discussed above, this uncertainty reflects the fact that there are a relatively small number of $PM_{10-2.5}$ studies that have evaluated co-pollutant models, particularly co-pollutant models that have included $PM_{2.5}$, and a very limited body of controlled human exposure evidence supporting the plausibility of a causal relationship between $PM_{10-2.5}$ and mortality and morbidity at ambient concentrations. The Administrator notes that these important limitations in the overall body of health evidence introduce uncertainty into the interpretation of individual epidemiological studies, particularly those studies reporting associations with $PM_{10-2.5}$ that are not statistically significant. Given this, the Administrator reaches the conclusion that it is appropriate to place relatively little weight on epidemiological studies reporting associations with $PM_{10-2.5}$ that are not statistically significant in single-pollutant and/or co-pollutant models.[136]

With regard to this conclusion, the Administrator notes that, for single-city mortality studies conducted in the United States where ambient PM_{10} concentration data were available for comparison to the current standard, positive and statistically significant $PM_{10-2.5}$ effect estimates were only reported in study locations that would likely have violated the current PM_{10} standard during the study period (U.S. EPA, 2011a, Figure 3–2). In U.S. study locations that would likely have met the current standard, $PM_{10-2.5}$ effect estimates for mortality were positive, but not statistically significant (U.S. EPA, 2011a, Figure 3–2). In considering U.S. study locations where single-city morbidity studies were conducted, and which would likely have met the current PM_{10} standard during the study period, the Administrator notes that $PM_{10-2.5}$ effect estimates were both positive and negative, with most not statistically significant (U.S. EPA, 2011a, Figure 3–3).

In addition, in considering single-city analyses for the locations evaluated in a large U.S. multi-city mortality study (Zanobetti and Schwartz, 2009), the Administrator notes that associations in most of the study locations were not statistically significant and that this was the only study to estimate ambient $PM_{10-2.5}$ concentrations as the difference between county-wide PM_{10} and $PM_{2.5}$ mass. As discussed in the proposal, the Administrator notes that it is not clear how computed $PM_{10-2.5}$ measurements, such as those used by Zanobetti and Schwartz (2009), compare with the $PM_{10-2.5}$ concentrations obtained in other studies either by direct measurement by calculating the difference using co-located samplers (U.S. EPA, 2009a, section 6.5.2.3). For these reasons, as in the proposal, the Administrator notes that there is considerable uncertainty in interpreting the associations, and especially the concentrations at which such associations may have occurred, in these single-city analyses.

The Administrator acknowledges that an approach to considering the available scientific evidence and air quality information that emphasizes the above considerations differs from the approach taken by CASAC. Specifically, CASAC placed a substantial amount of weight on individual studies, particularly those reporting positive health effects associations in locations that met the current PM_{10} standard during the study period. In emphasizing these studies, as well as the limited number of supporting studies that have evaluated co-pollutant models and the small number of supporting experimental studies, CASAC concluded that ''the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard'' (Samet, 2010d, p. 7) and recommended revising the current PM_{10} standard (Samet, 2010d).

The Administrator has carefully considered CASAC's advice and recommendations. She notes that in making its recommendation on the current PM_{10} standard, CASAC did not discuss its approach to considering the important uncertainties and limitations in the health evidence, and did not discuss how these uncertainties and limitations are reflected in its recommendation. As discussed above, such uncertainties and limitations contributed to the conclusions in the Integrated Science Assessment that the $PM_{10-2.5}$ evidence is only suggestive of a causal relationship, a conclusion that CASAC endorsed (Samet, 2009e,f). Given the importance of these uncertainties and limitations to the interpretation of the evidence, as reflected in the weight of evidence conclusions in the Integrated Science Assessment and as discussed above, the Administrator judges that it is appropriate to consider and account for them when drawing conclusions about the potential implications of individual $PM_{10-2.5}$ health studies for the current standard.

In light of the above approach to considering the scientific evidence, air quality information, and associated uncertainties, the Administrator reaches the following conclusions:

(1) When viewed as a whole the available evidence and information suggests that the degree of public health protection provided against short-term exposures to $PM_{10-2.5}$ should be maintained but does not need to be increased beyond that provided by the current PM_{10} standard. This conclusion emphasizes the important uncertainties and limitations associated with the overall body

[136] The Administrator acknowledges that this approach to interpreting the evidence differs in emphasis from the approach she has adopted for the evidence relating to $PM_{2.5}$. As discussed above in section III.E.4, for fine particles the Administrator has considered not only whether study results are statistically significant (or remain so after application of co-pollutant models), but she also places emphasis on the overall pattern of results across the epidemiological literature. This includes giving some credence to studies that reported statistically non-significant associations. This difference in emphasis stems from the much stronger overall body of evidence available for fine particles, compared to coarse particles. As discussed above, when the available $PM_{2.5}$ scientific evidence and its associated uncertainties were considered, the Integrated Science Assessment concluded that the evidence was sufficient to conclude that causal relationships exist with mortality and cardiovascular effects, and that a causal relationship is likely to exist with respiratory effects. In contrast, the Integrated Science Assessment concluded that the evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. A suggestive determination is made when the ''[e]vidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out'' (U.S. EPA, 2009a, section 1.5). The suggestive judgment for $PM_{10-2.5}$ reflects the greater degree of uncertainty associated with this body of evidence.

of health evidence and air quality information for $PM_{10-2.5}$, as discussed above and as reflected in the Integrated Science Assessment weight-of-evidence conclusions; that $PM_{10-2.5}$ effect estimates for the most serious health effect, mortality, were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers; and that $PM_{10-2.5}$ effect estimates for morbidity endpoints were both positive and negative in locations that met the current standard, with most not statistically significant.[137]

(2) The degree of public health protection provided by the current standard is not greater than warranted. This conclusion notes that positive and statistically significant associations with mortality were reported in single-city U.S. study locations likely to have violated the current PM_{10} standard.[138]

In reaching these conclusions, the Administrator notes that the Policy Assessment also discussed the potential for a revised PM_{10} standard (i.e., with a revised form and level) to be ''generally equivalent'' to the current standard, but to better target public health protection to locations where there is greater concern regarding $PM_{10-2.5}$-associated health effects (U.S. EPA, 2011a, sections 3.3.3 and 3.3.4).[139] In considering such a potential revised standard, the Policy Assessment discusses the large amount of variability in PM_{10} air quality correlations across monitoring locations and over time (U.S. EPA, 2011a, Figure 3–7) and the regional variability in the relative degree of public health protection that could be provided by the current and potential alternative standards (U.S. EPA, 2011a, Table 3–2). In light of this variability, the Administrator notes the Policy Assessment conclusion that no single revised PM_{10} standard (i.e., with a revised form and level) would provide public health protection equivalent to that provided by the current standard, consistently over time and across locations (U.S. EPA, 2011a, section 3.3.4). That is, a revised standard, even one that is meant to be ''generally equivalent'' to the current PM_{10} standard, could increase protection in some locations while decreasing protection in other locations.

In considering the appropriateness of revising the current PM_{10} standard in this way, the Administrator notes the following:

(1) As discussed above, positive $PM_{10-2.5}$ effect estimates for mortality were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers, while positive and statistically significant associations with mortality were reported in locations likely to have violated the current PM_{10} standard.

(2) Also as discussed above, effect estimates for morbidity endpoints in locations that met the current standard were both positive and negative, with most not statistically significant.

(3) Important uncertainties and limitations associated with the overall body of health evidence and air quality information for $PM_{10-2.5}$, as discussed above and as reflected in the Integrated Science Assessment weight-of-evidence conclusions, call into question the extent to which the type of quantified and refined targeting of public health protection envisioned under a revised standard could be reliably accomplished.

Given all of the above considerations, the Administrator notes that there is a large amount of uncertainty in the extent to which public health would be improved by changing the locations to which the PM_{10} standard targets protection. Therefore, she reaches the conclusion that the current PM_{10} standard should not be revised in order to change that targeting of protection.

In considering all of the above, including the scientific evidence, the air quality information, the associated uncertainties, CASAC's advice, and public comments received on the proposed rule, the Administrator reaches the conclusion in the current review that the existing 24-hour PM_{10} standard, with its one-expected exceedance form and a level of 150 μg/m³, is requisite (i.e., neither more protective nor less protective than necessary) to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. In light of this conclusion, with this rule the Administrator retains the current PM_{10} standard.

V. Communication of Public Health Information

Sections 319(a)(1) and (3) of the CAA require the EPA to establish a uniform air quality index for reporting of air quality. These sections specifically direct the Administrator to ''promulgate regulations establishing an air quality monitoring system throughout the United States which utilizes uniform air quality monitoring criteria and methodology and measures such air quality according to a uniform air quality index'' and ''provides for daily analysis and reporting of air quality based upon such uniform air quality index * * *'' In 1979, the EPA established requirements for index reporting (44 FR 27598, May 10, 1979). The requirement for State and local agencies to report the AQI appears in 40 CFR 58.50, and the specific requirements (e.g., what to report, how to report, reporting frequency, calculations) are in appendix G to 40 CFR part 58.

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily by AQI reporting through EPA's AIRNow Web site.[140] The current AQI has been in use since its inception in 1999.[141] It provides accurate, timely, and easily understandable information about daily levels of pollution (40 CFR 58.50). The AQI establishes a nationally uniform system of indexing pollution levels for ozone, carbon monoxide, nitrogen

[137] This is not to say that the EPA could not adopt or revise a standard for a pollutant for which the evidence is suggestive of a causal relationship. Indeed, with respect to thoracic coarse particles itself, the DC Circuit noted that ''[a]lthough the evidence of danger from coarse PM is, as the EPA recognizes, 'inconclusive', the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health.'' *American Farm Bureau Federation* v *EPA* 559 F. 3d at 533. As explained in the text above, it is the Administrator's judgment that significant uncertainties presented by the evidence and information before her in this review, both as to causality and as to concentrations at which effects may be occurring, best support a decision to retain rather than revise the current primary 24-hour PM_{10} standard.

[138] There are similarities with the conclusions drawn by the Administrator in the last review. There, the Administrator concluded that there was no basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times. 71 FR 61202. In addition, the Administrator concluded that there was a high degree of uncertainty in the relevant population exposures implied by the morbidity studies suggesting that there is little basis for concluding that a greater degree of protection is warranted. *Id.* The D.C. Circuit in *American Farm Bureau Federation* v *EPA* explicitly endorsed this reasoning. 559 F. 3d at 534.

[139] As discussed in detail above (section IV.C.2.d) and in the Policy Assessment (U.S. EPA, 2011a, sections 3.3.3 and 3.3.4), a revised standard that is generally equivalent to the current PM_{10} standard could provide a degree of public health protection that is similar to the degree of protection provided by the current standard, across the United States as a whole. However, compared to the current PM_{10} standard, such a generally equivalent standard would change the degree of public health protection provided in some specific areas, providing increased protection in some locations and decreased protection in other locations.

[140] See *http://www.airnow.gov/.*

[141] In 1976, the EPA established a nationally uniform air quality index, then called the Pollutant Standard Index (PSI), for use by State and local agencies on a voluntary basis (41 FR 37660, September 7, 1976). In August 1999, the EPA adopted revisions to this air quality index (64 FR 42530, August 4, 1999) and renamed the index the AQI.

dioxide, PM, and sulfur dioxide. The AQI is also recognized internationally as a proven tool to effectively communicate air quality information to the public.

The AQI converts pollutant concentrations in a community's air to a number on a scale from 0 to 500. Reported AQI values enable the public to know whether air pollution levels in a particular location are characterized as good (0–50), moderate (51–100), unhealthy for sensitive groups (101–150), unhealthy (151–200), very unhealthy (201–300), or hazardous (301–500). The AQI index value of 100 typically corresponds to the level of the short-term (e.g., daily or hourly standard) NAAQS for each pollutant. Below an index value of 100, an intermediate value of 50 was defined either as the level of the annual standard if an annual standard has been established (e.g., $PM_{2.5}$, nitrogen dioxide), or as a concentration equal to one-half the value of the short-term standard used to define an index value of 100 (e.g., carbon monoxide). An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (i.e., unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous) on a given day. An AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (i.e., moderate or good). The underlying health information that supports the NAAQS review also supports the selection of the AQI ''breakpoints''—the ambient concentrations that delineate the various AQI categories for each pollutant.

Historically, state and local agencies have primarily used the AQI to provide general information to the public about air quality and its relationship to public health. For more than a decade, many states and local agencies, as well as the EPA and other Federal agencies, have been developing new and innovative programs and initiatives to provide more information to the public in a more timely way. These initiatives, including air quality forecasting, real-time data reporting through the AirNow Web site, and state and local air quality action day programs, can serve to provide useful, up-to-date, and timely information to the public about air pollution and its effects. Such information will help individuals take actions to avoid or to reduce exposures to ambient pollution at levels of concern to them. Thus, these programs have significantly broadened the ways in which state and local agencies can meet the nationally uniform AQI reporting requirements and contribute to state and local efforts to provide community health protection.

With respect to an AQI value of 50, the historical approach is to set it at the same level of the annual primary standard, if there is one. This is consistent with the previous AQI sub-index for $PM_{2.5}$, in which the AQI value of 50 was set at 15 μg/m³ in 1999, consistent with the level of the annual $PM_{2.5}$ standard at that time. In recognition of the proposed change to the annual $PM_{2.5}$ standard summarized in section III.F of the proposal, the EPA proposed a conforming change to the $PM_{2.5}$ sub-index of the AQI to be consistent with the proposed change to the annual standard. As discussed below, no state or local agencies, or their organizations (e.g., NACAA), that commented on the proposed changes to the AQI disagreed with our proposed approach. Based on these comments, the EPA continues to see no basis for deviating from this approach in this review. Thus, the EPA is taking final action to set an AQI value of 50 at 12.0 μg/m³, 24-hour average, consistent with the final decision on the annual $PM_{2.5}$ standard level (section III.F).

With respect to an AQI value of 100, which is the basis for advisories to individuals in sensitive groups, in the proposal we described two general approaches that could be used to select the associated $PM_{2.5}$ level. By far the most common approach, which has been used with all of the other sub-indices, is to set an AQI value of 100 at the same level as the short-term standard. In the proposal, the EPA recognized that some state and local air quality agencies have expressed a strong preference that the Agency set an AQI value of 100 equal to any short-term standard (77 FR 38964). These agencies typically express the view that this linkage is useful for the purpose of communicating with the public about the standard, as well as providing consistent messages about the health impacts associated with daily air quality. The EPA proposed to use this approach to set the AQI value of 100 at 35 μg/m³, 24-hour average, consistent with the proposed decision to retain the current 24-hour $PM_{2.5}$ standard. *Id.*

An alternative approach discussed in the proposal (77 FR 38964), was to directly evaluate the health effects evidence to select the level for an AQI value of 100. This was the approach used in the 1999 rulemaking to set the AQI value of 100 at a level of 40 μg/m³, 24-hour average,[142] when the 24-hour standard level was 65 μg/m³. This alternative approach was used in the case of the $PM_{2.5}$ sub-index, because the annual and 24-hour $PM_{2.5}$ standards set in 1997 were designed to work together, and the intended degree of health protection against short-term risks was not defined by the 24-hour standard alone, but rather by the combination of the two standards working in concert. Indeed, at that time, the 24-hour standard was set to provide supplemental protection relative to the principal protection provided by the annual standard. In the proposal, the EPA solicited comment on this alternative approach in recognition that, as proposed, the 24-hour $PM_{2.5}$ standard is intended to continue to provide supplemental protection against effects associated with short-term exposures of $PM_{2.5}$ by working in conjunction with the annual standard to reduce 24-hour exposures to $PM_{2.5}$. The EPA recognized that in the past, some state and local air quality agencies have expressed support for this alternative approach. Using this alternative approach could have resulted in consideration of a lower level for an AQI value of 100, based on the discussion of the health information pertaining to the level of the 24-hour standard in section III.E.4 of the proposal. The EPA encouraged state and local air quality agencies to comment on both the approach and the level at which to set an AQI value of 100 together with any supporting rationale. Of the state or local agencies, or their organizations (e.g., NACAA), that commented on the proposed changes to the AQI, only one organization, NESCAUM, expressed some support for this approach. In its comments, NESCAUM expressed support for a 24-hour standard set at 30 μg/m³, 24-hour average. NESCAUM also expressed the view that EPA should carefully consider how to set the breakpoint for an AQI value of 100. NESCAUM expressed the view that if the EPA were to keep the 24-hour $PM_{2.5}$ standard at 35 μg/m³, the annual standard would be controlling, and a 24-hour breakpoint at that level (35 μg/m³) would not be very effective for the purposes of public health messaging. However, other agencies, such as Georgia Department of Natural Resources (Georgia DNR), expressed the view that linkage between the short-term standard and the AQI of 100 is useful for the purpose of communicating with the public about the standard as well as providing consistent messages about the health

[142] Currently, we are cautioning members of sensitive groups at the AQI value of 100 at 35 μg/m³, 24-hour average, consistent with more recent guidance from the EPA with regard to the development of State emergency episode contingency plans (Harnett, 2009, Attachment B).

impacts associated with the daily air quality. Based on these comments, the EPA sees no basis for deviating from the approach proposed in this review. Thus, the EPA is taking final action to set an AQI value of 100 at 35 µg/m³, 24-hour average, consistent with the final decision on the 24-hour $PM_{2.5}$ standard level (section III.F).

With respect to an AQI value of 150, this level is based upon the same health effects information that informs the selection of the level of the 24-hour standard and the AQI value of 100. The AQI value of 150 was set in the 1999 rulemaking at a level of 65 µg/m³, 24-hour average. In considering what level to propose for an AQI value of 150, we stated the view that the health effects evidence indicates that the level of 55 µg/m³, 24-hour average, is appropriate to use [143] in conjunction with an AQI value of 100 set at the level of 35 µg/m³. The Agency's approach to selecting the levels at which to set the AQI values of 100 and 150 inherently recognizes that the epidemiological evidence upon which these decisions are based provides no evidence of discernible thresholds, below which effects do not occur in either sensitive groups or in the general population, at which to set these two breakpoints. Therefore, the EPA concluded the use of a proportional adjustment would be appropriate. Commenters did not comment on this proposed approach to revising the AQI value of 150; thus, the EPA is taking final action to set an AQI value of 150 at 55 µg/m³, 24-hour average.

Based on the air quality and health considerations discussed in section V of the proposal, the EPA concluded that it was appropriate to propose to retain the current level of 500 µg/m³, 24-hour average, for the AQI value of 500. In addition, the EPA solicited comment on alternative levels and approaches to setting a level for the AQI value of 500, as well as supporting information and rationales for such alternative levels. The EPA also solicited any additional information, data, research or analyses that may be useful to inform a final decision on the appropriate level to set the AQI value of 500. Receiving no information with which to inform alternative approaches to setting an AQI value of 500, the EPA is taking final action to retain the current level of 500 µg/m³, 24-hour average, for the AQI value of 500.

For the intermediate breakpoints in the AQI between the values of 150 and 500, the EPA proposed $PM_{2.5}$ concentrations that generally reflected a linear relationship between increasing index values and increasing $PM_{2.5}$ values (77 FR 38965). The available scientific evidence of health effects related to population exposures to $PM_{2.5}$ concentrations between the level of the 24-hour standard and an AQI value of 500 suggested a continuum of effects in this range, with increasing $PM_{2.5}$ concentrations being associated with increasingly larger numbers of people likely to experience such effects. The generally linear relationship between AQI values and $PM_{2.5}$ concentrations in this range is consistent with the health evidence. This also is consistent with the Agency's practice of setting breakpoints in symmetrical fashion where health effects information does not suggest particular levels.

Table 2 below summarizes the finalized breakpoints for the $PM_{2.5}$ sub-index.[144] Table 2 shows the intermediate breakpoints for AQI values of 200, 300 and 400 based on a linear interpolation between the proposed levels for AQI values of 150 and 500. If a different level were to be set for an AQI value of 150 or 500, intermediate levels would be calculated based on a linear relationship between the selected levels for AQI values of 150 and 500.

TABLE 2—BREAKPOINTS FOR $PM_{2.5}$ SUB-INDEX

AQI category	Index values	Proposed breakpoints (µg/m³, 24-hour average)
Good	0–50	0.0–(12.0)
Moderate	51–100	(12.1)–35.4
Unhealthy for Sensitive Groups	101–150	35.5–55.4
Unhealthy	151–200	55.5–150.4
Very Unhealthy	201–300	150.5–250.4
Hazardous	301–400	250.5–350.4
	401–500	350.5–500.4

In retaining the 500 level for the AQI as described above, we note that the EPA is not establishing a Significant Harm Level (SHL) for $PM_{2.5}$. The SHL is an important part of air pollution Emergency Episode Plans, which are required for certain areas by CAA section 110(a)(2)(G) and associated regulations at 40 CFR 51.150, under the Prevention of Air Pollution Emergency Episodes program. The Agency believes that air quality responses established through an Emergency Episode Plan should be developed through a collaborative process working with State and Tribal air quality, forestry and agricultural agencies, Federal land management agencies, private land managers and the public. Therefore, if in future rulemaking the EPA proposes revisions to the Prevention of Air Pollution Emergency Episodes program, the proposal will include a SHL for $PM_{2.5}$ that is developed in collaboration with these organizations. As discussed in the 1999 Air Quality Index Reporting Rule (64 FR 42530), if a future rulemaking results in a SHL that is different from the 500 value of the AQI for $PM_{2.5}$, the AQI will be revised accordingly.

The EPA also received more general comments on AQI reporting, comments that did not pertain to setting specific breakpoints. One set of commenters (e.g., API and UARG), expressed the view that changes to the AQI are not appropriate. They noted that air quality is getting better, and in fact is better than when EPA established the AQI. These commenters stated that the proposed changes to the annual standard and the AQI would mean that the public would hear less often that air quality is good, and thereby would receive apparently inconsistent or misleading messages that air quality is

[143] We note that this level is consistent with the level recommended in the more recent EPA guidance (Harnett, 2009, Attachment B), which is in use by many State and local agencies.

[144] As discussed in section VII.C below, the EPA is also updating the data handling procedures for reporting the AQI and corresponding updates for other AQI-sub-indices presented in Table 2 of appendix G of 40 CFR part 58.

worse. The AQI has been revised several times in conjunction with revisions to the standards. State and local air quality agencies and organizations are proficient at communicating with the public about the reasons for changes to the AQI. Therefore, the EPA strongly disagrees with these commenters that the public will receive inconsistent or misleading messages. Recognizing the importance of the AQI as a communication tool that allows the public to take exposure reduction measures when air quality may pose health risks, the EPA agrees with state and local air quality agencies and organizations that favored revising the AQI at the same time as the primary standard.

A few state and local air quality agencies and organizations recommended against using near-roadway $PM_{2.5}$ monitors for AQI reporting. In support of this comment, they expressed the following views, that near-roadway monitors are source-oriented, represent micro-scale conditions, and the agencies don't have experience using them for AQI reporting. The EPA disagrees with the comment in that these monitors will be sited at existing near-road stations sited to be representative of area-wide $PM_{2.5}$ concentrations indicative of general population exposure. Accordingly, data from these near-road monitors should be included in the AQI since they provide information about $PM_{2.5}$ levels that millions of people, who work, live and go to school near busy roadways, are exposed to. The stations are representative of somewhat elevated concentrations in near-road environments, but since these stations represent many such locations throughout a metropolitan area, they are appropriate for characterizing exposure in typical portions of major urban areas. The EPA is committed to helping air quality agencies develop appropriate ways to report $PM_{2.5}$ levels from these monitors using the AQI.

VI. Rationale for Final Decisions on the Secondary PM Standards

This section presents the Administrator's final decisions regarding the need to revise the current suite of secondary $PM_{2.5}$ and PM_{10} standards to address visibility impairment and other welfare effects considered in this review. Specifically, this section describes the Administrator's final decision to retain the current suite of secondary PM standards to address PM-related visibility impairment as well as other PM-related welfare effects, including ecological effects, effects on materials, and climate impacts. This suite of standards includes an annual $PM_{2.5}$ standard of 15 μg/m^3, a 24-hour $PM_{2.5}$ standard of 35 μg/m^3, and a 24-hour PM_{10} standard of 150 μg/m^3. The Administrator is revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. Contrary to what was proposed, the Administrator has decided not to establish a distinct standard to address PM-related visibility impairment. The rationale for this decision is presented below.

The Administrator's final decisions on the secondary standards are based on a thorough review of the latest scientific information published through mid-2009 on welfare effects associated with fine and coarse particles in the ambient air, as presented in the Integrated Science Assessment. The final decisions also take into account: (1) Staff assessments of the most policy-relevant information presented and assessed in the Integrated Science Assessment and staff analyses of air quality and visibility effects presented in the Visibility Assessment and the Policy Assessment, upon which staff conclusions regarding appropriate considerations in this review are based; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the Integrated Science Assessment, Visibility Assessment, and Policy Assessment at public meetings, in separate written comments, and in CASAC's letters to the Administrator; (3) the multiple rounds of public comments received during the development of these documents, both in connection with CASAC meetings and separately; and (4) public comments received on the proposal.

In particular, this section presents background information on the EPA's previous and current reviews of the secondary PM standards (section VI.A), a summary of the proposed decisions regarding the secondary PM standards (section VI.B), a discussion of significant public comments received on those proposed decisions (section VI.C), and the Administrator's final decisions on the secondary PM standards (section VI.D).

A. Background

The current suite of secondary PM standards is identical to the suite of primary PM standards set in 2006, including 24-hour and annual $PM_{2.5}$ standards and a 24-hour PM_{10} standard. The current secondary $PM_{2.5}$ standards are intended to provide protection from PM-related visibility impairment, whereas the entire suite of secondary PM standards is intended to provide protection from other PM-related effects on public welfare, including effects on sensitive ecosystems, materials damage and soiling, and climatic and radiative processes.

The approach used for reviewing the current suite of secondary PM standards built upon and broadened the approaches used in previous PM NAAQS reviews. The following discussion focuses particularly on the current secondary $PM_{2.5}$ standards related to visibility impairment and provides a summary of the approaches used to review and establish secondary $PM_{2.5}$ standards in the last two reviews (section VI.A.1); judicial review of the 2006 standards that resulted in the remand of the secondary annual and 24-hour $PM_{2.5}$ NAAQS to the EPA (section VI.A.2); and the approach used in this review for evaluating the secondary $PM_{2.5}$ standards (section VI.A.3).

1. Approaches Used in Previous Reviews

The original secondary $PM_{2.5}$ standards were established in 1997, and a revision to the 24-hour standard was made in 2006. The approaches used in making final decisions on secondary standards in those reviews, as well as the current review, utilized different ways to consider the underlying body of scientific evidence. They also reflected an evolution in EPA's understanding of the nature of the effect on public welfare from PM-related visibility impairment, from an approach that focused only on Federal Class I area visibility impacts to a more multifaceted approach that also considered PM-related impacts on visibility in non-Federal Class I areas, such as in urban areas. This evolution occurred in conjunction with the expansion of available PM data and information from visibility-related studies of public perception, valuation, and personal comfort and well-being.

In 1997, the EPA revised the PM NAAQS in part by establishing new identical primary and secondary $PM_{2.5}$ standards. In revising the secondary standards, the EPA recognized that PM produces adverse effects on visibility and that impairment of visibility was being experienced throughout the U.S., in multi-state regions, urban areas, and remote mandatory Federal Class I areas alike. However, in considering an appropriate level for a secondary standard to address adverse effects of $PM_{2.5}$ on visibility, the EPA concluded that the determination of a single national level was complicated by important regional differences influenced by factors such as background and current levels of $PM_{2.5}$, composition of $PM_{2.5}$, and average relative humidity. Variations in these factors across regions could thus result in situations where attaining an appropriately protective concentration of fine particles in one region might or might not provide adequate protection in a different region. The EPA also determined that there was insufficient information at that time to establish a level for a national secondary standard that would represent a threshold above which visibility conditions would always be adverse and below which visibility conditions would always be acceptable.

Based on an assessment of the potential visibility improvements that would result from reaching attainment with the new primary standards for $PM_{2.5}$, the EPA concluded that attainment of the annual and 24-hour $PM_{2.5}$ primary standards would lead to visibility improvements in the eastern U.S. at both urban and regional scales, but little or no change in the western U.S., except in and near certain urban areas.

The EPA also considered the potential effectiveness of a regional haze program, required by sections 169A and 169B of the CAA [145] to address those effects of PM on visibility that would not be addressed through attainment of the primary $PM_{2.5}$ standards. The regional haze program would be designed to address the widespread, regionally uniform type of haze caused by a multitude of sources. The structure and requirements of sections 169A and 169B of the CAA provide for visibility protection programs that can be more responsive to the factors contributing to regional differences in visibility than can programs addressing the kinds of nationally applicable secondary NAAQS considered in the 1997 review. The regional haze visibility goal is more protective than a secondary NAAQS since the goal is to eliminate any anthropogenic impairment rather than to provide a level of protection from visibility impairment that is requisite to protect the public welfare. Thus, an important factor considered in the 1997 review was whether a regional haze program, in conjunction with secondary standards set identical to the suite of $PM_{2.5}$ primary standards, would provide appropriate protection for visibility in non-Federal Class I areas. The EPA concluded that the two programs and associated control strategies should provide such protection due to the regional approaches needed to manage emissions of pollutants that impair visibility in many of these areas.

For these reasons, in 1997 the EPA concluded that a national regional haze program, combined with a nationally applicable level of protection achieved through secondary $PM_{2.5}$ standards set identical to the primary $PM_{2.5}$ standards, would be more effective for addressing regional variations in the adverse effects of $PM_{2.5}$ on visibility than would be national secondary standards for PM with levels lower than the primary $PM_{2.5}$ standards. The EPA further recognized that people living in certain urban areas may place a high value on unique scenic resources in or near these areas and as a result might experience visibility problems attributable to sources that would not necessarily be addressed by the combined effects of a regional haze program and $PM_{2.5}$ secondary standards. The EPA concluded that in such cases, state or local regulatory approaches, such as past action in Colorado to establish a local visibility standard for the City of Denver, would be more appropriate and effective in addressing these special situations because of the localized and unique characteristics of the problems involved. Visibility in an urban area located near a mandatory Federal Class I area could also be improved through state implementation of the then-current visibility regulations, by which emission limitations can be imposed on a source or group of sources found to be contributing to ''reasonably attributable'' impairment in the mandatory Federal Class I area.

Based on these considerations, in 1997 the EPA set secondary $PM_{2.5}$ standards identical to the primary $PM_{2.5}$ standards, that would work in conjunction with the Regional Haze Program to be established under sections 169A and 169B of the CAA, as the most appropriate and effective means of addressing the public welfare effects associated with visibility impairment. Together, the two programs and associated control strategies were expected to provide appropriate protection against PM-related visibility impairment and enable all regions of the country to make reasonable progress toward the national visibility goal.

In 2006, the EPA revised the suite of secondary $PM_{2.5}$ standards to address visibility impairment by making the suite of secondary standards identical to the revised suite of primary $PM_{2.5}$ standards. The EPA's decision regarding the need to revise the suite of secondary $PM_{2.5}$ standards reflected a number of new developments that had occurred and sources of information that had become available following the 1997 review. First, the EPA promulgated a Regional Haze Program in 1999 (65 FR 35713, July 1, 1999) which required states to establish goals for improving visibility in Federal Class I areas and to adopt control strategies to achieve these goals. Second, extensive new information from visibility and fine particle monitoring networks had become available, allowing for updated characterizations of visibility trends and PM concentrations in urban areas, as well as Federal Class I areas. These new data allowed the EPA to better characterize visibility impairment in urban areas and the relationship between visibility and $PM_{2.5}$ concentrations. Finally, additional studies in the U.S. and abroad provided the basis for the establishment of standards and programs to address specific visibility concerns in a number of local areas. These studies (Denver, Phoenix, and British Columbia) utilized photographic representations of visibility impairment and produced reasonably consistent results in terms of the visual ranges found to be generally acceptable by study participants. The EPA considered the information generated by these studies useful in characterizing the nature of particle-induced haze and for informing judgments about the acceptability of various levels of visual air quality in urban areas across the U.S. Based largely on this information, the Administrator concluded that it was appropriate to revise the secondary $PM_{2.5}$ standards to provide increased protection from visibility impairment principally in urban areas, in conjunction with the regional haze program for protection of visual air quality in Federal Class I areas.

In so doing, the Administrator recognized that PM-related visibility impairment is principally related to fine particle concentrations and that perception of visibility impairment is most directly related to short-term, nearly instantaneous levels of visual air quality. Thus, in considering whether the then-current suite of secondary standards would provide the appropriate degree of protection, he concluded that it was appropriate to focus on just the 24-hour secondary $PM_{2.5}$ standard to provide requisite protection.

The Administrator then considered whether $PM_{2.5}$ mass remained the appropriate indicator for a secondary

[145] In 1977, Congress established as a national goal ''the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Federal Class I areas which impairment results from manmade air pollution,'' section 169A(a)(1) of the CAA. The EPA is required by section 169A(a)(4) of the CAA to promulgate regulations to ensure that ''reasonable progress'' is achieved toward meeting the national goal.

standard to protect visibility, primarily in urban areas. The Administrator noted that PM-related visibility impairment is principally related to fine particle levels. Hygroscopic components of fine particles, in particular sulfates and nitrates, contribute disproportionately to visibility impairment under high humidity conditions. Particles in the coarse mode generally contribute only marginally to visibility impairment in urban areas. With the substantial addition to the air quality and visibility data made possible by the national urban $PM_{2.5}$ monitoring networks, an analysis conducted for the 2006 review found that, in urban areas, visibility levels showed far less difference between eastern and western regions on a 24-hour or shorter time basis than implied by the largely non-urban data available in the 1997 review. In analyzing how well $PM_{2.5}$ concentrations correlated with visibility in urban locations across the U.S., the 2005 Staff Paper concluded that clear correlations existed between 24-hour average $PM_{2.5}$ concentrations and calculated (i.e., reconstructed) light extinction, which is directly related to visual range (U.S. EPA, 2005, p. 7–6). These correlations were similar in the eastern and western regions of the U.S. These correlations were less influenced by relative humidity and more consistent across regions when $PM_{2.5}$ concentrations were averaged over shorter, daylight time periods (e.g., 4 to 8 hours) when relative humidity in eastern urban areas was generally lower and thus more similar to relative humidity in western urban areas. The 2005 Staff Paper noted that a standard set at any specific $PM_{2.5}$ concentration would necessarily result in visual ranges that vary somewhat in urban areas across the country, reflecting the variability in the correlations between $PM_{2.5}$ concentrations and light extinction. The 2005 Staff Paper concluded that it was appropriate to use $PM_{2.5}$ as an indicator for standards to address visibility impairment in urban areas, especially when the indicator is defined for a relatively short period (e.g., 4 to 8 hours) of daylight hours (U.S. EPA, 2005, p. 7–6). Based on their review of the Staff Paper, most CASAC Panel members also endorsed such a $PM_{2.5}$ indicator for a secondary standard to address visibility impairment (Henderson, 2005a, p. 9). Based on the above considerations, the Administrator concluded that $PM_{2.5}$ should be retained as the indicator for fine particles as part of a secondary standard to address visibility protection, in conjunction with averaging times from 4 to 24 hours.

In considering what level of protection against PM-related visibility impairment would be appropriate, the Administrator took into account the results of the public perception and attitude surveys regarding the acceptability of various degrees of visibility impairment in the U.S. and Canada, state and local visibility standards within the U.S., and visual inspection of photographic representations of several urban areas across the U.S. In the Administrator's judgment, these sources provided useful but still quite limited information on the range of levels appropriate for consideration in setting a national visibility standard primarily for urban areas, given the generally subjective nature of the public welfare effect involved. Based on photographic representations of varying levels of visual air quality, public perception studies, and local and state visibility standards, the 2005 Staff Paper had concluded that 30 to 20 μg/m³ $PM_{2.5}$ represented a reasonable range for a national visibility standard primarily for urban areas, based on a sub-daily averaging time (U.S. EPA, 2005, p. 7–13). The upper end of this range was below the levels at which illustrative scenic views are significantly obscured, and the lower end was around the level at which visual air quality generally appeared to be good based on observation of the illustrative views. This concentration range generally corresponded to median visual ranges in urban areas within regions across the U.S. of approximately 25 to 35 km, a range that was bounded above by the visual range targets selected in specific areas where state or local agencies placed particular emphasis on protecting visual air quality. In considering a reasonable range of forms for a $PM_{2.5}$ standard within this range of levels, the 2005 Staff Paper had concluded that a concentration-based percentile form was appropriate, and that the upper end of the range of concentration percentiles for consideration should be consistent with the 98th percentile used for the primary standard and that the lower end of the range should be the 92nd percentile, which represented the mean of the distribution of the 20 percent most impaired days, as targeted in the regional haze program (U.S. EPA, 2005 pp. 7–11 to 7–13). While recognizing that it was difficult to select any specific level and form based on then-currently available information (Henderson, 2005a, p. 9), the CASAC Panel was generally in agreement with the ranges of levels and forms presented in the 2005 Staff Paper.

The Administrator also considered the level of protection that would be afforded by the proposed suite of primary $PM_{2.5}$ standards (71 FR 2681, January 17, 2006), on the basis that although significantly more information was available than in the 1997 review concerning the relationship between fine PM levels and visibility across the country, there was still little available information for use in making the relatively subjective value judgment needed in selecting the appropriate degree of protection to be afforded by such a standard. In so doing, the Administrator compared the extent to which the proposed suite of primary standards would require areas across the country to improve visual air quality with the extent of increased protection likely to be afforded by a standard based on a sub-daily averaging time. Based on such an analysis, the Administrator observed that the predicted percent of counties with monitors not likely to meet the proposed suite of primary $PM_{2.5}$ standards was actually somewhat greater than the predicted percent of counties with monitors not likely to meet a sub-daily secondary standard with an averaging time of 4 daylight hours, a level toward the upper end of the range recommended in the 2005 Staff Paper, and a form within the recommended range. Based on this comparison, the Administrator tentatively concluded that revising the secondary 24-hour $PM_{2.5}$ standard to be identical to the proposed revised primary $PM_{2.5}$ standard (and retaining the then-current annual secondary $PM_{2.5}$ standard) was a reasonable policy approach to addressing visibility protection primarily in urban areas. In proposing this approach, the Administrator also solicited comment on a sub-daily (4- to 8-hour averaging time) secondary $PM_{2.5}$ standard (71 FR 2675 to 2781, January 17, 2006).

In commenting on the proposed decision, the CASAC requested that a sub-daily standard to protect visibility ''be favorably reconsidered'' (Henderson, 2006a, p.6). The CASAC noted three cautions regarding the proposed reliance on a secondary $PM_{2.5}$ standard identical to the proposed 24-hour primary $PM_{2.5}$ standard: (1) $PM_{2.5}$ mass measurement is a better indicator of visibility impairment during daylight hours, when relative humidity is generally low; the sub-daily standard more clearly matches the nature of visibility impairment, whose adverse effects are most evident during the daylight hours; using a 24-hour $PM_{2.5}$ standard as a proxy introduces error and uncertainty in protecting visibility; and sub-daily standards are used for other NAAQS and should be the focus for visibility; (2) CASAC and its monitoring subcommittees had repeatedly commended EPA's initiatives promoting the introduction of continuous and near-continuous PM monitoring and recognized that an expanded deployment of continuous $PM_{2.5}$ monitors would be consistent with setting a sub-daily standard to protect visibility; and (3) the analysis showing a similarity between percentages of counties not likely to meet what the CASAC Panel considered to be a lenient 4- to 8-hour secondary standard and a secondary standard identical to the proposed 24-hour primary standard was a numerical coincidence that was not indicative of any fundamental relationship between visibility and health. The CASAC Panel further stated that ''visual air quality is substantially impaired at $PM_{2.5}$ concentrations of 35 $\mu g/m^3$'' and that ''[i]t is not reasonable to have the visibility standard tied to the health standard, which may change in ways that make it even less appropriate for visibility concerns'' (Henderson, 2006a, pp. 5 to 6).

In reaching a final decision, the Administrator focused on the relative protection provided by the proposed primary standards based on the above-mentioned similarities in percentages of counties meeting alternative standards and on the limitations in the information available concerning studies of public perception and attitudes regarding the acceptability of various degrees of visibility impairment in urban areas, as well as on the subjective nature of the judgment required. In so doing, the Administrator concluded that caution was warranted in establishing a distinct secondary standard for visibility impairment and that the available information did not warrant adopting a secondary standard that would provide either more or less protection against visibility impairment in urban areas than would be provided by secondary standards set equal to the proposed primary $PM_{2.5}$ standards.

2. Remand of 2006 Secondary $PM_{2.5}$ Standards

As noted above in section II.B.2 above, several parties filed petitions for review challenging EPA's decision to set the secondary NAAQS for fine PM identical to the primary NAAQS. On judicial review, the D.C. Circuit remanded to the EPA for reconsideration the secondary NAAQS for fine PM because the Agency's decision was unreasonable and contrary to the requirements of section 109(b)(2). *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512 (D.C. Cir., 2009).

The petitioners argued that the EPA's decision lacked a reasoned basis. First, they asserted that the EPA never determined what level of visibility was ''requisite to protect the public welfare.'' They argued that the EPA unreasonably rejected the target level of protection recommended by its staff, while failing to provide a target level of its own. The court agreed, stating that ''the EPA's failure to identify such a level when deciding where to set the level of air quality required by the revised secondary fine PM NAAQS is contrary to the statute and therefore unlawful. Furthermore, the failure to set any target level of visibility protection deprived the EPA's decision-making of a reasoned basis.'' 559 F. 3d at 530.

Second, the petitioners challenged EPA's method of comparing the protection expected from potential standards. They contended that the EPA relied on a meaningless numerical comparison, ignored the effect of humidity on the usefulness of a standard using a daily averaging time, and unreasonably concluded that the primary standards would achieve a level of visibility roughly equivalent to the level the EPA staff and CASAC deemed ''requisite to protect the public welfare.'' The court found that the EPA's equivalency analysis based on the percentages of counties exceeding alternative standards ''failed on its own terms.'' The same table showing the percentages of counties exceeding alternative secondary standards, used for comparison to the percentages of counties exceeding alternative primary standards to show equivalency, also included six other alternative secondary standards within the recommended CASAC range that would be more ''protective'' under EPA's definition than the adopted primary standards. Two-thirds of the potential secondary standards within the CASAC's recommended range would be substantially more protective than the adopted primary standards. The court found that the EPA failed to explain why it looked only at one of the few potential secondary standards that would be less protective, and only slightly less so, than the primary standards. More fundamentally, however, the court found that the EPA's equivalency analysis based on percentages of counties demonstrated nothing about the relative protection offered by the different standards, and that the tables offered no valid information about the relative visibility protection provided by the standards. 559 F. 3d at 530–31.

Finally, the Staff Paper had made clear that a visibility standard using $PM_{2.5}$ mass as the indicator in conjunction with a daily averaging time would be confounded by regional differences in humidity. The court noted that the EPA acknowledged this problem, yet did not address this issue in concluding that the primary standards would be sufficiently protective of visibility. 559 F. 3d at 530. Therefore, the court granted the petition for review and remanded for reconsideration the secondary $PM_{2.5}$ NAAQS.

3. General Approach Used in the Policy Assessment for the Current Review

The approach used in this review broadened the general approaches used in the last two PM NAAQS reviews by utilizing, to the extent available, enhanced tools, methods, and data to more comprehensively characterize visibility impacts. As such, the EPA took into account considerations based on both the scientific evidence (''evidence-based'') and a quantitative analysis of PM-related impacts on visibility (''impact-based'') to inform conclusions related to the adequacy of the current secondary $PM_{2.5}$ standards and alternative standards that were appropriate for consideration in this review. As in past reviews, the EPA also considered that the secondary NAAQS should address PM-related visibility impairment in conjunction with the Regional Haze Program, such that the secondary NAAQS would focus on protection from visibility impairment principally in urban areas in conjunction with the Regional Haze Program that is focused on improving visibility in Federal Class I areas. The EPA again recognized that such an approach remains the most appropriate and effective means of addressing the public welfare effects associated with visibility impairment in areas across the country.

The Policy Assessment drew from the qualitative evaluation of all studies discussed in the Integrated Science Assessment (U.S. EPA, 2009a). Specifically, the Policy Assessment considered the extensive new air quality and source apportionment information available from the regional planning organizations, long-standing evidence of PM effects on visibility, and limited public preference study information from four urban areas (U.S. EPA, 2009a, chapter 9), as well as the integration of evidence across disciplines (U.S. EPA, 2009a, chapter 2). In addition, limited information that had become available regarding the characterization of public preferences in urban areas provided some new perspectives on the usefulness of this information in informing the selection of target levels of urban visibility protection. On these bases, the Policy Assessment again focused assessments on visibility conditions in urban areas.

The conclusions in the Policy Assessment reflected EPA staff's understanding of both evidence-based and impact-based considerations to inform two overarching questions related to (1) the adequacy of the current suite of $PM_{2.5}$ standards and (2) what potential alternative standards, if any, should be considered in this review to provide appropriate protection from PM-related visibility impairment. In addressing these broad questions, the discussions in the Policy Assessment were organized around a series of more specific questions reflecting different aspects of each overarching question (U.S. EPA, 2011a, Figure 4–1). When evaluating the visibility protection afforded by the current or any alternative standards considered, the Policy Assessment took into account the four basic elements of the NAAQS: indicator, averaging time, level, and form.

B. Proposed Decisions on Secondary PM Standards

At the time of proposal, the Administrator proposed to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment, focused primarily on visibility in urban areas. This proposed standard was to be defined in terms of a $PM_{2.5}$ visibility index, which would use measured $PM_{2.5}$ mass concentration, in combination with speciation and relative humidity data, to calculate $PM_{2.5}$ light extinction, translated into the deciview (dv) scale; a 24-hour averaging time; a 90th percentile form, averaged over 3 years; and a level of 28–30 dv. To address other non-visibility welfare effects, the Administrator proposed to retain the current suite of secondary PM standards generally, while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this proposed change to the primary annual $PM_{2.5}$ standard. Each of these proposed decisions is described in more detail in the proposal and below.

1. PM-Related Visibility Impairment

As discussed in Section VI.B of the proposal, the Administrator's proposed decision regarding a distinct secondary standard to provide protection from visibility impairment reflected careful consideration of the following: (1) The latest scientific information on visibility effects associated with PM as described in the Integrated Science Assessment (U.S. EPA, 2009a); (2) insights gained from assessments of correlations between ambient $PM_{2.5}$ and visibility impairment prepared by EPA staff in the Visibility Assessment (U.S. EPA, 2010b); and (3) specific conclusions regarding the need for revisions to the current standards (i.e., indicator, averaging time, form, and level) that, taken together, would be requisite to protect the public welfare from adverse effects on visual air quality. This section summarizes key information from the proposal regarding the nature of visibility impairment, including the relationship between ambient PM and visibility, temporal variations in light extinction, periods during the day of interest for assessing visibility conditions, and exposure durations of interest (section VI.B.1.a); limited public perceptions and attitudes about visibility impairment and the impacts of visibility impairment on public welfare (section VI.B.1.b); CASAC advice regarding the need for, and design of, secondary standards to protect visibility (section VI.B.1.c); and the Administrator's proposed conclusions regarding setting a distinct standard to address visibility impairment (section VI.B.1.d).

a. Nature of PM-Related Visibility Impairment

As noted at the time of proposal, the fundamental science characterizing the contribution of PM, especially fine particles, to visibility impairment is well understood. This science provides the basis for the Integrated Science Assessment designation of the relationship between PM and visibility impairment as causal. New research available in this review, discussed in chapter 9 of the Integrated Science Assessment, continues to support and refine EPA's understanding of the effect of PM on visibility and the source contributions to that effect in rural and remote locations. This research provides new insights regarding the regional source contributions to urban visibility impairment and better characterization of the increment in PM concentrations and visibility impairment that occur in many cities (i.e., the urban excess) relative to conditions in the surrounding rural areas (i.e., regional background). Ongoing urban $PM_{2.5}$ speciated and aggregated mass monitoring has produced new information that has allowed for updated characterization of current visibility levels in urban areas.

i. Relationship Between Ambient PM and Visibility

Visibility impairment is caused by the scattering and absorption of light by suspended particles and gases in the atmosphere. When PM is present in the air, its contribution to light extinction typically greatly exceeds that of gases. The combined effect of light scattering and absorption by both particles and gases is characterized as light extinction, i.e., the fraction of light that is scattered or absorbed in the atmosphere. Light extinction can be quantified by a light extinction coefficient with units of 1/distance, which is often expressed as 1/(1 million meters) or inverse megameters (abbreviated Mm^{-1}) or in terms of an alternative scale known as the deciview scale, defined by the following equation: [146]

$$\text{Deciview (dv)} = 10 \ln (b_{ext} / 10\ Mm^{-1})$$

The deciview scale is frequently used in the scientific literature on visibility, as well as in the Regional Haze Program. In particular, the deciview scale is used in the public perception studies that were considered in the past and current reviews to inform judgments about an appropriate degree of protection to be provided by a secondary NAAQS.

The amount of light extinction contributed by PM depends on the particle concentration as well as on the particle size distribution and composition and also on the relative humidity. As described in detail in section VI.B.1.a of the proposal, visibility scientists have developed an algorithm, known as the IMPROVE algorithm,[147] to estimate light extinction using routinely monitored fine particle ($PM_{2.5}$) speciation and coarse particle mass ($PM_{10-2.5}$) data, as well as data on relative humidity. There is both an original and a revised version of the IMPROVE algorithm (Pitchford *et al.,* 2007). The revised version was developed to address observed biases in the predictions using the original algorithm under very low and very high

[146] As used in the Regional Haze Program, the term b_{ext} refers to light extinction due to $PM_{2.5}$, $PM_{10-2.5}$, and ''clean'' atmospheric gases. In the Policy Assessment, in focusing on light extinction due to $PM_{2.5}$, the deciview values include only the effects of $PM_{2.5}$ and the gases. The ''Rayleigh'' term associated with clean atmospheric gases is represented by the constant value of 10 Mm^{-1}. Omission of the Rayleigh term would create the possibility of negative deciview values when the $PM_{2.5}$ concentration is very low.

[147] The algorithm is referred to as the IMPROVE algorithm because it was developed specifically to use the aerosol monitoring data generated at network sites and with equipment specifically designed to support the IMPROVE program and was evaluated using IMPROVE optical measurements at the subset of sites that make those measurements (Malm *et al.,* 1994).

light extinction conditions.[148] These IMPROVE algorithms are routinely used to calculate light extinction levels on a 24-hour basis in Federal Class I areas under the Regional Haze Program.

In either version of the IMPROVE algorithm, the concentration of each of the major aerosol components is multiplied by a dry extinction efficiency value and, for the hygroscopic components (i.e., ammoniated sulfate and ammonium nitrate), also multiplied by an additional factor to account for the water growth to estimate these components' contribution to light extinction. Summing the contribution of each component gives the estimate of total light extinction per unit distance denoted as the light extinction coefficient (b_{ext}), as shown below for the original IMPROVE algorithm.

$b_{ext} \approx 3 \times f(RH) \times$ [Sulfate]
+ 3 × *f*(RH) x [Nitrate]
+ 4 × [Organic Mass]
+ 10 × [Elemental Carbon]
+ 1 × [Fine Soil]
+ 0.6 × [Coarse Mass]
+ 10

Light extinction (b_{ext}) is in units of Mm^{-1}, the mass concentrations of the components indicated in brackets are in units of $\mu g/m^3$, and *f*(RH) is the unitless water growth term that depends on relative humidity. The final term of 10 Mm^{-1} is known as the Rayleigh scattering term and accounts for light scattering by the natural gases in unpolluted air. Despite the simplicity of this algorithm, it performs reasonably well and permits the contributions to light extinction from each of the major components (including the water associated with the sulfate and nitrate compounds) to be separately approximated. Inspection of the PM component-specific terms in the simple original IMPROVE algorithm shows that most of the $PM_{2.5}$ components contribute 5 times or more light extinction than a similar concentration of $PM_{10-2.5}$.

The *f*(RH) term in the original algorithm reflects the increase in light scattering caused by particulate sulfate and nitrate under conditions of high relative humidity. Particles with hygroscopic components (e.g., particulate sulfate and nitrate) contribute more light extinction at higher relative humidity than at lower relative humidity because they change size in the atmosphere in response to ambient relative humidity conditions. For relative humidity below 40 percent the *f*(RH) value is 1, but it increases to 2 at approximately 66 percent, 3 at approximately 83 percent, 4 at approximately 90 percent, 5 at approximately 93 percent, and 6 at approximately 95 percent relative humidity. The result is that both particulate sulfate and nitrate are more efficient per unit mass in light extinction than any other aerosol component for relative humidity above approximately 85 percent where their total light extinction efficiency exceeds the 10 m^2/g associated with elemental carbon (EC). PM containing elemental or black carbon (BC) absorbs light as well as scattering it, making it the component with the greatest light extinction contributions per unit of mass concentration, except for the hygroscopic components under these high relative humidity conditions.[149]

As noted above, subsequent to the development of the original IMPROVE algorithm, an alternative algorithm (variously referred to as the ''revised algorithm'' or the ''new algorithm'' in the literature) was developed. The revised IMPROVE algorithm is different from the original algorithm in several important ways. First, the revised algorithm employs a more complex split-component mass extinction efficiency to correct biases believed to be related to particle size distributions.[150] Specifically, the revised algorithm incorporates terms to account for particles representing the different dry extinction and water uptake from two size modes of sulfate, nitrate and organic mass.[151] Second, the revised algorithm uses a different multiplier for organic carbon for purposes of estimating organic carbonaceous material to better represent aged aerosol found in remote areas.[152] In addition, the revised algorithm includes a term for hygroscopic sea salt that can be important for remote coastal areas, and site-specific Rayleigh light scattering terms in place of a universal Rayleigh light scattering value. As noted in section VI.B.1.a of the proposal, the revised IMPROVE algorithm can yield higher estimates of current light extinction levels in urban areas on days with relatively poor visibility as compared to the original algorithm (Pitchford, 2010). This difference is primarily attributable to the split-component mass extinction efficiency treatment in the revised algorithm. This revised algorithm was evaluated at 21 *remote* locations and is generally used by RPOs and States for implementation of the Regional Haze Rule.

ii. Temporal Variations of Light Extinction

Particulate matter concentrations and light extinction in urban environments vary from hour to hour throughout the 24-hour day due to a combination of diurnal changes in meteorological conditions and systematic changes in emissions activity (e.g., rush hour traffic). Various factors combine to make early morning the most likely time for peak urban light extinction; although the net effects of the systematic urban- and larger-scale variations mean that peak daytime PM light extinction levels can occur any time of day, in many areas they occur most often in early morning hours (U.S. EPA, 2010b, sections 3.4.2 and 3.4.3; Figures 3–9, 3–10, and 3–12). This temporal pattern in urban areas contrasts with the general lack of a strong diurnal pattern in PM concentrations and light extinction in most Federal Class I areas, reflective of a relative lack of local sources as compared to urban areas. The use in the Regional Haze Program of 24-hour average concentrations in the IMPROVE algorithm is consistent with this general lack of a strong diurnal pattern in Federal Class I areas.

iii. Periods During the Day of Interest for Assessment of Visibility

As noted in sections VI.B.1.b and VI.B.1.c of the proposal, daytime visibility has dominated the attention of

[148] These biases were detected by comparing light extinction estimates generated from the IMPROVE algorithm to direct optical measurements in a number of rural Federal Class I areas.

[149] The IMPROVE algorithm does not explicitly separate the light-scattering and light-absorbing effects of elemental carbon.

[150] In either version of the IMPROVE algorithm, the concentration of each of the major aerosol components is multiplied by a dry extinction efficiency value and, for the hygroscopic components (i.e., ammoniated sulfate and ammonium nitrate), also multiplied by an additional factor to account for the water growth to estimate these components' contribution to light extinction. Both the dry extinction efficiency and water growth terms have been developed by a combination of empirical assessment and theoretical calculation using typical particle size distributions associated with each of the major aerosol components.

[151] The relative contributions of sulfate, nitrate, and organic mass concentrations to visibility impairment with the revised algorithm are different than with the original algorithm due to the combination of the dry extinction coefficient and f(RH) functions for derived concentrations of small and large particles. The apportionment of the total fine particle concentration of each of the three $PM_{2.5}$ components into the concentrations of the small and large size fractions was empirically developed for remote areas. The fraction of the fine particle component that is in the large mode is estimated by dividing the total concentration of the component by 20 $\mu g/m^3$. If the total concentration of a component exceeds 20 $\mu g/m^3$, all of it is assumed to be in the large mode.

[152] The revised IMPROVE algorithm uses a multiplier of 1.8 for rural areas instead of 1.4 as used in the original algorithm for the mean ratio of organic mass to organic carbon.

those who have studied the visibility effects of air pollution, particularly in urban areas. The EPA recognizes, however, that physically PM light extinction behaves the same at night as during the day and can contribute to nighttime visibility effects by enhancing the scattering of anthropogenic light, contributing to the ''skyglow'' within and over populated areas, adding to the total sky brightness, and contributing to the reduction in contrast of stars against the background. However, little research has been conducted on nighttime visibility, and the state of the science is not comparable to that associated with daytime visibility impairment, particularly in terms of the impact on human welfare. The Policy Assessment notes that the science is not available at this time to support adequate characterization specifically of nighttime PM light extinction conditions and the related effects on public welfare (U.S. EPA, 2011a, p. 4–18). Therefore the EPA has focused its assessments of PM visibility impacts in urban areas on daylight hours during this review.

iv. Exposure Durations of Interest

As noted in section VI.B.1.d of the proposal, the roles that exposure duration and variations in visual air quality within any given exposure period play in determining the acceptability or unacceptability of a given level of visual air quality have not been investigated via preference studies. In the preference studies available for this review, subjects were simply asked to rate the acceptability or unacceptability of each image of a haze-obscured scene, without being provided any suggestion of assumed duration or of assumed conditions before or after the occurrence of the scene presented. Preference and/or valuation studies show that atmospheric visibility conditions can be quickly assessed and preferences determined. The EPA is unaware of any studies that characterize the extent to which different frequencies and durations of exposure to visibility conditions contribute to the degree of public welfare impact that occurs.

The Policy Assessment considered a variety of circumstances that are commonly expected to occur in evaluating the potential impact of visibility impairment on the public welfare based on available information (U.S. EPA, 2011a, pp. 4–19 to 4–20). In some circumstances, such as infrequent visits to scenic vistas in natural or urban environments, people are motivated specifically to take the opportunity to view a valued scene and are likely to do so for many minutes to hours to appreciate various aspects of the vista they choose to view. However, the public has many more opportunities to notice visibility conditions on a daily basis in settings associated with performing daily routines (e.g., during commutes and while working, exercising, or recreating outdoors). As noted in the Policy Assessment, information regarding the fraction of the public that has only one or a few opportunities to experience visibility during the day, or on the role the duration of the observed visibility conditions has on wellbeing effects associated with those visibility conditions, is not available (U.S. EPA, 2011a, p. 4–20). However, it is possible that people with limited opportunities to experience visibility conditions on a daily basis would receive the entire impact of the day's visual air quality based on the visibility conditions that occur during the short time period when they can see it. Since this group could be affected on the basis of observing visual air quality conditions for periods as short as one hour or less, and because during each daylight hour there are some people outdoors, commuting, or near windows, the Policy Assessment judged that it would be appropriate to use the maximum hourly value of PM light extinction during daylight hours for each day for purposes of evaluating the adequacy of the current suite of secondary standards. Other observers may have access to visibility conditions throughout the day. For this group, it might be that an hour with poor or ''unacceptable'' visibility can be offset by one or more other hours with clearer conditions. Therefore, the proposal acknowledged that it might also be appropriate to consider a multi-hour daylight exposure period.

v. Periods of Fog and Rain

As discussed in section VI.C of the proposal, the EPA also recognized that it is appropriate to give special treatment to periods of fog and rain when considering whether current $PM_{2.5}$ standards adequately protect public welfare from PM-related visibility impairment. Visibility impairment occurs during periods with fog or precipitation irrespective of the presence or absence of PM. Therefore, it is logical that periods with naturally impaired visibility due to fog or precipitation should not be treated as having PM-impaired visibility. There are multiple ways to adjust visibility data to reduce the effects of fog and precipitation. In the Visibility Assessment, following the advice of CASAC, the EPA evaluated the effect of excluding daylight hours for which relative humidity was greater than 90 percent from analyses in order to avoid precipitation and fog confounding estimates of PM visibility impairment. For the 15 urban areas included in the Visibility Assessment, the EPA found that a 90 percent relative humidity cutoff criterion was effective in that on average less than 6 percent of the daylight hours were removed from consideration, yet those hours had on average ten times the likelihood of rain, six times the likelihood of snow/sleet, and 34 times the likelihood of fog compared with hours with 90 percent or lower relative humidity. In the Regional Haze program, the EPA utilizes monthly average relative humidity values based on 10 years of climatological data to reduce the effect of fog and precipitation. This approach focuses on longer-term averages for each monitoring site and thereby eliminates the effect of very high humidity conditions on visibility at those locations.

b. Public Perception of Visibility Impairment

As described in section VI.B.2 of the proposal, there are two main types of studies that evaluate the public perception of urban visibility impairment: urban visibility preference studies and urban visibility valuation studies. As noted in the Integrated Science Assessment, ''[b]oth types of studies are designed to evaluate individuals' desire (or demand) for good visual air quality (VAQ) where they live, using different metrics to evaluate demand. Urban visibility preference studies examine individuals' demand by investigating what amount of visibility degradation is unacceptable while economic studies examine demand by investigating how much one would be willing to pay to improve visibility'' (U.S. EPA, 2009a, p. 9–66). Because of the limited number of new studies on urban visibility valuation, the Integrated Science Assessment cites to the discussion in the 2004 Criteria Document of the various methods one can use to determine the economic valuation of changes in visibility, which include hedonic valuation, contingent valuation and contingent choice, and travel cost.

Contingent valuation studies are a type of stated preference study that measures the strength of preferences and expresses that preference in dollar values. Contingent valuation studies often include payment vehicles that require respondents to consider implementation costs and their ability to pay for visibility improvements in their responses. This study design aspect is critical because the EPA cannot consider implementations costs in setting either primary or secondary NAAQS. Therefore in considering the information available to help inform the standard-setting process, the EPA has focused on the public perception studies that do not embed consideration of implementation costs. Nonetheless, the EPA recognizes that valuation studies do provide additional evidence that the public is experiencing losses in welfare due to visibility impairment.[153] The public perception studies are described in detail below.

In order to identify levels of visibility impairment appropriate for consideration in setting secondary PM NAAQS to protect the public welfare, the Visibility Assessment comprehensively examined information that was available in this review regarding people's stated preferences regarding acceptable and unacceptable visual air quality.

Light extinction is an atmospheric property that by itself does not directly translate into a public welfare effect. Instead, light extinction becomes meaningful in the context of the impact of differences in visibility on the human observer. This has been studied in terms of the acceptability or unacceptability expressed for the visibility impact of a given level of light extinction by a human observer. The perception of the visibility impact of a given level of light extinction occurs in conjunction with the associated characteristics and lighting conditions of the viewed scene.[154] Thus, a given level of light extinction may be perceived differently by observers looking at different scenes or the same scene with different lighting characteristics. Likewise, different observers looking at the same scene with the same lighting may have different preferences regarding the associated visual air quality. When scene and lighting characteristics are held constant, the perceived appearance of a scene (i.e., how well the scenic features can be seen and the amount of visible haze) depends only on changes in light extinction. This has been demonstrated using the WinHaze model (Molenar *et al.,* 1994) that uses image processing technology to apply user-specified changes in light extinction values to the same base photograph with set scene and lighting characteristics.

Much of what is known about the acceptability of levels of visibility comes from survey studies in which participants were asked questions about their preference or the value they place on various visibility levels as displayed to them in scenic photographs and/or WinHaze images with a range of known light extinction levels. The Visibility Assessment (U.S. EPA, 2010b, chapter 2) reviewed the limited number of urban visibility preference studies currently available (i.e., four studies) to assess the light extinction levels judged by the participant to have acceptable visibility for those particular scenes.

The reanalysis of urban preference studies conducted in the Visibility Assessment for this review included three completed western urban visibility preference survey studies plus a pair of smaller focus studies designed to explore and further develop urban visibility survey instruments. The three western studies included one in Denver, Colorado (Ely *et al.,* 1991), one in the lower Fraser River valley near Vancouver, British Columbia (BC), Canada (Pryor, 1996), and one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group study was also conducted for Washington, DC (Abt Associates Inc., 2001). In response to an EPA request for public comment on the Scope and Methods Plan (74 FR 11580, March 18, 2009), comments were received (Smith, 2009) about the results of a new focus group study of scenes from Washington, DC, that had been conducted on subjects from both Houston, Texas, and Washington, DC, using scenes, methods and approaches similar to the method and approach employed in the EPA pilot study (Smith and Howell, 2009). When taken together, these studies from the four different urban areas included a total of 852 individuals, with each individual responding to a series of questions while viewing a set of images of various urban visual air quality conditions.

The approaches used in the four studies were similar and were all derived from the method first developed for the Denver urban visibility study. In particular, the studies all used a similar group interview type of survey to investigate the level of visibility impairment that participants described as ''acceptable.'' In each preference study, participants were initially given a set of ''warm up'' exercises to familiarize them with how the scene in the photograph or image appears under different VAQ conditions. The participants next were shown 25 randomly ordered photographs (images), and asked to rate each one based on a scale of 1 (poor) to 7 (excellent). They were then shown the same photographs or images again, in the same order, and asked to judge whether each of the photographs (images) would violate what they would consider to be an appropriate urban visibility standard (i.e. whether the level of impairment was ''acceptable'' or ''unacceptable''). The term ''acceptable'' was not defined, so that each person's response was based on his/her own values and preferences for VAQ. However, when answering this question, participants were instructed to consider the following three factors: (1) The standard would be for their own urban area, not a pristine national park area where the standards might be stricter; (2) The level of an urban visibility standard violation should be set at a VAQ level considered to be unreasonable, objectionable, and unacceptable visually; and (3) Judgments of standards violations should be based on visibility only, not on health effects. While the results differed among the four urban areas, results from a rating exercise show that within each preference study, individual survey participants consistently distinguish between photos or images representing different levels of light extinction, and that more participants rate as acceptable images representing lower levels of light extinction than they do images representing higher levels.

Given the similarities in the approaches used, the EPA staff concluded that it was reasonable to compare the results to identify overall trends in the study findings and to conclude that this comparison can usefully inform the selection of a range of levels for use in further analyses. However, the staff also noted that variations in the specific materials and methods used in each study introduce uncertainties that should also be considered when interpreting the results

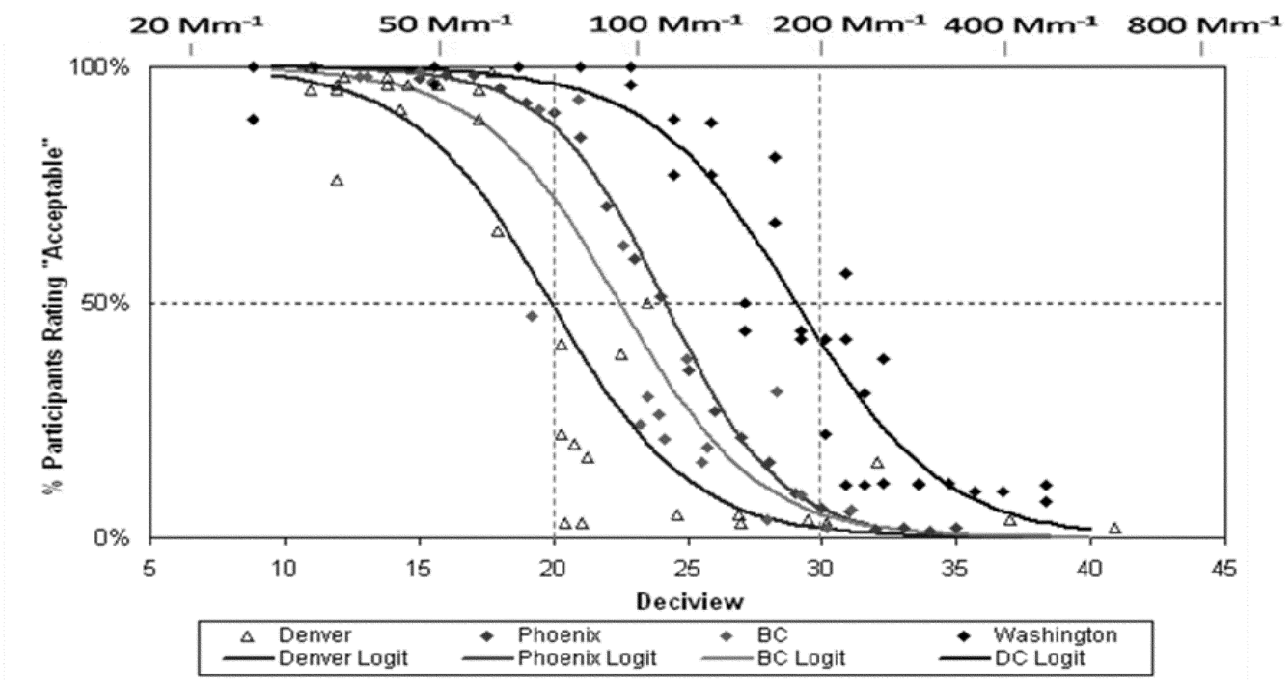
[153] In the regulatory impact analysis (RIA) accompanying this rulemaking, the EPA describes a revised approach to estimate urban residential visibility benefits that applies the results of several contingent valuation studies. The EPA is unable to apply the public perception studies to estimate benefits because they do not provide sufficient information on which to develop monetized benefits estimates. Specifically, the public perception studies do not provide preferences expressed in dollar values, even though they do provide additional evidence that the benefits associated with improving residential visibility are not zero. As previously noted in this preamble, the RIA is done for informational purposes only, and the proposed decisions on the NAAQS in this rulemaking are not in any way based on consideration of the information or analyses in the RIA.

[154] By ''characteristics of the scene'' the EPA means the distance(s) between the viewer and the object(s) of interest, the shapes and colors of the objects, the contrast between objects and the sky or other background, and the inherent interest of the objects to the viewer. Distance is particularly important because at a given value of light extinction, which is a property of air at a given point(s) in space, more light is actually absorbed and scattered when light passes through more air between the object and the viewer.

of these comparisons. Key differences between the studies include the following: (1) Scene characteristics; (2) image presentation methods (e.g., projected slides of actual photos, projected images generated using WinHaze (a significant technical advance in the method of presenting visual air quality conditions), or use of a computer monitor screen; (3) number of participants in each study; (4) participant representativeness of the general population of the relevant metropolitan area; and (5) specific wording used to frame the questions used in the group interview process.

In the Visibility Assessment, each study was evaluated separately and figures developed to display the percentage of participants that rated the visual air quality depicted in each photograph as ''acceptable.'' Ely *et al.* (1991) introduced a ''50% acceptability'' criterion analysis of the Denver preference study results. The 50 percent acceptability criterion is designed to identify the visual air quality level (defined in terms of deciviews or light extinction) that best divides the photographs into two groups: Those with a visual air quality rated as acceptable by the majority of the participants, and those rated not acceptable by the majority of participants. The Visibility Assessment adopted this criterion as a useful index for comparison between studies. The results of each analysis were then combined graphically to allow for visual comparison. This information was then carried forward into the Policy Assessment. Figure 5 presents the graphical summary of the results of the studies in the four cities and draws on results previously presented in Figures 2–3, 2–5, 2–7, and 2–11 of chapter 2 in the Visibility Assessment. Figure 5 also contains lines at 20 dv and 30 dv that generally identify a range where the 50 percent acceptance criteria occur across all four of the urban preference studies (U.S. EPA, 2011a, p. 4–24). Out of the 114 data points shown in Figure 5, only one photograph (or image) with a visual air quality below 20 dv was rated as acceptable by less than 50 percent of the participants who rated that photograph.[155] Similarly, only one image with a visual air quality above 30 dv was rated acceptable by more than 50 percent of the participants who viewed it.[156]

Figure 5. Summary of Results of Urban Visibility Studies in Four Cities, Showing the Identified Range of the 50% Acceptance Criteria[157]



Source: U.S. EPA, 2011a, Figure 4-2; U.S. EPA 2010b, Figure 2-16

As Figure 5 above shows, each urban area has a separate and unique response curve that appears to indicate that it is distinct from the others.[158] These curves are the result of a logistical regression analysis using a logit model of the greater than 19,000 ratings of haze images as acceptable or unacceptable. The model results can be used to estimate the visual air quality in terms of dv values where the estimated response functions cross the 50 percent acceptability level, as well as any alternative criteria levels. Selected examples of these are shown in Table 4–

[155] Only 47 percent of the British Columbia participants rated a 19.2 dv photograph as acceptable.

[156] In the 2001 Washington, DC study, a 30.9 dv image was used as a repeated slide. The first time it was shown 56 percent of the participants rated it as acceptable, but only 11 percent rated it as acceptable the second time it was shown. The same visual air quality level was rated as acceptable by 4 percent of the participants in the 2009 study (Test 1). All three points are shown in Figure 5.

[157] Top scale shows light extinction in inverse megameter units; bottom scale in deciviews. Logit analysis estimated response functions are shown as the color-coded curved lines for each of the four urban areas.

[158] At present, data is only available for four urban areas, as presented in Figure 5 and discussed throughout this section. Additional research could help inform whether the range identified by combining the results of the studies depicted in Figure 5 is more broadly representative.

1 of the Policy Assessment (U.S. EPA, 2011a; U.S. EPA, 2010b, Table 2–4). This table shows that the logit model results also support the upper and lower ends of the range of 50th percentile acceptability values (e.g., near 20 dv for Denver and near 30 dv for Washington, DC) already identified in Figure 5.

Based on the composite results and the effective range of 50th percentile acceptability across the four urban preference studies shown in Figure 5 and Table 4–1 of the Policy Assessment, benchmark levels of (total) light extinction were selected in a range from 20 dv to 30 dv (75 to 200 Mm^{-1}) [159] for the purpose of provisionally assessing whether visibility conditions would be considered acceptable (i.e., less than the low end of the range), unacceptable (i.e., greater than the high end of the range), or potentially acceptable (within the range) based on the very limited public preference information. A midpoint of 25 dv (120 Mm^{-1}) was also selected for use in the assessment. This level is also very near to the 50th percentile criterion value from the Phoenix study (i.e., 24.2 dv), which is by far the best of the four studies in terms of the fit of the data to the response curve and the representativeness of study participants. Based on the currently available information, the Policy Assessment concluded that the use of 25 dv to represent the middle of the distribution of results seemed well supported (U.S. EPA, 2011a, p. 4–25).

These three benchmark values provide a low, middle, and high set of light extinction conditions that are used to provisionally define daylight hours with urban haze conditions that have been judged unacceptable by at least 50 percent of the participants in one or more of these preference studies. As discussed above, PM light extinction is taken to be (total) light extinction minus the Rayleigh scatter,[160] such that the low, middle, and high levels correspond to PM light extinction levels of about 65 Mm^{-1}, 110 Mm^{-1}, and 190 Mm^{-1}. In the Visibility Assessment, these three light extinction levels were called Candidate Protection Levels (CPLs). This term was also used in the Policy Assessment and in the proposal notice. It is important to note, however, that the degree of protection provided by a secondary NAAQS is not determined solely by any one component of the standard but by all the components (i.e., indicator, averaging time, form, and level) being applied together. Therefore, the Policy Assessment noted that the term CPL is meant only to indicate target levels of visibility within a range that the EPA staff felt appropriate for consideration that could, in conjunction with other elements of the standard, including indicator, averaging time, and form, potentially provide an appropriate degree of visibility protection.

In characterizing the Policy Assessment's confidence in each CPL and across the range, a number of issues were considered (U.S. EPA, 2011a, p. 4–26). Looking first at the two studies that define the upper and lower bounds of the range, the Policy Assessment considered whether they represent a true regional distinction in preferences for urban visibility conditions between western and eastern U.S. There was little information available to help evaluate the possibility of a regional distinction especially given that there have been preference studies in only one eastern urban area. Smith and Howell (2009) found little difference in preference response to Washington, DC, haze photographs between the study participants from Washington, DC, and those from Houston, Texas.[161] This provides some limited evidence that the value judgment of the public in different areas of the country may not be an important factor in explaining the differences in these study results.

In further considering what factors could explain the observed differences in preferences across the four urban areas, the Policy Assessment noted that the urban scenes used in each study had different characteristics (U.S. EPA, 2011a, p. 4–26). For example, each of the western urban visibility preference study scenes included mountains in the background while the single eastern urban study did not. It is also true that each of the western scenes included objects at greater distances from the camera location than in the eastern study. There is no question that objects at a greater distance have a greater sensitivity to perceived visibility changes as light extinction is changed compared to otherwise similar scenes with objects at a shorter range. This alone might explain the difference between the results of the eastern study and those from the western urban studies. Having scenes with the object of greatest intrinsic value nearer and hence less sensitive in the eastern urban area compared with more distant objects of greatest intrinsic value in the western urban areas could further explain the difference in preference results.

Another question considered was whether the high CPL value that is based on the eastern preference results is likely to be generally representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. Such areas would include the middle of the country, many areas in the eastern U.S., and possibly some areas in the western U.S. as well.[162] Based on the currently available information, the Policy Assessment concluded that the high end of the CPL range (30 dv) is an appropriate level to consider (U.S. EPA, 2011a, p. 4–27).

With respect to the low end of the range, the Policy Assessment considered factors that might further refine its understanding of the robustness of this level. The Policy Assessment concluded that additional urban preference studies, especially with a greater variety in types of scenes, could help evaluate whether the lower CPL value of 20 dv is generally supportable (U.S. EPA, 2011a, p. 4–27). Further, the reason for the noisiness in data points around the curves apparent in both the Denver and British Columbia results compared to the smoother curve fit of Phoenix study results could be explored. One possible explanation discussed in the Policy Assessment is that these older studies use photographs taken at different times of day and on different days to capture the range of light extinction levels needed for the preference studies. In contrast, the use of WinHaze in the Phoenix (and Washington, DC) study reduced variations that affect scene appearance preference rating and avoided the uncertainty inherent in using ambient measurements to

[159] These values were rounded from 74 Mm^{-1} and 201 Mm^{-1} to avoid an implication of greater precision than is warranted. Note that the middle value of 25 dv when converted to light extinction is 122 Mm^{-1} is rounded to 120 Mm^{-1} for the same reason. Assessments conducted for the Visibility Assessment and the first and second drafts of the Policy Assessment used the unrounded values. The Policy Assessment considered the results of assessment using unrounded values to be sufficiently representative of what would result if the rounded values were used that it was unnecessary to redo the assessments. That is why some tables and figures in the Policy Assessment reflected the unrounded values.

[160] Rayleigh scatter is light scattering by atmospheric gases which is on average about 10 Mm^{-1}.

[161] The first preference study using WinHaze images of a scenic vista from Washington, DC was conducted in 2001 using subjects who were residents of Washington, DC. More recently, Smith and Howell (2009) interviewed additional subjects using the same images and interview procedure. The additional subjects included some residents of the Washington, DC area and some residents of the Houston, Texas area.

[162] In order to examine this issue, an effort would have to be made to see if scenes in such areas could be found that would be generally comparable to the western scenes (e.g., scenes that contain valued scenic elements at more sensitive distances than that used in the eastern study). This is only one of a family of issues concerning how exposure to urban scenes of varying sensitivity affects public perception for which no preference study information is currently available.

represent sight path-averaged light extinction values. Reducing these sources of noisiness and uncertainty in the results of future studies of sensitive urban scenes could provide more confidence in the selection of a low CPL value.

Based on the above considerations, and recognizing the limitations in the currently available information, the Policy Assessment concluded that it is reasonable to consider a range of CPL values including a high value of 30 dv, a mid-range value of 25 dv, and a low value of 20 dv (U.S. EPA, 2011a, p. 4–27). Based on its review of the second draft Policy Assessment, CASAC also supported this set of CPLs for consideration by the EPA in this review. CASAC noted that these CPL values were based on all available visibility preference data and that they bound the study results as represented by the 50 percent acceptability criteria. While recommending that further visibility preference studies be conducted to reduce remaining uncertainties,[163] CASAC concluded that this range of levels was ''adequately supported by the evidence presented'' (Samet, 2010d, p. iii).

c. Summary of Proposed Conclusions

i. Adequacy of the Current Standards for PM-Related Visibility Impairment

At the time of proposal, the Administrator provisionally concluded that the current suite of secondary PM standards is not sufficiently protective of visual air quality, and that consideration should be given to an alternative secondary standard that would provide additional protection against PM-related visibility impairment, with a focus primarily in urban areas. This proposed conclusion was based on the information presented in the proposal with regard to the nature of PM-related visibility impairment, the results of public perception surveys on the acceptability of varying degrees of visibility impairment in urban areas, analyses of the number of days that are estimated to exceed a range of candidate protection levels under conditions simulated to just meet the current standards, and the advice of CASAC. This section summarizes key points from section VI.C of the proposal regarding visibility under current conditions, the degree of protection afforded by the current standards, and CASAC's advice regarding the adequacy of the current standards.

As discussed in section VI.C.1 of the proposal, to evaluate visibility under current conditions the Visibility Assessment and Policy Assessment estimated PM-related light extinction[164] levels for 15 urban areas[165] in the United States. Consistent with the emphasis in this review on the hourly or multi-hour time periods that might reasonably characterize the visibility effects experienced by various segments of the population, these analyses focused on using maximum 1-hour and 4-hour values of PM light extinction during daylight hours for purposes of evaluating the degree of visibility impairment. Hourly average PM-related light extinction was analyzed in terms of both PM_{10} and $PM_{2.5}$ light extinction. For reasons discussed above, hours with relative humidity greater than 90 percent were excluded from consideration. Recent visibility conditions in these urban areas were then compared to the CPLs identified above. The Visibility Assessment, which focused on PM_{10} light extinction in 14 of the 15 urban areas during the 2005 to 2007 time period,[166] found that all 14 areas had daily maximum hourly PM_{10} light extinction values estimated to exceed even the highest CPL some of the days. Except for the two Texas areas and the non-California western urban areas, all of the other urban areas were estimated to have maximum hourly PM_{10} concentrations that exceeded the high CPL on about 20 percent to over 60 percent of the days. All 14 of the urban areas were estimated to have maximum hourly PM_{10} concentrations that exceeded the low CPL on about 40 percent to over 90 percent of the days. In general, areas in the East and in California tend to have a higher frequency of hourly visibility conditions estimated to be above the high CPL compared with those in the western U.S.

The Policy Assessment repeated the Visibility Assessment-type modeling based on $PM_{2.5}$ light extinction and data from the more recent 2007 to 2009 time period for the same 15 study areas (including St. Louis). While the estimates of the percentage of daily maximum hourly $PM_{2.5}$ light extinction values exceeding the CPLs were somewhat lower than for PM_{10} light extinction, the patterns of these estimates across the study areas was found to be similar. More specifically, except for the two Texas and the non-California western urban areas, all of the other urban areas were estimated to have maximum hourly $PM_{2.5}$ concentrations that exceeded the high CPL on about 10 percent up to about 50 percent of the days based on $PM_{2.5}$ light extinction, while all 15 areas were estimated to have maximum hourly $PM_{2.5}$ concentrations that exceeded the low CPL on over 10 percent to over 90 percent of the days.

To evaluate how PM-related visibility would be affected by just meeting the current suite of $PM_{2.5}$ secondary standards, the Policy Assessment applied the proportional rollback approach described in section VI.C.2 of the proposal to all the $PM_{2.5}$ monitoring sites in each study area.[167] After adjusting for composition, the Policy Assessment applied the original IMPROVE algorithm to calculate the PM_{10} light extinction, using ''rolled back'' $PM_{2.5}$ component concentrations, the current conditions $PM_{10-2.5}$ concentration for the day and hour, and relative humidity for the day and hour.

In these analyses, the Policy Assessment estimated both $PM_{2.5}$ and PM_{10} light extinction in terms of both daily maximum 1-hour average values and multi-hour (i.e., 4-hour) average values for daylight hours. Figure 4–7 and Table 4–6 of the Policy Assessment displayed the results of the rollback procedures as a box and whisker plot of daily maximum daylight 1-hour $PM_{2.5}$ light extinction and the percentage of daily maximum hourly $PM_{2.5}$ light extinction values estimated to exceed the CPLs when just meeting the current

[163] ''CASAC has also identified needs for the next review cycle in terms of further research on a number of topics related to urban visibility; * * *. In particular, there is a need for the Agency to conduct additional urban visibility preference studies over a broad range of urban areas and viewing conditions, to further evaluate and refine the range of visibility levels considered to be acceptable in the current assessment.'' (Samet, 2010a)

[164] PM-related light extinction is used here to refer to the light extinction caused by PM regardless of particle size; PM_{10} light extinction refers to the contribution by particles sampled through an inlet with a particle size 50 percent cutpoint of 10 µm diameter; and $PM_{2.5}$ light extinction refers to the contribution by particles sampled through an inlet with a particle size 50 percent cutpoint of 2.5 µm diameter.

[165] The 15 urban areas are Tacoma, Fresno, Los Angeles, Phoenix, Salt Lake City, Dallas, Houston, St. Louis, Birmingham, Atlanta, Detroit, Pittsburgh, Baltimore, Philadelphia, and New York.

[166] Comments on the second draft Visibility Assessment from those familiar with the monitoring sites in St. Louis indicated that the site selected to provide continuous PM_{10} monitoring, although less than a mile from the site of the $PM_{2.5}$ data, was not representative of the urban area and resulted in unrealistically large $PM_{10-2.5}$ values. The EPA staff considered these comments credible and set aside the St. Louis assessment results for PM_{10} light extinction. Thus, results and statements in the Policy Assessment regarding PM_{10} light extinction applied to only the other 14 areas. However, results regarding $PM_{2.5}$ light extinction in most cases applied to all 15 study areas because the St. Louis estimates for $PM_{2.5}$ light extinction were not affected by the PM_{10} monitoring issue.

[167] Phoenix and Salt Lake City met the current $PM_{2.5}$ NAAQS under current conditions and required no reduction.

suite of $PM_{2.5}$ secondary standards for all 15 areas considered in the Visibility Assessment (including St. Louis) (excluding hours with relative humidity greater than 90 percent). These displays showed that the daily maximum 1-hour average $PM_{2.5}$ light extinction values in all of the study areas other than the three western non-California areas were estimated to exceed the high CPL on about 8 percent up to over 30 percent of the days and to exceed the middle CPL on about 30 percent up to about 70 percent of the days, while all areas except Phoenix were estimated to have daily maximum 1-hour average $PM_{2.5}$ light extinction values that exceeded the low CPL on over 15 percent to about 90 percent of the days. Figure 4–8 and Table 4–7 of the Policy Assessment present results based on daily maximum 4-hour average values. These displays show that the daily maximum 4-hour average $PM_{2.5}$ light extinction values in all of the study areas other than the three western non-California areas and the two areas in Texas were estimated to exceed the high CPL on about 4 percent up to over 15 percent of the days and to exceed the middle CPL on about 15 percent up to about 45 percent of the days, while all areas except Phoenix were estimated to have daily maximum 4-hour average $PM_{2.5}$ light extinction values that exceeded the low CPL on over 10 percent to about 75 percent of the days. A similar set of figures and tables were developed in terms of PM_{10} light extinction (U.S. EPA, 2011a, Figures 4–5 and 4–6, Tables 4–4 and 4–5).

Taking the results of these analyses focusing on 1-hour and 4-hour maximum light extinction values into account, the Policy Assessment concluded that the available information in this review clearly called into question the adequacy of the current suite of $PM_{2.5}$ standards in the context of public welfare protection from visibility impairment, primarily in urban areas, and supported consideration of alternative standards to provide appropriate protection (U.S. EPA, 2011a, p. 4–39). This conclusion was based in part on the large percentage of days, in many urban areas, that were estimated to have maximum 1-hour or 4-hour light extinction values that exceed the range of CPLs identified for consideration under simulations of conditions that would just meet the current suite of $PM_{2.5}$ secondary standards. In particular, for air quality that was simulated to just meet the current $PM_{2.5}$ standards, greater than 10 percent of the days were estimated to have peak light extinction values that exceed the highest, least protective CPL of 30 dv in terms of $PM_{2.5}$ light extinction for 9 of the 15 urban areas, based on 1-hour average values, and would thus likely fail to meet a 90th percentile-based standard at that level. For these areas, the percent of days estimated to have maximum 1-hour values that exceed the highest CPL ranged from over 10 percent to over 30 percent. Similarly, when the middle CPL of 25 dv was considered, greater than 30 percent up to approximately 70 percent of the days were estimated to have peak light extinction that exceeded that CPL in terms of $PM_{2.5}$ light extinction, for 11 of the 15 urban areas, based on 1-hour average values. Based on a 4-hour averaging time, 5 of the areas were estimated to have at least 10 percent of the days with peak light extinction exceeding the highest CPL in terms of $PM_{2.5}$ light extinction, and 8 of the areas were estimated to have at least 30 percent of the days with peak light extinction exceeding the middle CPL in terms of $PM_{2.5}$ light extinction. For the lowest CPL of 20 dv, the percentages of days with 4-hour maximum light extinction estimated to exceed that CPL are even higher for all cases considered. Based on all of the above, the Policy Assessment concluded that PM light extinction estimated to be associated with just meeting the current suite of $PM_{2.5}$ secondary standards in many areas across the country exceeded levels and percentages of days that could reasonably be considered to be important from a public welfare perspective (U.S. EPA, 2011a, p. 4–40).

Further, the Policy Assessment concluded that use of the current indicator of $PM_{2.5}$ mass, in conjunction with the current 24-hour and annual averaging times, is clearly called into question for a national standard intended to protect public welfare from PM-related visibility impairment (U.S. EPA, 2011a, p. 4–40). This is because such a standard is inherently variable in the degree of protection provided because of regional differences in relative humidity and species composition of $PM_{2.5}$, which are critical factors in the relationship between the mix of fine particles in the ambient air and the associated impairment of visibility. The Policy Assessment noted that this concern was one of the important elements in the court's decision to remand the $PM_{2.5}$ secondary standards set in 2006 to the Agency.

Thus, in addition to concluding that the available information clearly calls into question the adequacy of the protection against PM-related visibility impairment afforded by the current suite of $PM_{2.5}$ standards, the Policy Assessment also concluded that it clearly calls into question the appropriateness of each of the current standard elements: indicator, averaging time, form, and level (U.S. EPA, 2011a, p. 4–40).

After reviewing the information and analysis in the second draft Policy Assessment, CASAC concluded that the ''currently available information clearly calls into question the adequacy of the current standards and that consideration should be given to revising the suite of standards to provide increased public welfare protection'' (Samet, 2010d, p. iii). CASAC noted that the detailed estimates of hourly PM light extinction associated with just meeting the current standards ''clearly demonstrate that current standards do not protect against levels of visual air quality which have been judged to be unacceptable in all of the available urban visibility preference studies.'' Further, CASAC stated, with respect to the current suite of secondary $PM_{2.5}$ standards, that ''[T]he levels are too high, the averaging times are too long, and the $PM_{2.5}$ mass indicator could be improved to correspond more closely to the light scattering and absorption properties of suspended particles in the ambient air'' (Samet, 2010d, p. 9).

After considering the available evidence and the advice of CASAC, the Administrator concluded at the time of proposal that such information did provide an appropriate basis to inform a conclusion as to whether the current standards afford adequate protection against PM-related visibility impairment in urban areas. The Administrator took into account the information discussed above with regard to the nature of PM-related visibility impairment, the results of public perception surveys on the acceptability of varying degrees of visibility impairment in urban areas, analyses of the number of days on which peak 1-hour or 4-hour light extinction values are estimated to exceed a range of candidate protection levels under conditions simulated to just meet the current standards, and the advice of CASAC. She noted the clear causal relationship between PM in the ambient air and impairment of visibility, the evidence from the visibility preference studies, and the rationale for determining a range of candidate protection levels based on those studies. She also noted the relatively large number of days when maximum 1-hour or 4-hour light extinction values were estimated to exceed the three candidate protection levels, including the highest level of 30 dv, under the current standards. While recognizing the limitations in the available information on public perceptions of the acceptability of varying degree of visibility impairment and the information on the number of days estimated to exceed the CPLs, she concluded that such information provided an appropriate basis to inform a conclusion as to whether the current standards provide adequate protection against PM-related visibility impairment in urban areas. Based on these considerations, and placing great importance on the advice of CASAC, the Administrator provisionally concluded that the current standards are not sufficiently protective of visual air quality, and that consideration should be given to an alternative secondary standard that would provide additional protection against PM-related visibility impairment, with a focus primarily in urban areas.

Having reached this conclusion, the Administrator also stated at the time of proposal that the current indicator of $PM_{2.5}$ mass, in conjunction with the current 24-hour and annual averaging times, is not well suited for a national standard intended to protect public welfare from PM-related visibility impairment. As noted in the proposal, the current standards do not incorporate information on the concentrations of various species within the mix of ambient particles, nor do they incorporate information on relative humidity, both of which play a central role in determining the relationship between the mix of PM in the ambient air and impairment of visibility. Such considerations were reflected both in CASAC's advice to set a distinct secondary standard that would more directly reflect the relationship between ambient PM and visibility impairment and in the court's remand of the current secondary $PM_{2.5}$ standards. Based on the above considerations, at the time of proposal the Administrator provisionally concluded that the current secondary $PM_{2.5}$ standards, taken together, are neither sufficiently protective nor suitably structured to provide an appropriate degree of public welfare protection from PM-related visibility impairment, primarily in urban areas. This led the EPA to consider alternative standards by looking at each of the elements of the standards—indicator, averaging time, form, and level—as discussed below.

ii. Indicator

At the time of proposal, the EPA considered three alternative indicators for a $PM_{2.5}$ standard designed to protect against visibility impairment: The current $PM_{2.5}$ mass indicator; directly measured $PM_{2.5}$ light extinction; and calculated $PM_{2.5}$ light extinction. Directly measured $PM_{2.5}$ light extinction is a measurement (or combination of measurements) of the light absorption and scattering caused by $PM_{2.5}$ under ambient conditions. Calculated $PM_{2.5}$ light extinction uses the IMPROVE algorithm to calculate $PM_{2.5}$ light extinction using measured $PM_{2.5}$ mass, speciated $PM_{2.5}$ mass, and measured relative humidity. The Policy Assessment evaluated each of these alternatives, finally concluding that consideration should be given to establishing a new calculated $PM_{2.5}$ light extinction indicator (U.S. EPA, 2011a, p. 4–51).

As discussed in section VI.D.1 of the proposal, the Policy Assessment concluded that consideration of the use of either directly measured $PM_{2.5}$ light extinction or calculated $PM_{2.5}$ light extinction as an indicator is justified because light extinction is a physically meaningful measure of the characteristic of ambient $PM_{2.5}$ that is most relevant and directly related to PM-related visibility effects (U.S. EPA, 2011a, p. 4–41). Further, as noted above, $PM_{2.5}$ is the component of PM responsible for most of the visibility impairment in most urban areas. In these areas, the contribution of $PM_{10-2.5}$ is a minor contributor to visibility impairment most of the time. The Policy Assessment also indicated that the available evidence demonstrated a strong correspondence between calculated $PM_{2.5}$ light extinction and PM-related visibility impairment, as well as the significant degree of variability in visibility protection across the U.S. allowed by a $PM_{2.5}$ mass indicator. The Policy Assessment recognized that while in the future it would be appropriate to consider a direct measurement of $PM_{2.5}$ light extinction it was not an appropriate option in this review because a suitable specification of the equipment and associated performance verification procedures cannot be developed in the time frame for this review.

(a) $PM_{2.5}$ Mass

In terms of utilizing a $PM_{2.5}$ mass indicator, the proposal noted that $PM_{2.5}$ mass monitoring methods are in widespread use, including the FRM involving the collection of periodic (usually 1-day-in-6 or 1-day-in-3) 24-hour filter samples. However, these routine monitoring activities do not include measurement of the full water content of the ambient $PM_{2.5}$ that contributes, often significantly, to visibility impacts. Further, the $PM_{2.5}$ mass concentration monitors do not provide information on the composition of the ambient $PM_{2.5}$, which plays a central role in the relationship between PM-related visibility impairment and ambient $PM_{2.5}$ mass concentrations. Additional analyses discussed in the proposal that looked at the contribution of $PM_{2.5}$ to total PM-related light extinction (defined in terms of hourly PM_{10} calculated light extinction) indicate that there is a poor correlation between hourly PM_{10} light extinction and hourly $PM_{2.5}$ mass principally due to the impact of the water content of the particles on light extinction, which depends on both the composition of the $PM_{2.5}$ and the ambient relative humidity. Both composition and especially relative humidity vary during a single day, as well as from day-to-day, at any site and time of year. Also, there are systematic regional and seasonal differences in the distribution of ambient humidity and $PM_{2.5}$ composition conditions that make it impossible to select a $PM_{2.5}$ concentration that generally would correspond to the same PM-related light extinction levels across all areas of the nation. Analyses discussed in the proposal quantify the projected uneven protection that would result from the use of 1-hour average $PM_{2.5}$ mass as the indicator.

(b) Directly Measured $PM_{2.5}$ Light Extinction

PM light extinction has a nearly one-to-one relationship to light extinction, unlike $PM_{2.5}$ mass concentration. As explained above, $PM_{2.5}$ is the component responsible for the large majority of PM light extinction in most places and times. $PM_{2.5}$ light extinction can be directly measured using several instrumental methods, some of which have been used for decades to routinely monitor the two components of $PM_{2.5}$ light extinction (light scattering and absorption) or to jointly measure both as total light extinction (from which Rayleigh scattering is subtracted to get $PM_{2.5}$ light extinction). As noted at the time of proposal, there are a number of advantages to direct measurements of light extinction for use in a secondary standard relative to estimates of $PM_{2.5}$ light extinction calculated using $PM_{2.5}$ mass and speciation data. These include greater accuracy of direct measurements with shorter averaging times and overall greater simplicity when compared to the need for measurements of multiple parameters to calculate PM light extinction.

In evaluating whether direct measurement of $PM_{2.5}$ or PM_{10} light extinction is appropriate to consider in the context of this PM NAAQS review, the EPA solicited comment from the Ambient Air Monitoring and Methods

Subcommittee (AAMMS) of CASAC. The CASAC AAMMS recommended that consideration of direct measurement should be limited to $PM_{2.5}$ light extinction, and that although instruments suitable for this purpose are commercially available at present, research is expected to produce even better instruments in the near term. The CASAC AAMMS advised against choosing any currently available commercial instrument, or even a general measurement approach, as an FRM because to do so could discourage development of other potentially superior approaches. Instead, the CASAC AAMMS recommended that the EPA develop performance-based approval criteria for direct measurement methods in order to put all approaches on a level playing field.

At the present time, the EPA has not undertaken to develop and test such performance-base approval criteria. The EPA anticipates that if an effort were begun it would take at least several years before such criteria would be ready for regulatory use. Thus, the Policy Assessment concluded that while in the future it would be appropriate to consider a direct measurement of $PM_{2.5}$ light extinction, or the sum of separate measurements of light scattering and light absorption, as the indicator for the secondary $PM_{2.5}$ standard, this is not an appropriate option in this review because a suitable specification of the equipment or appropriate performance-based verification procedures cannot be developed in the time frame for this review (U.S. EPA, 2011a, p. 4–51, –52).

(c) Calculated $PM_{2.5}$ Light Extinction

For the reasons discussed above, the Policy Assessment concluded that a calculated $PM_{2.5}$ light extinction indicator would be the preferred approach. $PM_{2.5}$ light extinction can be calculated from $PM_{2.5}$ mass, combined with speciated $PM_{2.5}$ mass concentration data plus relative humidity data, as is presently routinely done on a 24-hour average basis under the Regional Haze Program using data from the rural IMPROVE monitoring network. This same calculation procedure, using a 24-hour average basis, could be used for a NAAQS focused on protecting against PM-related visibility impairment primarily in urban areas. This approach would use the type of data that is routinely collected from the urban CSN [168] in combination with monthly average relative humidity data based on long-term climatological means as used in the Regional Haze Program (U.S. EPA, 2011a, Appendix G, section G.2). The proposal discussed the complex approach utilized in the Visibility Assessment for calculating hourly $PM_{2.5}$ light extinction [169] and discussed various simplified approaches for calculating these hourly values that were analyzed in the Policy Assessment. The Policy Assessment concluded that each of these simplified approaches provided reasonably good estimates of $PM_{2.5}$ light extinction and each would be appropriate to consider as the indicator for a distinct hourly or multi-hour secondary standard (U.S. EPA, 2011a, p. 4–48). The proposal also recognized that the Policy Assessment identified a number of variations on these simplified approaches that it would be appropriate to consider, including:

(1) The use of the split-component mass extinction efficiency approach from the revised IMPROVE algorithm[170]

(2) The use of more refined value(s) for the organic carbon multiplier [171]

(3) The use of the reconstructed 24-hour $PM_{2.5}$ mass (i.e., the sum of the five $PM_{2.5}$ components from speciated monitoring) as a normalization value for the hourly measurements from the $PM_{2.5}$ instrument as a way of better reflecting ambient nitrate concentrations

(4) The use of historical monthly or seasonal, or regional, speciation averages

Overall, the analyses conducted for the Visibility Assessment and Policy Assessment indicated that the use of a calculated $PM_{2.5}$ light extinction indicator would provide a much higher degree of uniformity in terms of the degree of protection from visibility impairment across the country than a $PM_{2.5}$ mass indicator, because a calculated $PM_{2.5}$ light extinction indicator would directly incorporate the effects of humidity and $PM_{2.5}$ composition differences between various regions. Further, the proposal noted that the Policy Assessment concluded that consideration could be given to defining a calculated $PM_{2.5}$ light extinction indicator on either a 24-hour or a sub-daily basis (U.S. EPA, 2011a, p. 4–52). However, the Policy Assessment noted that approval of continuous FEM monitors has been based only on 24-hour average, not hourly, $PM_{2.5}$ mass. In addition, there are mixed results of data quality assessments on a 24-hour basis for these monitors, as well as the near absence of performance data for sub-daily averaging periods. Thus, while it is possible to utilize data from $PM_{2.5}$ continuous FEMs on a 1-hour or multi-hour (e.g., 4-hour) basis, these factors increase the uncertainty of utilizing continuous methods to support 1-hour or 4-hour $PM_{2.5}$ mass measurements as an input to the light extinction calculation. Therefore, as noted at the time of proposal, until issues regarding the comparability of 24-hour $PM_{2.5}$ mass values derived from continuous FEMs and filter-based FRMs [172] are resolved, there is reason to be cautious about relying on a calculation procedure that uses hourly $PM_{2.5}$ mass values reported by continuous FEMs in combination with speciated $PM_{2.5}$ mass values from 24-hour filter-based samplers.

(d) CASAC Advice

In reviewing the second draft Policy Assessment, CASAC stated that it ''overwhelmingly * * * would prefer the direct measurement of light extinction,'' recognizing it as the property of the atmosphere that most directly relates to visibility effects (Samet, 2010d, p. iii). CASAC noted that ''[I]t has the advantage of relating directly to the demonstrated harmful welfare effect of ambient PM on human visual perception.'' However, CASAC also concluded that the calculated $PM_{2.5}$ light extinction indicator ''appears to be a reasonable approach for estimating hourly light extinction'' (Samet, 2010d, p. 11). Further, based on CASAC's understanding of the time that would be required to develop an FRM for this indicator, CASAC agreed with the staff preference presented in the second draft Policy Assessment for a calculated $PM_{2.5}$ light extinction indicator. CASAC noted that ''[I]ts reliance on procedures that

[168] About 200 sites in the CSN routinely measure 24-hour average $PM_{2.5}$ chemical components using filter-based samplers and chemical analysis in a laboratory, on either a 1-day-in-3 or 1-day-in-6 schedule (U.S. EPA, 2011a, Appendix B, section B.1.3).

[169] As noted at the time of proposal, the sheer size of the ambient air quality, meteorological, and chemical transport modeling data files involved with the Visibility Assessment approach would make it very difficult for state agencies or any interested party to consistently apply such an approach on a routine basis for the purpose of implementing a national standard defined in terms of the Visibility Assessment approach.

[170] If the revised IMPROVE algorithm were used to define the calculated $PM_{2.5}$ mass-based indicator, it would not be possible to algebraically reduce the revised algorithm to a two-factor version as described above and in Appendix F of the Policy Assessment for the simplified approaches. Instead, five component fractions would be determined from each day of speciated sampling, and then either applied to hourly measurements of $PM_{2.5}$ mass on the same day or averaged across a month and then applied to measurements of $PM_{2.5}$ mass on each day of the month.

[171] An organic carbon (OC)-to-organic mass (OM) multiplier of 1.6 was used for the assessment, which was found to produce a value of OM comparable to the one derived with the original, albeit more complex, Visibility Assessment method.

[172] Filter-based FRMs are designed to adequately quantify the amount of $PM_{2.5}$ collected over 24-hours. They cannot be presumed to be appropriate for quantifying average concentrations over 1-hour or 4-hour periods.

have already been implemented in the CSN and routinely collected continuous $PM_{2.5}$ data suggest that it could be implemented much sooner than a directly measured indicator'' (Samet, 2010d, p. iii).[173]

(e) Administrator's Proposed Conclusions on Indicator

At the time of proposal, while agreeing with CASAC that a directly measured PM light extinction indicator would provide the most direct link between PM in the ambient air and PM-related light extinction, the Administrator provisionally concluded that this was not an appropriate option in this review because a suitable specification of currently available equipment or performance-based verification procedures cannot be developed in the time frame of this review. Taking all of the above considerations and CASAC advice into account, the Administrator provisionally concluded that a new calculated $PM_{2.5}$ light extinction indicator, similar to that used in the Regional Haze Program (i.e., using an IMPROVE algorithm as translated into the deciview scale), was the appropriate indicator to replace the current $PM_{2.5}$ mass indicator. Such an indicator, referred to as a $PM_{2.5}$ visibility index, would appropriately reflect the relationship between ambient PM and PM-related light extinction, based on the analyses discussed in the proposal and incorporation of factors based on measured $PM_{2.5}$ speciation concentrations and relative humidity data. In addition, selection of this type of indicator would address, in part, the issues raised in the court's remand of the 2006 p.m.$_{2.5}$ standards. The Administrator also noted that such a $PM_{2.5}$ visibility index would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by virtue of directly incorporating the effects of differences in $PM_{2.5}$ composition and relative humidity across the country.

Based on these above considerations, the Administrator proposed to set a distinct secondary standard for $PM_{2.5}$ defined in terms of a $PM_{2.5}$ visibility index (i.e., a calculated $PM_{2.5}$ light extinction indicator, translated into the deciview scale) to protect against PM-related visibility impairment primarily in urban areas. The Administrator proposed that such an index be based on the original IMPROVE algorithm in conjunction with monthly average relative humidity data based on long-term climatological means as used in the Regional Haze Program. The EPA solicited comment on all aspects of the proposed indicator, especially:

(1) The proposed use of a $PM_{2.5}$ visibility index rather than a PM_{10} visibility index which would include an additional term for coarse particles;

(2) Using the revised IMPROVE algorithm rather than the original IMPROVE algorithm;

(3) The use of alternative values for the organic carbon multiplier in conjunction with either the original or revised IMPROVE algorithm;

(4) The use of historical monthly, seasonal, or regional speciation averages;

(5) Alternative approaches to determining relative humidity; and

(6) Simplified approaches to generating hourly $PM_{2.5}$ light extinction values for purposes of calculating an hourly or multi-hour indicator.

iii. Averaging Times

In this review, as discussed in section VI.D.2 of the proposal, consideration of appropriate averaging times for use in conjunction with a $PM_{2.5}$ visibility index was informed by information related to the nature of PM visibility effects and the nature of inputs to the calculation of $PM_{2.5}$ light extinction, as discussed above. The EPA considered both sub-daily (1- and 4-hour averaging times) and 24-hour averaging times. In considering sub-daily averaging times, the EPA has also considered what diurnal periods and ambient relative humidity conditions would be appropriate to consider in conjunction with such an averaging time.

As an initial matter, the Policy Assessment considered sub-daily averaging times. Taking into account what is known from available studies concerning how quickly people experience and judge visibility conditions, the possibility that some fraction of the public experiences infrequent or short periods of exposure to ambient visibility conditions, and the typical rate of change of the path-averaged PM light extinction over urban areas, the initial analyses conducted as part of the Visibility Assessment focused on a 1-hour averaging time. In its review of the first draft Policy Assessment, CASAC agreed that a 1-hour averaging time would be appropriate to consider, noting that PM effects on visibility can vary widely and rapidly over the course of a day and such changes are almost instantaneously perceptible to human observers (Samet, 2010c, p. 19). The Policy Assessment noted that this view related specifically to a standard defined in terms of a directly measured PM light extinction indicator, in that CASAC also noted that a 1-hour averaging time is well within the instrument response times of the various currently available and developing optical monitoring methods.

However, CASAC also advised that if a $PM_{2.5}$ mass indicator were to be used, it would be appropriate to consider ''somewhat longer averaging times—2 to 4 hours—to assure a more stable instrumental response'' (Samet, 2010c, p. 19). In considering this advice, the Policy Assessment concluded that since a calculated $PM_{2.5}$ light extinction indicator relies in part on measured $PM_{2.5}$ mass, it would be appropriate to consider a multi-hour averaging time on the order of a few hours (e.g. 4-hours). A multi-hour averaging time might reasonably characterize the visibility effects experienced by the segment of the population who have access to visibility conditions often or continuously throughout the day. For this segment of the population, it may be that their perception of visual air quality reflects some degree of offsetting an hour with poor visual air quality with one or more hours of clearer visual conditions. Further, the Policy Assessment recognized that a multi-hour averaging time would have the effect of averaging away peak hourly visibility impairment, which can change significantly from one hour to the next (U.S. EPA, 2011a, p. 4–53; U.S. EPA, 2010b, Figure 3–12).

In considering either 1-hour or multi-hour averaging times, the Policy Assessment recognized that no data are available with regard to how the duration and variation of time a person spends outdoors during the daytime impacts his or her judgment of the acceptability of different degrees of visibility impairment. As a consequence, it is not clear to what degree, if at all, the protection levels found to be acceptable in the public preference studies would change for a multi-hour averaging time as compared to a 1-hour averaging time. Thus, the Policy Assessment concluded that it is appropriate to consider a 1-hour or multi-hour (e.g., 4-hour) averaging time as the basis for a sub-daily standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator (U.S. EPA, 2011a, p. 4–53).

In addition, as discussed above, some data quality uncertainties have been observed with regard to hourly data collected by FEMs. Specifically, as part of the review of data from all continuous FEM $PM_{2.5}$ instruments operating at state/local monitoring sites, the Policy Assessment noted that the occurrence of questionable outliers in 1-

[173] In commenting on the second draft Policy Assessment, CASAC did not have an opportunity to review the assessment of continuous $PM_{2.5}$ FEMs compared to collocated FRMs (Hanley and Reff, 2011) as presented and discussed in the final Policy Assessment (U.S. EPA, 2011a, p. 4–50).

hour data submitted to AQS from continuous FEM $PM_{2.5}$ instruments had been observed at some of these sites (Evangelista, 2011). Some of these outliers were questionable simply by virtue of their extreme magnitude, as high as 985 μg/m^3, whereas other values were questionable because they were isolated to single hours with much lower values before and after, a pattern that is much less plausible than if the high concentrations were more sustained.[174] The Policy Assessment noted that any current data quality problems might be resolved in the normal course of monitoring program evolution as operators become more adept at instrument operation and maintenance and data validation or by improving the approval criteria and testing requirements for continuous instruments. Regardless, the Policy Assessment noted that multi-hour averaging of FEM data could serve to reduce the effects of such outliers relative to the use of a 1-hour averaging time.

The Policy Assessment noted that there are significant reasons to consider using $PM_{2.5}$ light extinction calculated on a 24-hour basis to reduce the various data quality concerns described above with respect to relying on continuous $PM_{2.5}$ monitoring data. However, the Policy Assessment recognized that 24 hours is far longer than the hourly or multi-hour time periods that might reasonably characterize the visibility effects experienced by various segments of the population, including both those who do and do not have access to visibility conditions often or continuously throughout the day. Thus, the Policy Assessment concluded that the appropriateness of considering a 24-hour averaging time would depend upon the extent to which PM-related light extinction calculated on a 24-hour average basis would be a reasonable and appropriate *surrogate* for PM-related light extinction calculated on a sub-daily basis.

To examine this relationship, the EPA conducted comparative analyses of 24-hour and 4-hour averaging times in conjunction with a calculated $PM_{2.5}$ indicator. For these analyses, 4-hour average $PM_{2.5}$ light extinction was calculated based on using the Visibility Assessment approach. The 24-hour average $PM_{2.5}$ light extinction was calculated using the original IMPROVE algorithm and long-term relative humidity conditions to calculate $PM_{2.5}$ light extinction. Based on these analyses,[175] which are presented and discussed in Appendix G of the Policy Assessment, scatter plots comparing 24-hour and 4-hour calculated $PM_{2.5}$ light extinction were constructed for each of the 15 cities included in the Visibility Assessment and for all 15 cities pooled together (U.S. EPA, 2011a, Figures G–4 and G–5). Though there was some scatter around the regression line for each city because the calculated 4-hour light extinction values included day-specific and hour-specific influences that are not captured by the simpler 24-hour approach, these analyses generally showed good correlation between 24-hour and 4-hour average $PM_{2.5}$ light extinction, as evidenced by reasonably high city-specific and pooled R^2 values, generally in the range of over 0.6 to over 0.8.[176] This suggested that $PM_{2.5}$ light extinction calculated on a 24-hour basis is a reasonable and appropriate surrogate to $PM_{2.5}$ light extinction calculated on a sub-daily basis.

Taking the above considerations and CASAC's advice into account, the Policy Assessment concluded that it would be appropriate to consider a 24-hour averaging time, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and an appropriately specified standard level, as discussed below. By using site-specific daily data on $PM_{2.5}$ composition and site-specific long-term relative humidity conditions, this 24-hour average indicator would provide more consistent protection from $PM_{2.5}$-related visibility impairment than would a secondary $PM_{2.5}$ NAAQS based only on 24-hour or annual average $PM_{2.5}$ mass. In particular, this approach would account for the systematic difference in humidity conditions between most eastern states and most western states. The Policy Assessment also concluded that it would also be appropriate to consider a multi-hour, sub-daily averaging time, for example a period of 4 hours, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and with further consideration of the data quality issues discussed above. Such an averaging time, to the extent that data quality issues can be appropriately addressed, would be more directly related to the short-term nature of the perception of visibility impairment, short-term variability in PM-related visual air quality, and the short-term nature (hourly to multiple hours) of relevant exposure periods for segments of the viewing public. Such an averaging time would still result in an indicator that is less sensitive than a 1-hour averaging time to short-term instrument variability with respect to $PM_{2.5}$ mass measurement. In conjunction with consideration of a multi-hour, sub-daily averaging time, the Policy Assessment concluded that consideration should be given to including daylight hours only and to applying a relative humidity screen of approximately 90 percent to remove hours in which fog or precipitation is much more likely to contribute to the observed visibility impairment (U.S. EPA, 2011a, p. 4–58). Recognizing that a 1-hour averaging time would be even more sensitive to data quality issues, including short-term variability in hourly data from currently available continuous monitoring methods, the Policy Assessment concluded that it would not be appropriate to consider a 1-hour averaging time in conjunction with a calculated $PM_{2.5}$ light extinction indicator in this review (U.S. EPA, 2011a, p. 4–58).

As noted above, in its review of the first draft Policy Assessment, CASAC concluded that PM effects on visibility can vary widely and rapidly over the course of a day and such changes are almost instantaneously perceptible to human observers (Samet, 2010c, p. 19). Based in part on this consideration, CASAC agreed that a 1-hour averaging time would be appropriate to consider in conjunction with a directly measured PM light extinction indicator, noting that a 1-hour averaging time is well within the instrument response times of the various currently available and developing optical monitoring methods. At that time, CASAC also advised that if a $PM_{2.5}$ mass indicator were to be used, it would be appropriate to consider ''somewhat longer averaging times—2- to 4-hours—to assure a more stable instrumental response'' (Samet, 2010c, p. 19). Thus, CASAC's advice on averaging times that would be appropriate for consideration was predicated in part on the capabilities of monitoring methods that were available for the alternative indicators discussed in the draft Policy Assessment. CASAC's views on a multi-hour averaging time would also apply to the calculated $PM_{2.5}$ light extinction indicator since hourly $PM_{2.5}$ mass measurements are also required for this

[174] Similarly questionable hourly data were not observed in the 2005 to 2007 continuous $PM_{2.5}$ data used in the Visibility Assessment, all of which came from early-generation continuous instruments that had not been approved as FEMs. However, only 15 sites and instruments were involved in the Visibility Assessment analyses, versus about 180 currently operating FEM instruments submitting data to AQS. Therefore, there were more opportunities for very infrequent measurement errors to be observed in the larger FEM data set.

[175] These analyses are also based on the use of a 90th percentile form, averaged over 3 years, as discussed below in section VI.D.3 and in section 4.3.3 of the Policy Assessment (U.S. EPA, 2011a).

[176] The EPA staff noted that the R^2 value (0.44) for Houston was notably lower than for the other cities.

indicator when calculated on a sub-daily basis.

It is important to note that at the time it provided advice on suitable averaging times, CASAC did not have the benefit of EPA's subsequent assessment of the data quality issues associated with the use of continuous FEMs as the basis for hourly $PM_{2.5}$ mass measurements. Furthermore, since CASAC only commented on the first and second drafts of the Policy Assessment, neither of which included discussion of a calculated $PM_{2.5}$ indicator based on a 24-hour averaging time, CASAC did not have a basis to offer advice regarding a 24-hour averaging time. In addition, the 24-hour averaging time is not based on consideration of 24-hours as a relevant exposure period, but rather as a surrogate for a sub-daily period of 4 hours, which is consistent with CASAC's advice concerning an averaging time associated with the use of a $PM_{2.5}$ mass indicator.

Taking into account the information discussed above with regard to analyses and conclusions presented in the final Policy Assessment the Administrator recognized that hourly or sub-daily, multi-hour averaging times, within daylight hours and excluding hours with relative humidity above approximately 90 percent, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. On the other hand, she recognized that data quality uncertainties have recently been associated with currently available instruments that would be used to provide the hourly $PM_{2.5}$ mass measurements that would be needed in conjunction with an averaging time shorter than 24-hours. As a result, while the Administrator recognized the desirability of a sub-daily averaging time, she had strong reservations about proposing to set a standard at this time in terms of a sub-daily averaging time.

In considering the information and analyses related to consideration of a 24-hour averaging time, the Administrator recognized that the Policy Assessment concluded that $PM_{2.5}$ light extinction calculated on a 24-hour averaging basis is a reasonable and appropriate surrogate for sub-daily $PM_{2.5}$ light extinction calculated on a 4-hour average basis. In light of this finding and the views of CASAC based on its reviews of the first and second drafts of the Policy Assessment, the Administrator proposed to set a distinct secondary standard with a 24-hour averaging time in conjunction with a $PM_{2.5}$ visibility index.

iv. Form

As discussed in section VI.D.3 of the proposal, the ''form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether the standard is achieved. The form of the current 24-hour $PM_{2.5}$ NAAQS is such that the level of the standard is compared to the 3-year average of the annual 98th percentile value of the measured indicator. The purpose in averaging for three years is to provide stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year. The use of a multi-year percentile form, among other things, makes the standard less subject to the possibility of transient violations caused by statistically unusual indicator values, thereby providing more stability to the air quality management process that may enhance the practical effectiveness of efforts to implement the NAAQS. Also, a percentile form can be used to take into account the number of times an exposure might occur as part of the judgment on protectiveness in setting a NAAQS. For all of these reasons, the Policy Assessment concluded it would be appropriate to consider defining the form of a distinct secondary standard in terms of a 3-year average of a specified percentile air quality statistic (U.S. EPA, 2011a, p. 4–58).

The urban visibility preference studies that provided results leading to the range of CPLs being considered in this review offer no information that addresses the frequency of time that visibility levels should be below those values. Given this lack of information, and recognizing that the nature of the public welfare effect is one of aesthetics and/or feelings of well-being, the Policy Assessment concluded that it would not be appropriate to consider eliminating all exposures above the level of the standard and that allowing some number of hours/days with reduced visibility can reasonably be considered (U.S. EPA, 2011a, p. 4–59). In the Visibility Assessment, 90th, 95th, and 98th percentile forms were assessed for alternative PM light extinction standards (U.S. EPA, 2010b, section 4.3.3). In considering these alternative percentiles, the Policy Assessment noted that the Regional Haze Program targets the 20 percent most impaired days for improvements in visual air quality in Federal Class I areas. If improvement in the 20 percent most impaired days were similarly judged to be appropriate for protecting visual air quality in urban areas, a percentile well above the 80th percentile would be appropriate to increase the likelihood that all days in this range would be improved by control strategies intended to attain the standard. A focus on improving the 20 percent most impaired days suggests that the 90th percentile, which represents the median of the distribution of the 20 percent worst days, would be an appropriate form to consider. Strategies that are implemented so that 90 percent of days have visual air quality that is at or below the level of the standard would reasonably be expected to lead to improvements in visual air quality for the 20 percent most impaired days. Higher percentile values within the range assessed could have the effect of limiting the occurrence of days with peak PM-related light extinction in urban areas to a greater degree. In considering the limited information available from the public preference studies, the Policy Assessment found no basis to conclude that it would be appropriate to consider limiting the occurrence of days with peak PM-related light extinction in urban areas to a greater degree.

Another aspect of the form discussed in the proposal for a sub-daily averaging time was whether to include all daylight hours or only the maximum daily daylight hour(s). The maximum daily daylight 1-hour or multi-hour form would be most directly protective of the welfare of people who have limited, infrequent or intermittent exposure to visibility during the day (e.g., during commutes), but spend most of their time without an outdoor view. For such people a view of poor visibility during their morning commute may represent their perception of the day's visibility conditions until the next time they venture outside during daylight, which may be hours later or perhaps the next day. Other people have exposure to visibility conditions throughout the day. For those people, it might be more appropriate to include every daylight hour in assessing compliance with a standard, since it is more likely that each daylight hour could affect their welfare.

The Policy Assessment did not have information regarding the fraction of the public that has only one or a few opportunities to experience visibility during the day, nor did it have information on the role the duration of the observed visibility conditions has on wellbeing effects associated with those visibility conditions. However, it is logical to conclude that people with limited opportunities to experience visibility conditions on a daily basis would experience the entire impact associated with visibility based on their short-term exposure. The impact of visibility for those who have access to visibility conditions often or continuously during the day may be based on varying conditions throughout the day.

In light of these considerations, the analyses conducted as part of the Visibility Assessment analyses included both the maximum daily hour and the all daylight hours forms. The Policy Assessment noted that there is a close correspondence between the level of protection afforded for all 15 urban areas by a maximum daily daylight 1-hour approach using the 90th percentile form and an all daylight hours approach combined with the 98th percentile form (U.S. EPA, 2010b, section 4.1.4). This suggested that reductions in visibility impairment required to meet either form of the standard would provide protection to both fractions of the public (i.e., those with limited opportunities and those with greater opportunities to view PM-related visibility conditions). CASAC generally supported consideration of both types of forms without expressing a preference based on its review of information presented in the second draft Policy Assessment (Samet, 2010d, p. 11).

In conjunction with a calculated $PM_{2.5}$ light extinction indicator and alternative 24-hour or sub-daily (e.g., 4-hour) averaging times, based on the above considerations, and given the lack of information on and the high degree of uncertainty over the impact on public welfare of the number of days with visibility impairment over a year, the Policy Assessment concluded that it would be appropriate to give primary consideration to a 90th percentile form, averaged over three years (U.S. EPA, 2011a, p. 4–60). Further, in the case of a multi-hour, sub-daily alternative standard, the Policy Assessment concluded that it would be appropriate to give primary consideration to a form based on the maximum daily multi-hour period in conjunction with the 90th percentile form (U.S. EPA, 2011a, p. 4–60). This sub-daily form would be expected to provide appropriate protection for various segments of the population, including those with limited opportunities during a day and those with more extended opportunities over the daylight hours to experience PM-related visual air quality.

Though CASAC did not provide advice as to a specific form that would be appropriate, it took note of the alternative forms considered in that document and encouraged further analyses in the final Policy Assessment that might help to clarify a basis for selecting from within the range of forms identified. In considering the available information and the conclusions in the final Policy Assessment in light of CASAC's comments, at the time of proposal the Administrator concluded that a 90th percentile form, averaged over 3 years, is appropriate, and proposed such a form in conjunction with a $PM_{2.5}$ visibility index and a 24-hour averaging time.

v. Level

As discussed in section VI.D.4 of the proposal, in considering appropriate levels for a 24-hour standard defined in terms of a $PM_{2.5}$ visibility index and an 90th percentile form, averaged over 3 years, the Policy Assessment took into account the evidence- and impact-based considerations discussed above, with a focus on the results of public perception and attitude surveys related to the acceptability of various levels of visual air quality and on the important limitations in the design and scope of such available studies. The Policy Assessment considered a variety of approaches for identifying appropriate levels for such a standard, including utilizing both adjusted and unadjusted CPLs derived from the visibility preference studies.

The Policy Assessment interpreted the results from the visibility preferences studies conducted in four urban areas to define a range of low, middle, and high CPLs for a sub-daily standard (e.g., 1- to 4-hour averaging time) of 20, 25, and 30 dv, which are approximately equivalent to $PM_{2.5}$ light extinction of values of 65, 110, and 190 Mm^{-1}. The CASAC generally supported this approach, noting that the ''EPA staff's approach for translating and presenting the technical evidence and assessment results is logically conceived and clearly presented. The 20–30 deciview range of levels chosen by EPA staff as 'Candidate Protection Levels' is adequately supported by the evidence presented'' (Samet, 2010d, p. 11).[177] The Policy Assessment also recognized that to define a range of alternative levels that would be appropriate to consider for a 24-hour calculated $PM_{2.5}$ light extinction standard, it would be appropriate to consider whether some adjustment to these CPLs is warranted since these preference studies cannot be directly interpreted as applying to a 24-hour exposure period (as noted above and in Policy Assessment section 4.3.1). Considerations related to such adjustments are more specifically discussed below.

In considering alternative levels for a sub-daily standard based directly on the four preference study results, the Policy Assessment noted that the individual low and high CPLs are in fact generally reflective of the results from the Denver and Washington, DC studies respectively, and the middle CPL is very near to the 50th percentile criteria result from the Phoenix study, which was by far the best of the studies, providing somewhat more support for the middle CPL.

In considering the results from the four visibility preference studies, the Policy Assessment recognized that currently available studies are limited in that they were conducted in only four areas, three in the U.S. and one in Canada. Further, the Policy Assessment recognized that available studies provide no information on how the duration and variation of time a person spends outdoors during the daytime may impact their judgment of the acceptability of different degrees of visibility impairment. As such, there is a relatively high degree of uncertainty associated with using the results of these studies to inform consideration of a national standard for any specific averaging time. Nonetheless, the Policy Assessment concluded, as did CASAC, that these studies are appropriate to use for this purpose (U.S. EPA, 2011a, p. 4–61).

Using approaches described in section VI.C.4 of the proposal, the Policy Assessment explored various approaches to adjusting the CPLs derived from the preference studies to inform alternative levels for a 24-hour standard. These various approaches, based on analyses of 2007–2009 data from the 15 urban areas assessed in the Visibility Assessment, focused on estimating CPLs for a 24-hour standard that would provide generally equivalent protection as that provided by a 4-hour standard with CPLs of 20, 25, and 30 dv. In conducting these analyses, staff initially expected that the values of 24-hour average $PM_{2.5}$ light extinction and daily maximum daylight 4-hour average $PM_{2.5}$ light extinction would differ on any given day, with the shorter term peak value generally being larger. This would mean that, in concept, the level of a 24-hour standard should include a

[177] In 2009, the DC Circuit remanded the secondary $PM_{2.5}$ standards to the EPA in part because the Agency failed to identify a target level of protection, even though EPA staff and CASAC had identified a range of target levels of protection that were appropriate for consideration. The court determined that the Agency's failure to identify a target level of protection as part of its final decision was contrary to the statute and therefore unlawful, and that it deprived EPA's decision-making of a reasoned basis. See 559F. 3d at 528–31; see also section VI.A.2 above and the Policy Assessment, section 4.1.2.

downward adjustment compared to the level of a 4-hour standard to provide generally equivalent protection. As discussed more fully in section G.5 of Appendix G and summarized below, this initial expectation was not found to be the case across the range of CPLs considered. In fact, as shown in Tables G–7 and G–8 of Appendix G and in the corrected version of Table G–6 found in Frank *et al.* (2012b),[178] in considering estimates aggregated or averaged over all 15 cities as well as the range of city-specific estimates for the various approaches considered, these analyses indicated that the generally equivalent 24-hour levels ranged from somewhat below the 4-hour level to just above the 4-hour level for each of the CPLs.[179] In all cases, the range of city-specific estimates of generally equivalent 24-hour levels included the 4-hour level for each of the CPLs of 20, 25, and 30 dv. As noted in the proposal, looking more broadly at these results could support consideration of using the same CPL for a 24-hour standard as for a 4-hour standard, recognizing that there is no one approach that can most closely identify a generally equivalent 24-hour standard level in each urban area for each CPL. The use of such an unadjusted CPL for a 24-hour standard would place more emphasis on the relatively high degree of spatial and temporal variability in relative humidity and fine particle composition observed in urban areas across the country, so as to reduce the potential of setting a 24-hour standard level that would require more than the intended degree of protection in some areas.

In considering the appropriate level of a secondary standard focused on protection from PM-related urban visibility impairment based on either a 24-hour or a multi-hour, sub-daily (e.g., 4-hour) averaging time, the EPA has been mindful of the important limitations in the available evidence from public preference studies. These uncertainties and limitations are due in part to the small number of stated preference studies available for this review; the relatively small number of study participants and the extent to which the study participants may not be representative of the broader study area population in some of the studies; and the variations in the specific materials and methods used in each study such as scene characteristics, the range of VAQ levels presented to study participants, image presentation methods and specific wording used to frame the questions used in the group interviews. In addition the EPA has noted that the scenic vistas available on a daily basis in many urban areas across the country generally may not have the inherent visual interest or the distance between viewer and object of greatest intrinsic value as in the Denver and Phoenix preference studies, and that there is the possibility that there could be regional differences in individual preferences for VAQ.

It is also important to note that as in past reviews, the EPA is considering a national visibility standard in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in urban, non-urban, and Federal Class I areas across the country. The EPA recognizes that programs implemented to meet a national standard focused primarily on the visibility problems in urban areas can be expected to improve visual air quality in surrounding non-urban areas as well, as would programs now being developed to address the requirements of the Regional Haze Program established for protection of visual air quality in Federal Class I areas. The EPA also believes that the development of local programs, such as those in Denver and Phoenix, can continue to be an effective and appropriate approach to provide additional protection, beyond that afforded by a national standard, for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas.

The Policy Assessment concluded that it is appropriate to give primary consideration to alternative standard levels toward the upper end of the ranges identified above for 24-hour and sub-daily standards, respectively (U.S. EPA, 2011a, p. 4–63). Thus, the Policy Assessment concluded it is appropriate to consider the following alternative levels: A level of 28 dv or somewhat below, down to 25 dv, for a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, a 90th percentile form, and a 24-hour averaging time; and a standard level of 30 dv or somewhat below, down to 25 dv, for a similar standard but with a 4-hour averaging time (U.S. EPA, 2011a, p. 4–63). The Policy Assessment judged that such standards would provide appropriate protection against PM-related visibility impairment primarily in urban areas. The Policy Assessment noted that CASAC generally supported consideration of the 20–30 dv range as CPLs and, more specifically, that support for consideration of the upper part of the range of the CPLs derived from the public preference studies was expressed by some CASAC Panel members during the public meeting on the second draft Policy Assessment. The Policy Assessment concluded that such a standard would be appropriate in conjunction with the Regional Haze Program to achieve appropriate levels of protection against PM-related visibility impairment in areas across the country (U.S. EPA, 2011a, p. 4–63).

Based on the considerations discussed above and in section VI.D.4 of the proposal, and taking into account the advice of CASAC, at the time of proposal the Administrator concluded that it would be appropriate to establish a target level of protection—for a standard defined in terms of a $PM_{2.5}$ visibility index; a 90th percentile form averaged over 3 years; and a 24-hour averaging time—equivalent to the protection afforded by such a sub-daily (i.e., 4-hour) standard at a level of 30 dv, which is the upper end of the range of CPLs identified in the Policy Assessment and generally supported by CASAC. More specifically, the Administrator provisionally concluded that a 24-hour level of either 30 dv or 28 dv could be construed as providing such a degree of protection, and that either level was supported by the available information and was generally consistent with the advice of CASAC. Thus, the EPA proposed two options for the level of a new 24-hour standard (defined in terms of a $PM_{2.5}$ visibility index and a 90th percentile form, averaged over 3 years) to provide appropriate protection from PM-related visibility impairment: Either 30 dv or 28 dv. As noted in the proposal, the option of setting such a 24-hour standard at a level of 30 dv would reflect recognition that there is considerable spatial and

[178] Note that the city-specific ranges shown in Table G–6, Appendix G of the Policy Assessment are incorrectly stated for Approaches C and E. Drawing from the more detailed and correct results for Approaches C and E presented in Tables G–7 and G–8, respectively, the city-specific ranges in Table G–6 for Approach C should be 17–21 dv for the CPL of 20 dv; 21–25 dv for the CPL of 25 dv; and 24–30 dv for the CPL of 30 dv; the city-specific ranges in Table G–6 for Approach E should be 17–21 dv for the CPL of 20 dv; 21–26 dv for the CPL of 25 dv; and 25–31 dv for the CPL of 30 dv. In the EPA's reanalysis comparing 4- vs. 24-hour values, Frank et al. (2012b) recreated Table G–6 using the correct values from Tables G–7 and G–8.

[179] As discussed in more detail in Appendix G of the Policy Assessment, some days have higher values for 24-hour average light extinction than for daily maximum 4-hour daylight light extinction, and consequently an adjusted ''equivalent'' 24-hour CPL can be greater than the original 4-hour CPL. This can happen for two reasons. First, the use of monthly average historical RH data will lead to cases in which the *f*(RH) values used for the calculation of 24-hour average light extinction are higher than all or some of the four hourly values of *f*(RH) used to determine daily maximum 4-hour daylight light extinction on the same day. Second, $PM_{2.5}$ concentrations may be greater during non-daylight periods than during daylight hours.

temporal variability in the key factors that determine the value of the $PM_{2.5}$ visibility index in any given urban area, such that there is a relatively high degree of uncertainty as to the most appropriate approach to use in selecting a 24-hour standard level that would be generally equivalent to a specific 4-hour standard level. Selecting a 24-hour standard level of 30 dv would reflect a judgment that such substantial degrees of variability and uncertainty should be reflected in a higher standard level than would be appropriate if the underlying information were more consistent and certain. Alternatively, the option of setting such a 24-hour standard at a level of 28 dv would reflect placing more weight on statistical analyses of aggregated data from across the study cities and not placing as much emphasis on the city-to-city variability as a basis for determining an appropriate degree of protection on a national scale.

The information available for the Administrator to consider when setting the secondary PM standard raises a number of uncertainties. While CASAC supported moving forward with a new standard on the basis of the available information, CASAC also recognized these uncertainties, referencing the discussion of key uncertainties and areas for future research in the second draft of the Policy Assessment. In discussing areas of future research, CASAC stated that: ''The range of 50% acceptability values discussed as possible standards are based on just four studies (Figure 4–2), which, given the large spread in values, provide only limited confidence that the benchmark candidate protection levels cover the appropriate range of preference values. Studies using a range of urban scenes (including, but not limited to, iconic scenes—''valued scenic elements'' such as those in the Washington, DC study), should also be considered'' (Samet, 2010d, p. 12). The EPA solicited comment on how the Administrator should weigh those uncertainties as well as any additional comments and information to inform her consideration of these uncertainties.

In addition, the EPA solicited comment on a number of other issues related to the level of the standard, including:

(1) Both of the proposed levels and the various approaches to identifying generally equivalent levels upon which the alternative proposed levels are based.

(2) A broader range of levels down to 25 dv in conjunction with a 24-hour averaging time.

(3) A range of alternative levels from 30 to 25 dv in conjunction with a sub-daily (e.g., 4-hour) averaging time.

(4) The strengths and limitations associated with the public preference studies and the use of these studies to inform the selection of a range of levels that could be used to provide an appropriate degree of public welfare protection when combined with the other elements of the standard (i.e. indicator, form and averaging time).

(5) Specific aspects of the public preference studies, including the extent to which the 50 percent acceptability criterion is an appropriate basis for establishing target protection levels in the context of establishing a distinct secondary NAAQS to address PM-related visibility impairment in urban areas; how the variability among preference studies in the extent to which study participants may be representative of the broader study area population should be weighed in the context of considering these studies in reaching proposed conclusions on a distinct secondary NAAQS; and the extent to which the ranges of VAQ levels presented to participants in each of the studies may have influenced study results and on how this aspect of the study designs should appropriately be weighed in the context of considering these studies in the context of this review.

vi. Administrator's Proposed Conclusions Regarding PM Standards To Protect Visibility

At the time of proposal, based on the considerations described above, the Administrator proposed to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment, focused primarily on visibility in urban areas. This proposed visibility standard was to be defined in terms of a $PM_{2.5}$ visibility index, which would use measured $PM_{2.5}$ mass, combined with $PM_{2.5}$ speciation data and relative humidity data, to calculate $PM_{2.5}$ light extinction, translated into the deciview (dv) scale; a 24-hour averaging time; a 90th percentile form, averaged over 3 years; and a level of 28–30 dv.

vii. Related Technical Analysis

At the time of proposal, the EPA conducted a two-pronged technical analysis of the relationships between the proposed $PM_{2.5}$ visibility index standard and the current 24-hour $PM_{2.5}$ mass-based standard (Kelly, *et al.,* 2012a). This analysis was designed to provide technical information to inform key issues related to implementing a distinct secondary standard for visibility as proposed. Specifically, the EPA recognized that significant technical issues were likely to arise for new or modified emissions sources conducting air quality analyses for purposes of demonstrating that they would not cause or contribute to a violation of the visibility standard under the Prevention of Significant Deterioration (PSD) program. Such a demonstration for the proposed secondary $PM_{2.5}$ visibility index standard could require each PSD applicant to predict, via air quality modeling, the increase in visibility impairment, in terms of the proposed $PM_{2.5}$ visibility index, that would result from the proposed source's emissions in conjunction with an assessment of existing air quality (visibility impairment) conditions in terms of the proposed $PM_{2.5}$ visibility index. The EPA noted that if this demonstration were to be attempted using the six-step procedure that the EPA proposed to use for calculating $PM_{2.5}$ visibility index design values from monitored air concentrations of $PM_{2.5}$ components, significant technical issues with the modeling procedures could arise.

To address these technical issues, the EPA sought to explore whether sources that met the requirements pertaining to the 24-hour mass-based standard of 35 μg/m³ would also meet the requirements pertaining to the proposed visibility index standard. As described in Kelly *et al.* (2012a), the first prong of the analysis addressed aspects of a PSD significant impact analysis by evaluating whether an individual source's impact resulting in a small increase in the ambient $PM_{2.5}$ concentration would produce a comparably small increase in visibility impairment. This analysis included estimates of $PM_{2.5}$ speciation profiles based on direct $PM_{2.5}$ emission profiles for a broad range of source categories and for theoretical upper and lower bound scenarios.

The second prong of the analysis addressed aspects of a PSD cumulative impact analysis by exploring the relationship between the three-year design values for the existing 24-hour $PM_{2.5}$ standard and coincident design values for the proposed $PM_{2.5}$ visibility index standard based on recent air quality data. This aspect of the analysis indicated that increases in 24-hour $PM_{2.5}$ design values generally correspond to increases in visibility index design values, and vice-versa. The analysis further explored the appropriateness of using a demonstration that a source does not cause or contribute to a violation of the 24-hour $PM_{2.5}$ standard as a surrogate for a demonstration that a source does not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index standard. This analysis was based on 2008 to 2010 air quality data, and compared the proposed level of 35 μg/m³ for the 24-hour $PM_{2.5}$ standard and for illustrative purposes an alternative standard level of 12 μg/m³ for the annual $PM_{2.5}$ standard with the proposed levels of 28 or 30 dv for the secondary $PM_{2.5}$ visibility index standard with a 24-hour averaging time and a 90th percentile form. The results indicated that all (for the 30 dv level) or nearly all (for the 28 dv level) areas in attainment of the 24-hour $PM_{2.5}$ standard would also have been in attainment of the proposed secondary $PM_{2.5}$ visibility index standard.

Based on this technical analysis, the EPA proposed that there is sufficient evidence that a demonstration that a source does not cause or contribute to a violation of the mass-based 24-hour $PM_{2.5}$ standard serves as a suitable surrogate for demonstrating that a source does not cause or contribute to a violation of the proposed secondary 24-hour $PM_{2.5}$ visibility index standard under the PSD program. As such, the EPA proposed to conclude that many or all sources undergoing PSD review for $PM_{2.5}$ could rely upon their analysis for demonstrating that they do not cause or contribute to a violation of the mass-based 24-hour $PM_{2.5}$ standard to also show that they do not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index standard, if a distinct visibility standard were finalized.

Although this proposed ''surrogacy policy'' was designed to address an implementation-related issue, the second prong of the technical analysis addresses the broader technical question of the relationship between the existing 24-hour $PM_{2.5}$ standard and the proposed $PM_{2.5}$ visibility index standard in terms of the degree of protection likely to be afforded by each standard. Specifically, the analysis indicated that depending on the level of the proposed $PM_{2.5}$ visibility index standard, the existing 24-hour $PM_{2.5}$ mass-based standard would be as protective or in some areas *more* protective of visibility than a distinct secondary standard set within the range of levels proposed. Commenters on the proposed $PM_{2.5}$ visibility index explored the implications of this analysis at length, as discussed further below in section VI.C.1.f. For this reason, the analysis is described in some detail here.

Kelly *et al.* (2012a) noted that the relationship between design values for the 24-hour $PM_{2.5}$ standard and the proposed secondary visibility index standard is not obvious *a priori* because of differences in design value calculations for the standards. However, closer examination of this relationship indicated that increases or decreases in 24-hour $PM_{2.5}$ design values correspond, respectively, to increases or decreases in visibility index values. Specifically, based on measurements from 102 sites with complete data from 2008–2010, Kelly *et al.* (2012a) found linear correlations between the 24-hour $PM_{2.5}$ design values and the visibility index design values with r^2 values ranging from 0.65 to 0.98 across these sites, with an average r^2 value of 0.75 across all U.S. sites. Moreover, the data indicated that no design value existed where the visibility index design value exceeded 30 dv, but the 24-hour $PM_{2.5}$ standard level of 35 µg/m³ was attained. Visibility index design values for certain sites in the Industrial Midwest were shown to exceed 28 dv despite the fact that the 24-hour $PM_{2.5}$ design values for these sites were below 35 µg/m³. This was attributed to the combination of high nitrate and sulfate fractions, substantial RH adjustment factors, and $PM_{2.5}$ distribution characteristics that led to relatively high visibility index design values for a given 24-hour $PM_{2.5}$ design value for counties in the Industrial Midwest.[180] Kelly *et al.* (2012a) concluded that the ''overall, design values based on 2008–2010 data suggest that counties that attain 24-hour $PM_{2.5}$ NAAQS level of 35 µg/m³ would attain the proposed secondary $PM_{2.5}$ visibility index NAAQS level of 30 dv and generally attain the level of 28 dv'' (pp. 17–18). In addition, the Kelly *et al.* analysis indicated that at sites that violated both the 24-hour $PM_{2.5}$ level and the proposed visibility index 30 dv level, the proposed level of 30 dv would likely be attained if $PM_{2.5}$ concentrations were reduced such that the 24-hour $PM_{2.5}$ level of 35 µg/m³ was attained (Kelly *et al.,* 2012a, p.15).[181] A key implication of this analysis, therefore, was that within the range of levels proposed by the EPA for a visibility index standard (28–30 dv), the 24-hour $PM_{2.5}$ standard of 35 µg/m³ would be controlling in almost all (at 28 dv) or all (at 30 dv) instances.

2. Other (Non-Visibility) PM-related Welfare Effects

In the 2006 review, the EPA concluded that there was insufficient information to consider a distinct secondary standard based on PM-related impacts to ecosystems, materials damage and soiling, and climatic and radiative processes (71 FR 61144, October 17, 2006). Specifically, there was a lack of evidence linking various non-visibility welfare effects to specific levels of ambient PM. In that review, to provide a level of protection for these welfare-related effects, the secondary standards were set equal to the revised primary standards to directionally improve the level of protection afforded vegetation, ecosystems, and materials (71 FR 61210, October 17, 2006).

This section briefly outlines key conclusions discussed more fully in section VI.E of the proposal regarding the non-visibility welfare effects of PM. These conclusions relate to the climate, ecological (including effects on plants, soil and nutrient cycling, wildlife and water) and materials damage effects of PM. For all of these effects, the Policy Assessment concluded that there is insufficient information at this time to revise the current suite of secondary standards. It is important to note that the Policy Assessment explicitly excluded discussion of the effects associated with deposited particulate matter components of NO_X and SO_x and their transformation products which are addressed fully in the joint review of the secondary NO_2 and SO_2 NAAQS.

a. Evidence of Other Welfare Effects Related to PM

With regard to the role of PM in climate, the proposal noted that there is considerable ongoing research focused on understanding aerosol contributions to changes in global mean temperature and precipitation patterns. The Integrated Science Assessment concluded ''that a causal relationship exists between PM and effects on climate, including both direct effects on radiative forcing and indirect effects that involve cloud feedbacks that influence precipitation formation and cloud lifetimes'' (U.S. EPA, 2009a, section 9.3.10). These effects are discussed in more detail in section VI.E.1 of the proposal, which provides information on the major aerosol components of interest for climate processes, including black carbon (BC), organic carbon (OC), sulfates, nitrates, and mineral dusts, and the nature, magnitude, and direction (e.g., cooling vs. warming) of various aerosol impacts on climate.[182] The Policy Assessment concluded that aerosols alter climate processes directly through radiative forcing and by indirect effects on cloud brightness, changes in precipitation, and

[180] Kelly *et al.* (2012a) also noted that ''Regional reductions in sulfate $PM_{2.5}$ due to emission controls planned as part of national rules as well as emission reductions associated with potential annual standard violations are expected to improve visibility in this region'' (p. 17).

[181] The analysis also showed that attaining the 24-hour $PM_{2.5}$ standard level of 35 µg/m³ would result in achieving a lower $PM_{2.5}$ visibility index level in certain areas of the country, largely western areas, than would be achieved in other areas of the country. This is due to differences in the composition of ambient $PM_{2.5}$ and the lower relative humidity in those areas.

[182] Atmospheric PM is referred to as aerosols in the remainder of this section to be consistent with the Integrated Science Assessment.

possible changes in cloud lifetimes (U.S. EPA, 2011a, p. 5–10). Further, the Policy Assessment noted that the major aerosol components that contribute to climate processes (i.e. BC, OC, sulfate, nitrate and mineral dusts) vary in their reflectivity, forcing efficiencies and even in the direction of climate forcing, though there is an overall net climate cooling associated with aerosols in the global atmosphere (U.S. EPA, 2009a, section 9.2.10). The Policy Assessment concluded that the current mass-based $PM_{2.5}$ and PM_{10} secondary standards were not an appropriate or effective means of focusing protection against PM-associated climate effects due to these differences in components (U.S. EPA, 2011a, p. 5–11). In addition, in light of the significant uncertainties in current scientific information and the lack of sufficient data, the Policy Assessment concluded it is not currently feasible to conduct a quantitative analysis for the purpose of informing revisions of the current secondary PM standards based on climate (U.S. EPA, 2011a, p. 5–11). Overall the Policy Assessment concluded that there is insufficient information at this time to base a national ambient standard on climate impacts associated with current ambient concentrations of PM or its constituents (U.S. EPA, 2011a, p. 5–11, –12).[183]

With regard to ecological effects, the proposal noted that several ecosystem components (e.g., plants, soils and nutrient cycling, wildlife and water) are impacted by PM air pollution, which may alter the services provided by affected ecosystems. Ecological effects include both direct effects due to deposition (e.g., wet, dry or occult) to vegetation surfaces and indirect effects occurring via deposition to ecosystem soils or surface waters where the deposited constituents of PM then interact with biological organisms. Some of the ecological effects considered in this review include direct effects to metabolic processes of plant foliage; contribution to total metal loading resulting in alteration of soil biogeochemistry and microbiology, and plant and animal growth and reproduction; and contribution to total organics loading resulting in bioaccumulation and biomagnification across trophic levels. Section VI.E.2 of the proposal summarizes key findings related to:

(1) Impacts on plants and the ecosystem services they provide due to deposition of PM to vegetative surfaces, which alters the radiation received by the plant, and uptake of deposited PM components by plants from soil or foliage, which can lead to stress and decreased photosynthesis;

(2) Impacts on ecosystem support services such as nutrient cycling, products such as crops and the regulation of flooding and water quality;

(3) Impacts on wildlife, especially due to biomagnification of heavy metals (especially Hg) up the food chain and bioconcentration of POPs and PBDEs; and

(4) Impacts of deposited PM, especially metals and organics, on the ecosystem services provided by water bodies, including primary production, provision of fresh water, regulation of climate and floods, recreational fishing and water purification.

The proposal noted that the Integrated Science Assessment had concluded that ecological evidence is sufficient to conclude that a causal relationship is likely to exist between deposition of PM and a variety of effects on individual organisms and ecosystems (U.S. EPA, 2009a, sections 2.5.3 and 9.4.7), and also noted that vegetation and other ecosystem components are affected more by particulate chemistry than size fraction. However, the proposal also pointed to the Integrated Science Assessment conclusion that it is generally difficult to characterize the nature and magnitude of effects and to quantify relationships between ambient concentrations of PM and ecosystem response due to significant data gaps and uncertainties as well as considerable variability that exists in the components of PM and their various ecological effects. There are few studies that link ambient PM concentrations to observed effect. Most direct ecosystem effects associated with particulate pollution occur in severely polluted areas near industrial point sources (quarries, cement kilns, metal smelting) (U.S. EPA, 2009a, sections 9.4.3 and 9.4.5.7).

Based on the evidence available at this time, the proposal noted the following key conclusions in the Policy Assessment:

(1) A number of significant environmental effects that either have already occurred or are currently occurring are linked to deposition of chemical constituents found in ambient PM.

(2) Ecosystem services can be adversely impacted by PM in the environment, including supporting, provisioning, regulating and cultural services.

(3) The lack of sufficient information to relate specific ambient concentrations of particulate metals and organics to a degree of impairment of a specific ecological endpoint hinders the identification of a range of appropriate indicators, levels, forms and averaging times of a distinct secondary standard to protect against associated effects.

(4) Data from regionally-based ecological studies can be used to establish probable local, regional and/or global sources of deposited PM components and their concurrent effects on ecological receptors.

The proposal noted that the Policy Assessment had concluded that the currently available information is insufficient for purposes of assessing the adequacy of the protection for ecosystems afforded by the current suite of PM secondary standards or establishing a distinct national standard for ambient PM based on ecosystem effects of particulates not addressed in the NO_X/SO_X secondary review (e.g., metals, organics) (U.S. EPA, 2011a, p. 5–24). Furthermore, the Policy Assessment had concluded that in the absence of information providing a basis for specific standards in terms of particle composition, the observations continue to support retaining an appropriate degree of control on both fine and coarse particles to help address effects to ecosystems and ecosystem components associated with PM (U.S. EPA, 2011a, p. 5–24).

With regard to materials damage, the proposal discussed effects associated with deposition of PM, including both physical damage (materials damage effects) and impaired aesthetic qualities (soiling effects). As with the other categories of welfare effects discussed above, the Integrated Science Assessment concluded that evidence is sufficient to support a causal relationship between PM and effects on materials (U.S. EPA, 2009a, sections 2.5.4 and 9.5.4). The deposition of PM can physically affect materials, adding to the effects of natural weathering processes, by potentially promoting or accelerating the corrosion of metals, by degrading paints and by deteriorating building materials such as stone, concrete and marble (U.S. EPA, 2009a, section 9.5). In addition, the deposition of ambient PM can reduce the aesthetic appeal of buildings and objects through soiling. The Policy Assessment made the following observations:

(1) Materials damage and soiling that occur through natural weathering processes are enhanced by exposure to atmospheric pollutants, most notably sulfur dioxide and particulate sulfates.

(2) While ambient particles play a role in the corrosion of metals and in the weathering of materials, no quantitative relationships between ambient particle concentrations and rates of damage have been established.

(3) While soiling associated with fine and course particles can result in increased cleaning frequency and repainting of surfaces, no quantitative relationships between particle characteristics and the frequency of cleaning or repainting have been established.

(4) Limited new data on the role of microbial colonizers in biodeterioration

[183] This conclusion would apply for both the secondary (welfare-based) and the primary (health-based) standards.

processes and contributions of black crust to soiling are not sufficient for quantitative analysis.

(5) While several studies in the PM Integrated Science Assessment and NO_X/SO_X Integrated Science Assessment suggest that particles can promote corrosion of metals there remains insufficient evidence to relate corrosive effects to specific particulate levels or to establish a quantitative relationship between ambient PM and metal degradation. With respect to damage to calcareous stone, numerous studies suggest that wet or dry deposition of particles and dry deposition of gypsum particles can enhance natural weathering processes.

The Policy Assessment concluded that none of the new evidence in this review called into question the adequacy of the current standards for protecting against material damage effects, that such effects could play no quantitative role in determining whether revisions to the secondary PM NAAQS are appropriate at this time, and that observations continue to support retaining an appropriate degree of control on both fine and coarse particles to help address materials damage and soiling associated with PM (U.S. EPA, 2011a, p. 5–29).

b. CASAC Advice

In advising the EPA regarding the non-visibility welfare effects, CASAC stated that it ''concurs with the Policy Assessment's conclusions that while these effects are important, and should be the focus of future research efforts, there is not currently a strong technical basis to support revisions of the current standards to protect against these other welfare effects'' (Samet, 2010c). More specifically, with regard to climate impacts, CASAC concluded that while there is insufficient information on which to base a national standard, the causal relationship is established and the risk of impacts is high, so further research on a regional basis is urgently needed (Samet, 2010c, p. 5). CASAC also noted that reducing certain aerosol components could lead to increased radiative forcing and regional climate warming while having a beneficial effect on PM-related visibility. As a consequence, CASAC noted that a secondary standard directed toward reducing PM-related visibility impairment has the potential to be accompanied by regional warming if light scattering aerosols are preferentially targeted.

With regard to ecological effects, CASAC concluded that the published literature is insufficient to support a national standard for PM effects on ecosystem services (Samet, 2010c, p.23). CASAC noted that the best-established effects are related to particles containing nitrogen and sulfur, which are being considered in the EPA's ongoing review of the secondary NAAQS for NO_X/SO_X. With regard to PM-related effects on materials, CASAC concluded that the published literature, including literature published since the last review, is insufficient either to call into question the current level of the standard or to support any specific national standard for PM effects on materials (Samet, 2010c, p.23). Nonetheless, with regard to both types of effects, CASAC noted the importance of maintaining an appropriate degree of control of both fine and coarse particles to address such effects, even in the current absence of sufficient information to develop a standard.

c. Summary of Proposed Decisions Regarding Other Welfare Effects

Based on the above considerations and the advice of CASAC, at the time of proposal the Administrator provisionally concluded that it would not be appropriate to establish any distinct secondary PM standards to address other non-visibility PM-related welfare effects, including ecological effects, effects on materials, and climate impacts. Nonetheless, the Administrator concurred with the conclusions of the Policy Assessment and CASAC advice that it is important to maintain an appropriate degree of control of both fine and coarse particles to address such effects. Noting that there is an absence of information that would support any different standards, the Administrator proposed generally to retain the current suite of secondary PM standards [184] to address non-visibility welfare effects. Specifically, the Administrator proposed to retain all aspects of the current secondary 24-hour $PM_{2.5}$ and PM_{10} standards. With regard to the secondary annual $PM_{2.5}$ standard, the Administrator proposed to retain the level of the current standard and to revise the form of the standard by removing the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard.

C. Public Comments on Proposed Decisions Regarding Secondary PM Standards

The EPA received a large number of comments on its proposed decisions with regard to secondary PM standards, with the large majority of those comments focusing on the proposal to set a distinct standard to protect against visibility impairment, discussed below in section VI.C.1. Very few commenters addressed the proposal to retain the existing secondary standards for non-visibility welfare effects, discussed below in section VI.C.2. As discussed in section VI.D. below, the Administrator has decided to retain the current suite of secondary PM standards generally, while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. The Administrator has also decided, contrary to what was proposed, not to establish a distinct secondary standard to address PM-related visibility impairment. This section discusses EPA's responses to the comments EPA received on its proposal, and the rationale behind the Administrator's final decisions is discussed in section VI.D. below.

1. Comments on Proposed Secondary Standard for Visibility Protection

a. Overview of Comments

Among those commenting on the proposal to set a distinct secondary $PM_{2.5}$ visibility index standard, a large majority of commenters, including more than 25 state and local agencies; regional organizations such as NACAA, NESCAUM, and WESTAR; and industry commenters, such as ACC, API, BP, EPRI, NCBA, NEDA–CAP, NMA, NSSGA, and UARG, opposed setting a distinct secondary standard for visibility at this time. Many commenters in this group expressed the view that such a standard was not needed, primarily on the basis that adequate protection was provided by the existing 24-hour secondary $PM_{2.5}$ standard. Some of these commenters also expressed legal concerns with the nature of the proposed standard. Other commenters in this group supported a distinct secondary standard for visibility in concept, but expressed the view that it was premature to set such a standard pending collection of additional visibility preference study data and the resolution of a number of key technical issues. Support for setting such a distinct secondary standard for visibility at this time came from a second group of commenters, including the Department of the Interior (National Park Service), several states, the Mid-Atlantic/Northeast Visibility Union (MANE–VU), the National Tribal Air Association (NTAA), environmental organizations such as the Appalachian Mountain Club, National Parks Conservation Association, Earthjustice (AMC, *et al.*) and the League of Women

[184] As summarized in section VI.A and Table 1 above, the current suite of secondary PM standards includes annual and 24-hour $PM_{2.5}$ standards and a 24-hour PM_{10} standard.

Voters of Texas. These commenters argued that the existing secondary standards are not sufficiently protective of visual air quality, and that a distinct secondary standard similar to the proposed visibility index standard is both necessary and appropriate to ensure adequate protection of visibility.

Commenters in both groups expressed concerns about various aspects of the proposed distinct secondary standard, including the indicator, averaging time, level, and form. In addition, a large number of commenters, including commenters from both groups, expressed concern and/or confusion over the relationship between the Regional Haze Program and the proposed distinct secondary standard for visibility, raising issues such as analytical differences in methods between the programs, monitoring issues, and other implementation challenges.

A discussion of the significant comments outlined above, including EPA's responses to the comments, is presented here, with more detailed discussion in the Response to Comments document. Comments relating to the specific elements of the proposed standard—indicator, averaging time, form and level—are discussed in sections VI.C.1.b-e, respectively. Comments related to the need for a distinct secondary standard at this time are discussed in section VI.C.f. Legal issues raised by commenters opposed to setting a secondary standard based on the proposed visibility index are discussed in section VI.C.g. Finally, comments related to the relationship between a distinct secondary standard and the Regional Haze Program are discussed in section VI.C.h.[185] While the EPA concludes in section VI.D below to retain the current suite of secondary $PM_{2.5}$ standards, the appropriateness of the protection that would be provided by the proposed $PM_{2.5}$ visibility index standard, and the relationship between this degree of protection and that provided by the current secondary 24-hour secondary $PM_{2.5}$ standard, are key elements in the Administrator's decision, and are discussed below.

b. Indicator

Numerous commenters, both those supporting a distinct secondary standard and those opposed to setting such a standard, expressed views on the suitability of utilizing a $PM_{2.5}$ calculated light extinction indicator for the standard as proposed. While these groups of commenters differed in terms of their views on the appropriateness of using calculated $PM_{2.5}$ light extinction as the basis for the indicator rather than relying on direct measurements of $PM_{2.5}$ light extinction, commenters from both groups expressed concern over specific elements of the proposed method of calculating $PM_{2.5}$ light extinction. In particular, commenters expressed differing views on which IMPROVE algorithm should be utilized; whether it is appropriate to exclude coarse particles from the indicator; and whether the proposed protocols for incorporating data on relative humidity and $PM_{2.5}$ species are appropriate.[186]

i. Comments on Calculated vs. Directly Measured Light Extinction

The majority of commenters in both groups noted the uncertainties associated with relying on a calculated light extinction indicator and stated a preference for utilizing direct light extinction measurements. However, recognizing the limitations on applying direct measurements at present, commenters supporting the proposal to set a distinct standard argued that relying on ''calculated light extinction is a reasonable first approach'' (DOI, p. 2). These commenters pointed to the advice of CASAC, which had acknowledged that it was not possible for the EPA to develop an FRM for direct measurement of light extinction within the time frame of this review and had concluded that relying on a calculated $PM_{2.5}$ light extinction indicator represented a reasonable approach that could be implemented sooner than a directly measured indicator. These commenters generally supported the proposal to adopt a calculated $PM_{2.5}$ light extinction indicator, at least as an interim approach.

Commenters opposed to setting a distinct standard generally argued that it was inappropriate to rely on a calculated light extinction indicator rather than direct measurements. Some of these commenters argued that the proposed calculated light extinction indictor is ill suited for a bright line standard because the method uses average humidity and a reconstructed visibility measurement calculated from $PM_{2.5}$ speciation filter analysis, rather than measuring what is actually observed by individuals. A number of commenters advocated postponing setting a distinct standard until an approach based on direct light extinction measurements can be adopted. Many of these commenters stated that relying on direct light extinction measurements would enable a standard to be based on a shorter averaging time, either 1-hour or sub-daily (4 to 6 hours), consistent with the more instantaneous nature of perceptions of visual air quality and the advice of CASAC in this review.

The EPA generally agrees with commenters that an indicator based on directly measured light extinction would provide the most direct link between PM in the ambient air and PM-related light extinction. However, as noted at the time of proposal and in accordance with the advice of CASAC, the EPA has concluded that this is not an appropriate option in this review because a suitable specification of currently available equipment or performance-based verification procedures could not be developed in the time frame of this review. Moreover, CASAC concluded that relying on a calculated $PM_{2.5}$ light extinction indicator based on $PM_{2.5}$ chemical speciation and relative humidity data represented a reasonable approach. The inputs that are necessary include measurements that are available through existing monitoring networks and approved protocols. Thus, the EPA remains confident that the available evidence demonstrates that a strong correspondence exists between calculated $PM_{2.5}$ light extinction and PM-related visibility impairment. Furthermore, CASAC agreed, noting that the proposed calculated $PM_{2.5}$ light extinction indicator based on the original IMPROVE algorithm ''appears to be a reasonable approach for estimating hourly light extinction'' (Samet, 2010d, p. 11) and ''its reliance on procedures that have already been implemented in the CSN and routinely collected continuous $PM_{2.5}$ data suggest that it could be implemented much sooner than a directly measured indicator'' (Samet, 2010d, p. iii). Thus it would not be appropriate to postpone setting a distinct secondary standard until an approach based on direct light extinction measurements could be adopted.

ii. Comments on Specific Aspects of Calculated Light Extinction Indicator

Some commenters, even those supporting the adoption of a calculated light extinction indicator, also expressed concern over specific aspects of the proposed indicator. First, a

[185] Comments pertaining to implementation issues, which the Administrator may not consider in making decisions about setting national ambient air quality standards, are discussed in the Response to Comments document, as are comments regarding monitoring issues related to the proposed distinct visibility index standard.

[186] Some commenters expressed concern about the omission of other contributors to visibility impairment from the visibility index, as discussed in the Response to Comments document.

number of commenters expressed concern over the proposal to use the original IMPROVE algorithm as the basis for the calculated light extinction indicator. These commenters noted that the original IMPROVE algorithm has been shown to have consistent biases at both low and high levels of light extinction. In particular, these commenters expressed concern with the algorithm's bias at higher levels of light extinction, which they pointed out were the conditions that might be encountered on hazier days in urban areas.

Some commenters supported use of the revised IMPROVE algorithm. These commenters noted that the revised equation has been through a peer review which confirmed that it is based on the best science and corrects the biases inherent in the original algorithm. Commenters also noted that this revised algorithm has been widely incorporated into Regional Haze plans, and urged the EPA to use this same equation in the visibility index for the sake of consistency: ''EPA approved this approach for regional haze and does not dispute its greater accuracy. Therefore, a national secondary ambient air quality standard based on criteria that accurately reflect the latest scientific knowledge logically should not revert to the original IMPROVE algorithm'' (Oklahoma DEQ, p. 2). Other commenters noted that both the original and the revised IMPROVE algorithms were designed in support of the Regional Haze Program which is focused on largely rural Class I areas, and that neither algorithm is necessarily suitable for urban areas. Noting that the EPA has not thoroughly evaluated the applicability of either IMPROVE algorithm in urban areas, these commenters urged additional research to evaluate the suitability of either algorithm (or an alternative approach) in urban areas.

Second, a number of commenters argued that exclusion of coarse PM from the calculated light extinction indicator was inappropriate. These commenters noted that coarse particulate matter is an important contributor to visibility impairment in many areas, particularly in the western U.S., and that the levels of ''acceptable'' visual air quality derived from the visibility preference studies reflected total light extinction due to the full mix of particles (including coarse PM) in ambient air. A few commenters noted that due to the exclusion of coarse particles, a ''deciview'' calculated for purposes of the proposed $PM_{2.5}$ visibility index is inconsistent with the unit as conventionally defined under the Regional Haze Program. Other commenters, however, supported the proposal to exclude coarse PM from the calculated light extinction indicator, noting the important role that $PM_{2.5}$ plays in urban visibility and arguing it would be more difficult to control the contribution of coarse particle sources such as wind-blown dust to urban visibility impairment.

Third, some commenters questioned why the EPA was proposing to rely on monthly average relative humidity (f(RH)) values when hourly humidity data are widely available, particularly in urban areas. One commenter argued that the EPA's proposed approach involves ''guessing relative humidity'' rather than relying on accurate, readily available measurements (Oklahoma DEQ, p. 1). The commenter stated that since relative humidity is highly variable and weather dependent, the proposed approach ''effectively undermines the capacity of the prescribed monitoring regime to identify periods when $PM_{2.5}$ adversely affects visibility.'' Other commenters supported this view, noting that relative humidity can vary substantially even within a 24-hour period, and that light extinction can be very sensitive to these changes. These commenters recommended that hourly or daily humidity measurements should be utilized in place of the proposed monthly average f(RH) values.

Some commenters also recommended that the EPA should utilize a 90 percent relative humidity screen rather than 95 percent cap for purposes of eliminating periods in which visibility impairment is due to rain or fog. These commenters claimed that under a 95 percent cap, both the average f(RH) values and the $PM_{2.5}$ visibility index values could be inflated in locations frequently affected by fog and/or precipitation. These commenters preferred the approach of excluding hours with relative humidity above 90 percent on the grounds that this approach would eliminate foggy/rainy hours irrespective of the frequency of occurrence.

The EPA does not agree with commenters who advocated using the revised IMPROVE algorithm. Both the original and the revised IMPROVE algorithms have been evaluated by comparing the calculated estimates of light extinction with coincident optical measurements. As discussed above in section VI.B.1.a.i, the revised algorithm was developed to address observed biases in the predictions using the original algorithm under very low and very high light extinction conditions, with further modifications and additions to better account for differences in particle composition and aging in remote areas.[187] However, the EPA does not believe that these same modifications and additions would necessarily be appropriate for calculating light extinction in urban areas. Instead, the EPA considers the original algorithm to be suitable for purposes of calculating urban light-extinction, although some adjustments may be appropriate for urban environments as well. The reasons why the original algorithm is suited to urban environments are discussed further below, along with adjustments that the EPA believes are likely appropriate based on the current (limited) state of knowledge.

First, the EPA considers that the multiplier of 1.8 used to convert OC to OM in the revised IMPROVE algorithm is too high for urban environments. The EPA is aware that there has been considerable debate within the research community about the appropriate multiplier to use to best represent urban environments. As discussed in Appendix F of the Policy Assessment (U.S. EPA, 2011a), the EPA used the SANDWICH mass closure approach (Frank, 2006) in the Urban Focused Visibility Assessment (U.S. EPA, 2010b) for purposes of calculating maximum daylight hourly $PM_{2.5}$ light extinction and evaluated which multiplier would produce 24-hour results most similar to the SANDWICH approach using 24-hour $PM_{2.5}$ organic carbon derived from the new Chemical Speciation Network (CSN) carbon monitoring protocol established in 2007.[188] Analyses presented in Appendix F of the Policy Assessment indicate that a multiplier of 1.6 is most appropriate for purposes of comparing the hourly $PM_{2.5}$ light extinction with calculated 24-hour extinction (see Appendix F, section F.6 for a full explanation). The EPA also considers this higher multiplier to be a better approach for urban CSN monitoring sites where the new measurements of organic carbon tend to be lower than those produced by the older NIOSH-type monitoring protocol

[187] Specifically, the revised IMPROVE algorithm incorporates additional terms to account for particles representing the different dry extinction and water uptake (f(RH)) from two size modes of sulfate, nitrate and organic mass, as well as adding a term for hygroscopic sea salt. There are also adjustments for the calculation of OM as 1.8*OC compared to 1.4*OC in the original algorithm to better account for the more aged PM organic components found in remote areas.

[188] Starting in 2007, the CSN adopted the IMPROVE monitoring protocol for the measurement of organic and elemental carbon using the IMPROVE analytical method and an IMPROVE-like sampler. The transition was completed in 2009. (See ''Modification of Carbon Procedures in the Speciation Network,'' *http://www.epa.gov/ttn/amtic/files/ambient/pm25/spec/faqcarbon.pdf*.)

(Malm, 2011). A multiplier of 1.6 is now used to calculate OM from OC measurements at CSN sites.

At the time of proposal, the EPA proposed to use the original IMPROVE algorithm with its 1.4 multiplier for converting OC to OM, but requested comment on whether this value was appropriate. Comments received by the Agency generally indicate that the OC-to-OM multiplier of 1.4 used in the original IMPROVE algorithm is too low for urban areas. Based on the analyses presented in Appendix F of the Policy Assessment, the EPA agrees with these commenters. However, the EPA also believes that it would be inappropriate to use a multiplier as high as 1.8 to convert OC to OM in urban areas. As noted by commenters, the organic mass contribution to visibility impairment can be large, and generally OM is significantly larger in urban areas compared to surrounding rural areas.[189] Because a large portion of the organic component of urban PM results from nearby emissions sources, the total OM mass is generally closer to the measured OC from which it is derived. This means it is appropriate to use a smaller multiplier to convert OC to OM in urban areas as compared to the value of 1.8 used in the revised algorithm, which is tailored to remote areas. The CASAC noted that urban OM includes fresh emissions and the EPA concluded in the Visibility Assessment that ‘‘the original version is considered more representative of urban situations when emissions are still fresh rather than aged as at remote IMPROVE sites’’ (U.S. EPA, 2010b, p. 3–19). Although the revised algorithm represents the best science of estimating extinction in *remote* areas with its aged aerosol, the commenters did not address how the EPA should modify the revised algorithm to best represent the more complex and different urban aerosol, particularly for OM. In light of all of these considerations, in particular the analyses the EPA conducted for Appendix F of the Policy Assessment and the fact that the monitoring method for organic carbon has recently changed in the CSN network, the EPA judges that a multiplier of 1.6 for urban areas would be most appropriate for purposes of calculating $PM_{2.5}$ light extinction in urban areas.[190] In formulating this judgment, the EPA recognizes that neither the original nor the revised IMPROVE algorithm has been tested for suitability in urban areas and that additional research is necessary to reduce the uncertainties about the most appropriate value for the OC to OM multiplier in urban environments. With regard to other changes between the original and revised IMPROVE algorithms, the EPA also does not believe that it would be appropriate to include a term for hygroscopic sea salt for urban light extinction, or to differentiate between different size modes of sulfate, nitrate, and organic mass as empirically defined by the revised IMPROVE algorithm. Unlike in some remote coastal locations, sea salt is not major contributor to light extinction in urban areas. Moreover, urban sources of salt include sanding of roads during the winter and those re-entrained particles are mostly in the coarse size range.

Like in remote areas, small and large size modes of sulfate, nitrate and organic mass would exist in the urban environment. However, the apportionment of the total fine particle concentration of each of the three $PM_{2.5}$ components into the concentrations of the small and large size fractions would likely need a different approach than that used for remote areas. This is because of the closer proximity of urban sources to their emissions. This is a particular concern not only for organic mass, which as explained previously has a large contribution from nearby urban emission sources, but also for $PM_{2.5}$ nitrate whose concentrations are also higher in urban areas compared to the surrounding regions. Thus, a higher portion of the total urban concentration may be in the small mode compared to remote areas and thus a different apportionment algorithm would be needed.

Finally, the EPA does not consider it necessary to employ site-specific Rayleigh light scattering terms in place of a universal Rayleigh light scattering value for purposes of calculating light extinction in urban areas for purposes of calculating the 90th percentile values. The site-specific Rayleigh value is most important to accurately estimate extinction on the best visibility days which is an essential metric for the regional haze program.

For all of these reasons, the EPA considers the original IMPROVE algorithm better suited to the task of calculating urban light extinction than the revised IMPROVE algorithm. However, the EPA does consider it appropriate to make certain adjustments to the original algorithm for purposes of calculating urban light extinction. As discussed above, the EPA believes it is appropriate to use a 1.6 multiplier to convert OC to OM in urban areas. In addition, the EPA believes it is appropriate to exclude the term for coarse particles from the equation. The EPA does not agree with commenters who suggested that coarse particles should be included in the calculated light extinction indicator. As noted in the proposal, $PM_{2.5}$ is the component of PM responsible for most of the visibility impairment in most urban areas. Currently available data suggest that $PM_{10-2.5}$ 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. While it is reasonable to assume that other urban areas in the desert southwestern region of the country may have conditions similar to the conditions shown for Phoenix, in fact few urban areas conduct continuous $PM_{10-2.5}$ monitoring. This significantly increases the difficulty of assessing the role of coarse particles in urban visibility impairment. For example, among the 15 urban areas assessed in this review, only four areas had collocated continuous PM_{10} data allowing calculation of hourly $PM_{10-2.5}$ data for 2005 to 2007. In addition, $PM_{10-2.5}$ is generally less homogenous in urban areas than $PM_{2.5}$ in that coarse particle concentrations exhibit greater temporal variability and a steeper gradient across urban areas than fine particles (U.S. EPA, 2009a, p. 3–72). This makes it more challenging to select sites that would adequately represent urban visibility conditions. Thus, while it would be possible to include a $PM_{10-2.5}$ light extinction term in a calculated light extinction indicator, as was done in the Visibility Assessment, there is insufficient information available at this time to assess the impact and effectiveness of such a refinement in providing public welfare protection in areas across the country (U.S. EPA, 2011a, pp. 4–41 to 4–42). Therefore, the EPA concludes that it is not appropriate to set a standard based on a calculated light extinction indicator that includes coarse particles at this time, and the calculated indicator should be based on $PM_{2.5}$ light extinction.

With regard to the suggestion by some commenters that the calculated light extinction indicator should be calculated using hourly humidity data,

[189] The difference between higher $PM_{2.5}$ mass in urban areas compared to surrounding regions, known as the urban excess, is largely attributed to organic mass (U.S. EPA, 2004b).

[190] The implications of this shift to a 1.6 multiplier for OC in urban areas for decisions about averaging time, level, and need for a distinct secondary standard are discussed further below in sections VI.C.1.c, VI.C.1.e, and VI.C.1.f, respectively.

the EPA disagrees that concurrent humidity measurements should be used. The use of longer-term averages for each monitoring site adequately captures the seasonal variability of relative humidity and its effects of visibility impairment, and this approach focuses more on the underlying aerosol contributions to visibility impairment and less on the day-to-day variations in humidity. This provides a more stable indicator for comparison to the NAAQS and one that is more directly related to the underlying emissions that contribute to visibility impairment.

With regard to the comments advocating the use of a 90 percent humidity screen as opposed to a 95 percent humidity cap, the EPA believes that relying on monthly average relative humidity values based on 10 years of climatological data appropriately reduces the effect of fog and precipitation. Although the approach of using a 95 percent humidity cap, as in the Regional Haze Program, includes some hours with relative humidity between 90–95 percent, the general approach of using a longer-term average for each monitoring site effectively eliminates the effect of very high humidity conditions on visibility at those locations.

Therefore, taking all of the above considerations and CASAC advice into account, the EPA continues to conclude that a calculated $PM_{2.5}$ light extinction indicator, similar to that used in the Regional Haze Program (i.e., using an IMPROVE algorithm as translated into the deciview scale), would be the most appropriate indicator to replace the current $PM_{2.5}$ mass indicator for a distinct secondary standard. Moreover, the EPA continues to conclude that this calculated indicator should based on the original IMPROVE algorithm, adjusted to use a 1.6 OC multiplier and exclude the term for coarse particles, in conjunction with monthly average relative humidity data (i.e., f(RH) values) based on long-term climatological means as used in the Regional Haze Program. A $PM_{2.5}$ visibility index defined in this way would appropriately reflect the relationship between ambient PM and PM-related light extinction, based on the analyses discussed in the proposal and reflecting the aerosol and relative humidity contributions to visibility impairment by incorporation of factors based on measured $PM_{2.5}$ speciation concentrations and climatological average relative humidity data. In addition, this type of indicator would address, in part, the issues raised in the court's remand of the 2006 $PM_{2.5}$ standards. Such a $PM_{2.5}$ visibility index would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by virtue of directly incorporating the effects of differences in $PM_{2.5}$ composition and relative humidity across the country.

c. Averaging Time

Few commenters specifically addressed the issue of averaging time. Those who did generally expressed the view that an hourly or sub-daily averaging time would be the most appropriate approach, as supported by CASAC and the EPA's own analyses in this review. These comments were generally consistent with the emphasis among all commenters on the desirability of adopting a directly measured light extinction indicator that could be measured on an hourly or sub-daily time scale. Some commenters noted that a standard based on a 4–6 hour averaging time would better capture peak daily light extinction while allowing stable signal quality; others urged EPA to adopt a 1-hour averaging time in conjunction with direct measurements. Commenters pointed to significant limitations associated with using a 24-hour averaging time, including the uncertainties in translating hourly or sub-daily visibility index values into 24-hour equivalent values. Some commenters criticized the analysis presented in the Policy Assessment comparing the 24-hour calculated light extinction values to the maximum daylight 4-hour calculated light extinction values. These commenters stated that the scatter plots and regressions presented in the Policy Assessment indicate there is considerable variation in the 24-hour vs. 4-hour relationship, and interpreted this to mean that 24-hour light extinction values are a poor surrogate for 4-hour values. For example, several industry commenters cited an analysis which noted that the correlation coefficient between the 24-hour and 4-hour values was as low as $r^2 = 0.42$ in Houston, and stated that the EPA was being overly ''optimistic'' in concluding that city-specific and pooled r^2 values in the range of 0.6 to 0.8 showed good correlation (UARG, Attachment 2, p. 27).

In addition, some commenters expressed concern over potential bias and greater uncertainty introduced by the inclusion of nighttime hours, noting that because relative humidity tends to be higher at night, inclusion of these hours could cause areas to ''record NAAQS exceedances that have no corresponding visibility impairment value'' (UARG, p. 36). Commenters also emphasized the poor fit of a 24-hour averaging time with the near instantaneous judgments about visibility impairment reflected in the visibility preference studies. Commenters also noted that there is greater hourly variation in PM concentrations and resulting visibility conditions in urban areas than in Class I areas; thus, while the Regional Haze Program uses 24-hour IMPROVE data, the commenters stated that a shorter averaging time is needed for an urban-focused $PM_{2.5}$ visibility standard. Some commenters objected to a 24-hour averaging time as unsupported by the record in this review: ''Because the science the Administrator relies on for the other elements of the proposed visibility standard is tied to short-term exposures to visibility impairment, the EPA has no basis for promulgating a standard that uses a 24-hour averaging time'' (API, p. 43). These commenters claimed that while the EPA may not have the information or infrastructure in place to allow the Agency to set a standard based on a 1-hour or other sub-daily averaging time, this does not justify moving to a 24-hour averaging time.

Among commenters supporting the proposed distinct secondary standard for visibility, many commenters recognized the limitations on monitoring methods and currently available data that led to the EPA's proposal to adopt a standard based on a 24-hour averaging time. Most of these commenters acknowledged that the lack of reliable hourly speciation data means that a 24-hour averaging time is the only workable approach for a standard based on calculated light extinction. Commenters advocating a distinct secondary standard for visibility therefore generally supported the proposal to adopt a 24-hour averaging time, at least as an interim approach until a directly measured light extinction indicator could be adopted in the future. This approach was also supported by a few industry commenters who noted that since a visibility index standard would be based on data from the IMPROVE and CSN monitors, which operate on a 24-hour basis with 1-in-3 (or 1-in-6) day sampling, ''it is imperative that EPA retain a 24-hour averaging time if a secondary visibility standard is promulgated'' (API, Attachment 2, p. 9).

In response to comments supporting a 1-hour or sub-daily (4- to 6- hour) averaging time in conjunction with a direct light extinction measurements, the EPA notes that, as discussed above in the response to comments on indicator, the Agency has concluded that a directly measured light extinction indicator is not an appropriate option in this review, independent of the decision on averaging time. Having reached the conclusion that a calculated $PM_{2.5}$ light extinction indicator would be most appropriate, the EPA has next considered what averaging time would be most desirable for such an indicator. As noted in the proposal, the EPA has recognized that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. Thus, the Agency agrees with commenters' general point that, as a starting premise, a sub-daily averaging time would generally be preferable.

However, as noted at the time of proposal and discussed above in section VI.B.1.c, important data quality uncertainties have recently been identified in association with currently available instruments that would be used to provide the hourly $PM_{2.5}$ mass measurements that would be needed in conjunction with an averaging time shorter than 24 hours. As a result, at this time the Agency has strong technical reservations about a secondary standard that would be defined in terms of a sub-daily averaging time. The data quality issues which have been identified, including short-term variability in hourly data from currently available continuous monitoring methods, effectively preclude adoption of a 1-hour averaging time in this review, given the sensitivity of a 1-hour averaging time to these data quality limitations. Even with regard to multi-hour averaging times, the EPA continues to conclude that the data quality concerns preclude adoption of a sub-daily averaging time.

Moreover, analyses conducted for the Policy Assessment indicate that $PM_{2.5}$ light extinction calculated on a 24-hour average basis would be a reasonable and appropriate surrogate for $PM_{2.5}$ light extinction calculated on a 4-hour basis. The scatter plots comparing 24-hour and 4-hour calculated $PM_{2.5}$ light extinction in the Policy Assessment (U.S. EPA, 2011a, Figures G–4 and G–5) do show some scatter around the regression line for each city. This was to be expected, since the calculated 4-hour light extinction includes day-specific and hour-specific influences that are not captured by the simpler 24-hour approach. Overall, however, in the EPA's view, both the city-specific and pooled 15-city 24-hour vs. 4-hour comparisons show strong correlation between the two averaging times. Moreover, the 90th percentile design values calculated for 4-hour vs. 24-hour light extinction are much more closely correlated than are the values for individual days in particular urban areas calculated using these two approaches. Thus, while the EPA agrees with commenters who pointed out the relatively low correlation between 4- and 24-hour values in cities such as Houston, the Agency points out that the correlations of 90th percentile values are much higher, particularly when one considers the average values across urban areas. In general, the 90th percentile values line up better and demonstrate closer to a one-to-one relationship.

The EPA has conducted a reanalysis (Frank *et al.,* 2012b) of the relationships between estimated 24-hour and 4-hour visibility impairment based on the variety of metrics discussed in Appendix G of the Policy Assessment that further supports this finding. The reanalysis more appropriately considered the uncertainty of the calculated 4-hour values. It also considered the effect of changing the OC to OM multiplier used in urban areas with the new CSN monitoring protocol from 1.4 to 1.6. The revised analysis shows that the 24-hour values are generally closer to the 4-hour values than originally estimated.

Since conclusions in the proposal about the relationship between 4-hour and 24-hour values were drawn not just on the basis of the city-specific results but also on the more robust 90th percentile values, the EPA disagrees with commenters who state that the Agency was overly optimistic in considering 24-hour values an appropriate surrogate for 4-hour values. Also, it is appropriate to focus on the 90th percentile design value comparison since the design values would determine attainment status and the degree of improvement in air quality that could be expected in areas instituting controls to meet the NAAQS. Therefore the EPA does not agree with commenters who state that a 24-hour averaging time cannot serve as an appropriate surrogate for sub-daily periods of visibility impairment. On the contrary, the EPA continues to conclude, on the basis of this analysis, that $PM_{2.5}$ light extinction calculated on a 24-hour basis is a reasonable and appropriate surrogate for sub-daily $PM_{2.5}$ light extinction calculated on a 4-hour basis.

The EPA recognizes that the effect of adopting a 24-hour averaging time may be to smooth out some of the hour-by-hour variability in visibility index values. (Indeed, this is true if we compare a 4-hour averaging time to a 1-hour averaging time as well.) Hour-specific influences which would be evident if an hourly or sub-daily averaging time were to be used will be masked to some extent when those hours are averaged together with other hours. This means, in part, that a 24-hour averaging time may effectively reduce peak values by means of averaging them together with other hours, which may have lower values. However, given the well documented variability in hourly visibility conditions, especially in urban areas, as noted by commenters, it is reasonable to assume that in some cases peak hours may be significantly influenced by atypical conditions, making it appropriate to adopt an averaging time that is sufficiently long to ensure that hour-specific influences are balanced against more typical conditions. Perhaps even more important is the concern that many peak hourly measurements may be significantly influenced by atypical instrument performance; this reinforces the conclusion that it is appropriate to adopt a longer averaging time, to ensure that hour-specific uncertainties are balanced against more robust measurements.

Thus, in agreement with commenters who supported a daily averaging time, the EPA concludes that a 24-hour averaging time would be appropriate for a distinct secondary standard based on a calculated $PM_{2.5}$ light extinction indicator.

d. Form

The EPA received very few comments with regard to the proposal to adopt a 90th percentile form, averaged over 3-years, in conjunction with a $PM_{2.5}$ visibility index and a 24-hour averaging time. One commenter stated that it was inappropriate to use a 90th percentile form, noting that this would result in the exclusion of a minimum of 36 days of data annually. The commenter expressed particular concern that this proposed approach, in combination with a 24-hour standard based on an unadjusted CPL, would not capture the worst visibility impairment and that this would undermine "the intent of setting a meaningful secondary visibility standard" (AMC, *et al.,* p. 2). Another commenter argued that the EPA had provided no scientific basis for why the 90th percentile form was suitable, and claimed that the Agency was making "a somewhat arbitrary judgment that people's welfare would be affected only if adverse urban visibility were to occur more than 10 percent of the time'' (API, Attachment 2, p. 4).

On other hand, a few commenters who appeared to generally support the proposal to use a 90th percentile form advocated averaging the 90th percentile values over longer time periods, arguing that averaging over only 3 years would not provide a stable assessment of visual air quality in the West because this time period is insufficient to properly account for western drought and fire cycles. These commenters pointed to the approach in the Regional Haze Program of averaging visibility impairment over 5 years, and noted that even within this longer time period data can be significantly influenced by high emissions during significant fire years.

The EPA disagrees with all of these comments. With regard to the comment opposing the 90th percentile form as inappropriately excluding the worst visibility days, the EPA notes that there is a significant lack of information on, and a high degree of uncertainty regarding, the impact on public welfare of the number of days with visibility impairment over the course of a year. For example, the visibility preference studies used to derive the range of CPLs considered in this review offered no information regarding the frequency of time that visibility levels should be below those values. Based on this limitation, the EPA concluded in the Policy Assessment that it would not be appropriate to consider eliminating all exposures above the level of the standard and that it was reasonable to consider allowing some number of days with reduced visibility. Recognizing that the Regional Haze Program focuses attention on the 20 percent worst visibility days (i.e., those at or above the 80th percentile of visibility impairment), the EPA continues to believe, as noted in the proposal, that a percentile well above the 80th percentile would be appropriate to increase the likelihood that all days in this range would be improved by control strategies intended to help areas attain the standard. Focusing on the 90th percentile, which represents the median of the distribution of the 20 percent worst visibility days, could be reasonably expected to lead to improvements in visual air quality on the 20 percent most impaired days. Thus, the EPA has made a reasoned judgment based on a full consideration of the upper end of the distribution of visibility impairment conditions and continues to conclude that it is appropriate to focus on the 90th percentile of visibility impairment values.

With regard to comments requesting the EPA adopt a longer multi-year averaging period for the 90th percentile values, the EPA disagrees that it would be appropriate to average the 90th percentile values over periods longer than 3 years. The EPA recognizes that a multi-year percentile form offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. Utilizing a 3-year average form provides stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year. The Agency has adopted this approach in other NAAQS, including the current secondary 24-hour $PM_{2.5}$ NAAQS, which has a 98th percentile form averaged over 3 years. However, adopting a multi-year averaging period longer than 3 years would increase the number of days with visibility impairment above the target level of protection and would therefore reduce the protectiveness of the standard. Based on this the EPA does not believe it would be appropriate to average 90th percentile values over a period as long as five years. Therefore, the EPA continues to conclude that a 90th percentile form, averaged over 3 years, would be appropriate, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and a 24-hour averaging time.

e. Level

With regard to level, commenters focused on two main themes. First, a large number of commenters addressed the information available from the public preference studies with regard to the acceptability of various levels of visual air quality. These comments, which are discussed in subsection VI.C.1.e.i below, address the EPA's use of visibility preference studies as the basis for the selection of a range of appropriate levels for the Administrator to consider. Many commenters challenged the use of these studies as the basis for setting a distinct secondary standard, arguing that limitations in these studies rendered them an unsuitable and insufficient basis on which to establish such a standard. Second, commenters expressed different views as to what level(s) of a distinct secondary standard would be appropriate, if the EPA were to set such a standard. These comments reflected consideration of the results of the public preference studies as well as analyses conducted in the Visibility Assessment and the Policy Assessment, as discussed in the proposal. Comments addressing the appropriateness of specific levels are discussed in subsection VI.C.1.e.ii below.

i. Comments on Visibility Preference Studies

A majority of commenters expressed the view that the existing preference studies provide an insufficient basis for selection by the Administrator of an appropriate level of public welfare visibility protection for a national standard. These commenters highlighted a number of limitations and uncertainties (enumerated below) associated with these studies as support for this view. In contrast, other commenters felt that despite certain limitations, these studies do provide a sufficient basis on which the Administrator can select an appropriate level of a standard to provide national public welfare visibility protection. The remainder of this section organizes and discusses these comments under four broad topic areas, including: (a) Limitations and uncertainties associated with the visibility preference studies; (b) preference study methods and design; (c) use of preference study results for determining adversity; (d) the appropriateness of using regionally varying preference study results to select a single level for a national standard.

(a) Preference Study Limitations and Uncertainties

A large and diverse number of limitations and uncertainties associated with the visibility preference studies have been identified and discussed in the public comments. Many of these same limitations and uncertainties were also identified and discussed by the EPA in the various documents developed throughout this review. The most important and fundamental limitations and uncertainties will be discussed here in the preamble, while more specific, unique or detailed comments will be addressed in the Response to Comments document.

The primary or most frequent limitation cited by many commenters relates to the small number of preference studies that are available in this review. In particular, some commenters note that these preference studies cover just four locations, only three of which occur in the U.S., that the two studies conducted in Washington, DC were pilot studies, not full preference studies, and/or that three of the preference studies were conducted in the West, while only one was conducted in the East, providing only limited geographic coverage. Typically, these same commenters also pointed out that taken together, these limited studies only included a total of 852 participants, which they claimed was too small a sample size and unrepresentative nationally. These commenters thus concluded that there is insufficient information, both geographically and demographically, upon which to select a national level of a visibility index for purposes of visibility protection.

In contrast, several commenters stated support for using the preference studies, concluding they provide an adequate basis, in spite of their limited nature. In particular, AMC *et al.* state:

> We believe that these studies provide sufficient results to inform setting a national visibility standard. While the number of studies is small, they do incorporate spatial variation and, in the case of Denver and Phoenix, varied populations* * *. EPA should have confidence, rather than uncertainty, in the fact that these studies used different methods and respondents and yield a range of 20–24 dv, with one outlier of 29. (AMC, *et al.,* pp. 6–7)

Regarding the first group of commenters, the EPA notes that it is well aware of the limited nature of the information, which it has described in great detail in the Integrated Science Assessment, Visibility Assessment, and Policy Assessment, as well as in section VI.B.2 of the proposed rule (77 FR 38973). The EPA further notes, however, that limited information does not preclude the Administrator from making judgments based on the best available science, taking into account the existing uncertainties and limitations associated with that available science. Thus, in reaching judgments based on the science, the Administrator appropriately weighs the associated uncertainties. The CASAC supported this view and concluded that the available information provided a sufficient basis on which the Administrator could form a judgment about requisite PM-related public welfare visibility protection. Specifically, CASAC stated ''[t]he 20–30 deciview range of levels chosen by EPA staff as 'Candidate Protection Levels' is adequately supported by the evidence presented'' (Samet, 2010b, p. iii). As discussed in the proposed rule (77 FR 38990), the Administrator recognized and explicitly took into account the uncertainties and limitations in the science in determining an appropriate degree of protection when she proposed a level at the upper end of the recommended range. As discussed below, the Administrator continues to be mindful of these uncertainties and limitations in reaching her final determination regarding what constitutes an appropriate degree of protection with respect to PM-related visibility impairment.

With respect to the comments of AMC *et al.,* the EPA agrees that these studies provide a sufficient basis to inform the Administrator's judgments regarding an appropriate level of protection from PM-related visibility impairment, but she recognizes that these studies, which are the only studies before her, are a limited source of information. However, the EPA does not agree that the Washington, DC, results represent an outlier, and thus the EPA believes these results are appropriately included in the range identified for the Administrator to consider.

Some commenters made the point that the EPA relied on much of this same evidence to reach the conclusion in 2006 that the information was too limited to allow selection of a national standard. For example, API stated:

> [T]he bulk of the VAQ preference studies were available during the previous PM NAAQS review and were considered by the Agency in its establishment of the 2006 p.m. secondary NAAQS * * *. The Proposed Rule does not mention this fact and does not explain why many of these same studies now compel EPA to propose this new secondary NAAQS * * *. The Proposed Rule notes in passing that, since the last review of the PM NAAQS, 'limited information that has become available regarding the characterization of public preferences in urban areas has provided some new perspectives on the usefulness of this information in informing the selection of target levels of urban visibility protection.' 77 Fed. Reg. at 38969/2. It is a serious oversight that the Proposed Rule makes no attempt to explain what that information is or how it affects the interpretation of the VAQ preference studies. This 'limited information' is an apparent reference to information provided by Dr. Anne Smith. (API, p. 37)

The EPA disagrees with these commenters. First, the EPA disagrees that it failed to distinguish between studies that were available in the previous review and the current review. The discussion in section VI.A.1 of the proposal specifically identifies the studies from Denver, Phoenix and British Columbia (77 FR 38967/2) as being considered in the last review. The EPA further disagrees with the implication that it is being circumspect about identifying the ''limited information that has become available regarding the characterization of public preferences in urban areas.'' Beginning in section VI.A.3 of the proposed rule (77 FR 38969), the EPA was clear about what information, both preexisting and new, it relied upon in this review to inform its views and provide the basis for its proposal. In section VI.B.2, the EPA elaborates on the specific information, tools, methods and data which are considered in relation to the public preference studies, including the new information available since the last review.

As noted above and in the proposal, in addition to the substantial PM urban air quality information and analyses new to this review, there are three other sources of information that have specifically ''provided some new perspectives on the usefulness of'' the preference studies ''in informing the selection of target levels of urban visibility protection'' (77 FR 38969). They include: (1) Results from additional urban visibility preference study experiments conducted for Washington, DC by Smith and Howell (2009) which added to the preference data for that location and shed light on the role of location in preference responses; (2) a review and reanalysis (Stratus Consulting, 2009) of the urban visibility public preference studies from the four urban areas, including the newly available Smith and Howell (2009) experiments which examined the similarities and differences between the studies and evaluated the potential significance of those differences on the study results; and (3) additional analyses, including most importantly a logit analysis (Deck and Lawson, 2010, as discussed in Chapter 2 and Appendix J of the Visibility Assessment), which was requested and reviewed by CASAC, which showed that each city's responses represented unique and statistically different curves. Taken together, these sources contributed to the EPA's current knowledge and understanding of each survey study's results, the appropriateness of comparing each study's results to the others, and the key uncertainties relevant to data interpretation. In addition, in the last review the decision to not adopt a distinct secondary standard was remanded as contrary to law and failing to provide a reasoned explanation for the decision. As such it is not appropriate for purposes of comparison with the Administrator's judgment and reasoning in this review.

(b) Preference Study Methods and Design

In addition to the limitations and uncertainties noted above, many comments also asserted the methodologies used in the preference studies are fundamentally flawed. Many commenters cited some of the same issues that have already been identified by the EPA as sources of uncertainty and potential factors in producing the statistically different study results (see section VI.B.1.b above). As noted above, the EPA is well aware of the issues raised regarding the adequacy of the preference studies to serve as a basis for a secondary NAAQS (see 77 FR 38975) and solicited comment on how these uncertainties should be considered (see 77 FR 38990). Most of these same commenters also pointed to an assessment of the preference studies methodology provided by Smith and Howell (2009) as the basis for their views, as indicated by the following comments:

Smith and Howell (2009) show that VAQ preference study outcomes are malleable and depend entirely on the design of the study. Accordingly, such studies do not identify any meaningful threshold of acceptable visibility conditions. Despite Smith and Howell's conclusions, EPA continues to assert that the VAQ preference studies can be used to identify minimally acceptable visibility conditions even though the Agency has never provided any valid scientific basis for discounting the Smith and Howell (2009) results. (API, p. 38)

Well-controlled preference studies discussed by Anne Smith of Charles River Associates at the March 2010 CASAC meeting demonstrated that the judgment of panel members was affected by the order in which photographs were presented and tendency to identify the middle of the range of visibility degradation as a threshold of acceptability. This points to a potential flaw in these studies and that artifacts caused by these tendencies may have influenced study results. Dismissing these inherent flaws in the existing preference studies and then using these studies to set a secondary NAAQS is arbitrary and capricious. (API, Attachment 2, p. 12)

EPA also fails to acknowledge that the only study conducted since the last review rebuts the validity of the VAQ preference studies previously conducted. (UARG, Attachment 2, p. 28)

As is explained in a more detailed discussion in the Response to Comments document, the EPA disagrees that the study conducted by Smith and Howell (2009) supports the conclusion that the preference study methodologies were fundamentally flawed; however, the EPA notes that their experiments do identify areas where additional research would be useful to further inform our limited understanding of public preferences in urban areas. The EPA views the Smith and Howell experiments as increasing the EPA's knowledge and understanding of the findings of the 2001 Washington, DC focus group pilot study (Abt, 2001) in several important ways, although this information still remains limited overall. Specifically, the Smith and Howell results suggest: (1) The 2001 results, while based on a small sample size of 9, were consistent with results from a larger sample of the general Washington, DC population; (2) an individual's preferences for visibility in one location may not depend on whether they live in that location; and (3) presentation method (i.e., changing from slide projection to computer monitor) did not appear to affect the reported preferences.

(c) Preference Study Results and Adversity

A number of comments were received regarding the EPA's use of preference study results to make the determination that adverse $PM_{2.5}$-related visibility effects on the public welfare are occurring. In this context, several commenters questioned whether the EPA had made the case that unacceptable levels of visual air quality based on preference study results alone can be equated with an adverse public welfare effect. These commenters suggested that unless preference study information is linked to personal comfort and well-being or other associated welfare effects, it cannot form the basis of a determination of adversity. For example, Kennecott Utah Copper LLC stated that:

Thus, EPA seemingly was building the foundation for a determination of what constitutes an adverse effect on visibility in the context of public welfare. However * * * EPA subsequently veered toward an oversimplified focus on public acceptance of visibility conditions * * *. EPA's discussion of visibility in the Policy Assessment and its proposed rule in the Federal Register focuses entirely on ''acceptable'' and ''unacceptable'' visual air quality and make no mention of an ''adverse effect'' in the context of visibility. EPA's reliance on only 3 urban preference studies represents a paucity of data and a wholesale abandonment of any effort to seek a scientifically measurable adverse effect. (Kennecott Utah Copper LLC, p. 26)

In response, the EPA first notes that the definition of effects on welfare included in section 302(h) of the CAA identifies both visibility and the broader category of effects on personal comfort and well-being as effects on welfare. In setting a secondary standard to address visibility impairment, the EPA considers the effect on the public from impairment of visibility as a separate and distinct welfare effect in its own right. The EPA is not required to translate this into terms of personal comfort and well-being, as visibility impairment is designated explicitly by Congress as an effect on welfare. While there may be a large degree of overlap among these different welfare effects, the EPA properly focuses on evaluating all of the information before the Agency on the effect visibility impairment has on the public, whether or not this impairment would also be categorized as having an adverse effect on personal comfort and well-being. It is in the context of all of this information that the EPA makes the judgment as to the appropriate degree of protection from known and anticipated adverse effects on the public from visibility impairment. The EPA recognizes that there is uncertainty about the degree of adversity to the public welfare associated with PM-related visibility impairment. However a secondary standard is designed to provide protection from ''known or anticipated'' adverse effects, and a bright line determination of adversity is not required in judging the requisite degree of protection under section 109(b)(2). Furthermore, the EPA disagrees that it has abandoned its consideration of visibility-related impacts on the welfare effect of personal comfort and well-being, as is made clear in the following quote:

Research has demonstrated that people are emotionally affected by low visual air quality, that perception of pollution is correlated with stress, annoyance, and symptoms of depression, and that visual air quality is deeply intertwined with a ''sense of place,'' affecting people's sense of the desirability of a neighborhood (U.S. EPA, 2009a, section 9.2.4). *Though it is not known to what extent these emotional effects are linked to different periods of exposure to poor visual air quality, providing additional protection against short-term exposures to levels of visual air quality considered unacceptable by subjects in the context of the preference studies would be expected to provide some degree of protection against the risk of loss in the public's ''sense of well-being.''* (77 FR 38973/1, emphasis added)

The approach taken to address such qualitative, but policy-relevant, information in this review is the same as in other NAAQS reviews. The review is initiated with a comprehensive assessment of all possible public health and welfare effects associated with PM in the Integrated Science Assessment. Then policy-relevant effects for which there is sufficient quantitative information to allow a determination of the change in risks associated with incremental changes in air quality are assessed (in this review, in the Visibility Assessment) and used to provide a quantitative basis to inform the selection of an appropriate range of levels for further consideration in the Policy Assessment. In the Policy Assessment, the EPA considers all important policy-relevant evidence and information, both quantitative and qualitative, in making recommendations regarding the range of policy options appropriate for the Administrator to consider. It is in the context of all of this information that the Administrator makes her final judgment as to the appropriate degree of protection from known and anticipated adverse effects on the public from visibility impairment.

Another issue raised in the comments regarding adversity is the EPA's decision to use the 50 percent acceptability criterion from the public preference studies in determining candidate protection levels of visibility impairment for the selection of a national level of visibility protection. For example, AMC *et al.* recommended ''a 75% acceptability criterion as a target that is in line with protecting the broader public from the negative effects of visibility impairment'' (AMC, *et al.,* p. 9).

In the Visibility Assessment, the EPA noted that the use of the 50 percent acceptance level for urban visibility was first presented in Ely *et al.* (1991) (U.S. EPA, 2010b, p. 2–5). Ely discussed the use of the 50 percent acceptability criterion as a reasonable basis for setting an urban visibility standard.

> The standard was determined based on a 50% acceptability criterion, that is, the standard was set at the level of extinction that would divide the slides into two groups: those judged acceptable and those judged unacceptable by a majority of the people in the study. The criterion is politically reasonable because it defines the point where a majority of the study participants begin to judge slides as representing unacceptable visibility. It is also consistent with psychological scaling theory which indicates that a ''true score'' exceeds a standard when more than 50% of the ''observed scores'' exceed that standard. (Ely *et al.,* 1991, p. 11)

As Ely described, the 50 percent acceptability criterion and the preference study conducted by Ely were used as the basis for setting the level of the Denver Visibility Standard in 1990. That same criterion was judged appropriate and selected for use in the Phoenix preference study (BBC research, 2003) and as the basis for setting the level of the Phoenix Visibility Standard in 2003. Most recently, the 50 percent acceptability criterion has been recommended by the British Columbia Visibility Coordinating Committee as the basis for the visibility standard currently under consideration by British Columbia, Canada. Furthermore, CASAC supported this approach, while recognizing the uncertainty associated with this issue. Specifically, CASAC agreed that ''the 50th percentile for the acceptability criteria is logical, given the noted similarities in methodologies employed in the 4 study areas. * * * In terms of choosing a specific percentile from the preference studies, we note that there may not be a ''preferred'' one, but in assessing preference studies to propose a PM secondary NAAQS, the 50th percentile is sufficient, as it is the basis for existing visibility indexes used in the Denver/Colorado Front Range and Phoenix metropolitan areas'' (Samet, 2009c, pp. 8–9). Therefore, after considering the information that served as the original basis for its selection as described in Ely *et al.,* 1991, and given its acceptance and use in existing visibility programs, the EPA continues to conclude, consistent with the advice of CASAC, that it is reasonable to use the 50 percent acceptability criterion in determining target levels of protection from visibility impairment.

(d) Appropriateness of using regionally varying preference study results to select a single level for a national standard.

A number of commenters raised concerns regarding the bases for and implications of the differences observed in the preference study results, concluding that these results were due to regionally varying factors and thus could not be used to set a national standard. For example, some commenters asserted that because the confidence intervals around the four 50 percent acceptability levels do not overlap at all, and because there are variations in preference study designs and inherent differences in the visual setting among cities and panels, the four preference curves and their associated 50 percent dv values are city-specific and statistically different. The commenters concluded, therefore, that it was inappropriate to aggregate the 50th percentile dv values from multiple studies and that they should instead be evaluated individually.

Other commenters expressed the related view that the preference study results cannot be used to set a national standard for visibility impairment because the results show that visibility preferences vary regionally. For example, API stated that:

> The 'one-size-fits-all' approach * * * is not viable because it does not account for regional and city-specific factors that have been made evident in the disparity of preference study data * * *. It is well known, for example, that the level of light extinction to which people in different areas of the country are accustomed, as well as the urban setting, are the primary factors that affect a person's visual perception of an urban vista. Thus, the degree to which extinction threshold can be related to human welfare is inevitably regionally-dependent. (API, Attachment 2, p. 4)

Some of these commenters argued that because acceptable visual air quality is regionally dependent, it would be more appropriate to develop distinct visibility standards at the state or local level. Others pointed out that areas which lack ''important visibility vistas'' might not need standards at all, since flat areas without significant terrain have a limited maximum visual range (NEDA/CAP, p. 3).

Other commenters stated that due to regionally varying factors, such as relative humidity, it is not possible to select a single level for a national standard to protect visibility across the United States. In particular, these commenters pointed to differences between Eastern and Western areas, arguing that a single national standard could not offer the appropriate degree of protection in locations with distinct characteristics. For example:

> [T]he proposed method falls short because it is not temporally or geographically representative enough to have any meaning * * *. The uncertainty evidenced in these studies and the non-uniformity between the western and eastern vistas makes it impossible at this time to set an acceptable light extinction value that would appropriately address visibility concerns in non-Class I areas. (New York DOH/DEC, pp. 5–6)

The EPA agrees that the preference curves and the 50 percent dv levels are separate and distinct data points representing four different VAQ preference curves for four unique urban scenes. However, the EPA does not consider the fact that the four curves are distinct as a weakness of the approach or a reason that the results cannot be compared. In addition, the EPA does not agree that the study results necessarily support a conclusion that preferences are regionally dependent. In particular, the EPA notes that the results of Smith and Howell (2009) which show that participants in Houston and Washington, DC did not have significantly different views on acceptable air quality in Washington, DC, provide limited support for the conclusion that people's preferences differ less because of where they live and more because of the scene they are viewing.

On the other hand, the existing literature indicates that people's preferences for VAQ depend in large part on the characteristics and sensitivity of the scene being viewed. The EPA understands there is a wide variety or range of urban scenes within the United States. These sensitive urban scenes include those with natural vistas such as the Colorado Rocky Mountains as well as those with iconic man-made urban structures like the Washington Monument. The EPA believes that the scenes presented in the four urban areas include important types of sensitive valued urban scenes and therefore, when considered together, can inform the selection of a level of acceptable urban VAQ at the national scale, taking into account the variation across the country evidenced in the studies. This is discussed further in the next section, below.

The EPA does agree with commenters that there are regionally varying factors that are important to take into account when setting a national standard for visibility protection. Section VI.A above regarding the history of the secondary PM NAAQS review discusses the evolution of the EPA's understanding regarding the regional differences in PM concentrations, relative humidity and other factors. As a result, the current review has gone to great lengths to address these factors, leading to the EPA's proposal to use the IMPROVE algorithm to calculate light extinction in order to take into account the varying effects of relative humidity and speciated PM. While this approach does not result in a uniform level of ambient $PM_{2.5}$, it does ensure a nationally uniform level of visibility protection. The EPA refers the reader to other sections of the final rule, including sections VI.B.1.a, VI.B.1.c, VI.C.1.b and VI.C.1.f, and the Response to Comments document for a more detailed response as to how it is taking these variables into account.

ii. Specific Comments on Level

The EPA received relatively few comments endorsing a specific level for a distinct secondary standard for visibility. In general, commenters who opposed setting a distinct secondary standard at this time did not address the question of what level would be appropriate if the EPA were to set a distinct secondary standard for visibility; similarly, commenters who supported adopting a distinct secondary standard at this time generally did not recommend a specific level. However, a few commenters did provide comments in support of a specific level or range of levels, with some commenters advocating standards at the upper end of the range of proposed levels (i.e., 30 dv), while others supported levels below the lower end of the proposed range (i.e., below 28 dv).

As discussed above, a large number of commenters argued that the currently available data are insufficient to determine what constitutes a standard that would be neither more nor less protective than necessary and that no standard should be set at this time. These commenters pointed to the limitations and uncertainties in the preference studies discussed above as the basis for this claim. These commenters pointed to significant variation in the results of the preference studies in support of their arguments that the studies should not be used to derive a level for a distinct secondary standard for visibility. For example, one consultant cited by several industry commenters argued that the proposed level of 28 or 30 dv did not reflect the substantial difference in visibility preferences between the East and the West reflected in the preference studies (UARG, Attachment 2, p. 11), and that it did not reflect the full range of preferences (i.e., potential 50 percent acceptability levels) likely to exist nationwide (UARG, Attachment 2, p. 19). This commenter further objected to the EPA's proposal for a level of 28 or 30 dv on the grounds that the EPA had inaccurately adjusted 4-hour values into 24-hour values. Based on his analysis, the consultant concluded that ''a range of adjusted values from 28 to 32 dv is needed'' to account for the majority of the spread between the 4-hour vs. 24-hour equivalent values at the upper end of the distribution of values.

A number of commenters questioned whether the proposed range of levels was appropriate. One industry commenter claimed that the EPA had not explicitly justified why a standard within the proposed range was requisite, stating that ''EPA makes no attempt to explain how the proposed level of the standard is neither lower nor higher than necessary to protect public welfare'' (NSSGA, p. 15). Arizona DEQ noted that since the proposed calculated light extinction indicator excluded coarse particles and Rayleigh scattering, the proposed levels of 28 or 30 dv were inconsistent with the visibility preference studies, which considered total light extinction. Noting these perceived problems with the proposed range of levels, a few commenters noted that if the EPA were to set a distinct secondary standard, the level should be set no lower than 30 dv, ''to account for inconsistent value judgments, a great deal of spatial and temporal variability, and a very high level of uncertainty'' (Texas CEQ, p. 7).

In contrast, some commenters supporting the EPA's proposal for a distinct secondary standard for visibility stated that the proposed range of levels from 28–30 dv was insufficiently protective based on a 24-hour averaging time, and recommended a lower level for the visibility index standard. These commenters expressed the view that the proposed levels of 28 or 30 dv represented neither adequate surrogates for equivalent 4-hour values, as the EPA claimed, nor sufficiently protective levels based on recent air quality data. Several commenters stated that the EPA's own analyses suggested that a standard set at a level of 28 or 30 dv was insufficiently protective based on a 24-hour averaging time. One commenter emphasized that the Policy Assessment had indicated a level between 25–28 dv was appropriate for a standard calculated on a 24-hour average, and encouraged the EPA to adopt a standard level of 25 dv. Several environmental groups provided comments stating that a 24-hour average would underestimate a 4-hour value by 13–42 percent and certain areas of the country—particularly the Northeast—would be affected disproportionately. These commenters suggested that a 24-hour $PM_{2.5}$ visibility index standard should be set at a level of 18.6–20 dv. The Department of the Interior pointed to recent air quality data indicating that visibility on the 20% worst days in several large metropolitan areas, including Birmingham, Fresno, New York City, Phoenix, and Washington, DC was below 29 dv. While noting that these calculations were based on IMPROVE calculations which include contributions from coarse PM mass, DOI expressed the view that the proposed level of 28 to 30 dv would not provide adequate visibility protection compared to the current 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ and recommended that the standard be set at a level of 25 dv consistent with the results of the Phoenix visibility preference study.

In contrast, the states of Arizona and Colorado submitted comments arguing that the visibility preference studies conducted in Phoenix and Denver, respectively, were designed to address a specific local problem and that the results of these studies were not an appropriate basis for selecting the level of a national standard. For example, Arizona DEQ noted:

> The cited studies were conducted considering total light extinction; including extinction resulting from particulate matter and Rayleigh scattering. Visibility impairment due to coarse particulate matter can be an important contributor in Arizona, specifically in the Phoenix area where ongoing measurements have been made. Therefore, ADEQ believes that the proposed levels of the secondary visibility standard are inconsistent with applicable urban studies. (Arizona DEQ, p. 2)

Similarly, the Colorado Department of Public Health and the Environment noted that the Denver visibility standard was designed to address ''brown clouds'', i.e., strong inversions that occur in the Denver metropolitan area, and that this standard ''is based on a specific view of Denver'' associated with particular sight paths and direct measurement methods. The commenter stated that this standard ''is applicable only to this location,'' and that these limitations make it potentially unsuitable for application as ''a national secondary standard, particularly a proposed standard that does not use a direct measurement method'' (Colorado DPHE, p. 2).

While acknowledging the uncertainties and limitations associated with the visibility preference studies as discussed above, the EPA continues to conclude, as did CASAC, that the preference studies are appropriate to use as the basis for selecting a target level of protection from visibility impairment. However, the EPA agrees with commenters who emphasize the high degree of variability in visibility conditions and the potential variability in visibility preferences across different parts of the country. In light of the associated uncertainty, as noted in the proposal, the Administrator judged it appropriate to establish a target level of protection equivalent to the upper end of the range of Candidate Protection Levels (CPLs) identified in the Policy Assessment and generally supported by CASAC. Thus, the EPA proposed to set a 24-hour visibility index standard that would provide protection equivalent to the protection afforded by a 4-hour standard set at a level of 30 dv. In light of the comments received on the proposal, in particular comments emphasizing the uncertainty and variability in the results of the public preference studies, the EPA continues to conclude that this approach is warranted, and that it is appropriate to set a target level of protection equivalent to the protection that would be afforded by a 4-hour, 30 dv visibility index standard.

Moreover, the EPA disagrees with commenters who argued that the EPA's approach for translating 4-hour CPLs into equivalent 24-hour values was inappropriate. In adjusting 4-hour values for purposes of defining an appropriate level for a 24-hour standard, the EPA noted at the time of proposal that there were multiple approaches for estimating generally equivalent levels on a city-specific or national basis. While expressing the view that it was appropriate to consider the two approaches with the highest r^2 values (Approaches A and B in Appendix G of the Policy Assessment),[191] which used regressions of 90th percentile light extinction values, the EPA determined it would also be appropriate to consider the city-specific estimates resulting from Approaches C and E which showed greater variability than the aggregated estimates. Approaches C and E generated a range of city-specific estimates of generally equivalent 24-hour levels that encompassed the range of levels considered appropriate for 4-hour CPLs, including the CPL of 30 dv at the upper end of that range. This information provided support for using the same CPL for a 24-hour standard as for a 4-hour standard, since no single approach could generate an equivalent 24-hour standard level in each urban area for each CPL. The EPA continues to conclude, as it did at the time of proposal, that using an unadjusted 4-hour CPL for purposes of establishing a target level of protection for a 24-hour standard is appropriate because this approach places more emphasis on the relatively high degree of spatial and temporal variability in relative humidity and fine particle composition observed in urban areas across the country, consistent with EPA's reanalysis discussed below.

The EPA has conducted a reanalysis (Frank *et al.,* 2012b) of the relationships between estimated 24-hour and 4-hour visibility impairment based on the variety of metrics discussed in Appendix G of the Policy Assessment. The reanalysis has more appropriately considered the uncertainty of the calculated 4-hour values. The revised analysis shows that the 24-hour equivalent level is generally closer to the 4-hour value at the upper end of the range of CPLs than originally estimated, as can be seen in the results for Approaches B, C, and D.[192] For example, the reanalysis indicates that Approach B yields an adjusted 24-hour CPL of 29 dv[193] as generally being equivalent to a 4-hour CPL of 30 dv, while Approach C yields a 24-hour equivalent CPL of 29 dv averaged across cities and a range of city-specific values from 25–36 dv.[194] [195] Not only are the 90th percentile and pooled average values closer to the 4-hour CPL of 30 dv, the range of city-specific results shows a wider spread that clearly encompasses the unadjusted 4-hour value of 30 dv near the midpoint of the city-specific range. This provides support for concluding that the EPA's approach to translating of 4-hour CPLs into equivalent 24-hour values was appropriate, and that it is appropriate to use unadjusted 4-hour values for purposes of selecting a level for a standard based on a 24-hour averaging time.[196]

Moreover, the EPA disagrees with commenters who argue that the currently available evidence is sufficient to justify establishing a target level of protection at 25 dv or below. The EPA recognizes that 25 dv represents the middle of the range of 50 percent acceptability levels from the 4 cities studied, and represents the 50 percent acceptability level from the Phoenix study, which the Agency has acknowledged as the best of the four studies in terms of having the least noise in the preference study results and the most representative selection of participants. The EPA also notes the caveats discussed in the proposal regarding whether it would be appropriate to interpret results from the western studies as generally representative of a broader range of scenic vistas in urban areas across the country. The Policy Assessment noted significant differences in the

[191] In particular, EPA staff expressed a preference for Approach B in the Policy Assessment. However, in light of the additional information provided by the other approaches explored in Appendix G of the Policy Assessment and the reanalysis in Frank, *et al.* (2012b), the EPA judges it more appropriate to consider the range of values resulting from all five analytical approaches for purposes of informing decisions about the equivalent level of a 24-hour standard.

[192] Approach E as presented in the Policy Assessment is based on the median values for each city; these results are not affected by the regression analyses. Therefore, Approach E was not included in the reanalysis, and the results remain unchanged from those reported in the corrected Table G–6 as reported in Frank, *et al.,* 2012b.

[193] In Appendix G of the Policy Assessment, a 24-hour adjusted CPL of 28 dv was estimated to be equivalent to a 4-hour value of 30 dv under Approach B (annual 90th percentile values regression).

[194] In Appendix G of the Policy Assessment, under Approach C (all-days city-specific regression), a 24-hour adjusted CPL of 27 dv was estimated to be equivalent to a 4-hour CPL of 30 dv when averaged across cities, while city-specific values were estimated to range from 24–30 dv.

[195] In the reanalysis, Approach D (all days pooled regression) generated results of 28 dv for the 24-hour CPL equivalent to a 4-hour value of 30 dv as compared to a value of 27 dv in the original analysis described in Appendix G.

[196] The analysis in Appendix G of the Policy Assessment used the 4-hour light extinction value treated as the independent (x-axis) variable in an ordinary least squares regression. The EPA now concludes that this regression approach was not the most appropriate approach because that variable has error and in fact may be more uncertain than the calculated 24-hour extinction values. The Frank et al. (2012b) reanalysis uses an orthogonal regression instead of ordinary least squares regression and results in slopes closer to the 1:1 line for all the results, particularly for Dallas, TX. Furthermore, consistent with the EPA's conclusion that a higher multiplier for converting OC to OM would be appropriate (see section VI.C.1.b.ii above), the reanalysis substitutes a 1.6 multiplier for converting OC to OM in the calculation of 24-hour values instead of the value of 1.4 that was used in calculating 24-hour values for Appendix G. The higher multiplier is more consistent with the SANDWICH approach used to calculate the 4-hour values found in Appendix G. See Frank et al. (2012b) for a more detailed explanation.

characteristics of the urban scenes used in each study, with western urban visibility preference study scenes including mountains in the background and objects at greater distances, while scenes in the eastern study did not. Since objects at a greater distance have a greater sensitivity to perceived visibility changes as light extinction changes compared to otherwise similar scenes with objects at a shorter range, this likely explains part of the difference between the results of the eastern study and results of the western studies. In the proposal, the EPA noted that the scenic vistas available on a daily basis in many urban areas across the country generally do not have the inherent visual interest or the distance between viewer and object of greatest intrinsic value as in the Denver and Phoenix preference studies. Also, the Agency takes note of the caution expressed by Colorado and Arizona about using the results of the Denver and Phoenix preference studies, which were aimed at addressing specific local visibility problems, to inform the choice of level for a national standard. Therefore, the Agency considers it reasonable to conclude, especially in light of the significant uncertainties, that it is appropriate to place less weight on the western preference results and that the high CPL value (30 dv) that is based on the eastern preference results is likely to be more representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. These areas would include the middle of the country and many areas in the eastern U.S., as well as some western areas. As a result, the EPA concludes that it is more appropriate to establish a target level of protection at the upper end of the range of 24-hour CPLs considered, recognizing that no one level will be ''correct'' for every urban area in the country.

In considering the upper end of this range, the EPA must identify a target level of protection that is considered requisite to protect public welfare from a national perspective, recognizing that the same target level would apply in all locations. Making this judgment requires a balancing of the risks to the public welfare and the substantial uncertainties surrounding appropriate levels of visibility protection. As acknowledged in the proposal, the EPA recognizes that setting a target level of protection for a 24-hour standard at 30 dv would reflect a judgment that the current substantial degrees of variability and uncertainty inherent in the public preference studies should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain. Also, a 24-hour visibility index at a level of 30 dv would reflect recognition that there is considerable spatial and temporal variability in the key factors that determine the value of the $PM_{2.5}$ visibility index in any given urban area, such that there is a relatively high degree of uncertainty as to the most appropriate approach to use in selecting a 24-hour standard level that would be generally equivalent to a specific 4-hour standard level. In light of these uncertainties, the EPA continues to believe that it is appropriate to establish a target level of protection for visual air quality of 30 dv, averaged over 24-hours, with a form as discussed above.

In reaching this conclusion, the EPA notes that any national ambient air quality standard for visibility would be designed to work in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in all areas of the country, including urban, non-urban, and Federal Class I areas. While the Regional Haze Program is focused on improving visibility in Federal Class I areas and a secondary visibility index NAAQS would focus on protecting visual air quality principally in urban areas, both programs could be expected to provide benefits in surrounding areas. In addition, the development of local programs, such as those in Denver and Phoenix, can continue to be an effective and appropriate approach to provide additional protection, beyond that afforded by a national standard, for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas. With regard to comments from the Department of Interior noting that many large metropolitan areas have 24-hour IMPROVE values below 30 dv on the worst 20 percent of days already, the EPA notes that the purpose of establishing NAAQS is to ensure adequate protection of public welfare everywhere, not to mandate continuous improvements in areas that may already be relatively clean. In fact, the evidence from the IMPROVE program that many urban areas have total 24-hour PM-related light extinction below 29 dv on the 20 percent worst visibility days suggests that many areas have relatively good visual air quality already.

f. Need for a Distinct Secondary Standard To Protect Visibility

Numerous commenters questioned whether a distinct secondary standard for visibility is necessary in light of the analysis described in section VI.B.1.c.vii above (Kelly *et al.,* 2012a) which indicated that a 24-hour mass-based $PM_{2.5}$ standard of 35 μg/m³ would protect against visibility impacts exceeding the range of levels considered in the proposal (28–30 dv). While this analysis was conducted in support of proposed implementation requirements for a distinct secondary standard (specifically, the modeling demonstrations that would be required under the PSD program), the second prong of the analysis showed that within the range of levels proposed by the EPA for the visibility index NAAQS (28–30 dv), the 24-hour $PM_{2.5}$ standard of 35 μg/m³ would generally be controlling. Kelly *et al.* (2012a) concluded that ''overall, design values based on 2008–2010 data suggest that counties that attain 24-hour $PM_{2.5}$ NAAQS level of 35 μg/m³ would attain the proposed secondary $PM_{2.5}$ visibility index NAAQS level of 30 dv and generally attain the level of 28 dv'' (pp. 17–18).

Citing this conclusion, many state and local agencies and industry commenters argued that a visibility index standard in the range proposed (28–30 dv) would provide no additional protection beyond that afforded by the existing secondary 24-hour $PM_{2.5}$ NAAQS, and therefore no distinct visibility standard was necessary. These commenters advocated retaining the current 24-hour $PM_{2.5}$ mass-based standard to protect against visibility effects. ''Since the 24-hour $PM_{2.5}$ standard already protects the welfare the 24-hour $PM_{2.5}$ visibility standard is designed to protect, the new standard is duplicative and unnecessary'' (South Dakota DENR, p. 2). Furthermore, a number of state commenters objected to the additional resource burden associated with implementing a standard which had, in their view, no practical effect: ''If the 24-hour $PM_{2.5}$ mass standard has the same effect as the visibility standard, crafting complex regulations to implement another standard seems redundant'' (South Carolina DHEC, p. 3). Other states agreed: ''A $PM_{2.5}$-related Visibility Index appears redundant since the benefits achieved from the current primary and secondary annual and 24-hour $PM_{2.5}$ standards already provide reductions that would improve visibility. Establishing a new $PM_{2.5}$ secondary standard for visibility would be an additional complication and burden to the states that is not warranted'' (Indiana DEM, p. 5).

In addition, several commenters submitted additional analyses supporting their position that a 35 μg/m³ 24-hour $PM_{2.5}$ standard would provide at least equivalent protection to a distinct 24-hour visibility standard within the range of levels proposed (API, Attachment 2, p. 8 and Attachment 3, p. 1).

In responding to these comments stating that a distinct visibility standard is not needed, the EPA notes as an initial matter that the Administrator provisionally concluded at the time of proposal that the current PM standards were not sufficiently protective of visual air quality, and that consideration should be given to an alternative secondary standard that would provide additional protection against PM-related visibility impairment, especially in urban areas. This provisional conclusion was based on the results of public preference surveys on the acceptability of varying degrees of visibility impairment in urban areas, analyses of the number of days on which peak 1-hour or 4-hour light extinction values were estimated to exceed a range of CPLs under conditions simulated to just meet the current standards, and the advice of CASAC. The Administrator also noted that the current indicator of $PM_{2.5}$ mass, in conjunction with the current 24-hour and annual averaging times, was not well suited for purposes of protecting visibility, since it does not incorporate species composition or relative humidity, both of which play a central role in determining the impact of ambient PM on visibility. Taking into account the advice of CASAC and the court's remand of the current secondary $PM_{2.5}$ standards, the Administrator provisionally concluded that the current secondary standards were neither sufficiently protective nor suitably structured to provide an appropriate degree of public welfare protection from PM-related visibility impairment. As a result, the EPA proposed a new, distinct secondary standard that was designed to address these deficiencies.

The EPA notes that in critiquing the proposed secondary standard, commenters generally did not advocate that the form of the existing mass-based $PM_{2.5}$ standards was better suited *scientifically* to the task of protecting against visibility impairment. Rather, the commenters' position that a distinct secondary standard was not needed for purposes of protecting visibility was based almost entirely on the relative *degree of protection* likely to be afforded by the existing standards (in particular, the existing 24-hour $PM_{2.5}$ standard) as compared to the proposed visibility index, along with the relatively large uncertainties associated with the latter. Thus, for all the reasons discussed in the proposal with regard to the scientific appropriateness of an indicator that takes into account both species composition and relative humidity, the EPA continues to conclude that the proposed standard based on a visibility index would be appropriate scientifically to provide targeted protection of visibility, since it would provide a measure of PM-related light extinction that directly takes into account the factors (i.e., species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in the ambient air and PM-related visibility impairment.

Furthermore, the EPA disagrees with commenters who stated that implementation concerns, in particular the additional resource burden associated with implementing a distinct secondary standard, should alter the Agency's decision making with regard to a standard to protect visibility. The EPA may not take the costs of implementation into account in setting or revising the NAAQS.

However, in light of the results of the Kelly *et al.* (2012a) analysis and the views expressed by commenters on the implications of this analysis for conclusions regarding the adequacy of the current secondary 24-hour $PM_{2.5}$ standard, the EPA has reconsidered some of the conclusions drawn at the time of proposal, in particular with regard to the degree of protection that would be provided by the current secondary standard. Based on a review of comments related to indicator, averaging time, form and level, the Agency has concluded that (as described in sections VI.C.1b-e above) a standard defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction), a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, and a level of 30 dv, would provide sufficient but not more than necessary protection of the public welfare with regard to visual air quality. Having identified this target level of protection, the EPA is now in a position to compare it specifically to the existing secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³ for purposes of determining whether it would provide more, the same, or less protection from visibility impairment. The EPA must consider both whether the existing secondary 24-hour $PM_{2.5}$ standard of 35 μg/m³ is sufficient (i.e. not under-protective) and whether it is more stringent than necessary (i.e. over-protective).

With regard to the degree to which the existing secondary 24-hour $PM_{2.5}$ standard provides sufficient but not more than necessary protection for visibility, the EPA first notes that the kind of area-specific analysis conducted in Kelly *et al.* (2012a) is essential for addressing the court remand of the 2006 secondary standards. In the case of the 2006 secondary standards, the EPA had argued that the 35 μg/m³ 24-hour $PM_{2.5}$ standard was requisite because one part of the proposed range for a distinct secondary standard the Agency had considered would affect the attainment status of a somewhat fewer counties than the 35 μg/m³ 24-hour $PM_{2.5}$ standard. The court rejected this kind of rough balancing, finding that the EPA's equivalency analysis based on percentages of counties demonstrated nothing about the relative protection offered by the different standards. Based on this, an area-by-area evaluation of the relative degree of protection offered by different standards should be conducted to the extent air quality data is available.

Kelly *et al.* (2012a) performed such an evaluation. Based on 2008–2010 data, there are no areas that would have exceeded a 30 dv, 24-hour visibility index standard that would not also have exceeded a 24-hour $PM_{2.5}$ standard of 35 μg/m³. Stated another way, all areas that met the 24-hour $PM_{2.5}$ standard of 35 μg/m³ would have had visual air quality at least as good as 30 dv (24-hour average, based on 90th percentile form averaged over 3 years). The Kelly (2012a) analysis also showed that for some areas, particularly in the West, areas that would have met a 24-hour $PM_{2.5}$ standard of 35 μg/m³ would have had visual air quality better than 30 dv for the $PM_{2.5}$ visibility index standard, and that at sites that violated both the 24-hour level and the visibility index 30 dv level, the visibility index level of 30 dv would likely be attained if $PM_{2.5}$ concentrations were reduced such that the 24-hour $PM_{2.5}$ level of 35 μg/m³ was attained.

The EPA has conducted a reanalysis (Kelly *et al.,* 2012b) to update the area-by-area analysis in the original Kelly *et al.* (2012a) analysis in three respects. First, noting that the original Kelly *at al.* (2012a) analysis used a 1.4 multiplier to convert OC to OM at those monitors not using the new CSN monitoring protocol, the EPA recalculated the visibility index design values for 2008–2010 using a higher multiplier for converting OC to OM at monitors not already using the new CSN monitoring protocol SANDWICH approach, consistent with the Agency's view that it is more appropriate to use a multiplier of 1.6 at such monitors as compared to 1.4, as described in section VI.C.1.a.ii, above.[197] The recomputed visibility design index values for 2008–2010 show the same overall relationship to 24-hour $PM_{2.5}$ design values as presented in Kelly *et al.,* 2012a.

Second, the EPA repeated the calculations comparing visibility index design values with 24-hour $PM_{2.5}$ design values using 2009–2011 data, the most recent three years of air quality information currently available.[198] Third, the EPA modified the area-by-area evaluation to ensure consistency with the data completeness criteria of 40 CFR part 50, Appendix N, including the removal of data approved by EPA as exceptional events, for the current 24-hour $PM_{2.5}$ standard and the proposed visibility index standard.

The results of this reanalysis, as presented in Kelly *et al.* (2012b), show a similar pattern to that described in the original Kelly memo. Specifically, the analysis indicates that there were no areas with visibility impairment above 30 dv that did not also exceed the 24-hour $PM_{2.5}$ standard of 35 µg/m³. The updated memo concludes that the results for 2009–2011 corroborate the findings for 2008–2010.

Based on these analyses (Kelly *et al.,* 2012a; 2012b), the EPA concludes with a high degree of confidence that having air quality that meets the 24-hour $PM_{2.5}$ standard of 35 µg/m³ would be sufficient to ensure areas would not exceed 30 dv. The EPA notes that this conclusion from Kelly *et al.* (2012a) is supported by two analyses submitted by industry commenters (API, Attachments 2 and 3).

At the time of proposal, the EPA had reached a different conclusion, specifically that the 35 µg/m³ 24-hour $PM_{2.5}$ standard was not sufficiently protective. This conclusion was based, in part, on the analyses conducted for the Visibility Assessment and Policy Assessment regarding 1- to 4-hour peak light extinction values based on 2007–2009 data. For the reasons outlined above in sections VI.B.1.c and VI.C.1.c, the EPA originally focused on hourly or sub-daily timeframes for evaluating visibility conditions. However, data quality concerns effectively precluded adoption of a 1-hour or sub-daily averaging time in this review, and ultimately the EPA has concluded that a 24-hour averaging time can serve as an appropriate surrogate. In reaching this conclusion, the EPA has recognized that adopting a 24-hour averaging time will likely smooth out some of the hour-by-hour variability in visibility index values, and will effectively reduce peak values by averaging them together with other hours. In concluding it is appropriate to adopt a 24-hour averaging time, which limits the impact of hour-specific influences, the Agency is now placing less weight on the results of the 1-hour and 4-hour analyses presented in the Visibility Assessment and the Policy Assessment which focused on identifying the percent of days with peak hourly light extinction above various CPLs. In light of the Agency's conclusion that a 24-hour averaging time would be appropriate, the Agency has determined to place more weight on analyses of visibility conditions over a 24-hour time period, especially the results in Kelly *et al.* (2012a and 2012b). In addition, the EPA notes that the Kelly *et al.* analyses reflects updated air quality information from more recent years of data (2008–2010 for Kelly *et al.,* 2012a; 2009–2011 for Kelly *et al.* 2012b) as compared to the air quality information used in the Visibility Assessment and Policy Assessment.

In light of all of these considerations, including the results of the Kelly *et al.* (2012a; 2012b) analyses, and the supporting comments provided by a broad range of public commenters, the EPA now concludes that the 24-hour $PM_{2.5}$ standard of 35 µg/m³ provides sufficient protection in all areas against the effects of visibility impairment. The EPA concludes that the existing 24-hour $PM_{2.5}$ standard would provide *at least* the target level of protection for visual air quality defined by a visibility index set at 30 dv, as described above, which the EPA judges appropriate.

However, the EPA also recognizes that it is important to evaluate whether such a standard would be over-protective (i.e. more stringent than necessary to protect public welfare). The analyses presented in Kelly *et al.* (2012a; 2012b) indicates that the 24-hour $PM_{2.5}$ standard of 35 µg/m³ would achieve *more than* the target level of protection of visual air quality (30 dv) in some areas. That is, when meeting a mass-based standard of 35 µg/m³, some areas would have levels of PM-related visibility impairment far below 30 dv. Thus, when considered by itself and without consideration of the secondary standards adopted for purposes of non-visibility welfare effects, the 24-hour $PM_{2.5}$ standard of 35 µg/m³ would be over-protective of visibility in some areas. However, it is important to note that as long as the current secondary 24-hour $PM_{2.5}$ standard of 35 µg/m³ remains in effect, this overprotection for visibility would occur, regardless of whether a distinct secondary standard based on a visibility index set at 30 dv were adopted. These issues are discussed more fully in section VI.D, which outlines the Administrator's final conclusions on the secondary PM standards, below.

g. Legal Issues

Some commenters opposed the proposal to establish a distinct secondary standard that would be defined in terms of a $PM_{2.5}$ visibility index. The proposed standard would use measured $PM_{2.5}$ mass concentration, in combination with speciated $PM_{2.5}$ mass concentration and relative humidity data, to calculate $PM_{2.5}$ light extinction, translated to the deciview (dv) scale. The standard would also be defined in terms of a specified averaging time and form, and a level for the $PM_{2.5}$ visibility index set at one of two options—either 30 dv or 28 dv. The commenters argued that the entire approach proposed by the EPA is inconsistent with the requirements of CAA section 109(b). They pointed to a number of different aspects of the proposal which in their view made it incompatible with the CAA. For example, the Utility Air Resources Group (UARG) stated:

> In the past, EPA has always used a measure of PM mass as the indicator for both primary and secondary PM NAAQS. Such a standard is, as a general matter, consistent with the directive in the CAA that the NAAQS ''specify a level of air quality'' and targets for control the listed criteria air pollutant. CAA § 109(b)(2). The standard contained in EPA's proposed rule does neither of these things. Instead, it would (1) regulate relative humidity, which is not a criteria pollutant; (2) fail to ''specify a level of air quality'' as required by section 109(b)(2) of the CAA; and (3) result in a standard necessitating nationally variable PM concentrations instead of a standard establishing a nationally uniform, minimally acceptable PM concentration. (UARG, p. 22–23)

Other commenters raised similar or related issues, arguing that the EPA improperly set a visibility standard, and not a $PM_{2.5}$ standard, and that NAAQS can only be set in terms of a level or concentration of the air pollutant. Commenters also argued that an endangerment finding and air quality criteria would be needed before the EPA could set a standard based on PM components. Each of these comments is discussed below.

As an initial matter, the commenters argued that the proposed standard is unlawful because it is ''not a $PM_{2.5}$ standard at all, but rather a visibility standard, and visibility is neither an air pollutant nor a criteria pollutant for which a NAAQS may be promulgated''

[197] Some of the OC measurements were produced with CSN's newer monitoring protocol and did not require a change in the computed OM.

[198] The 2011 air quality data were not yet available at the time of proposal.

(NMA/NCBA, p. 21). According to these commenters, the CAA requires that NAAQS be established as limits on the concentration of an air pollutant in ambient air, not limits on the ''identifiable effects'' caused by that air pollutant. These commenters claimed that reduced visibility due to light extinction is not an air pollutant but instead is an effect, noting that ''the Act's definition of 'air pollutant' speaks in terms of specific substances or matter in the ambient air'' (NSSGA, p. 8). The commenters pointed to the use of the term ''air pollutant'' in sections 109(a)(1)(A) and (b)(2) as support for their argument, as these provisions refer to setting standards for the ''air pollutant'' to address the effects associated with the presence of the air pollutant in the ambient air. They likewise pointed to section 108(a)(2)'s reference to the presence of the air pollutant in the ambient air. Since reduced visibility is not an air pollutant, they argue the EPA cannot set a NAAQS that is a standard for visibility. They argue that the proposed secondary standard it is not a $PM_{2.5}$ standard as it does not limit the concentration of $PM_{2.5}$ or any other fraction of particulate matter in the ambient air and therefore is not an ''ambient air quality standard'' for any pollutant.

One commenter argued that the EPA is required to ''specify a level of air quality'' under section 109(b)(2), which Congress intended as an acceptable concentration level of the air pollutant in the ambient air, noting that specification of acceptable visibility conditions is not the same as an acceptable air pollution concentration level. Citing *American Farm Bureau* v. *EPA,* 559 F.3d at 516, one commenter claimed that the court had affirmed that ''the NAAQS—whether primary or secondary—is a mass-based standard'' (Nevada DEP, p. 5). Commenters also refer to the legislative history of the 1970 amendments, referring to NAAQS as setting the ''maximum permissible ambient air level'' for an air pollutant. The commenters argue that the proposed standard is improper because it does not limit the concentration of $PM_{2.5}$ or any fraction of PM in ambient air, but improperly sets a limit on visibility effects.

With regard to humidity, these commenters argued that the proposed standard improperly regulates relative humidity because it is included in the calculation to determine the value of the visibility index. According to these commenters, the CAA allows the EPA to control criteria air pollutants through the NAAQS program, but not other various substances. The commenters stated that the EPA recognized this in the last review, treating humidity as a confounding factor and considering addressing it by measuring $PM_{2.5}$ mass-based concentration over the midday hours, when humidity would have the least effect. This would target the effects caused by PM, and not by humidity. Referring to *American Farm Bureau* v. *EPA,* 559 F.3d 512, 528 (DC Cir. 2009) and 77 FR at 38979 n.153. UARG contested the proposed calculated visibility index as it does not approach relative humidity as a confounding factor but instead ''embraces it and treats it as if it were a PM effect'' (UARG p. 24).

The commenters also stated that the use of a calculated visibility index, and the failure to exclude the effects of humidity, would result in acceptable PM concentrations that vary across the nation. These commenters claimed that such a standard is inconsistent with the requirements of the CAA because the proposed approach fails to establish a nationally uniform PM concentration standard. For example, API argued that the proposed visibility index approach is ''essentially specifying levels—not a level—of air quality'' (API, p. 29). UARG agreed, and stated that the Act ''requires that criteria pollutant concentrations *throughout the nation* reach, at the least, a *single,* specified ambient concentration level'' (UARG, p. 25, emphasis in original). The commenters argue that a $PM_{2.5}$ visibility index standard cannot provide equal protection nationwide due to geographic variation in key factors such as relative humidity that affect level of particles allowed in different areas. The commenters noted that establishing a single national level for the $PM_{2.5}$ visibility index would necessarily result in unequal acceptable $PM_{2.5}$ levels in different areas of the country, with lowest allowable $PM_{2.5}$ levels in urban areas in the Southeast and highest allowable levels in the arid West. UARG recognized that under section 108 the air quality criteria are to ''address those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant,'' but stated that while section 108 ''allows'' this, it has no bearing on this issue. Instead, the commenter stated that the EPA may take such information into account in setting a permissible concentration of the pollutant that is uniform and national (UARG, p. 25).

In addition, some commenters opposed to the proposed distinct secondary standard argued that in order to base a standard on measured levels of several speciated substances, the EPA must first make an endangerment finding and issue air quality criteria for each of the speciated substances included in the calculation of $PM_{2.5}$ light extinction. According to these commenters, ''EPA cannot use NAAQS to indirectly regulate multiple substances which are not criteria pollutants under the guise of establishing a visibility standard'' (NMA/NCBA, p. 21). Noting that air quality criteria for particulate matter were issued in 1969, NMA/NCBA argued that the 1969 Criteria Document ''did not establish air quality criteria for individual constituents that occur in particle form, instead it established criteria for particulate matter as a whole'' (p. 27). In light of the fact that criteria have never been issued for ''individual speciated components of particulate matter,'' these commenters argued, ''if EPA wishes to promulgate a rule such as its secondary visibility NAAQS, it first must make a finding that the speciated components listed in Appendix N endanger public health or welfare and then issue an air quality criteria document for those components'' (NMA/NCBA, p. 29). According to these commenters, the approach the EPA adopted in promulgating a NAAQS for lead supports this view:

> When EPA promulgated a NAAQS for lead, an individual substance in particle form, it did not assert that an endangerment finding or criteria document for lead was unnecessary because lead was already covered by the PM Criteria Document. Instead, EPA complied with the Section 108 and 109 NAAQS prerequisites for lead, just as it must do for Appendix N substances if it intends to promulgate a NAAQS for those substances. * * * [In 1976], EPA listed lead as an air pollutant that adversely affected public health or welfare, issued an air quality criteria document for lead, and promulgated a NAAQS for lead. 43 FR 46246 (Oct. 5, 1976). (NMA/NCBA, p. 29)

Finally, UARG argued that the EPA has in the past recognized that the secondary NAAQS is an inappropriate vehicle for regulating PM-related visibility, referring to 62 FR at 38680, including fn 49. UARG claimed the same situation continues, and the EPA has not provided a valid basis for changing this conclusion.

The EPA disagrees with the points raised by these commenters. While the EPA is not adopting the proposed secondary standard, as explained below, this decision is not based on concern over the EPA's authority to adopt a secondary standard such as the one proposed.

The proposed distinct secondary standard is a standard for $PM_{2.5}$, and is not a ''visibility standard.'' The proposed secondary standard is based on the mass concentration of $PM_{2.5}$ in the ambient air. The standard is defined in terms of calculated $PM_{2.5}$ light extinction which is based on the measurement of the mass concentration of ambient $PM_{2.5}$ over a 24-hour period. The measured mass concentration is adjusted based on information on the speciated mass components of the $PM_{2.5}$ and the relative humidity, resulting in a calculated visibility index. The level of the visibility index, combined with the form of the standard and averaging time, identifies whether a level of ambient mass concentration of $PM_{2.5}$ achieves the standard or not. Given any specific mass concentration of ambient $PM_{2.5}$, combined with information on speciation and relative humidity, it can be determined whether the specific mass concentration of ambient $PM_{2.5}$ achieved the NAAQS. Hence, the proposed secondary NAAQS specifies acceptable levels of ambient mass concentration of $PM_{2.5}$.

The combination of indicator, averaging time, form, and level of the proposed NAAQS is designed to provide the appropriate degree of protection from visibility impairment caused by ambient levels of $PM_{2.5}$. It does this by calculating the light extinction associated with ambient concentrations of $PM_{2.5}$ and specifying the level of acceptable $PM_{2.5}$ mass concentration in terms of this calculation. However this does not change the fact that the standard is for the air pollutant $PM_{2.5}$, and defines acceptable ambient levels of this air pollutant. It does not transform the standard into a ''visibility standard'' and not a standard for $PM_{2.5}$. While the commenters had additional concerns over the use of relative humidity in the calculation, and the variation around the country of acceptable mass concentrations, those issues are separate and do not change the fact that the proposed standard defined in terms of calculated $PM_{2.5}$ light extinction is based on measurement of $PM_{2.5}$ concentration in the ambient air, and is a NAAQS for $PM_{2.5}$.

With regard to the contention that section 109(b) limits the EPA to setting a standard that is based on the concentration of the pollutant in the ambient air, we note that the term ''concentration'' typically means some measure of relative content. For example, this would include relative measures such as mass per unit of volume or parts per million. The EPA has often used such metrics to define the NAAQS, largely because the scientific evidence of health or welfare effects supporting the NAAQS typically use such metrics in air pollution studies. For example, the current secondary standards for PM are defined in terms of the concentration of $PM_{2.5}$ and PM_{10} in the ambient air, measured as the dried mass of the particulate matter per unit of air. However section 109(b) does not require that a NAAQS be defined this way.

Sections 109(a) and (b) both use the general term ''air quality'' when discussing the EPA's obligation to set NAAQS. The NAAQS are clearly national ambient ''air quality'' standards under section 109(b), which specifies that the primary NAAQS ''shall be ambient air quality standards'' and the secondary NAAQS ''shall specify a level of air quality.'' Both the primary and secondary NAAQS are to be based on the ''air quality criteria,'' which are to accurately reflect the latest scientific knowledge on the effects on public health and welfare associated with ''the presence of such air pollutant in the ambient air, in varying quantities.'' Section 109(b), 108(a)(2). Congress spoke in broad terms, tasking the EPA with assessing the latest scientific knowledge about the public health and welfare associated with the presence of the pollutant in the air, without limiting this to consideration of only those effects associated with one or more measures of concentration of the air pollutant. Congress referred to any and all effects associated with the presence of the pollutant in the ambient air, not just the effects associated with the concentration of the pollutant in the ambient air. Based on this knowledge, the EPA is required to set standards for the quality of the air that will provide the appropriate degree of protection from these health and welfare effects, without limitation on how to measure or define air quality. While concentration in the air has typically been an appropriate way to set a standard to achieve these requirements, the more general terms used in section 108(a) and 109(b) do not limit the EPA to using concentration as the only way to measure air quality for purposes of setting a NAAQS. The EPA is charged with setting air quality standards, and has the discretion under section 109(b) to choose the metric for defining air quality that is appropriate to address the health or welfare effect at issue.

Congress did refer to ''concentration'' in certain situations. In section 109(c) Congress required the EPA to set a primary NAAQS for NO_2 concentration over 3 hours. This addressed Congress' concern over whether the then current NO_2 standard, which used concentration as a metric, provided adequate protection. Congress also called on CASAC to advise the Administrator on the relative contribution to ''air pollution concentrations'' of natural and anthropogenic sources, under section 109(d)(2)(C)(iii). This information is in addition to the advice CASAC is required to provide concerning appropriate revisions to the ''air quality criteria'' and to the NAAQS under section 109(d)(2)(B).[199] While these provisions refer to ambient concentrations of pollutants, this reflects the EPA's standard practice to date in setting NAAQS, and none of them change or limit the range of discretion provided under section 109(b) in setting NAAQS. They do not change the fact that the EPA is to set ''air quality'' standards, and is not limited to ''air concentration'' standards. The reference in the legislative history to a maximum permissible ambient air level for the pollutant also does not limit the EPA to a level of air pollutant concentration, as compared to a different metric for specifying the level of air quality, if that is judged to be appropriate.

The text of sections 108 and 109 does not support the limited interpretation commenters suggest. Instead these provisions provide the EPA with significant discretion in determining the metric for air quality that is appropriate to achieve the required degree of protection of public welfare. The commenters' interpretation would improperly limit this discretion, interfering with achieving the goals of section 109(b).

For example, in this review the EPA considered whether it would be appropriate to base a secondary NAAQS on direct measurement of the light extinction caused by $PM_{2.5}$. See 77 FR 38890, 38980–1 (June 29, 2012). There are several instrumental methods that directly measure $PM_{2.5}$ light extinction—the amount of light extinction caused by the presence of $PM_{2.5}$ in the ambient air. This is not a measure of the concentration of $PM_{2.5}$ in the air, but a measure of the light extinction caused by $PM_{2.5}$. This is clearly an effect associated with the presence of $PM_{2.5}$ in the ambient air,

[199] In a provision that is not part of the CAA, in 1990 Congress required EPA to request a report from the National Academy of Sciences on the role of secondary national ambient air quality standards, including information on the ''effects on welfare and the environment which are caused by ambient concentrations of pollutants'' listed under section 108, and the ''ambient concentrations of each such pollutant which would be adequate to protect welfare and the environment from such effects.'' Section 817(a) of the CAA Amendments of 1990, Pub. L. 101–549.

and this atmospheric property is directly related to visibility effects. Unlike $PM_{2.5}$ mass concentration, there is a close scientific relationship between directly measured $PM_{2.5}$ light extinction and visibility effects.

It would appear straightforward to say that $PM_{2.5}$ light extinction is a quality of the ambient air, and a secondary NAAQS that specified an acceptable level of $PM_{2.5}$ based on directly measured $PM_{2.5}$ light extinction would be an ''ambient air quality standard'' for the air pollutant that specifies a ''level of air quality'' designed to provide protection against visibility impairment. Unlike directly measured $PM_{2.5}$ light extinction, the mass concentration of $PM_{2.5}$ does not have the same direct relationship to light extinction, and specifying an acceptable level of mass concentration of $PM_{2.5}$ would be a more indirect and less effective way to provide protection from visibility impairment caused by the presence of $PM_{2.5}$ in the ambient air. Under the commenters' interpretation, the EPA would be precluded from specifying a level of air quality in terms of directly measured $PM_{2.5}$ light extinction, the more scientifically appropriate and direct measure of the effect $PM_{2.5}$ has on visibility. Instead the EPA would be limited to the more indirect and less effective specification of a level of concentration of $PM_{2.5}$.

The commenters also objected to the inclusion of relative humidity as an adjustment factor in the calculation of $PM_{2.5}$ light extinction. Contrary to the claims of these commenters, the use of calculated $PM_{2.5}$ light extinction does not regulate relative humidity. The proposed secondary standard would define acceptable levels of ambient $PM_{2.5}$, not acceptable levels of relative humidity. In addition, section 108 explicitly requires that the air quality criteria include information on the atmospheric conditions that can alter the effects of the air pollutant on public health or welfare, and relative humidity certainly has this kind of impact. Section 109(b) requires that the standard be based on the air quality criteria, indicating that this information can and should be taken into account in setting the standard. Including relative humidity as an adjustment factor in the calculation of $PM_{2.5}$ light extinction is a reasonable and straightforward way to use the scientific information in the air quality criteria in establishing a standard to provide protection from visibility impairment.[200]

Some commenters pointed to the EPA's position in the last review, stating that the EPA properly treated relative humidity as a confounding factor, and in this review improperly moves away from that position. See 77 FR at 38979, 71 FR 61144, 61205 (October 17, 2006). In the last review the EPA considered a distinct $PM_{2.5}$ mass-based secondary standard. In that context, limiting the measurement of $PM_{2.5}$ mass concentration to the mid-day hours when relative humidity had the least impact would promote the correlation between measured $PM_{2.5}$ mass concentration and light extinction, which would promote achievement of a relatively consistent degree of visibility protection across the country. However in this rulemaking the proposed calculated $PM_{2.5}$ light extinction standard achieves a consistent degree of visibility protection by directly accounting for humidity, in a scientifically defensible manner. The goal has not changed—achieving the desired degree of protection across the country. What has changed is that calculated $PM_{2.5}$ light extinction is a more direct and scientifically appropriate way to achieve that result.

Finally, it should be made clear that water is not a separate compound from $PM_{2.5}$ that confounds the impact $PM_{2.5}$ has on light extinction. As described in the Integrated Science Assessment, ''PM is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes'' (U.S. EPA, 2009a, p. 1–4). ''Particles composed of water soluble inorganic salts (i.e., ammoniated sulfate, ammonium nitrate, sodium chloride, etc.) are hygroscopic in that they absorb water as a function of relative humidity to form a liquid solution droplet. Aside from the chemical consequences of this water growth, the droplets become larger when relative humidity increases, resulting in increased light scattering. Hence, the same PM dry concentration produces more haze'' (U.S. EPA, 2009a, p. 9–6). Thus water is not a compound that is separate and apart from the particle that acts as an extraneous confounding factor.[201] The effect of relative humidity occurs after the water becomes part of the particle. Certain water soluble salts absorb water and the resulting particle is larger in size and scatters more light, increasing the visibility impact of the particle. But the particle is still a $PM_{2.5}$ particle. The fact that the PM NAAQS traditionally uses a measurement of the dried mass of the particles as the metric for the standard does not change the fact that the particles in the air include liquid droplets and particles that have increased in size because of absorption of water. These ambient $PM_{2.5}$ particles are what is in the air and impacting visibility, not just the dried mass of $PM_{2.5}$ that is measured in the laboratory and is currently used as the indicator for the PM NAAQS. Thus the commenters improperly claimed that the proposed secondary standard regulates water or relative humidity, and not $PM_{2.5}$, when in fact the proposed secondary standard accounts in a scientific manner for the fact that some $PM_{2.5}$ particles are larger in size and have a greater impact on light extinction when the relative humidity increases.

The commenters also raised concerns that a standard based on calculated $PM_{2.5}$ light extinction, compared to a standard based on just $PM_{2.5}$ mass concentration, improperly results in variable levels of acceptable $PM_{2.5}$ mass concentrations across the country. This stems from the adjustments in the calculation for speciated components of $PM_{2.5}$ and relative humidity. According to commenters, this is improper as section 109(b) requires that the NAAQS set a single, specified ambient concentration that is nationally uniform across the country.

As discussed above, the text of section 109(b) does not specify this limitation of a single national acceptable concentration. Instead the secondary NAAQS is to specify a level of air quality that achieves the appropriate degree of protection. The proposed secondary standard would do just that—specify a level of air quality, defined in terms of calculated $PM_{2.5}$ light extinction, that would achieve the desired degree of protection. The fact that this results in varying allowable levels of $PM_{2.5}$ mass concentrations is not inconsistent with the Act. The DC Circuit recently approved such a result. In the last review of the PM_{10} primary NAAQS, the court approved the EPA's choice of an indicator that was designed to allow varying levels of acceptable coarse PM. The court stated that:

The industry petitioners next argue that the 150 µg/m³ standard for PM_{10} will result in arbitrarily varying levels of coarse PM, and that the agency should instead have used a $PM_{10-2.5}$ indicator. The EPA does not dispute

[200] UARG recognizes these provisions, but argues, as above, that this is limited by the requirement that the EPA set a NAAQS based solely on ambient concentration.

[201] According to the Integrated Science Assessment, ''Confounding is '* * * a confusion of effects. Specifically, the apparent effect of the exposure of interest is distorted because the effect of an extraneous factor is mistaken for or mixed with the actual exposure effect (which may be null)' (Rothman and Greenland, 1998, 086599)'' (U.S. EPA, 2009a, p. 1–16).

that using the PM_{10} indicator will result in coarse PM levels that vary within the limit of 150 µg/m³. As the EPA explains: ''Because the PM_{10} indicator includes both coarse PM ($PM_{10-2.5}$) and fine PM ($PM_{2.5}$), the concentration of $PM_{10-2.5}$ allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. Thus, the level of coarse particles allowed varies depending on the level of fine particles present.'' *Id. at 61,195.*

Although the EPA acknowledges that a PM_{10} indicator will result in varying coarse PM levels, it does not agree that the variance will be arbitrary. The EPA agrees with the industry petitioners that protection from coarse particles should be targeted at urban areas, where coarse particles have been shown to pose the greatest danger. *Id. at 61,194.* But the agency argues that targeting of urban areas is effectively accomplished by using an indicator that permits the varying levels that the industry petitioners challenge. * * * *Id. at 61,195–96* (citations omitted). In other words: ''The varying levels of coarse particles allowed by a PM_{10} indicator will therefore target protection in urban and industrial areas where the evidence of adverse health effects associated with exposure to coarse particles is strongest.'' *Id.*

The EPA also offers a further rationale for tying the stringency of coarse PM regulation to increases in the level of $PM_{2.5}$.* * * EPA argues that it is ''logical to allow lower levels of coarse particles when fine particle concentrations are high.* * * [I]nclusion of $PM_{2.5}$ in the PM_{10} indicator for purposes of coarse particle protection would appropriately reflect the contribution that contaminants emitted in fine particle form can make to the overall health risk posed by coarse particles.'' *Id.*

In sum, we find that the EPA has provided a reasonable explanation for its decision[ ] * * * to utilize a standard that allows targeted variance in coarse PM levels in an inverse relationship to the amount of fine PM in the air. *American Farm Bureau* v. *EPA,* 559 F.3d 512, 534–5 (D.C. Cir. 2009).

A similar result applies here. Under the proposed secondary standard there would be a single level of air quality specified for the NAAQS. The standard would apply across the nation; it would not be a regional standard. The proposed standard would be the same standard everywhere—the acceptable level of mass concentration of $PM_{2.5}$ would be defined the same way across the nation, using the same method of calculating the allowable concentration of $PM_{2.5}$. The same degree of protection from visibility impairment would apply across the country. While the allowable amount of $PM_{2.5}$ could vary, this would be a reasoned way to achieve the desired degree of protection from visibility impairment. The requirements of section 109(b) would be satisfied.

Commenters also objected that the EPA could not set a NAAQS for the separate components of $PM_{2.5}$ without listing the components of $PM_{2.5}$ under section 108, based on an endangerment finding, and issuing air quality criteria for these components. They argued that the issuance of air quality criteria for particulate matter starting in 1969 did not provide a lawful basis for a proposed secondary standard that is based on components of PM, as the 1969 air quality was for particulate matter ''as a whole,'' defining PM as particles smaller than 500 micrometers (NMA/NCBA, p. 27). However, as discussed above, the proposed standard sets the allowable limit on ambient concentrations of $PM_{2.5}$. Information on both the speciated components of $PM_{2.5}$ and the relative humidity affect how much light extinction is associated with any specific level of $PM_{2.5}$, but the standard is for $PM_{2.5}$. The D.C. Circuit has made it clear that $PM_{2.5}$, just like PM_{10} and TSP before that, is an appropriate subset of PM for the EPA to focus on in setting the NAAQS based on the scientific evidence before the EPA. This focus of the NAAQS does not make the subset a new pollutant that requires listing and new air quality criteria under section 108 before setting a NAAQS. *American Trucking Association et al.* v. *EPA,* 175 F.3d 1027, 1055 (D.C. Cir. 1999). Commenters' interpretation would apply to $PM_{2.5}$ as well as to components of $PM_{2.5}$, and is inconsistent with the ATA decision. In addition, it is clear that the current air quality criteria do address the scientific basis for calculating $PM_{2.5}$ light extinction as the EPA proposed (U.S. EPA, 2009a, pp. 9–5 to 9–8).

Finally, at least one commenter argued that the EPA has concluded in prior reviews that the secondary NAAQS program is an inappropriate vehicle for regulating PM related visibility impairment (UARG, p. 26). UARG mischaracterized the EPA's past decision-making. In past reviews the EPA has been clear that the EPA should take into account the existence of the visibility program under section 169A, the regional haze program, when considering a secondary NAAQS and should not treat the secondary NAAQS as the sole mechanism to address visibility impairment across the country. That is the approach the EPA has taken in this and prior reviews. See 77 FR at 38990.

h. Relationship With Regional Haze Program

A large number of commenters expressed confusion and concern over differences between the proposed visibility index standard and the Regional Haze Program. This included commenters who supported setting a distinct secondary standard to protect visibility as well as those opposed to setting such a standard. A number of these commenters noted that visibility impairment would be assessed differently under the two approaches due to differences in the way light extinction is calculated, including different IMPROVE equations and differences in the inclusion and weighting of specific species and components. The commenters argued it would be inappropriate to have two different regimes for managing visibility impairment in the exact same location. These commenters claimed that since data from the IMPROVE monitoring network would inform nonattainment designations, as well as an area's obligations under the Regional Haze Program, there could be considerable confusion over how to draw nonattainment boundaries and what requirements would affect large sources in rural areas. These commenters also noted the resource burden associated with maintaining two different programs aimed at protecting visibility in the same geographic area. Some commenters argued that a visibility NAAQS should not apply to rural areas. The Department of the Interior requested that the EPA clearly define the geographic area to which the visibility index standard would be applicable, and suggested that Class I and Class II areas should generally be excluded from the standard. As discussed above, commenters questioned the need for a distinct visibility standard, arguing that the existing primary PM standards combined with the Regional Haze Program ensured adequate protection of visibility, even in urban areas.

In response to these comments relating to the overlap between the Regional Haze program and a distinct secondary standard designed to protect visibility principally in urban areas, the EPA notes that the objectives of each program are distinct. While the Regional Haze program is designed to eliminate man-made impairment of visibility in Federal Class I areas over the course of several decades, a distinct secondary standard for PM-related visibility impairment would be focused on providing a nationally applicable level of protection for all areas, particularly urban areas which do not receive targeted protection under the Regional Haze Program. Moreover, the metric used to assess visibility impairment differs between the two programs precisely because each program is aimed at a different aspect of the problem. Recognizing the importance of fresh emissions for urban visibility, the

Visibility Assessment focused on visibility impairment as measured by the original IMPROVE equation because ''the original version is considered more representative of urban situations when emissions are still fresh rather than aged as at remote IMPROVE sites'' (U.S. EPA, 2010b, p. 3–19). The Regional Haze Program, on the other hand, has shifted to a revised IMPROVE algorithm more suited to remote locations. While this difference is discussed in more detail in section VI.C.1.b above, the result is that each program would appropriately measure those aspects of visibility impairment most closely related to the problem the program is trying to prevent. Since the same data can be used to calculate both visibility impairment under the Regional Haze approach and the proposed visibility index, the additional calculation burden for state and local agencies would be light. Also, to the extent that there is any difference in terms of the emissions control obligations the two different programs would impose upon state and local areas, this is likely appropriate given the extent and nature of visibility impairment in those areas. The EPA notes that in general, there is likely to be substantial overlap in the control strategies a state or local area would pursue under either program. Thus, the EPA disagrees with commenters who stated that a distinct visibility standard as proposed would inherently conflict with the Regional Haze Program or that it would be appropriate to draw geographical distinctions that would explicitly exclude some areas (e.g., Class I areas) from the NAAQS. The EPA notes that the CAA requires that NAAQS be national in scope, and that the specific requirements laid out in the proposal for the distinct secondary standard would ensure that the protection it afforded would be appropriately targeted toward urban areas so that it could work in conjunction with—not be in conflict with—the Regional Haze Program under sections 169A and 169B of the CAA.

2. Comments on the Proposed Decision Regarding Non-Visibility Welfare Effects

Relatively few commenters addressed the proposal to retain the existing suite of secondary PM standards to address non-visibility welfare effects. A couple of states, including Mississippi and South Dakota, offered brief endorsements of the proposal. A few other commenters offered more extensive comments on the proposal to retain the existing secondary standards, and these commenters opposed this aspect of the proposal for one of two reasons. First, some commenters opposed the proposal to retain the current secondary annual $PM_{2.5}$ standard of 15 μg/m^3 in light of the proposal to revise the level of the primary annual $PM_{2.5}$ standard to a level between 12–13 μg/m^3. Expressing concern over the implications of this decision for the air quality planning obligations of states, these commenters argued that the EPA should revise the secondary $PM_{2.5}$ standards to be equivalent in all respects to the primary $PM_{2.5}$ standards. For example, the American Association of State Highway and Transportation Officials (AASHTO) supported ''retaining secondary standards that are consistent with the primary standards in order to reduce the complexity of the transportation and air quality planning processes, as well as the transportation conformity process'' (AASHTO, p. 3). Thus, if the EPA were to adopt a lower level for the primary annual $PM_{2.5}$ standard, the commenters recommended that the EPA adopt this same lower level for the primary secondary $PM_{2.5}$ standard as well.

In response to these comments, the EPA notes that the Agency lacks an appropriate scientific basis for revising the level of the secondary annual $PM_{2.5}$ standard. As noted above in section VI.B.2, there is an absence of information that would support any different secondary standards for PM. Comments related to the implementation challenges associated with distinct primary and secondary standards are not relevant to the Administrator's final decisions regarding what standards are requisite to protect the public welfare. Therefore, the EPA continues to conclude that it would be appropriate to retain the current suite of secondary PM standards [202] to address non-visibility welfare effects, while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard, as proposed.

Other commenters focused on the impacts of particulate matter on climate. One commenter cited a number of recent studies that considered mobile source black carbon emissions and associated climate impacts, and urged the EPA to protect the public welfare by setting ''higher standards for gasoline quality'' (Urban Air Initiative, p. 4). This commenter did not, however, advocate specific secondary NAAQS to address climate impacts of PM. More extensive comments on this same subject were provided by the Center for Biological Diversity (CBD), which urged the EPA to ''set a separate limit for black carbon within the overall $PM_{2.5}$ standard'' to ensure that public welfare is fully protected ''from the serious climate impacts of black carbon'' (CBD, p. 2). This commenter argued that ''[p]recaution is required for secondary NAAQS,'' citing *American Trucking Associations, Inc.* v. *EPA,* 283 F.3d 355, 369 (D.C. Cir. 2002):

> [N]othing in the Clean Air Act requires EPA to wait until it has perfect information before adopting a protective secondary NAAQS. Rather, the Act mandates promulgation of secondary standards requisite to protect public welfare from any ''*anticipated* adverse effects associated with'' regulated pollutants, 42 U.S.C. 7409(b)(2) (emphasis added), suggesting that EPA must act as soon as it has enough information (even if crude) to ''anticipate[]'' such effects[.]

The commenter stressed the growing scientific evidence regarding the impacts of black carbon on climate, and argued that the EPA's proposal ignores important research studies published within the last five years which provide improved estimates of the radiative forcing associated with black carbon, and the effects of black carbon on snow and ice, the Arctic climate, water availability and climate ''tipping points.'' The commenter also noted that reductions in cooling aerosol species, particularly sulfate, due to pollution control programs are leading to an ''unmasking'' of the true extent of warming due to the accumulation of greenhouse gases in the atmosphere. The commenter argued that this unmasking effect can be offset by ensuring ''that sufficient black carbon reductions accompany reductions in overall aerosol pollution'' (CBD, p. 10). The commenter also argued that the EPA did not consider the negative impacts of climate change on public health adequately in the proposal.

The commenter stated that the EPA had an obligation to address the impacts of black carbon in the PM NAAQS, despite the remaining uncertainties. The commenter pointed to the EPA's report to Congress on Black Carbon (U.S. EPA, 2012c), stating that the ''report shows that EPA is aware of the climate science and public health information that point to the importance of addressing black carbon pollution. EPA must use this information in its relevant decisionmaking'' (CBD, p. 13). The commenter also noted that the U.S. participates in a number of international forums that have recognized the need to take action on black carbon, and argued

[202] As summarized in section VI.A and Table 1 above, the current suite of secondary PM standards includes annual and 24-hour $PM_{2.5}$ standards and a 24-hour PM_{10} standard.

that the U.S. has ''an obligation under the Gothenburg Protocol to address black carbon pollution.'' The commenter challenged the uncertainties cited by EPA with regard to the climate impacts of aerosols generally, arguing that they ''do not apply to the regulation of black carbon'' (CBD, p. 14). Specifically, the commenter stated that ''there are significant anthropogenic sources of black carbon that contribute a large proportion of total black carbon emissions''; that ''there is enough information related to black carbon's impact to know that global temperatures will rise due to black carbon emissions''; that spatial and temporal heterogeneity in black carbon emissions do not matter for estimating likely climate effects; that ''[b]lack carbon's negative climate impacts do not depend upon details of cloud interactions with aerosols''; and that the EPA does not need to be able to quantify the health or climate benefits precisely to know that it is appropriate to control black carbon as a specific component of PM under the CAA (CBD, pp. 14–15).

As a result, the commenter concluded that the current size-based PM mass standard ''is insufficient to fully protect health and welfare,'' and that the EPA was obligated to establish a specific limit on black carbon as a component of PM. The commenter argued that ''Black carbon must be regulated separately and in addition to $PM_{2.5}$ because absent separate standards sulfates and nitrates may be more likely to be mitigated than the black carbon component of PM'' (CBD, p. 17). To support this point, the commenter cited the conclusion in the Policy Assessment that:

> The current standards that are defined in terms of aggregate size mass cannot be expected to appropriately target controls on components of fine and coarse particles that are related to climate forcing effects. Thus, the current mass-based $PM_{2.5}$ and PM_{10} secondary standards are not an appropriate or effective means of focusing protection against PM-associated climate effects due to these differences in components. (U.S. EPA, 2011a, p. 5–11)

The commenter also noted that existing regulations on diesel engines, which are the largest source of black carbon in the United States, do not affect existing engines and vehicles, and stated that ''The NAAQS program is one of the few opportunities to reduce black carbon from existing engines, industrial and biofuel sources within the United States and rapidly reduce emissions from this pollutant'' (CBD, p. 18).

The EPA agrees with the commenters' assertion that the scientific information about the impacts of aerosol species on climate is developing rapidly, and that understanding of the magnitude of aerosol effects on climate and the contribution of individual aerosol components to those effects has improved substantially over the past decade. The EPA also agrees that certain species, in particular black carbon, play a significant role in multiple aspects of climate. The Policy Assessment recognized that ''Aerosols can impact glaciers, snowpack, regional water supplies, precipitation and climate patterns,'' and may contribute to the melting of ice and snow, a decrease in surface albedo, and climate impacts in the Arctic and other locations (U.S. EPA, 2011a, p. 5–9). The contribution of black carbon to these effects is discussed in detail in the EPA's recent *Report to Congress on Black Carbon* (U.S. EPA, 2012c). In particular, black carbon plays an important role in heating the lower atmosphere by absorbing incoming solar radiation and outgoing terrestrial radiation, i.e. via ''direct'' radiative forcing.

However, the EPA disagrees that there is sufficient information available at this time to establish a NAAQS to protect against the climate impacts associated with current ambient concentrations of black carbon or other PM constituents. While the Integrated Science Assessment concluded that ''a causal relationship exists between PM and effects on climate, including both direct effects on radiative forcing and indirect effects that involve cloud feedbacks that influence precipitation formation and cloud lifetime'' (U.S. EPA, 2009a, section 9.3.10), it also identified substantial remaining uncertainties with regard to the contribution of individual aerosol species to these climate effects. The contribution of individual aerosol components to total aerosol direct radiative forcing is more uncertain than the global average (U.S. EPA, 2009a, section 9.3.6.6), and the indirect effects of aerosols and aerosol components remain highly uncertain, in particular with regard to their complex interactions with clouds.

With regard to black carbon, for example, the EPA disagrees with CBD's claims that ''black carbon's negative climate impacts do not depend upon details of cloud interactions with aerosols'' and that the uncertainties associated with climate impacts of aerosols generally do not apply to black carbon. In fact, the EPA has pointed to cloud interactions as the area of greatest uncertainty with regard to black carbon: recognizing that black carbon affects cloud reflectivity (albedo), lifetime, and stability as well as precipitation, the *Report to Congress on Black Carbon* noted that ''few quantitative estimates of these effects are available, and significant uncertainty remains. Due to all of the remaining gaps in scientific knowledge, it is difficult to place quantitative bounds on the forcing attributable to [black carbon] impacts on clouds at present'' (U.S. EPA, 2012c, p. 4). The Report acknowledged that ''most estimates of the forcing from aerosol indirect effects are based on all aerosol species (e.g. total PM) and are not estimated for individual species (e.g, BC alone)'' (U.S. EPA, 2012c, p. 40). The Report concluded that it remains unclear the extent to which black carbon contributes to the overall aerosol indirect effect, and did not assign any central estimate or even a range of possible values to the role of black carbon in the overall aerosol indirect effect. With regard to black carbon's net contribution to climate, therefore, the Report concluded:

> The direct and snow/ice albedo effects of BC are widely understood to lead to climate warming. However, the globally averaged net climate effect of BC also includes the effects associated with cloud interactions, which are not well quantified and may cause either warming or cooling. Therefore, though most estimates indicate that BC has a net warming influence, a net cooling effect cannot be ruled out. It is also important to note that the net radiative effect of all aerosols combined (including sulfates, nitrates, BC and OC) is widely understood to be negative (cooling) on a global average basis. (U.S. EPA, 2012c, p. 3)

Given the remaining uncertainties about the impact of aerosols on climate, there is even greater uncertainty with regard to how aerosol-induced climate change will affect public health. At this time, it is not possible to estimate the extent to which aerosols in general, let alone particular aerosol components, contribute to the occurrence or exacerbation of adverse health outcomes due to climate change. The EPA therefore disagrees with CBD's claim that the EPA should pursue black carbon reductions for purposes of reducing the impacts of climate change on public health.

The *Report to Congress on Black Carbon* also stressed the importance of considering co-emitted PM species, such as SO_2 and NO_X, in evaluating the benefits of black carbon mitigation options. Noting that many of these co-emitted particles and gases have a cooling influence on climate, the Report noted the difficulty of estimating the net effect of various mitigation measures on net radiative forcing or other climate variables. The EPA concluded that the location and timing of emissions reductions would be critically important for achieving climate benefits, and that ''more research is needed on the benefits of individual control measures in specific locations to support policy decisions made at the national level'' (U.S. EPA, 2012c, p. 140). Thus, the EPA disagrees with CBD's claim that spatial and temporal heterogeneity in black carbon emissions do not matter for estimating likely climate effects, and continues to believe that being able to quantify the climate impacts of various aerosol species, alone and in combination, is essential for informing any possible revisions to the current secondary PM standards based on climate.

Furthermore, while the EPA agrees with the commenter that a large percentage of black carbon emissions come from anthropogenic sources, including diesel engines and vehicles, the EPA notes that existing regulations on mobile diesel engines are already reducing these emissions substantially. Between 1990 and 2005, new engine requirements resulted in a 32 percent reduction in black carbon emissions from mobile sources, and a further 86 percent reduction from 2005 levels is projected to occur by 2030 as vehicles and engines meeting existing regulations are phased into the fleet (U.S. EPA, 2012c, p. 175). Long-term historic data indicate that there has been a dramatic overall decline in black carbon emissions over the past century, due to changes in fuel use, more efficient combustion practices, and implementation of PM controls. Therefore, the EPA disagrees with CBD's claim that a distinct black carbon NAAQS is necessary to achieve reductions in black carbon emissions. Clearly, U.S. emissions of black carbon are already declining substantially, suggesting that the existing mass-based PM standards, though not targeting black carbon specifically, have been effective in achieving black carbon emissions reductions in practice. As acknowledged in the *Report to Congress on Black Carbon,* ''While [black carbon] is not the direct target of existing programs, it has been reduced through controls aimed at reducing ambient $PM_{2.5}$ concentrations and/or direct particle emissions'' (U.S. EPA, 2012c, p. 161). The EPA has acknowledged the need to encourage PM mitigation strategies that focus on reducing directly emitted $PM_{2.5}$ for purposes of reducing black carbon, and this is reflected in U.S. commitments under the Gothenburg Protocol: the new provisions in the Protocol pertaining to PM encourage parties to develop national inventories and projections for black carbon, and to ''give priority'' to black carbon when implementing measures to control PM. However, the EPA notes that the U.S. has not yet ratified the PM amendments to the Gothenburg Protocol, and furthermore, these amendments do not require action specifically to reduce black carbon, but rather encourage countries to take such actions voluntarily within the context of their broader PM reduction strategies. Thus the EPA disagrees with the commenter that the U.S. has an ''obligation'' to reduce black carbon under the Gothenburg Protocol, or that it has ''agree[d] to choose mitigation options for particulate matter that focus on black carbon reductions'' under the Protocol (CBD, p. 13).

In sum, the EPA notes the substantial remaining the uncertainties and gaps with regard to the climate impacts of PM components, including black carbon. These include the uncertainties associated with the spatial and temporal heterogeneity of PM components that contribute to climate forcing; the uncertainties associated with measurement of aerosol components; the inadequate consideration of aerosol impacts in climate modeling; and the currently insufficient data on local and regional microclimate variations and the heterogeneity of cloud formations. As a result, the EPA continues to conclude that it is not currently feasible to conduct a quantitative analysis for the purpose of informing revisions of the current secondary PM standards based on climate, and that there is insufficient information at this time to base a national ambient standard on climate impacts associated with current ambient concentrations of PM or any of its constituents.[203]

D. Conclusions on Secondary PM Standards

This section describes the Administrator's conclusions regarding the secondary PM standards and the rationale leading to the Administrator's final decision to retain the current suite of secondary PM standards, including an annual $PM_{2.5}$ standard of 15 μg/m³ a 24-hour $PM_{2.5}$ standard of 35 μg/m³, and a 24-hour PM_{10} standard of 150 μg/m³, to address PM-related visibility impairment as well as other PM-related welfare effects, including ecological effects, effects on materials, and climate impacts. Specifically, this section explains the Administrator's decision, consistent with the proposal, to retain the current suite of secondary PM standards generally, while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. It also explains the Administrator's decision, contrary to what was proposed, not to establish a distinct standard to address PM-related visibility impairment.

In reaching conclusions regarding the need to revise the secondary PM standards for both visibility and non-visibility welfare effects, the Administrator has taken into account several key factors, including: (1) The latest scientific information on both visibility and non-visibility welfare effects associated with PM, as previously described; (2) the advice of CASAC; and (3) the comments received during the public comment period, as discussed above. Based on this information, the Administrator has reached final conclusions about the secondary PM standards and made final decisions about those standards, as outlined below. Because the Administrator's final conclusions with regard to the need to establish a distinct secondary standard to protect against visibility impairment reflect, in part, her conclusions on secondary PM standards for non-visibility welfare effects, section VI.D.1 first outlines her conclusions regarding secondary PM standards to address non-visibility welfare effects. This is followed by section VI.D.2 which outlines her conclusions regarding a secondary PM standard to address PM-related visibility impairment. Finally, section VI.D.3 summarizes the Administrator's final decisions with regard to the secondary PM standards for both visibility and non-visibility welfare effects.

1. Conclusions Regarding Secondary PM Standards To Address Non-Visibility Welfare Effects

With regard to the secondary PM standards to address non-visibility welfare effects, the Administrator concludes that it is generally appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address non-visibility PM-related welfare effects. This conclusion is based on the considerations discussed above in section VI.B.2, including the latest scientific information and the advice of CASAC, and the public comments received on the proposal, as discussed above in section VI.C.2. The Administrator concurs with the advice of CASAC and the conclusions expressed at the time of proposal that it is important to maintain an appropriate

[203] This conclusion applies for both the secondary (welfare-based) and the primary (health-based) standards.

degree of control of both fine and coarse particles to address non-visibility welfare effects, including ecological effects, effects on materials, and climate impacts. In the absence of information that would support any different standards the Administrator concludes that it is appropriate to retain the existing suite of secondary standards to address non-visibility welfare effects, as proposed. More specifically, the Administrator concludes it is appropriate to retain all aspects of the current 24-hour $PM_{2.5}$ and PM_{10} standards. With regard to the secondary annual $PM_{2.5}$ standard, the Administrator concludes that it is appropriate to retain a level of 15.0 µg/m³ for this standard while revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. In reaching this conclusion, the Administrator notes that no areas in the country are currently using the option for spatial averaging to demonstrate attainment with the secondary annual $PM_{2.5}$ standard.

2. Conclusions Regarding Secondary PM Standards for Visibility Protection

Having reached the conclusion that it is generally appropriate to retain the existing secondary standards to protect against non-visibility welfare effects, the Administrator next considered the target level of protection that would be requisite to protect public welfare with regard to visual air quality. The Administrator then determined whether to adopt a distinct secondary standard to achieve this target level of protection. In making this decision, the Administrator compared the degree of protection for visibility that would be provided by such a distinct secondary standard to the degree of protection provided by the existing secondary standards, focusing specifically on the secondary 24-hour $PM_{2.5}$ standard of 35 µg/m³.[204]

Based on the considerations discussed above in section VI.B and VI.C, the Administrator first concludes that a target level of protection for a secondary standard is most appropriately defined in terms of a $PM_{2.5}$ visibility index as proposed, since it would provide a measure of PM-related light extinction that directly takes into account the factors (i.e., species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in the ambient air and PM-related visibility impairment. Such a $PM_{2.5}$ visibility index standard would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by virtue of directly incorporating the effects of differences in $PM_{2.5}$ composition and relative humidity across the country.

In defining a target level of protection based on a $PM_{2.5}$ visibility index, the Administrator has considered specific aspects of such an index, including the appropriate indicator, averaging time, level, and form. First, with regard to indicator, the Administrator notes the conclusion of CASAC that relying on a calculated $PM_{2.5}$ light extinction indicator based on $PM_{2.5}$ chemical speciation and relative humidity data represented a reasonable approach. Based on the analyses conducted in support of this rulemaking, as described above, as well as the advice of CASAC, the Administrator concludes that a calculated $PM_{2.5}$ light extinction indicator that utilizes the original IMPROVE algorithm, adjusted to use a 1.6 OC multiplier and exclude the term for coarse particles, in conjunction with monthly average relative humidity data (i.e., f(RH) values) based on long-term climatological means would be the most appropriate indicator for a $PM_{2.5}$ visibility index standard.

With regard to averaging time, the Administrator notes that both CASAC and EPA staff have concluded that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. However, in light of the important data quality uncertainties that have recently been identified in association with currently available instruments that would be used to provide the hourly $PM_{2.5}$ mass measurements that would be needed in conjunction with an averaging time shorter than 24 hours, the Administrator concludes it would not be appropriate at this time to set a standard based on a sub-daily averaging time. Moreover, the Administrator notes that analyses conducted by the EPA during this review clearly indicate that $PM_{2.5}$ light extinction calculated on a 24-hour average basis would be a reasonable and appropriate surrogate for $PM_{2.5}$ light extinction calculated on a 4-hour basis. Thus, the Administrator concludes that a 24-hour averaging time would be appropriate for a $PM_{2.5}$ visibility index. The Administrator recognizes that a 24-hour averaging time would effectively reduce the influence of peak hours of visibility impairment on visibility index values, but concludes that in light of the concern that peak hourly measurements may be significantly influenced by atypical conditions and/or atypical instrument performance, it is appropriate to adopt a longer averaging time to ensure that hour-specific influences and uncertainties are balanced against more robust measurements.

With regard to form, the Administrator notes that consistent with the approach taken in other NAAQS, including the current 24-hour $PM_{2.5}$ NAAQS, a multi-year percentile form offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. Utilizing a three-year average form provides stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year. Moreover, considering the lack of information on and the high degree of uncertainty regarding the impact on public welfare of the number of days with visibility impairment over the course of a year, the Administrator considers it reasonable to focus on the 90th percentile, which represents the median of the distribution of the 20 percent worst visibility days, a key focus of the Regional Haze program. The Administrator concludes that ensuring that 90 percent of days have visual air quality that is at or below the target level of protection could be reasonably expected to lead to improvements in visual air quality on the 20 percent most impaired days, and that the limited information available in this review provides no basis for adopting a different form which would limit the occurrence of days with peak PM-related light extinction in urban areas to a greater degree. Therefore, the Administrator concludes that a 90th percentile form, averaged over 3 years, is appropriate, for purposes of establishing a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index.

With regard to level, the Administrator concludes that in light of the uncertainty associated with the high degree of variability in visibility conditions and the potential variability in visibility preferences across different parts of the country, it is appropriate to establish a target level of protection based on the upper end of the range of Candidate Protection Levels (CPLs)

[204] This focus on the 24-hour $PM_{2.5}$ standard reflects the Administrator's judgments that PM-related visibility impairment is principally related to fine particle concentrations and that perception of visibility impairment is most directly related to short-term levels of visual air quality.

identified in the Policy Assessment (i.e., 20–30 dv) and generally supported by CASAC. Thus, the Administrator concludes that it would be appropriate to set a target level of protection in terms of a $PM_{2.5}$ visibility index with a 24-hour averaging time that would provide protection equivalent to the protection afforded by a 4-hour $PM_{2.5}$ visibility index with a level of 30 dv. Furthermore, the Administrator notes that the approaches used to estimate generally equivalent levels for a 24-hour $PM_{2.5}$ visibility index generated 90th percentile 24-hour values similar to the 4-hour values and a range of city-specific estimates of generally equivalent 24-hour levels that encompassed the range of levels considered appropriate for 4-hour CPLs, including the CPL of 30 dv at the upper end of that range. The Administrator thus concludes that it would be appropriate to use an unadjusted 4-hour CPL for purposes of establishing a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index.

In considering the alternative levels proposed for a 24-hour standard, either 28 dv or 30 dv, the Administrator concludes that the current substantial degrees of variability and uncertainty inherent in the public preference studies should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain. In addition, she concludes that, in light of the significant uncertainties, it is appropriate to place less weight on the results of western visibility preference studies and that the CPL value (30 dv) that is based on the eastern preference study results is likely to be more representative of urban areas that do not have associated mountains or other valued objects visible in the distant background For all of these reasons, the Administrator concludes that it is appropriate to set a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index at 30 dv.

In summary, in light of all the information available in this review, the Administrator concludes that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction), a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv, would be requisite to protect public welfare with regard to visual air quality.

In reaching this conclusion, the Administrator notes that any national ambient air quality standard to address PM-related visibility impairment would be designed to work in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in all areas of the country, including urban, non-urban, and Federal Class I areas. While the Regional Haze Program is focused on improving visibility in Federal Class I areas and a secondary NAAQS to address PM-related visibility impairment would focus on protecting visual air quality principally in urban areas, both programs could be expected to provide benefits in surrounding areas. In addition, the development of local programs, such as those in Denver and Phoenix, could continue to be an effective and appropriate approach to provide additional protection, beyond that afforded by a national standard, for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas.

Having concluded that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index, with a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv, would be requisite to protect public welfare with regard to visual air quality, the Administrator next has to determine whether to adopt such a visibility index as a distinct secondary standard. This determination requires considering such a secondary standard not in isolation but in the context of the full suite of secondary standards. As discussed above, the Administrator has determined to retain the current suite of secondary PM standards to address non-visibility welfare effects (except for the form of the annual standard). A distinct secondary standard to address visibility impairment is properly considered in a context where there is also a 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$.

In this context, the Administrator has considered the degree of protection from visibility impairment afforded by the existing secondary $PM_{2.5}$ standards. The Administrator has considered both whether the existing 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ is sufficient (i.e. not under-protective) and whether it is not more stringent than necessary (i.e. not over-protective).

As discussed above in section VI.C.1.f, the results of the Kelly *et al.* (2012a; 2012b) analyses indicate that based on 2008–2010 and 2009–2011 data, all areas meeting the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ had visual air quality at least as good as 30 dv (24-hour average, based on 90th percentile form averaged over 3 years). This means that it is highly likely that the secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would be controlling relative to a 24-hour standard based on a $PM_{2.5}$ visibility index set at a level of 30 dv, and highly unlikely that areas would exceed the target level of protection for visibility of 30 dv without also exceeding the existing secondary 24-hour standard. On the basis of this evidence, and the supporting public comments, the Administrator judges that the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ provides sufficient protection in all areas against the effects of visibility impairment—i.e., that the existing 24-hour $PM_{2.5}$ standard would provide *at least* the target level of protection for visual air quality of 30 dv which the Administrator judges appropriate.

The Administrator also recognizes that the analyses presented in Kelly *et al.* (2012a; 2012b) indicate that the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ also would likely achieve *more than* the target level of protection of visual air quality (30 dv) in some areas. That is, when meeting a mass-based standard of 35 $\mu g/m^3$, some areas would have levels of PM-related visibility impairment below 30 dv. Thus, the 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would be over-protective in some areas (i.e. more stringent than necessary) relative to the target level of protection for visibility. This is not surprising, as the current mass-based standard does not account for variation in particle species and relative humidity. The 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would provide more than the necessary protection in the areas where this would be expected, for example western areas with lower relative humidity.

In light of the Administrator's conclusion that it is appropriate to retain the current secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ for non-visibility welfare effects, the Administrator notes that this standard will remain in place regardless of whether she elects to set a distinct secondary standard in terms of a $PM_{2.5}$ visibility index. The issue is not whether to adopt a $PM_{2.5}$ visibility index standard when viewed in isolation, but whether such a distinct secondary standard should be adopted in addition to the current secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$. The EPA notes that adoption of such a distinct secondary standard is not needed to provide sufficient protection from visibility impairment with respect to the target level of protection determined above. In addition, adoption of such a distinct secondary standard would not change the fact that the current secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would result in over-protection from visibility impairment in certain areas of the country. Such over-protection will occur whether or not such a distinct secondary standard is adopted. In effect, adopting such a distinct secondary standard would have no impact on the degree of protection provided from visibility impairment. Since sufficient protection from visibility impairment would be provided for all areas of the country without adoption of a distinct secondary standard, and adoption of a distinct secondary standard will not change the degree of over-protection provided for some areas of the country, the Administrator judges that adoption of such a distinct secondary standard is not needed to provide requisite protection for both visibility and non-visibility related welfare effects.

It is important to note that this conclusion is based on the specific target level of protection determined above, and the specific set of current secondary standards. The Administrator's conclusion with regard to the sufficiency of the protection provided by the current suite of secondary standards is based on comparing the a 30 dv target level of protection for a $PM_{2.5}$ visibility index standard against the degree of protection provided by the current secondary 24-hour $PM_{2.5}$ standard of 35 µg/m^3. It is the combination of the specific target level of protection and the current suite of secondary standards that is the basis for the decision not to adopt a distinct secondary standard in terms of a $PM_{2.5}$ visibility index at this time.

The EPA recognizes that, as in the last review, the final decision is to not adopt a distinct secondary standard to address visibility impairment. While the DC Circuit remanded the decision on a secondary standard in the last review, the EPA's decision in this review has addressed the issues raised in the court's remand. Here the EPA has clearly identified the target degree of protection (defined in terms of a $PM_{2.5}$ visibility index at a level of 30 dv based on a 24-hour averaging time, and a 90th percentile form, averaged over 3 years) that would be requisite to protect public welfare with regard to visual air quality. The EPA has carefully compared this degree of protection with that provided by the current secondary 24-hour $PM_{2.5}$ standard of 35 µg/m^3, based on an area-specific analysis of recent air quality data and concluded that the degree of protection from visibility impairment provided by the current secondary standard is sufficient to protect public welfare consistent with section 109(b)(2). This provides a clear basis for judging that the current secondary 24-hour $PM_{2.5}$ standard of 35 µg/m^3 would provide sufficient protection. The analysis also shows that the current secondary 24-hour $PM_{2.5}$ standard would provide more protection than is needed in some areas, largely because it does not take into account variable factors such as relative humidity. However, the EPA has recognized that adoption of a distinct secondary standard to address visibility, in addition to retaining the current secondary standard, would not change this result. The EPA has therefore concluded that adoption of such a distinct secondary standard, in addition to the current suite of secondary PM standards, is not needed to provide requisite protection for both visibility and non-visibility related welfare effects. Thus the EPA's decision has carefully considered and accounted for the views of the court in the remand of the 2006 NAAQS.

E. Administrator's Final Decisions on Secondary PM Standards

To address PM-related welfare effects, including ecological effects, effects on materials, climate impacts, and visibility impairment, the Administrator is retaining the current suite of secondary PM standards, except for a change to the form of the annual standard. Specifically, to address PM-related non-visibility welfare effects including ecological effects, effects on materials, and climate impacts, the EPA is retaining the current secondary 24-hour $PM_{2.5}$ and PM_{10} standard and is revising only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this change to the primary annual $PM_{2.5}$ standard. With respect to PM-related visibility impairment, the Administrator has identified a target degree of protection, defined in terms of a $PM_{2.5}$ visibility index (based on speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction), a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, and a level of 30 deciviews (dv), which she judges to be requisite to protect public welfare with regard to visual air quality. The EPA's analysis of monitoring data provides the basis for concluding that the current secondary 24-hour $PM_{2.5}$ standard would provide sufficient protection, and in some areas greater protection, relative to this target protection level. Adding a distinct secondary standard to address PM-related visibility impairment would not affect this protection. Since sufficient protection from visibility impairment will be provided for all areas of the country without adoption of a distinct secondary standard, and adoption of a distinct secondary standard will not change the degree of over-protection of visual air quality provided for some areas of the country by the secondary 24-hour $PM_{2.5}$ standard, the Administrator judges that adoption of a distinct secondary standard, in addition to the current suite of secondary standards, is not needed to provide requisite protection for both visibility and non-visibility related welfare effects.

VII. Interpretation of the NAAQS for PM

This section discusses the EPA Administrator's final decisions on the revisions proposed to the data handling procedures for the primary and secondary $PM_{2.5}$ standards. Appendix N to 40 CFR part 50 describes the computations necessary for determining when the $PM_{2.5}$ standards are met and also addresses which measurement data are appropriate for comparison to the standards; as well, it specifies associated data reporting protocols, data completeness criteria, and rounding conventions. The EPA is modifying appendix N to conform to the revised $PM_{2.5}$ standards; most notably, the EPA is amending the appendix N procedures by removing the option for spatial averaging. In addition to making changes to appendix N that correspond to the changes in the annual standard form and the revised primary annual standard level, the EPA is also finalizing additional proposed revisions to the appendix in order to codify existing practices currently included in guidance documents or implemented as EPA standard operating procedures; better align appendix N language and requirements with changes in $PM_{2.5}$ ambient monitoring and reporting requirements; provide greater clarity and transparency in the provisions; and enhance consistency with data handling protocols utilized for other pollutants.

A. Revised Amendments to Appendix N: Interpretation of the NAAQS for $PM_{2.5}$

As discussed in sections III and VI above, the EPA Administrator has decided to: (1) Revise the form and level of the primary annual $PM_{2.5}$ standard, and retain the current primary 24-hour $PM_{2.5}$ standard (section III.F) and (2) retain the current secondary 24-hour $PM_{2.5}$ standard, and revise the form and retain the level of the secondary annual $PM_{2.5}$ standard (for visibility and non-visibility-related welfare protection) (section VI.E). Appendix N is being revised to conform to those changes to the standards. In the proposal, the EPA recommended additional data handling procedures to appendix N for the proposed distinct secondary standard to address $PM_{2.5}$-related visibility impairment. However, as discussed in section VI.E, the Administrator has decided not to establish the proposed distinct secondary standard to address visibility impairment, and therefore, the associated proposed data handling procedures related to that proposed standard are not included in the final revised appendix N.

In addition to the changes to appendix N necessitated by the annual NAAQS form and level revisions (discussed in depth in sections III and VI above), the EPA is also finalizing additional revisions to appendix N in order to: (1) Better align appendix N language and requirements with changes in the $PM_{2.5}$ ambient monitoring and reporting requirements as discussed in section VIII below; (2) enhance consistency with recently codified changes in data handling procedures for other criteria pollutants; (3) codify existing practices currently included in guidance documents or implemented as the EPA standard operating procedures; and (4) provide enhanced clarity and consistency in the articulation and application of appendix N provisions. Key elements of the finalized revisions to appendix N are summarized in sections VII.A.1 through VII.A.4 below which correspond to the similarly numbered sections in appendix N. The proposed potential new fifth section of appendix N dealt with the proposed distinct $PM_{2.5}$-related visibility secondary standard that was not finalized by the Administrator and thus the proposed appendix N section 5 is not included in the final appendix N. Furthermore, proposed changes to sections 1 through 4 of appendix N that also dealt with the proposed secondary visibility index standard (e.g., term definitions, rounding conventions, etc.) are also omitted from the final revised appendix.

1. General

As proposed, the EPA is finalizing modifications to section 1.0 of appendix N to provide additional clarity regarding the scope and interpretation of the $PM_{2.5}$ NAAQS. This appendix section now references the finalized revisions of the primary annual $PM_{2.5}$ standard (40 CFR 50.18) and the retained secondary $PM_{2.5}$ NAAQS. With regard to the appendix N term definitions which are delineated in this initial section, the EPA has added, modified, and eliminated term definitions, as appropriate, in accordance with the final data handling rule revisions such as the modification of terms that referenced spatial averaging. Additional term definitions were also added to reference otherwise unchanged appendix N content in an effort to streamline the appendix text, enhance clarity and thus improve readability and understanding. In particular, the definition of data substitution tests was shortened, and a definition for ''test design value'' (TDV) was added for completeness and for further clarity. This term was previously part of the data substitution definition and now it is more explicitly defined. The EPA notes that there were no substantive public comments received with regard to this section.

2. Monitoring Considerations; Spatial Averaging

As proposed, the EPA has finalized revisions to section 2.0 of appendix N consistent with the concurrent modification of the form of the primary annual $PM_{2.5}$ standard that removes the option for spatial averaging. As described in more detail in section III.E.3.a above, the EPA decided to remove this option as part of the form of the primary annual $PM_{2.5}$ standard in light of analysis that indicates that the existing constraints on spatial averaging, as modified in 2006, may be inadequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on susceptible populations (Schmidt 2011a, Analysis A).

With respect to the form of the secondary annual $PM_{2.5}$ standard, as discussed in section VI.E above, the EPA has decided to retain the current secondary annual $PM_{2.5}$ standard to provide protection for welfare effects. In the proposal, the EPA believed it would be reasonable and appropriate to align the data handling procedures for the primary and secondary annual $PM_{2.5}$ standards and remove the option for spatial averaging for the secondary annual $PM_{2.5}$ standard to be consistent with the revised form of the primary annual $PM_{2.5}$ standard (FR 77 39000, June 29, 2012). The EPA noted that no areas in the country are currently using the option for spatial averaging to demonstrate attainment with the secondary annual $PM_{2.5}$ standard. There were no comments on the proposed change and the EPA has therefore concluded it appropriate to remove the option for spatial averaging for the secondary annual $PM_{2.5}$ standard from Appendix N.

Consistent with the revised form of the primary and secondary annual $PM_{2.5}$ standards, the levels of both standards will be compared to measurements from each appropriate (i.e., ''eligible'') monitoring site in an area, as specified in 40 CFR 58.30, with no allowance for spatial averaging. Thus, for an area with multiple eligible monitoring sites, the site with the highest design value would determine the attainment status for that area. As a result of the decision to eliminate the spatial averaging option for both the primary and secondary annual standards, the EPA omitted all references to the spatial averaging option in the finalized version of appendix N. See section III.E.3.a above for a discussion of EPA's response to received public comment on the issue of removal of the spatial averaging option.

3. Requirements for Data Use and Reporting for Comparisons With the NAAQS for $PM_{2.5}$

In the proposal, the EPA suggested changes to section 3.0 of appendix N to correspond to the proposed new secondary standard to address PM-related visibility impairment. Since the EPA is not finalizing the proposed distinct secondary standard to address visibility impairment, none of these proposed changes are necessary and are not being made. The EPA is, however, finalizing proposed changes to improve consistency with procedures used for other NAAQS as well as to improve consistency with current standard operating procedures. Specifically, the EPA proposed revisions to this section regarding: (1) Clarification of monitoring data appropriate to compare to the $PM_{2.5}$ NAAQS; (2) clarification of procedures for combining monitoring data from collocated instruments into a single ''combined site'' record; and (3) codification of the current standard operating procedure whereby the EPA uses data for which the certification deadline has passed but the monitoring agency has not requested certification of the data to determine compliance with the $PM_{2.5}$ NAAQS provided the data are complete and accurate (thus making appendix N consistent with data handling appendices for other criteria pollutants). In the final revision to appendix N, the EPA is incorporating all the above noted modifications to section 3 of appendix N. Additional details describing the incorporated modifications are provided below.

With regard to clarification of which monitoring data are appropriate for comparison to the $PM_{2.5}$ NAAQS, the proposal acknowledged important data quality concerns associated with the $PM_{2.5}$ measurements collected by continuous $PM_{2.5}$ FEMs and referenced a subsequent preamble proposal section that discussed the issue in more depth and put forward a solution to mitigate the data quality concerns. The revised monitoring rule, promulgated today in conjunction with the PM NAAQS revision, includes, as proposed, language allowing monitoring agencies to identify $PM_{2.5}$ FEMs that are not providing data of sufficient comparability to the FRM and, with EPA approval, to allow such data to be deemed ineligible for comparisons with the $PM_{2.5}$ NAAQS [205]; see detailed discussion of this decision in section VIII.A.1 below. Rule language for the definition of ''suitable monitors'' in section 1.0 of the finalized revised appendix N accommodates and references this monitoring rule revision codified in 40 CFR 58.11.

With respect to the procedures for combining monitored data from collocated instruments into a single ''combined site'' data record, the EPA proposed to revise the current methodology in situations where an FRM monitor operating on a non-daily schedule is collocated with a continuous FEM monitor (that has acceptable comparability with an FRM). As noted in the proposal, the EPA was not advocating a change to the actual procedures for constructing a combined site record but rather a modification to the subsequent evaluation of whether the specific measurements were considered ''creditable'' or ''extra'' samples.[206] The language clarification proposed is currently standard operating procedure in Agency design value computations so the language modification in appendix N merely proposed to modify actual practices.[207] The revised appendix N finalized in today's action incorporates the modification as proposed. The EPA notes that there were no substantive public comments received regarding this change.

4. Comparisons with the $PM_{2.5}$ NAAQS

Section 4.0 of appendix N specifies the procedures for comparing monitored data to the $PM_{2.5}$ standards. The EPA proposed revisions to section 4.0 of appendix N to: (1) Provide consistency with the proposed primary and secondary annual $PM_{2.5}$ standards; (2) expand the data completeness assessments to be consistent with current guidance and standard operating procedures; and (3) simplify the procedure for calculating annual 98th percentile concentrations when using an approved seasonal sampling schedule.

Consistent with the proposed decisions to revise the level of the primary annual $PM_{2.5}$ standard (section III.E.4.b.iii) and to retain the current level of the secondary annual $PM_{2.5}$ standard (section VI.B.1.c.vi), the EPA proposed to modify section 4.1(a) of appendix N to separately list the levels of the primary and secondary annual $PM_{2.5}$ standards. The final revised appendix N incorporates this proposed change; this appendix N section now references the revised primary annual standard level of 12.0 μg/m³ and the retained secondary annual standard level of 15.0 μg/m³. However, as discussed above with respect to the final decision to not establish a distinct secondary standard to provide protection for visibility impairment, the final appendix N now explicitly references all $PM_{2.5}$ secondary standard protection (that is, protection from visibility impairment and non-visibility-related welfare effects) to be provided by the revised annual standard with retained level of 15.0 μg/m³ and the retained 24-hour standard with retained level of 35 μg/m³. Consistent with the final decisions to remove the option for spatial averaging for the primary annual $PM_{2.5}$ standard (section III.F), as well as for the secondary annual $PM_{2.5}$ standard (section VII.A.2), the EPA amended section 4.4 of appendix N to remove equations and associated instructions relating to spatial averaging.

With regard to assessments of data completeness, the EPA proposal included two additional data substitution tests [208] (making a total of three data substitution tests) into appendix N for validating annual and 24-hour $PM_{2.5}$ design values otherwise deemed incomplete (via the 75 percent and 11 creditable sample minimum quarterly data completeness requirements). The EPA proposed to add these tests in order to codify existing practices currently included in guidance documents (U.S. EPA, 1999) and implemented as EPA standard operating procedures, and further, to make the data handling procedures for $PM_{2.5}$ more consistent with the procedures used for other NAAQS. While the need for data substitution will lessen as more continuous $PM_{2.5}$ monitors continue to be deployed in $PM_{2.5}$ networks, the EPA believes that these substitution procedures are important to ensure that available data, if incomplete, can be confidently used to make comparisons to the NAAQS. As noted in the EPA proposal, data substitution tests are diagnostic in nature; that is; they are only used in an illustrative manner to show that the NAAQS status based on incomplete data is reasonable. As codified in section 4 of Appendix N, data are substituted for missing data to produce a ''test design value'' which is compared to the level of the NAAQS. If the test design value passes the diagnostic test, the ''incomplete'' design value (without the data substitutions) is then considered a valid design value. If an ''incomplete'' design value does not pass any data substitution test, then the original

[205] The EPA also allows use of alternative methods where explicitly stated in the monitoring methodology requirements (appendix C of 40 CFR part 58), such as $PM_{2.5}$ Approved Regional Methods (ARMs) which can be used to determine compliance with the NAAQS. Monitoring agencies identifying ARMs that are not providing data of sufficient quality will also be allowed to exclude these data in making comparisons to the $PM_{2.5}$ NAAQS. Currently, there are no designated ARMs for $PM_{2.5}$.

[206] Data for a combined site record originates by default from the designated ''primary'' monitor at the site location and is then augmented with data from collocated FRM or FEM monitors whenever valid data are not generated by the primary monitor. Samples in the combined site record are deemed ''creditable'' or ''extra'' according to the required sampling frequency for a specific monitoring site (i.e., ''site-level sampling frequency'') which, by default, is defined to be the same as the sampling frequency required of the primary monitor. Samples in the combined site data record that correspond to scheduled days according to the site-level sampling frequency are deemed ''creditable'' and, thus, are considered for determining whether or not a specific monitoring site meets data completeness requirements. These samples also determine which daily value in the ranked list of daily values for a year represents the annual 98th percentile concentration. Samples that are not deemed ''creditable'' are classified as ''extra'' samples. These samples do not count towards data completeness requirements and do not affect which daily values represent the annual 98th percentile concentration; ''extra'' samples, however, are candidates for selection as the 98th percentile.

[207] Before the introduction of continuous FEMs, when two or more samplers were collocated at the same site, monitoring agencies typically identified the sampler that operated on the more frequent sampling schedule as the ''primary'' monitor for developing a single site record. However, due to concerns regarding the comparability of FEMs to FRMs operated in some monitoring agency networks, and as briefly discussed above and in more detail in section VIII.B.3.b.iii below, many monitoring agencies have kept the FRM as the ''primary'' monitor and delegated the continuous FEM (which samples more frequently, except in cases where the FRM operates on an ''every day'' schedule) to be the ''supplemental'' (non-primary) collocated monitor. In such cases, FEM measurements reported on the FRM ''off'' days were technically considered ''extra.'' In light of this practice, EPA modified standing operating procedures whereby supplemental collocated FEM samples reported on the FRM ''off'' days would be considered ''scheduled'' and ''creditable.'' Thus, collocated FEM samples would count towards data capture rates (actually, increasing both the numerator and the denominator in the capture rate equation), and also would count towards identifying annual 98th percentile concentrations. Further, if data from a supplemental collocated FEM are missing on an FRM ''off'' day (and no unscheduled FRM data are reported that day), the EPA proposed not to identify these as ''scheduled'' days consistent with current practice, and thus, reported data generated from the supplemental collocated continuous FEMs can only help increase data capture rates (77 FR 39001, June 29, 2012)).

[208] Data substitution tests are supplemental data completeness assessments that use estimates of 24-hour average concentrations to fill in for missing data (i.e., ''data substitution'').

design value is still considered incomplete (and not valid for NAAQS comparisons). Previously, section 4.1(c) of appendix N specified only one data substitution test for validating an otherwise incomplete design value. That diagnostic test only applied to the primary and secondary annual $PM_{2.5}$ standard and only applies in instances of a violation; this test is referred to as the ''minimum quarterly value'' test and is used to determine if the NAAQS has not been met. The two proposed additional data substitution tests were to be applicable for making comparisons to the primary and secondary annual and 24-hour $PM_{2.5}$ standards, specifically to show that the NAAQS had been met. One of these proposed tests uses collocated PM_{10} data to fill in ''slightly incomplete''[209] data records, and the other uses quarter-specific maximum values to fill in slightly incomplete data records; these two test are referred to as the ''collocated PM_{10} test'' and the ''maximum quarterly value test'', respectively. Both tests are designed to confirm that the $PM_{2.5}$ design value is valid and is less than the level of the NAAQS.

The EPA received several comments on the proposed addition of the two data substitution tests to determine that the NAAQS was met. The majority of comments generally supported the proposed addition of data substitution tests. However, one commenter questioned the general philosophy of all appendix N data substitution tests (i.e., the existing ''over NAAQS'' test and the two proposed ''under NAAQS'' tests) by suggesting that there were more appropriate techniques for filling in for missing data that would result in better estimates of true design value level. The EPA believes that the data substitution tests provided in the finalized appendix N are all very conservative approaches to verify that the NAAQS standards are either met or not met, and that the test design values are not to be used as the best estimators of the design value concentration.[210]

Another commenter questioned, and argued against, the use of collocated PM_{10} data in $PM_{2.5}$ data substitution tests. The commenter stressed that this type of test is not consistent with those established for other pollutants. The commenter further argued that while PM_{10} and $PM_{2.5}$ are both measurements of particulate matter, they are essentially different pollutants with different sources and different dispersion characteristics, and further, that the ratio of $PM_{2.5}$ to PM_{10} varies spatially and temporally. In general, the commenter claimed that the EPA had offered no explanation of why PM_{10} data were valid for a $PM_{2.5}$ data substitution test. At the time of proposal, the EPA believed that PM_{10} data would be appropriate for a $PM_{2.5}$ data substitution test. After consideration of public comments and additional air quality analyses, the EPA has decided that a collocated PM_{10} test is largely redundant with the maximum quarterly value test and thus not necessary to include it in Appendix N. The EPA has analyzed the most recent three years of $PM_{2.5}$ and PM_{10} data (2009–2011) and assessed the separate benefit of the PM_{10} substitution routine compared to the maximum quarterly value test (Schmidt, 2012b). In this assessment of 2009–2011 $PM_{2.5}$ design values which did not meet the nominal data completeness requirements, the EPA found that the collocated PM_{10} test was almost entirely redundant with the maximum quarterly value test. It was also very infrequently needed as a separate test. For the annual NAAQS, the maximum quarter value test in 100 cases resulted in a test design value (TDV_{max}) less than or equal to 12.0 μg/m³. There were only two additional cases (i.e. 2 percent) when TDV_{max} was greater than 12.0 μg/m³ but the TDV associated with the collocated PM_{10} test was less than 12.0 μg/m³. Similarly for the 24-hour NAAQS, the maximum quarter value test in 116 cases resulted in a test design value (TDV_{max}) less than or equal to 35 μg/m³ and again only 2 additional sites (less than 2 percent) passed the collocated PM_{10} test but not the maximum quarterly value test. Furthermore, the maximum quarterly value tests allowed the annual and 24-hour design value to be validated approximately 5 times more often than through the use of the collocated PM_{10} test. Accordingly, the EPA has decided to not include the collocated PM_{10} data substitution tests in Appendix N, and thereby further simplify the data handling procedures for making comparisons to the annual and daily NAAQS.

With regard to identifying annual 98th percentile concentrations for comparison to the primary and secondary 24-hour $PM_{2.5}$ standards, the EPA suggested in the proposal to simplify the procedures used with an approved seasonal sampling schedule. Specifically, the EPA proposed to eliminate the use of a special formula for calculating annual 98th percentile concentrations with a seasonal sampling schedule and thereby proposed to use only one method for calculating annual 98th percentile concentrations for all sites (77 FR 39002, June 29, 2012).

The proposal explained that with an approved seasonal sampling schedule, a site is typically required to sample during periods of the year when the highest concentrations are expected to occur, but less frequently during periods of the year when lower concentrations are expected to occur (77 FR 39002, June 29, 2012). This type of sampling schedule generally leads to an unbalanced data record; that is, a data record with proportionally more ambient measurements (with respect to the total number of days in the sampling period) in the ''high'' season and proportionally fewer ambient measurements in the ''low'' season. In the last review, the EPA revised section 4.5 of appendix N to include a special formula for computing annual 98th percentile values when a site operates on an approved seasonal sampling schedule. This special formula accounted for an unbalanced data record and was consistent with guidance documentation (US EPA, 1999), and, where appropriate, with official OAQPS design value calculations (71 FR 61211, October 17, 2006). In cases where there is a balanced[211] (or near-balanced) data record, the special formula yields the same result as the regular procedure for calculating annual 98th percentile concentrations.

To qualify for a seasonal sampling schedule, monitoring agencies are required to co-locate a continuous $PM_{2.5}$ instrument with the seasonal sampling FRM. Since the last review, there has been considerable deployment of continuous $PM_{2.5}$ FEM monitors. In situations where a $PM_{2.5}$ FRM monitor operating on a non-daily periodic schedule (such as a 1-day-in-3 or a 1-day-in-6 schedule) is collocated with a continuous $PM_{2.5}$ FEM monitor, data are combined based on procedures stated in section 3.0 of appendix N as modified, as discussed in section VII.A.3 above. Combining collocated FRM and FEM data effectively results in a site which samples everyday and results in a balanced data record. In such a case, if a site used a seasonal sampling schedule regime for the FRM monitor, these data would be balanced by the every-day

[209] Slightly incomplete is defined as less than 75 percent but at least 50 percent quarterly data capture.

[210] Appendix N states that when the data substitution tests are satisfied, then the NAAQS design values derived from reported $PM_{2.5}$ data which otherwise would be considered to be incomplete shall be considered valid for comparisons to the $PM_{2.5}$ NAAQS.

[211] A balanced data record has the same proportion of ambient measurements (with respect to the total number of days in the sampling period) in the ''high'' season as in the ''low'' season.

FEM data and there would be no need for the special formula for calculating annual 98th percentile concentrations on the combined site data.

As EPA noted in the proposal, there are very few $PM_{2.5}$ FRM monitors that operated on an approved seasonal sampling schedule (only 15 sites out of approximately 1,000 total sites in 2010) and that for almost half of those sites, the collocated continuous instrument was a $PM_{2.5}$ FEM (77 FR 39002, June 29, 2012). The proposal stated that for the 3-year period 2008 to 2010, the annual 98th percentile concentrations calculated with the special formula at those 15 sites were approximately five percent lower than if the regular procedure was used. The EPA also noted in the proposal that, in the last review, the Agency modified the monitoring requirements for areas with an FRM operating on a non-daily schedule such that, when the design values were within five percent of the 24-hour $PM_{2.5}$ NAAQS, those areas would be required to increase the frequency of sampling to every day (40 CFR 58.12(d)(1); 71 FR 61165, October 17, 2006; 71 FR 61249, October 17, 2006). In consideration of these facts, the EPA proposed to simplify the data handling procedures for sites operating on a seasonal sampling schedule by eliminating the special formula and all references to it for the following reasons: (1) The small difference between 98th percentile concentrations calculated using the special formula versus the regular procedure and the small number of sites currently using the special formula; (2) the EPA requires every day sampling in areas with design values that are within five percent of the 24-hour $PM_{2.5}$ NAAQS; and (3) FRMs operating on an approved seasonal sampling schedule are required to be collocated with a continuous $PM_{2.5}$ instrument (and if that instrument were an FEM, the resulting combined site record would tend to be balanced over the year and thus the special formula would be superfluous) (77 FR 39002, June 29, 2012). Thus, the EPA proposal included only one method for calculating annual 98th percentile concentrations, the ''regular'' table look-up method specified in section 4.5(a)(1) of appendix N.

In light of the rationale provided above and because EPA received no significant negative comments regarding the proposal, the EPA concludes it is appropriate to eliminate the special seasonal sampling 98th percentile identification procedure from appendix N. The final revised appendix N specifies only one method for identifying annual 98th percentile concentrations; the table look-up method is now the only permitted technique for identifying annual 98th percentile concentrations.

B. Exceptional Events

The EPA is finalizing primary annual $PM_{2.5}$-specific deadlines in 40 CFR 50.14 by which air agencies [212] must flag ambient air quality data that they believe have been affected by exceptional events and submit initial descriptions of those events. The EPA is also finalizing the deadlines by which air agencies must submit detailed exceptional events documentation to support the exclusion of those data from the EPA's monitoring-based determinations of attainment or nonattainment with the revised primary annual $PM_{2.5}$ NAAQS. The final exceptional events-related schedule is aligned with the designations schedule, discussed in greater detail in section IX, and is promulgated as proposed and as supported by multiple commenters. Without revisions to 40 CFR 50.14, an air agency may not be able to flag and submit documentation for some relevant data either because the generic deadlines may have already passed by the time the new or revised NAAQS is promulgated or because the generic deadlines require documentation submission at least 12 months prior to the date that the EPA must make a regulatory decision.

The EPA acknowledges the concern raised by a few commenters that numerous wildfires occurred between 2010 and 2012 that air agencies may determine influenced ambient air quality concentrations potentially affecting compliance with the revised primary annual $PM_{2.5}$ NAAQS, and that air agencies may want to submit detailed exceptional events documentation associated with multiple wildfires. Commenters further noted that 1 year to provide documentation of these potential exceptional events may not be sufficient. The EPA believes that the promulgated schedules provide sufficient time for air agencies to submit information related to the annual standard and for the EPA to fully consider and act on the submitted information during the initial area designation process. The EPA recently released draft exceptional events guidance that clarifies key provisions of the 2007 Exceptional Events Rule, provides examples of best practices, and streamlines the documentation development process. The guidance provides approaches that are broadly applicable to all event/pollutant combinations and would apply to many PM events, including wildfire/PM combinations. Additionally, the EPA has posted several concurred upon wildfire/PM exceptional event demonstration packages on its Web site at: *http://www.epa.gov/ttn/analysis/exevents.htm*. Considered together, the EPA believes this guidance will help air agencies submit information in a timely manner.[213] The EPA notes that under the promulgated schedule, except for events that occur in December 2012, air agencies will have more than 1 year to provide documentation for these potential events. The EPA intends to work with potentially affected areas to identify, screen, and prioritize events potentially influencing compliance with the primary annual $PM_{2.5}$ NAAQS and associated area designations.

Also in response to comments, the EPA is clarifying that this preamble language and the associated promulgated exceptional events schedules apply only to the NAAQS that the EPA is newly promulgating or revising in this action, that is, the revised primary annual $PM_{2.5}$ NAAQS. The promulgated exceptional event schedule revisions do not apply to the retained PM standards (i.e., secondary PM standards, primary 24-hour PM_{10}, primary 24-hour $PM_{2.5}$). Further, the revised/extended exceptional event schedules apply only to those data the EPA will use to establish initial area designations for the revised primary annual $PM_{2.5}$ NAAQS.

The ''Treatment of Data Influenced by Exceptional Events; Final Rule'' (72 FR 13560, March 22, 2007), known as the Exceptional Events Rule and codified at 40 CFR 50.14, contains generic deadlines for an air agency to submit to the EPA specified information about exceptional events and associated air pollutant concentration data. As discussed in the proposal, without revisions to 40 CFR 50.14, an air agency may not be able to flag and submit documentation for some relevant data because the generic deadlines may have already passed by the time the new or revised NAAQS is promulgated. Similarly, revisions to 40 CFR 50.14 are needed because air agencies may not be able to flag and submit documentation for events that occurred in December of 2013 by 1 year before the designations

[212] References to ''air agencies'' are meant to include state, local, and tribal air agencies responsible for implementing the Exceptional Events Rule.

[213] The EPA released draft exceptional events guidance documents (U.S. EPA, 2012e) for public comment via a Notice of Availability in the **Federal Register** on July 6, 2012 (77 FR 39959).

are made in 2014 as is required by the existing generic schedule requires.

To support appropriate consideration of exceptional event data influencing ambient air quality concentrations potentially affecting compliance with the revised primary annual $PM_{2.5}$ NAAQS, the EPA is adopting revisions to 40 CFR 50.14 to change the submission dates for claimed exceptional events information affecting $PM_{2.5}$ data considered during the initial area designations process under the promulgated revised primary annual $PM_{2.5}$ NAAQS. As proposed, for air quality data collected in 2010 or 2011, the EPA is extending to July 1, 2013 the otherwise applicable generic deadlines of July 1, 2011 and July 1, 2012, respectively, for flagging data and providing an initial description of an event (40 CFR 50.14(c)(2)(iii)). The EPA is retaining the existing generic deadline in the Exceptional Events Rule of July 1, 2013 for flagging data and providing an initial description of events occurring in 2012. Similarly, the EPA is revising to December 12, 2013, the deadline for submitting documentation to justify exceptional events occurring in 2010 through 2012 and potentially influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS. The EPA believes these revisions/extensions will provide adequate time for air agencies to review potential $PM_{2.5}$ exceptional events influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS from 2010 to 2012, to notify the EPA by flagging the relevant data and providing an initial description in AQS, and to submit documentation to support claims for exceptional events. These schedule revisions will also allow the EPA to fully consider and act on the submitted information during the initial area designation process.

If an air agency intends the EPA to consider in the revised primary annual $PM_{2.5}$ designations decisions whether $PM_{2.5}$ data collected during 2013 influence compliance with the primary annual $PM_{2.5}$ NAAQS, then the air agency must flag these data by the generic Exceptional Event Rule deadline of July 1, 2014. The EPA is finalizing August 1, 2014, as the deadline for submitting documentation to justify $PM_{2.5}$-related exceptional events occurring in 2013 and potentially influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS. The EPA believes that these deadlines provide air agencies with adequate time to review and identify potential exceptional events that occur in calendar year 2013 and for the EPA to fully consider and act on the submitted information during the initial area designation process.

While the EPA will make every effort to designate areas for the primary annual $PM_{2.5}$ NAAQS on a 2 year schedule, the EPA recognizes that it may need up to an additional year for the designations process to ensure that states/tribes and the EPA base designations decisions on complete and sufficient information. If the EPA announces at a later date that it is extending the designations schedule beyond 2 years based on unavailability of data, the EPA will consider extending the 2013 exceptional event documentation submission schedule by promulgating additional revisions to 40 CFR 50.14.

Therefore, using the authority provided in CAA section 319(b)(2) and in the Exceptional Events Rule at 40 CFR 50.14 (c)(2)(vi), the EPA is finalizing the schedule for data flagging and submission of demonstrations for $PM_{2.5}$ exceptional events data potentially influencing compliance with the revised primary annual $PM_{2.5}$ NAAQS considered for initial area designations under the promulgated primary annual $PM_{2.5}$ NAAQS as presented in Table 3.

TABLE 3—REVISED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN INITIAL AREA DESIGNATIONS FOR THE 2012 $PM_{2.5}$ NAAQS

NAAQS Pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
$PM_{2.5}$/Primary Annual Standard (12.0 µg/m^3) Promulgated December 14, 2012	2010 and 2011	July 1, 2013	December 12, 2013.
	2012	July 1, 2013[a]	December 12, 2013.
	2013	July 1, 2014[a]	August 1, 2014.

[a] This date is the same as the general schedule in 40 CFR 50.14.

Note: The table of revised deadlines *only* applies to data the EPA will use to establish the initial area designations for the revised primary annual $PM_{2.5}$ NAAQS. The general schedule applies for all other purposes, most notably, for data used by the EPA for redesignations to attainment.

C. Updates for Data Handling Procedures for Reporting the Air Quality Index

There were no comments regarding the proposed updates for data handling procedures for reporting the AQI. However, two table footnotes that were part of the existing rule were inadvertently omitted from the proposal. The inadvertently dropped footnotes were footnotes 3 and 4 of Table 2 (''Breakpoints for the AQI'') of appendix G (''Uniform Air Quality Index (AQI) and Daily Reporting'') to Part 58. Since the footnotes are still applicable, the EPA has included them in the final rule. The final rule also codifies all changes identified in the EPA proposal regarding data handling procedures for the AQI.

VIII. Amendments to Ambient Monitoring and Reporting Requirements

The EPA is finalizing a number of changes to the ambient air monitoring, reporting, and network design requirements associated with the PM NAAQS. Ambient PM monitoring data are used to meet a variety of monitoring objectives including determining whether an area is in violation of the PM NAAQS. Ambient PM monitoring data are collected by state, local, and tribal monitoring agencies (''monitoring agencies'') in accordance with the monitoring requirements contained in 40 CFR parts 50, 53, and 58. This section discusses the monitoring changes that the EPA is finalizing to support the revised PM NAAQS summarized in sections III.F, IV.F, and VI.F above.

The monitoring changes being finalized primarily relate to the revised primary $PM_{2.5}$ NAAQS. Several monitoring changes were proposed specifically in support of a potential distinct secondary $PM_{2.5}$ visibility index standard; however, as explained in Section VI, EPA is not finalizing a distinct secondary standard using a visibility index and therefore is not finalizing the monitoring changes that would have been necessary to support it. The EPA did not propose any monitoring changes associated with the

PM_{10} NAAQS and is not adopting any in this final rule.

A. Issues Related to 40 CFR Part 53 (Reference and Equivalent Methods)

To be used in a determination of compliance with the PM NAAQS, PM data are typically collected using samplers or monitors employing an FRM or FEM. The EPA also allows use of alternative methods where explicitly stated in the monitoring methodology requirements (appendix C of 40 CFR part 58), such as $PM_{2.5}$ ARMs which can be used to determine compliance with the NAAQS. The EPA prescribes testing and approval criteria for FRM and FEM methods in 40 CFR part 53.

1. $PM_{2.5}$ and $PM_{10-2.5}$ Federal Equivalent Methods

As described in the proposal, the EPA continues to believe that an effective $PM_{2.5}$ monitoring strategy includes the use of both filter-based FRM samplers and well-performing continuous $PM_{2.5}$ monitors. Well-performing continuous $PM_{2.5}$ monitors would include both non-designated continuous $PM_{2.5}$ monitors and designated Class III [214] continuous FEMs that meet the performance criteria described in table C–4 of 40 CFR part 53 when comparing to a collocated FRM operated by the monitoring agency. Only designated methods (i.e., FRMs, FEMs, and ARMs) are approved to be used in comparison to the NAAQS; however, non-designated methods may be useful to meet other monitoring objectives (e.g., reporting the AQI). The use of Class III continuous FEMs at SLAMS is described in more detail in section VIII.B.3.b.ii below. Monitoring agencies are encouraged to evaluate the quality of data being generated by FEMs and, where appropriate, to reduce the use of manual, filter-based samplers to improve operational efficiency and to lower overall operating costs. To encourage such a strategy, the EPA is working with numerous stakeholders including the monitoring committee of NACAA, instrument manufacturers, and monitoring agencies to support national data analyses of continuous $PM_{2.5}$ FEM performance, and where such performance does not meet data quality objectives, to develop and institute a program of best practices to improve the quality and consistency of resulting data.

The EPA believes that progress is being made to implement well performing $PM_{2.5}$ continuous FEMs across the nation. As noted in the proposal, the first few steps involved the EPA developing and approving the testing and performance criteria which were finalized in 2006, followed by instrument companies performing field testing and submitting applications to the EPA, and the EPA review and approval, as appropriate, of Class III FEMs. In the current step, monitoring agencies are testing and assessing the data comparability from continuous $PM_{2.5}$ FEMs.

While EPA did not propose any changes to the performance or testing criteria in 40 CFR part 53 used to approve $PM_{2.5}$ continuous FEMs, the EPA did propose an administrative change to part 53.9—''Conditions of designations.'' See 77 FR 39006. This section describes a number of conditions that must be met by a manufacturer as a condition of maintaining designation of an FRM or FEM. Subsection (c) of this section reads, ''Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as part of a FRM or FEM shall function within the limits of the performance specifications referred to in 40 CFR 53.20(a), 53.30(a), 53.50, or 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in 40 CFR 53.4(b)(3).'' The EPA's intent in this requirement is to ensure that monitoring methods work within performance criteria, which includes methods for $PM_{2.5}$ and $PM_{10-2.5}$; however, there was no specific reference to performance criteria for Class II [215] and III $PM_{2.5}$ and $PM_{10-2.5}$ methods. The EPA proposed to link the performance criteria referred to in 40 CFR part 53.35 associated with Class II and III $PM_{2.5}$ and $PM_{10-2.5}$ 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.

All comments received on this proposed change were supportive and EPA is finalizing this change. The implication of this change is that instrument manufacturers and air agencies operating the equipment will have a shared responsibility for approved FEMs to meet required performance criteria for at least the first 12 months of operation, which is the typical warranty period for an instrument. By having a shared responsibility for an FEM to meet the performance criteria, instrument companies and air agencies will both be motivated to ensure the best practices for installing, operating, and servicing an instrument are carried out according to the instrument company's operating manual and other readily available materials [216] in support of each method.

2. Use of Chemical Speciation Network (CSN) Methods To Support the Proposed New Secondary $PM_{2.5}$ Visibility Index NAAQS

The EPA had proposed to use CSN methods to support the proposed new secondary $PM_{2.5}$ visibility index NAAQS; however, as explained in Section VI of this final rule, EPA is not finalizing the new secondary $PM_{2.5}$ visibility index NAAQS and therefore has no need to finalize the CSN methods to support such a standard.

Despite our decision not to finalize formal requirements for CSN methods, this network remains a critical component in our PM monitoring program. The EPA, monitoring agencies, and external scientists and policy makers use $PM_{2.5}$ data from the CSN to support several important monitoring objectives such as: Development of modeling tools and the application of source apportionment modeling for control strategy development to implement the NAAQS; health effects and exposure research studies; assessment of the effectiveness of emission reductions strategies through the characterization of air quality; and development of SIPs. The use of the CSN to support all of these objectives will continue.

B. Changes to 40 CFR Part 58 (Ambient Air Quality Surveillance)

1. Terminology Changes

The EPA proposed to revise several terms associated with $PM_{2.5}$ monitor placement to ensure consistency with other NAAQS and to conform with long-standing practices in siting of equipment by monitoring agencies (77 FR 39007).

The EPA proposed to revoke the term ''community-oriented'' and replace it

[214] Class III refers to those methods for $PM_{2.5}$ or $PM_{10-2.5}$ 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.

[215] Class II refers to those methods for $PM_{2.5}$ or $PM_{10-2.5}$ in which integrated samples are taken by filtration and subjected to a subsequent filter conditioning process followed by a gravimetric mass determination, but which is not a Class I equivalent methods because of substantial deviations from the design specification of the sampler specified for reference methods in appendix L or O (as applicable) of part 50 of the CFR.

[216] At the recent National Air Quality Conference in May of 2012, a training session on ''Best Practices for Operating $PM_{2.5}$ Continuous FEMs'' was conducted. Presentations from this session are publically available on EPA's web site at: *http://www.epa.gov/ttn/amtic/2012present.html*.

with the term ''area-wide.'' The term ''community-oriented,'' while used within the description of the design criteria for $PM_{2.5}$, is not defined and has not been used in the design criteria for other NAAQS pollutants. Appendix D to 40 CFR part 58 presents a functional usage of the term where sites at the neighborhood and urban scale area are considered to be ''community-oriented.'' In addition, population-oriented, micro- or middle-scale $PM_{2.5}$ monitoring may also be considered ''community-oriented'' when determined by the Regional Administrator to represent many such locations throughout a metropolitan area. The EPA proposed to replace this usage of ''community-oriented'' with the term ''area-wide'' in the text of the $PM_{2.5}$ network design criteria and to define it in 40 CFR 58.1 to provide a more consistent usage of this concept throughout appendix D of 40 CFR part 58. Specifically, the EPA proposed that the terminology would read—''Area-wide means all monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro-or middle-scale that are representative of many such locations in the same CBSA.''

The EPA proposed to revoke the term ''Community Monitoring Zone'' (CMZ) and to remove references to it in 40 CFR part 58. Community monitoring zone is currently defined as ''an optional averaging area with established, well defined boundaries, such as county or census block, within an MPA [217] that has relatively uniform concentrations of annual $PM_{2.5}$ as defined by appendix N of 40 CFR part 50 of this chapter. Two or more community oriented state and local air monitoring stations (SLAMS) monitors within a CMZ that meet certain requirements as set forth in appendix N of 40 CFR part 50 may be averaged for making comparisons to the annual $PM_{2.5}$ NAAQS.'' The EPA proposed to revoke this term and references to it since, as discussed in section VII.A.2 above, the EPA proposed to eliminate all references to the now-revoked spatial averaging option throughout appendix N.

The one comment directly addressing the proposed rule changes (from a state air agency) supported the proposal. A few industry commenters noted the change in the context of how monitoring data are used to compare to the NAAQS, but did not address the proposed specific terminology changes. However, as explained in section III.E.3.a, several industry commenters did provide comments critical of EPA's proposal to revoke spatial averaging which is related to revoking the term ''Community Monitoring Zone''.

For the reasons explained above, the EPA is finalizing its proposed change to revoke the term ''community-oriented'' and to replace it with the term ''area-wide.'' The EPA is also finalizing its proposal to revoke the term ''Community Monitoring Zone'' (CMZ) and references to it in 40 CFR part 58.

2. Special Considerations for Comparability of $PM_{2.5}$ Ambient Air Monitoring Data to the NAAQS

In general, ambient monitors must meet a basic set of requirements before the resulting data can be used for comparison to the NAAQS. These requirements include the presence and implementation of an approved quality assurance project plan; the use of methods that are reference, equivalent, or other approved method as described in appendix C to 40 CFR part 58; and compliance with the probe and siting path criteria as described in appendix E to 40 CFR part 58. While these 40 CFR part 58 requirements apply to any monitor that provides data for comparison to the NAAQS, there are certain additional restrictions that apply only to $PM_{2.5}$ monitoring.[218] These additional restrictions provide that sites must be ''population-oriented'' for comparison to either the 24-hour or annual NAAQS, and specifically for comparison to the annual NAAQS, sites must be sited to represent area-wide locations. There is a related provision that provides for comparing sites at micro- or middle-scales to the annual $PM_{2.5}$ NAAQS when the site is determined by the Regional Administrator to represent a larger region of localized high ambient $PM_{2.5}$ concentration.

These provisions have been in the monitoring regulations since the inception of the $PM_{2.5}$ NAAQS. Nonetheless, these provisions and the fact that such monitoring requirements are not found in the requirements for all other criteria pollutants have created areas of uncertainty for the EPA and state, local, and tribal agencies that base implementation decisions on monitoring requirements through programs such as dispersion modeling, SIP planning, and the calculation of transportation conformity budgets. For example, in developing modeling guidance to support near-road transportation conformity modeling, the EPA struggled to determine how the identification of acceptable $PM_{2.5}$ receptor locations can be reconciled with the $PM_{2.5}$ monitoring regulations that reference potentially acceptable (or unacceptable) monitoring locations that may, or may not, be considered unique for purposes of comparing to the annual $PM_{2.5}$ NAAQS. Accordingly, the EPA proposed to revise these particular $PM_{2.5}$ requirements for consistency with long-standing practices in all other NAAQS pollutant monitoring networks, and to ensure that interpretation of the monitoring rules does not cause ambiguity in implementation examples that also include the treatment of unmonitored areas (see 77 FR 39007–009). Each of these topics is described below.

a. Eliminating the Term ''Population Oriented'' From Section 58.30

The EPA proposed to remove the term ''population oriented'' from section 58.30 so that there would no longer be an explicit requirement that $PM_{2.5}$ monitoring sites be ''population-oriented'' for comparison to the $PM_{2.5}$ NAAQS. The EPA noted that this requirement is not entirely consistent with the definition of ''ambient'' used in the NAAQS. The EPA's definition of ambient air is specified in 40 CFR 50.1—''*Ambient air* means that portion of the atmosphere, external to buildings, to which the general public has access.'' The EPA's definition of ''population-oriented'' is provided in 40 CFR 58.1—''*Population-oriented monitoring (or sites)* means residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day.'' The NAAQS are standards for concentrations ''in the ambient air'' [219]—i.e., air to which members of the public could be exposed— and all monitors used for NAAQS regulatory purposes must be representative of ambient air concentrations.[220] Consistent with this requirement and the long-standing practice of monitoring agencies locating ambient monitors, the EPA's experience is that $PM_{2.5}$ monitors are placed in areas that are representative of population exposures. There are no $PM_{2.5}$ monitors currently operating as

[217] Monitoring Planning Area (MPA) means a contiguous geographic area with well established, well defined boundaries, such as a CBSA, county or State, having a common areas that is used for planning monitoring locations for $PM_{2.5}$.

[218] These are found in 40 CFR 58.30 (Special considerations for data comparisons to the NAAQS).

[219] See 40 CFR part 50.

[220] See, e.g., 40 CFR 58.1 (defining ''federal reference method'' as ''a method for sampling and analyzing the ambient air for an air pollutant * * *'')

''non-population oriented'' and the EPA does not believe that the requirement for near-road monitoring (discussed in detail further below) will result in monitors that are not representative of population exposures. At the same time, the specification that certain $PM_{2.5}$ monitors must be ''population-oriented'' in the rules has created substantial confusion in how to treat potential locations of exposure for NAAQS-related regulatory requirements other than monitoring network design, such as in applying modeling as part of a PSD or SIP exercise.[221]

The EPA's intention in proposing to remove the term ''population oriented'' from section 58.30 was to remove a potential source of inconsistency in the monitoring rules as they apply for all the NAAQS. As noted earlier, the NAAQS provide protection for the public health and welfare in areas where the public can be exposed. For all other criteria pollutants, the monitoring requirements have no such restriction on the comparability of a monitor. In the case of $PM_{2.5}$ however, the additional restriction of monitors being required to be ''population-oriented'' for comparability to the NAAQS has existed. The term ''population oriented'' has lacked a quantitative definition (e.g., the interpretation of ''substantial number'' in the definition of ''population-oriented''), therefore monitoring agencies and those stakeholders who based implementation strategies and decisions on monitoring regulations have been uncertain about which locations would meet requirements described in § 58.30, which do not exist for any other NAAQS. Monitoring agencies are also not in a position to precisely forecast where future residential, commercial, or recreational development may occur, therefore requiring that $PM_{2.5}$ monitors that are to be compared to the NAAQS can only be located where ''substantial numbers of people'' live, work, or play (i.e., in the present tense) represents an unwise limitation on the flexibility of monitoring agencies to revise their $PM_{2.5}$ networks to account for anticipated changes in demographics or development as well as a contradiction with the inherent applicability of the NAAQS in ambient air locations where the public has access (e.g., in any location outside the perimeter of a industrial facility). From an operational standpoint, we note that revoking this term would not change the requirements in the $PM_{2.5}$ network design criteria. To the extent that the phrase ''population-oriented'' served to emphasize the need for micro- or middle-scale monitors to be representative of locations with population exposure to be comparable to the annual NAAQS, the definition of ambient air, together with the requirement in revised section 58.30 that such sites must be ''area-wide'' to be comparable to the annual NAAQS, adequately serves the same purpose. By revising the $PM_{2.5}$ monitoring rules to ensure consistency with the long-standing definition of ambient air applied to the other NAAQS pollutants, the EPA will be able to more clearly define how to treat potential exposure receptors for other NAAQS regulatory requirements, regardless of whether monitoring exists or not.

Public comments on this issue were supported by air agencies and public health and environmental groups. Two commenters from state agencies supported the proposed change, with one noting further that regardless of a change it is still the air agency's responsibility to plan a network with sites that are appropriate for comparison to the NAAQS. Several public health and environmental groups supported revoking ''population oriented'' as a condition for comparability of $PM_{2.5}$ monitoring sites to the NAAQS stating that retaining such a policy is inconsistent with the text, purpose and intent of the Clean Air Act. Most industry commenters did not support revoking ''population-oriented'' as a condition for comparison to the NAAQS. Most of these comments raised concerns with using data from an area where potentially no one is exposed.

In considering these comments, the EPA agrees that it is appropriate for individual air agencies to provide a recommendation in the annual monitoring network plan regarding whether any site may or may not be appropriate for comparison to the $PM_{2.5}$ (or any) NAAQS. The roles of the air agency and the EPA in this process of identifying whether a site is, or is not, consistent with the network plan requirements for a NAAQS are specified in the already-established monitoring requirements of § 58.10. In this approval process, the air agency initiates the recommendations and the EPA has the responsibility to approve, as appropriate, any plans that provide for changes to the network.

EPA disagrees with the industry comments. As noted above, monitors (including those for $PM_{2.5}$) must already meet the test of being representative of ambient air to be compared to the NAAQS, and thus such monitors meeting this test will be sited in locations where people are already located, or where they could be exposed, whether or not the term ''population oriented'' appears in section 58.30. Moreover, as discussed below, comparisons to the annual $PM_{2.5}$ NAAQS can be only be from monitors ''that are representative of area-wide air quality.'' ''Area-wide'' monitors are those at the neighborhood scale or larger, or at smaller scales if they are representative of many such locations in the same CBSA. The EPA anticipates that a monitor that is sited as representative of ambient air at the neighborhood scale or larger (or of ambient air at many smaller areas) will be representative of population exposure. This conclusion is further supported by the fact that all current monitors used for comparison with the $PM_{2.5}$ NAAQS are designated as ''population-oriented.''[222]

After consideration of the public comments, the EPA is finalizing its decision to revoke use of ''population-oriented'' as a condition for comparability of $PM_{2.5}$ monitoring sites to the NAAQS. The EPA concludes that the ''population-oriented'' language is unnecessary and inconsistent with other monitoring rules, and should therefore be removed.

b. Applicability of Micro- and Middle-Scale Monitoring Sites to the Annual $PM_{2.5}$ NAAQS

The EPA proposed language in 40 CFR section 58.30 to clarify when data from $PM_{2.5}$ monitoring sites at micro- and middle-scale locations can be compared to the annual $PM_{2.5}$ NAAQS. The EPA's intent was to provide consistency and predictability in the interpretation of the monitoring regulations. The EPA's current rules state that ''$PM_{2.5}$ data that are representative, not of area-wide but rather, of relatively unique population-oriented micro-scale, or localized hot spot, or unique population-oriented middle-scale impact sites are only eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. For example, if the $PM_{2.5}$ monitoring site is adjacent to a unique dominating local $PM_{2.5}$ source or can be shown to have average 24-hour concentrations representative of a smaller than neighborhood spatial scale, then data from a monitor at the site would only be eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS.'' We proposed clarifying language to

[221] Examples include dispersion modeling to support NAAQS attainment planning, associated SIP development, and the calculation of transportation conformity budgets.

[222] The last known non population-oriented site at Sun Metro in El Paso Texas (AQS ID: 48–141–0053), was shut down in October 2010 and is in the process of being moved to a nearby neighborhood.

explicitly state that measuring $PM_{2.5}$ in micro- and middle-scale environments near emissions of mobile sources, such as a highway, does not constitute being impacted by a ''unique'' source and so could be compared to the annual $PM_{2.5}$ NAAQS. We explained that mobile sources are rather ubiquitous and there are many locations throughout an urban area where elevated exposures attributable to such sources could occur. Therefore, we proposed that in most cases the potential location for a $PM_{2.5}$ monitoring site, including micro- and middle-scale sites near roadways, would be eligible for comparison to the annual NAAQS. We further noted that the existing definition of ''middle scale'' in appendix D to part 58 already indicates that traffic corridors can be middle scale, and hence not unique, and therefore comparable to the annual $PM_{2.5}$ NAAQS (as well as to the 24-hour $PM_{2.5}$ NAAQS) (77 FR 39008).

Air agencies that commented on this part of the proposed rule offered a variety of positions. One air agency stated that sites at these smaller scales should not be compared to the annual NAAQS. Another air agency stated that these sites should be considered for comparison with the annual $PM_{2.5}$ NAAQS only when the air agency initiates a decision that such sites at these smaller scales are area-wide. A different air agency offered that all micro- and middle-scale sites should be compared to the annual NAAQS since the wording of the provision is problematic and will be difficult for agencies to implement.

Industry commenters were largely against finalizing such a provision. The major concern raised was that such a provision combined with other related provisions represented an unwarranted tightening of the NAAQS. Some industry commenters pointed out that there are examples of unique locations in near road environments and as such EPA should not presume that $PM_{2.5}$ monitors in these locations should be applicable to the annual $PM_{2.5}$ NAAQS.

In considering comments on this part of the rule, the EPA notes that there are already examples of where the States and EPA have determined certain micro- and middle-scale locations as applicable to the annual NAAQS and others where they were determined as not applicable to the annual $PM_{2.5}$ NAAQS. These cases exist where a State proposed and the Regional Administrator determined that either the micro-scale or middle-scale site did or did not represent many similar areas in a CBSA (40 CFR 58.30 and section 4.7 to Appendix D, part 58). The EPA also notes that the existing descriptions of the types of micro- and middle-scale sites which are unique and cited in § 58.30 are not being amended and that data from these types of sites would remain as not comparable to the annual $PM_{2.5}$ NAAQS. Accordingly, $PM_{2.5}$ data that are representative, not of area-wide but rather, of relatively unique population-oriented microscale, or localized hot spots, or unique middle scale impact sites will only be eligible for comparison to the 24-hour NAAQS. Our proposal was to clarify language to explicitly state that measuring $PM_{2.5}$ in micro- and middle-scale environments near emissions of mobile sources, such as a highway, does not constitute being impacted by a ''unique'' source and so the site could be compared to the annual $PM_{2.5}$ NAAQS. However, in light of public comments pointing out that there are cases where near-road environments can be considered a unique location; EPA is not finalizing this part of the rule language. Examples of such locations that are considered unique and should therefore not be considered applicable to the annual $PM_{2.5}$ NAAQS are explained later in section VIII.B.3.b.i. As noted in the preamble to the proposed rule (77 FR 39008–09), air agencies and the EPA will use the annual monitoring network plan described in 40 CFR 58.10 for identification and approval of sites that are suitable and sites that are not suitable for comparison with the annual $PM_{2.5}$ NAAQS.

The EPA disagrees with those comments that asserted that the proposed change would have represented a tightening of the NAAQS. As explained in section III.E.3.a on the form of the annual NAAQS, the EPA carefully considered that areas such as traffic corridors were potential high exposure areas, since a significant fraction of the population, including at-risk populations, live in proximity to major roads and should be afforded the degree of protection intended by the revisions to the form and level of the annual $PM_{2.5}$ standard being adopted. Monitoring in such areas as traffic corridors does not make the annual standard more stringent than intended, but rather affords the populations of such middle- and micro-scale areas (where determined to represent area-wide air quality) the requisite level of protection from long-term exposure to $PM_{2.5}$.

3. Changes to Monitoring for the National Ambient Air Monitoring System

a. Background

As described in appendix D to 40 CFR part 58, the ambient air monitoring networks must be designed to meet three basic monitoring objectives:

(a) Provide air pollution data to the general public in a timely manner. Data can be presented to the public in a number of attractive ways including through air quality maps, newspapers, Internet sites, and as part of weather forecasts and public advisories.

(b) Support compliance with ambient air quality standards and emissions strategy development. Data from FRM, FEM, and ARM monitors for NAAQS pollutants will be used for comparing an area's air pollution levels against the NAAQS. Data from monitors of various types can be used in the development of attainment and maintenance plans. SLAMS, and especially National Core Monitoring Network (NCore) [223] station data, will be used to evaluate the regional air quality models used in developing emission strategies and to track trends in air pollution abatement control measures' impact on improving air quality. In monitoring locations near major air pollution sources, source-oriented monitoring data can provide insight into how well industrial sources are controlling their pollutant emissions.

(c) Support for air pollution research studies. Air pollution data from the NCore network can be used to supplement data collected by researchers working on health effects assessments and atmospheric processes or for monitoring methods development work.

To support the air quality management work indicated in the three basic air monitoring objectives, a network must be designed with a variety of types of monitoring sites. Monitoring sites must be capable of informing managers about many things including the peak air pollution levels, typical levels in populated areas, air pollution transported into and outside of a city or region, and air pollution levels near specific sources. Following is a listing of six general site types: (a) Sites located to determine the highest concentrations expected to occur in the area covered by the network (highest concentration); (b)

[223] NCore is a multi-pollutant network that integrates several advanced measurements for particles, gases and meteorology (U.S. EPA, 2011a, Appendix B, section B.4). Measurements required at NCore include $PM_{2.5}$ mass and speciation, $PM_{10-2.5}$ mass, ozone, CO, SO_2, NO, NO_y, and basic meteorology.

sites located to measure typical concentrations in areas of high population density (population oriented); (c) sites located to determine the impact of significant sources or source categories on air quality (source impact or source oriented); (d) sites located to determine general background concentration levels (general background); and (e) sites located to determine the extent of regional pollutant transport among populated areas (regional transport); and in support of secondary standards (welfare related impacts).

b. Primary $PM_{2.5}$ NAAQS

The EPA proposed to add a near-road component to the $PM_{2.5}$ network design criteria and to clarify the use of approved $PM_{2.5}$ continuous FEMs at SLAMS.

ii. Addition of a Near-Road Component to the $PM_{2.5}$ Monitoring Network

The EPA proposed to add a near-road component to the $PM_{2.5}$ monitoring network (77 FR 39009). The EPA explained that there are gradients in near-roadway $PM_{2.5}$ that are most likely to be associated with heavily travelled roads (particularly those with significant heavy-duty diesel activity), and that the largest numbers of impacted populations are located in the largest CBSAs in the country (Ntziachristos *et al.,* 2007; Ross *et al.,* 2007; Yanosky *et al.,* 2009; Zwack *et al.,* 2011). The EPA further noted that by adding a modest number of $PM_{2.5}$ monitoring sites that are leveraged with measurements of other pollutants in the near-road environment, a number of key monitoring objectives will be supported, including collection of NAAQS comparable data in the near-road environment, support for long-term health studies investigating adverse effects on people, providing a better understanding of pollutant gradients impacting neighborhoods that parallel major roads, availability of data to validate performance of models simulating near-road dispersion, characterization of areas with potentially elevated concentrations and/or poor air quality, implementation of a multi-pollutant paradigm as stated in the NO_2 NAAQS proposed rule (74 FR 34442, July 15, 2009), and monitoring goals consistent with existing objectives noted in the specific design criteria for $PM_{2.5}$ described in appendix D, 4.7.1(b) to 40 CFR part 58.

The monitoring methods that are appropriate for this purpose are an FRM, FEM, or ARM. The EPA recognized that there are limitations in the ability of some of these methods to accurately measure $PM_{2.5}$ mass due to the incomplete retention of semi-volatile material on the sampling medium (U.S. EPA, 2009a, section 3.4.1.1). This limitation is relevant to the near-road environment as well as to other environments where PM is expected to have semi-volatile components. The EPA also recognized that continuous $PM_{2.5}$ FEMs, which provide mass concentration data on an hourly basis, are better suited to accomplish the goals of near-road monitoring as they will complement the time resolution of the other air quality measurements and traffic data collected at the same sites. In this regard, particular $PM_{2.5}$ FEMs are generally better suited for near-road monitoring than FRMs. However, filter-based FRMs do offer some advantages which may be highly desirable for near-road monitoring, such as readily available filters for later chemical analysis such as for elemental composition by x-ray fluorescence and black carbon (BC) by transmissometry. As a result of these tradeoffs, monitoring agencies are encouraged to select one or more $PM_{2.5}$ methods for deployment at near-road monitoring stations that best meet their agencies monitoring objectives while ensuring that at least one of those methods is appropriate for comparison to the NAAQS (i.e., a FRM, FEM, or ARM). The EPA believes that by allowing monitoring agencies to choose the FRM, FEM, or ARM method(s) that best fits their needs, whether filter-based or continuous, the data will still be able to meet the objectives cited above while ensuring maximum flexibility for the monitoring agencies in the operation of their network.

The EPA believes that requiring a modest network of near-road compliance $PM_{2.5}$ monitors is necessary to provide characterization of concentrations in near-road environments including for comparison to the NAAQS. These long-term monitors will supplement shorter-term networks to support the tracking of long-term trends [224] of near-road $PM_{2.5}$ mass concentrations and other pollutants in near-road environments where people are exposed. Therefore, the EPA proposed to require near-roadway monitoring of $PM_{2.5}$ at one location within each CBSA with a population of one million persons or greater. The EPA believes that this network will be adequate to support the NAAQS since the largest CBSAs are likely to have greater numbers of exposed populations, a higher likelihood of elevated near-road $PM_{2.5}$ concentrations, and a wide range of diverse situations with regard to traffic volumes, traffic patterns, roadway designs, terrain/topography, meteorology, climate, surrounding land use and population characteristics. Given the latest population data available, the proposed requirement would result in approximately 52 required near-road $PM_{2.5}$ monitors across the country. An indirect benefit of this network design is that monitoring agencies in these largest CBSAs are more likely to already have redundant monitors that could be relocated to the near-road environment, reducing costs for equipment and ongoing operation.[225] While only a single near-road $PM_{2.5}$ monitor is required within each of the CBSAs, agencies may elect to add additional $PM_{2.5}$ monitoring sites in near-road environments.

While the EPA recognized that the location of maximum concentration of $PM_{2.5}$ exposure from roadway sources might differ from the maximum location of NO_2 or other pollutants, the EPA proposed to require that near-road $PM_{2.5}$ monitors be collocated with the planned NO_2 monitors. The NO_2 network design considers multiple factors that are also relevant for $PM_{2.5}$ concentrations (i.e., average annual daily traffic, fleet mix, roadway design, congestion patterns, terrain, and meteorology) and significant thought and review has already gone into its design, including pilot studies at five locations, and the development of a technical assistance document in conjunction with the affected monitoring agencies and the CASAC AAMMS (Russell and Samet, 2010b) to support deployment. Further, this collocation will allow multiple pollutants to be tracked in the near-road environment. To the extent that air agencies are still determining the optimum location for their multi-pollutant [226] near-road monitoring stations, EPA encourages consideration of sites that best reflect measurement of maximum concentrations associated with exposure of people living in areas

[224] For example, the emissions used for the PM NAAQS RIA modeling show that nationwide on-road primary $PM_{2.5}$ emissions are expected to be reduced by 63% between 2007 and 2020. Additionally, the elemental carbon portion of the on-road emissions is expected to drop by 81 percent between 2007 and 2020. Therefore, we expect that measured near-road $PM_{2.5}$ gradients will be much lower in the future as elemental carbon is a large fraction of the gradient, due to future impacts of existing mobile source controls.

[225] EPA Regional Administrator approval would be required prior to the discontinuation of SLAMS monitors, based on the criteria described in 40 CFR 58.14(c).

[226] NO_2, CO, and now $PM_{2.5}$ measurements are all expected to be collocated at near-road monitoring stations.

that parallel major roads, to maximize the value of the data for use later in health studies. Therefore, while compromises may be necessary when siting a multi-pollutant near road monitoring station, on balance, the EPA believes this is the most efficient and beneficial approach for deployment of this component of the network.

The EPA notes that the planned 52 near-road monitors represent a small number of the total approximate 900 operating $PM_{2.5}$ monitoring stations across the country. The EPA could have proposed more near-road sites, however, the addition of sites in lower population CBSAs is not expected to lead to much if any difference in characterization of air quality since the bump in $PM_{2.5}$ concentration associated with near-road environments in lower population CBSAs, which typically have correspondingly less travelled roads, is expected to be very small. The EPA could also have proposed multiple sites in larger CBSAs; however, State monitoring programs are already working towards representative near-road monitoring stations and there is a synergistic value in ensuring these measurements are collocated with multiple other measurements to serve the monitoring objectives noted above. Since EPA has already finalized requirement of CO monitoring at near-road stations in CBSA's with a population of 1 million or more at sites that are collocated with NO_2, there would be less value in requiring any more than 52 $PM_{2.5}$ monitors as any more stations will not have CO for use in multi-pollutant monitoring objectives (e.g., health studies and model evaluation).

Ideally, near-road sites would be located at the elevation and distance from the road where maximum $PM_{2.5}$ levels occur in this environment, representing locations where populations are exposed; for example, in apartments and other housing; schools located along major roadways; industrial parks where workers exposed; and in recreational areas such as greenways, bikeways, and other park facilities that are often developed along roads. Specific to probe and siting criteria for near-road $PM_{2.5}$ monitors, which is explained later in this section, EPA did not set additional criteria on what the elevation and distance requirements should be, beyond what is already defined for $PM_{2.5}$ or near-road NO_2 monitors for reasons explained above. Also, the EPA did not propose that the near-road $PM_{2.5}$ monitors be located within a specific distance of other area-wide sites; however, monitoring agencies are encouraged to consider that a near-road site selected in accordance with monitoring requirements and also located in proximity to a robust area-wide site, such as an NCore station, would provide useful information in characterizing the near-road contribution to multiple pollutants, including $PM_{2.5}$ and tracking the decreasing trend that is expected in the $PM_{2.5}$ near-road gradient over time, due to future impacts of existing mobile source controls.

The timeline to implement the near-road $PM_{2.5}$ monitors should be as minimally disruptive to on-going operations of monitoring agency programs as possible recognizing monitoring agency resource constraints, while still meeting the need to collect for near-road $PM_{2.5}$ data in a timely fashion. Since the near-road $PM_{2.5}$ monitors were proposed to be collocated with the emerging near-road NO_2 network that was scheduled to be operational by January 1, 2013,[227] the EPA believes it is appropriate to wait until after the near-road NO_2 network is established before implementing the near-road $PM_{2.5}$ monitors. Therefore, the EPA proposed that each $PM_{2.5}$ monitor planned for collocation with a near-road NO_2 monitoring site be implemented no later than January 1, 2015.

The EPA received comments from a number of air agencies, industrial groups, and environmental and public health organizations on its proposal to require $PM_{2.5}$ monitoring in near-road environments.

Among comments from air agencies, several commenters did not support the addition of near road monitoring citing the challenges of siting these stations and the additional cost it would require to operate the monitors. Several air agencies recognized the value of adding monitors to provide better characterization of exposures in near-road environments, but recommended a slower deployment of the $PM_{2.5}$ monitors so that it can be phased in over a multi-year period. Several air agencies recommended that the $PM_{2.5}$ monitoring in the near-road environment be deployed on a phased-in schedule with the first such monitors being required no sooner than one year after deployment of the NO_2 sites. These air agencies stated that phasing in of the $PM_{2.5}$ monitors in the near road environment would allow more time to learn and share information on what worked best in deploying the NO_2 monitors at near-road monitoring stations, since NO_2 is the first pollutant required to be monitored at near-road stations. A few air agencies identified a need to more clearly support or require the maintenance of as much of the existing network of neighborhood scale $PM_{2.5}$ monitoring sites as possible in regulatory text. These neighborhood scale $PM_{2.5}$ sites were identified by commenters as the most broadly representative sites for characterizing CBSA wide exposures that are supportive of a number of monitoring objectives. A few air agencies also identified a need for flexibility in the proposed network design requirement that $PM_{2.5}$ near-road monitors must be collocated with the NO_2 monitors in the near-road environment. The commenters suggested allowing flexibility for air agencies to meet the requirement for $PM_{2.5}$ in a near-road environment by siting at a different near-road location where $PM_{2.5}$ concentrations are expected to be high.

Most industry commenters did not support the addition of near-road monitoring for $PM_{2.5}$, again arguing that using data from such monitors, for comparison to the NAAQS, combined with other changes (i.e., elimination of ''population-oriented'' as a criteria for comparison to the NAAQS and the elimination of spatial averaging) would represent, in their judgement, a tightening of the $PM_{2.5}$ NAAQS. A few of these commenters asserted that monitoring in the near-road environment is not representative of ambient air exposures. A few industry comments noted that if the EPA required $PM_{2.5}$ monitoring in the near-road environment, any data collected should not be used for comparison to the NAAQS. One commenter stated it had no problem with monitoring in the near-road environment, so long as any such monitoring used to compare to the $PM_{2.5}$ annual NAAQS is population–oriented. One commenter stated that the decision to co-locate with NO_2 monitors was based on convenience and the intent of the NO_2 near-road monitoring is to find the highest micro-scale concentrations within a few meters of the most heavily travelled expressways, representing a unique situation.

Environmental and public health groups strongly support the addition of $PM_{2.5}$ monitoring to the near-road environment. Commenters cited the large number of people that live in proximity to major roadways[228] in their

[227] The EPA has proposed a revised timeline for deployment of the near-road NO_2 monitors, where all CBSAs with one million or more people are to have their first near-road NO_2 station operational by January 1, 2014 (77 FR 64244, October 19, 2012).

[228] One study identified that 45 million Americans live within 300 feet of a major roadway or other source of mobile emissions. The commenters' information is based on the American Housing Survey, which is available on the Web at:

Continued

support for adding these monitors, that such protection of people in these environments is long overdue, and that such data therefore be used for comparison to the NAAQS.

Regarding comments from air agencies that the near-road monitors are challenging to site and that there is additional cost in operating these monitors, the EPA maintains that the major challenges in siting would already be accomplished by implementing the required NO_2 monitoring stations in near-road environments since the EPA fully expects that the $PM_{2.5}$ monitors will be placed at the NO_2 near roadway stations and has revised the $PM_{2.5}$ monitoring requirements consistent with that expectation. The EPA also points out that the requirements for the minimum number of $PM_{2.5}$ monitors is unchanged and that in most cases the addition of near-road $PM_{2.5}$ monitors can be accomplished by relocating an existing monitor, with no net increase in monitors. Thus, while we are requiring a new component of the $PM_{2.5}$ monitoring network, the overall size of the network is expected to remain about the same, and we expect that air agencies can meet this requirement by relocating existing lower-priority monitors. In considering comments from air agencies on a schedule for implementing $PM_{2.5}$ monitors at near road monitoring stations, the EPA is persuaded by commenters from air agencies who stated that a phased deployment of the $PM_{2.5}$ monitors would be a better approach as it would allow agencies to learn from the deployment of the NO_2 monitors and a first phase of $PM_{2.5}$ monitors. Phasing in the deployment of monitors is also consistent with previous CASAC advice (Russell and Samet, 2010b) on a schedule for deployment of near-road NO_2 monitors.

Regarding comments from air agencies on maintaining the neighborhood scale monitoring stations as the largest part of the network as these sites are the most broadly representative of exposures across CBSAs, the EPA supports such a goal. Neighborhood scale monitoring sites remain the backbone of the $PM_{2.5}$ monitoring network and they will continue to represent over two thirds of the operating network following the deployment of the near-road monitors. The EPA expects that each CBSA required to monitor for $PM_{2.5}$ will maintain its existing highest concentration area-wide monitoring site (referred to as the design value site) and not attempt to move such sites to near-road environments. Maintaining the area-wide and largely neighborhood scale design value sites is critical to the long-standing goal of using data to support a variety of monitoring objectives. The EPA also recognizes that while every $PM_{2.5}$ monitor has value in some capacity at its current location, air agencies are expected to recommend relocation of monitors that are relatively low in priority to meet the near-road requirement.

Regarding comments from air agencies on the need for flexibility in the network design requirement that $PM_{2.5}$ near-road monitors must be collocated with the NO_2 monitors in the near-road environment, the EPA points out that it prefers to maintain this requirement so that the multi-pollutant data are available to support the monitoring objectives cited above. However, the EPA also recognizes there may be cases where an air agency recommends siting their near-road $PM_{2.5}$ monitor in another high concentration near-road environment. The EPA believes such cases will be very limited, but that these situations can be supported in one of two ways. First, EPA and the air agency can use their discretion to site two near-road $PM_{2.5}$ monitors in the area. Second, the EPA can use its discretion in approving a deviation from the $PM_{2.5}$ monitoring requirements as already exists in the network design criteria. Such deviations are to be approved by the Regional Administrator as described in section 4.7.1 of Appendix D to part 58.

Regarding the comment that $PM_{2.5}$ monitors in near-road environments were sited for convenience, which due to siting with NO_2 monitors a few meters from the road presents a unique situation, the EPA disagrees that these monitors were sited solely for convenience or that they would represent a unique situation within an urban area. On the initial point, the EPA believes that the characterization of representative maximum $PM_{2.5}$ concentrations due to on-road mobile sources and the appropriate location of such $PM_{2.5}$ monitors will be the same approximate locations that are the focus of the near-road NO_2 network. This is due to the fact that $PM_{2.5}$, like NO_X, is disproportionately influenced by heavy duty (HD) vehicles which are predominantly diesel fueled, when compared to light duty (LD) vehicles which are primarily gasoline fueled. Specifically, for both $PM_{2.5}$ and NO_X, HD vehicles emit more of these two pollutants and their precursors on a per vehicle basis than LD vehicles. The EPA recognized this fact in the near-road NO_2 network by requiring states to consider the fleet mix of candidate road segments where near-road monitoring might occur. In the design of the NO_2 near-road network where the $PM_{2.5}$ monitors will be installed, states were instructed to place a higher priority on those highly trafficked roads which have more diesel fueled vehicles using a metric called the fleet equivalent average annual daily traffic.[229] As such, the Agency believes it is appropriate that required near-road $PM_{2.5}$ monitors would be located with near-road NO_2 monitors as they are similarly influenced not only by fleet mix but also by total traffic count, congestion patterns, roadway design, terrain, and meteorology. On the second point with regard to such sites representing a unique situation within an urban area, EPA points out that the determination of a near-road micro- or middle-scale site being considered to represent ''area-wide'' air quality or ''unique'' will be made on a case by case basis with the monitoring agency providing such recommendations in their annual monitoring network plans described in § 58.10. Examples of such ''unique'' micro- and middle-scale locations are provided later in this section.

We do not accept the comment that siting some monitors in near roadway environments makes the standard impermissibly more stringent. A significant fraction of the population lives in proximity to major roads. These exposures occur in locations that represent ambient air for which the agency has a responsibility to ensure the public is protected with an adequate margin of safety. Ignoring monitoring results from such areas (or not monitoring at all) would abdicate this responsibility. Put another way, monitoring in such areas does not make the standard more stringent, but rather affords requisite protection to the populations, among them at-risk populations, exposed to fine particulate in these areas. Thus, the EPA has made a determination to protect all area-wide locations, including those locations with populations living near major roads that are representative of many such locations throughout an area. As discussed above, EPA concludes that the requirement to locate monitors to represent ambient air, along with other siting requirements, will ensure that monitors represent $PM_{2.5}$ concentrations in areas of potential public exposure.

http://www.census.gov/housing/ahs/data/ahs2009.html. The survey provides an estimate of the county's housing units in the U.S. that are located with 300 feet of a highway with four or more lanes, or a railroad, or an airport.

[229] See the Near-road NO_2 Monitoring Technical Assistance Document at: *http://www.epa.gov/ttn/amtic/files/nearroad/NearRoadTAD.pdf.*

We do recognize, however, the possibility that some near-road monitoring stations may be representative of relatively unique locations versus the more representative area-wide situation mentioned above. This could occur because an air agency made a siting decision based on NO_2 criteria that resulted in the characterization of a microscale environment that is not considered area-wide for $PM_{2.5}$; for example, due to proximity to a unique source like a tunnel entrance, nearby major point source, or other relatively unique microscale hot spot. In these types of scenarios, air agencies would identify the site as a unique monitor comparable only to the 24-hour $PM_{2.5}$ NAAQS per the language in section 58.30, and not comparable to the annual NAAQS, through the Annual Monitoring Network Plan process described earlier. Although EPA expects most near-road $PM_{2.5}$ monitors to be sited to represent area-wide conditions, since a vast majority of the near-road stations have yet to be installed, we believe that providing such clarity and flexibility in siting and NAAQS comparability is warranted.

After careful consideration of the public comments, the EPA is finalizing its decision to add $PM_{2.5}$ monitors to the near-road monitoring stations. The EPA is finalizing this decision as the near-road environment is an area where significant public exposure can occur, recognizing that this is a gap in the current $PM_{2.5}$ monitoring networks, and because these $PM_{2.5}$ monitors will be collocated with NO_2 monitors in the near-road environment, there will not be a significant additional burden on the air agencies.[230] However, in recognition of the comments from air agencies above, EPA is finalizing a revised and phased schedule for deployment of the $PM_{2.5}$ monitors at near-road stations. A minimum of one $PM_{2.5}$ monitor in each CBSA with a population greater than or equal to 2.5 million is to be collocated at a near-road NO_2 monitoring station and must to be operational by January 1, 2015. The remaining CBSAs (i.e., those CBSAs with populations greater than or equal to 1M, but less than 2.5M) must be operational by January 1, 2017. This schedule will ensure that air agencies have sufficient time to learn from deployment of the NO_2 monitors in near-road environments, that the highest population CBSAs begin operating their $PM_{2.5}$ monitors in near-road environments first, and that the remaining $PM_{2.5}$ monitors are deployed on the same schedule as the CO monitors (also, required by January 1, 2017).[231] In consideration of the comments regarding maintaining neighborhood scale monitoring sites as the largest portion of the network, the EPA is revising the wording of a requirement that requires at least one site to be in an area-wide location of expected maximum concentration, to wording that states that such sites must be in an area-wide location of expected maximum concentration while also being at the neighborhood or larger scale of representation.

iii. Use of $PM_{2.5}$ Continuous FEMs at SLAMS

The EPA proposed that each agency specify its intention and rationale to use or not use data from continuous $PM_{2.5}$ FEMs that are eligible for comparison to the NAAQS as part of its annual monitoring network plan due to the applicable EPA Region Office by July 1 each year. The proposal also provided that the EPA Regional Administrator would be responsible for approving annual monitoring network plans where agencies have provided a recommendation that certain $PM_{2.5}$ FEMs be considered ineligible for comparison to the NAAQS.

In 2006, the EPA finalized new performance criteria for approval of continuous $PM_{2.5}$ monitors as either Class III FEMs or ARMs. At the time of proposal, the EPA had already approved six $PM_{2.5}$ continuous FEMs[232] and there are nearly 200 of these monitors already operating in State, local, and Tribal networks. Monitoring agencies have been deploying and field-testing these units over the last couple of years and the EPA recently compiled an assessment of the FEM data in relationship to collocated FRMs (Hanley and Reff, 2011; U.S. EPA, 2011a, pp. 4–50 to 4–51). As described in the proposal (FR 38983), the EPA found that some sites with continuous $PM_{2.5}$ FEMs have an acceptable degree of comparability with collocated FRMs, while others had poor data comparability that would not meet the performance criteria used to approve the FEMs (71 FR 61285–61286, Table C–4, October 17, 2006). The EPA is encouraging use of the FEM data from those sites with acceptable data comparability including for purposes of comparison to the NAAQS. For sites with unacceptable data comparability, the EPA is working closely with the monitoring committee of the NACAA, instrument manufacturers, and monitoring agencies to document best practices on these methods to improve the comparability and consistency of resulting data wherever possible. The EPA believes that the performance of many of these continuous $PM_{2.5}$ FEMs at locations with poor data comparability can be improved to a point where the acceptance criteria noted above can be met.

Given the varying data comparability of continuous $PM_{2.5}$ FEMs noted above, we believe that a need exists for flexibility in the approaches for how such data are used, particularly for the objective of determining NAAQS compliance. Accordingly, we proposed that monitoring agencies address the use of data from $PM_{2.5}$ continuous FEMs in their annual monitoring network plans due to the applicable EPA Regional Office by July 1 of each year for any cases where the agency believes that the data generated by $PM_{2.5}$ continuous FEMs in their network should not to be compared to the NAAQS. The annual network plans would include assessments such as comparisons of continuous FEMs to collocated FRMs, and analyses of whether the resulting statistical performance would meet the established approval criteria. Based on these quantitative analyses, monitoring agencies would have the option of requesting that data from continuous FEMs be excluded from NAAQS comparison subject to EPA approval; however, these data could still be utilized for other objectives such as AQI reporting.

The issue exists of whether such data use provisions should be prospective only (i.e., future NAAQS comparability excluded based on an analysis of recent past performance) or a combination of retrospective and prospective (i.e., the implications of unacceptable FEM performance impacting usage of previously collected data as well as future data). In the proposal, the EPA stated that in most cases, monitoring agencies should be restricted to addressing prospective data issues to provide stability and predictability in the long-term $PM_{2.5}$ data sets used for supporting attainment decisions. However, in the first year after this proposed option would become effective, we indicated it would be appropriate to provide monitoring agencies with a one-time opportunity to review already reported continuous $PM_{2.5}$ FEM data and request that data with unacceptable performance be restricted (retrospectively) from NAAQS

[230] The incremental one-time cost of moving the 52 monitors required to be located in the near-road environment is described in section X.B—Paperwork Reduction Act.

[231] 76 FR 54294, August 31, 2011.

[232] The EPA maintains a list of approved Reference and Equivalent Methods on its Web site at: *http://www.epa.gov/ttn/amtic/criteria.html*.

comparability. Accordingly, in the first year after this rule becomes effective, we proposed that monitoring agencies have the option of requesting in their annual monitoring network plans that a portion or all of the existing continuous $PM_{2.5}$ FEM data, as applicable, as well as future data, be restricted from NAAQS comparability for the period of time that the plan covers.[233] In the proposal we stated that annual monitoring network plans in subsequent years would only need to cover new data for the period of time that the plan covers.

As noted above, in cases where an agency is operating a $PM_{2.5}$ continuous FEM that is not meeting the expected performance criteria used to approve the FEMs (71 FR 61285 to 61286, Table C–4, October 17, 2006) when compared to their collocated FRMs, an agency can recommend that the data not be used for comparison to the NAAQS. However, all required SLAMS would still be required to have an operating FRM (or other well performing FEM) to ensure a data record is available for comparison to the NAAQS. In cases where a $PM_{2.5}$ continuous FEM was not meeting the expected performance criteria, and the Regional Administrator has approved a recommendation that the FEM data not be considered eligible for comparison to the NAAQS, the data would still be required to be loaded to AQS; however, these data would be identified distinctly from data used for comparison to the NAAQS.

The goal of proposing to allow monitoring agencies the opportunity to recommend not having data from $PM_{2.5}$ continuous FEMs as comparable to the NAAQS is to ensure that only high quality data (i.e., data from FRMs which are already well established and new continuous FEMs that meet the performance criteria used to approve FEMs when compared to collocated FRMs operated in each agencies network) are used when comparing data to the $PM_{2.5}$ NAAQS. Under the current monitoring regulations, a monitoring agency can identify a $PM_{2.5}$ continuous FEM as an SPM, which allows the monitor to be operated for up to 24 months without its data being used in comparison to the NAAQS. While 24 months should be sufficient time to operate the monitor across all seasons, assess the data quality, and in some cases resolve operational issues with the instrument, it may still leave some agencies with monitors whose data are not sufficiently comparable to data from their FRMs. In these cases there may be a disincentive to continue operating the $PM_{2.5}$ continuous FEM, especially in networks where the monitoring data are near the level of the NAAQS. With the proposed provision, where a monitoring agency can recommend not having data from $PM_{2.5}$ continuous FEMs be comparable to the NAAQS, a monitoring agency can continue to operate their $PM_{2.5}$ continuous FEM to support other monitoring objectives (e.g., diurnal characterization of $PM_{2.5}$, AQI forecasting and reporting), while working through options for improved data comparability while still providing data for comparison to the NAAQS from an FRM.

The EPA believes that an assessment of FEM performance should include several elements based on the original performance criteria. The Agency also believes that certain modifications to the performance criteria are appropriate in recognition of the differences between how monitoring agencies operate routine monitors and how instrument manufacturers conduct required FRM and FEM testing protocols. The details below summarize these issues.

The EPA proposed to use the performance criteria used to approve the FEMs (71 FR 61285 to 61286, Table C–4, October 17, 2006) for those agencies that recommend not having data from $PM_{2.5}$ continuous FEMs be comparable to the NAAQS. To accommodate how routine monitoring networks operate, the EPA proposed that agencies seeking to demonstrate insufficient data comparability base their assessment mainly on collocated data from FRMs and continuous FEMs at monitoring stations in their network. The EPA does not believe it is practical to utilize the requirement in table C–4 of 40 CFR part 53 for having multiple FRMs and FEMs at each site since such arrangements are not typically found in monitoring agency networks. Accordingly, the requirement for assessing intra-method replicate precision would be inapplicable. Another consideration is the range of 24-hour data concentrations, for instance, the performance criteria in table C–4 of 40 CFR part 53, provides for an acceptable concentration range of 3 to 200 $\mu g/m^3$. However, the EPA notes that during an evaluation of data quality from two FEMs (U.S. EPA, 2011a, p. 4–50), the Agency found that including low concentration data was helpful for understanding whether an intercept or slope was driving a potential bias in an instrument. Therefore, the EPA proposed that agencies may include low concentration data (i.e., below 3 $\mu g/m^3$) for purposes of evaluating the data comparability of continuous FEMs. With regard to the minimum number of samples needed for the assessment, the EPA notes that a minimum of 23 sample pairs are specified for each season in table C–4 of 40 CFR part 53. Having 23 sample pairs per season should be easily obtainable within one year for sites with a FRM operating on at least a 1 in 3 day sample frequency and we proposed that this requirement be applicable to the assessments being discussed here. For sites on a one in 6 day sampling frequency, two years of data may be necessary to meet this requirement. The EPA recognizes that it would be best to assess the data based on the most recently available information; however, having data across all seasons in multiple years will provide a more robust data set for use in the data comparability assessment; therefore, the EPA proposed that data quality assessments be permitted to utilize up to the last three years of data for purposes of recommending not having data from $PM_{2.5}$ continuous FEMs be comparable to the NAAQS.

The EPA recognizes that only a portion of continuous $PM_{2.5}$ FEMs will be collocated with FRMs, and it would be impractical to restrict the applicability of data comparability assessments to only those sites that had collocated FRM and FEM monitors. In these cases, the monitoring agency will be permitted to group the sites that are not collocated with an FRM with another similar site that is collocated with an FRM for purposes of recommending that the data are not eligible for use in comparison to the NAAQS. Monitoring agencies may recommend having $PM_{2.5}$ continuous FEM data eligible for comparison to the NAAQS from locations where the method has been demonstrated to provide acceptable data comparability, while also recommending not having it eligible in other types of areas where the method has not been demonstrated to meet data comparability criteria. For example, a rural site may be more closely associated with aged particles where volatilization issues are minimized resulting in acceptable data comparability between filter-based and continuous methods, while a highly populated urban site with fresh emissions with higher volatility may result in higher readings on the $PM_{2.5}$ continuous FEM that would not meet the expected performance criteria as compared to a collocated FRM. In all cases where a monitoring agency chose to group sites for purposes of identifying a subset of $PM_{2.5}$ continuous FEMs that would not be comparable to the

[233] Data from any $PM_{2.5}$ monitor being used to meet minimum monitoring requirements could not be restricted from NAAQS comparability.

NAAQS, the assessment submitted with the annual monitoring network plan would have to provide sufficient detail to support the identification of which combinations of method and sites would, and would not, be comparable to the NAAQS, as well as the rationale and quantitative basis for the grouping and recommendation.

Most comments received on this issue were from air agencies. All air agencies either supported the proposal or supported it with a recommendation to continue to allow for retrospective assessments to be used such that data would not be compared to the NAAQS, if such an assessment showed that the data were not of sufficient comparability to a collocated FRM such that the continuous FEM should not be compared to the NAAQS. One air agency supported the proposal, except though it had reservations about how to best group sites together when a particular $PM_{2.5}$ continuous FEM is not collocated with a FRM.

The EPA notes the support by air agencies to finalize this provision. EPA also notes that all commenters who offered input on the retrospective use of assessments were supportive of allowing continued retrospective assessments in annual monitoring networks plans so that data may be recommended as excluded from comparison to the NAAQS under certain provisions. However, the EPA has some reservations about how and under what circumstances such an allowance should be made. The EPA notes the concern expressed from one agency about how to best group sites together when considering an assessment.

On the issue of whether to allow data collected to be retrospectively excluded from comparison to the NAAQS, the EPA notes there are a number of considerations, including that several air agencies support such a policy. The EPA has evaluated how this issue can be achieved and believes that some consideration should be allowed, but also wants to ensure there is a consistent and easily recognizable interpretation of such cases where air agencies recommend excluding already collected and reported data. To help illustrate the possible outcomes of how this could work consider the following examples. Example 1: An agency finds that the bias between a collocated $PM_{2.5}$ continuous FEM and FRM are acceptable, but near the limit of that acceptability and then finds a year later that the assessment indicates that the bias is just outside the limit of that acceptability. Such relatively small changes where an assessment indicates flipping in or out of the acceptable bias are in themselves acceptable since the overall Data Quality Objectives (DQOs) can still be met. The overall DQOs can still be met since there are a number of other factors that feed into the DQOs such as precision, data completeness, and especially sample frequency, which when operating a continuous FEM is a daily sample. Daily sampling provides less uncertainty than sampling at the one-in-three day or one-in-six day sampling frequencies, which are routinely employed by filter-based FRM samplers. Therefore, in this example the existing data should still be compared to the NAAQS, but the air agency should thoughtfully consider whether to recommend [234] and the EPA will consider whether to approve that any new data from $PM_{2.5}$ continuous FEMs are used in comparison to the NAAQS. If an air agency recommends to not use a $PM_{2.5}$ continuous FEM for comparison to the NAAQS, it would need to ensure another approved method (i.e., a filter-based FRM/FEM or other continuous FEM which is performing within acceptable performance criteria) is operating at the site or sites of interest. This would be expected for all SLAMS, but at a minimum the design value monitoring station for the area of interest would be required to have another approved $PM_{2.5}$ method (i.e., an FRM, other filter-based FEM, or other continuous FEM or ARM with acceptable data comparability) operating on the required sample frequency or more often for that location. Example 2: A $PM_{2.5}$ continuous FEM operated by an air agency is found to have a significant bias compared to a collocated FRM. If the air agency finds cause to invalidate the data (e.g., a flow sensor is found to be outside of acceptable limits), then it should invalidate the relevant data (i.e., data from the period going back to the last successful flow check or audit or other information that points to a cause that the flow sensor is not meeting its performance criteria) for all data uses and there is no follow-up issue of retrospective analysis. A case of finding cause to invalidate data would be based on validation criteria found in an air agencies approved quality assurance project plan (QAPP). Example 3: A $PM_{2.5}$ continuous FEM operated by an air agency and previously identified as appropriate to compare to the NAAQS, is found to have a significant and unacceptable bias compared to a collocated FRM and there is no other reason to invalidate the data. That is, all other information points to the data being valid; however, there has been a significant shift in the comparability of the $PM_{2.5}$ continuous FEM compared to a collocated FRM (which itself is found to be operating correctly and data are valid). A significant shift in the comparability would be noticeable by comparing assessments for a site from one year to the next and seeing a significant and unacceptable change in one of the key statistical metrics used in the evaluation (i.e., additive or multiplicative bias). Such a case of retrospectively recommending not using $PM_{2.5}$ continuous FEM data should also take into account all other available information that can help inform approving such a recommendation as part of an annual monitoring network plan. For example, do data from the $PM_{2.5}$ performance evaluation program data also suggest an unacceptable bias for a specific period of interest with this method as used in the air agencies network? Note: This type of assessment is often limited by the small number of samples taken in the PEP program relative to the large number of collocated samples expected when an FRM and $PM_{2.5}$ continuous FEM are collocated. In this type of example, the air agency might want to recommend not using the continuous FEM data for comparison to the NAAQS; however, the continuous FEM data could be appropriate for use in reporting the Air Quality Index (AQI) or other data uses either as is or if statistically correlated [235] and corrected back to the collocated FRM. So in this last example, the $PM_{2.5}$ continuous FEM data would be stored separately in the EPA's data system so that they are eligible for use in AQI calculations, but not used in comparison to the NAAQS, if approved by the EPA. Again, the air agency should thoughtfully consider and state its position and rationale in the annual monitoring network plan on whether any future data should be compared to the NAAQS.

Another issue to consider is the transparent and consistent use of $PM_{2.5}$ continuous FEM data from a method where one air agency recommends using the data for comparison to the NAAQS and another specifically recommends to not use it for comparison to the NAAQS. The use of the annual monitoring plans ensures that the process is transparent; however, it may not ensure a consistent

[234] Through the annual monitoring network plan explained in § 58.10.

[235] The EPA has had a long-standing policy of allowing $PM_{2.5}$ continuous data to be statistically correlated and corrected to use in AQI reporting. A report is available on this: See ''Data Quality Objectives (DQOs) for Relating Federal Reference Method (FRM) and Continuous $PM_{2.5}$ Measurements to Report an Air Quality Index (AQI), EPA–454/B–02–002, November 2002''.

approach if one agency recommends exclusion of data and another agency does not. For example, consider two adjacent air agencies operating the same make and model of a $PM_{2.5}$ continuous FEM, where one air agency recommends using data and the other air agency recommends not using it for comparison to the NAAQS. While on its face it may seem straightforward that a method with acceptable comparability to a collocated FRM should perform similarly in other air agency networks where they have similar aerosol composition and climate, in practice there are a number of other variables that affect data comparability. Such factors that lead to differences in comparability might include differences in installation, training, development of SOPs, control of shelter conditions, maintenance of the continuous FEM, and performance of the FRMs which are being used as the basis of comparison to the continuous FEM. Also, there may be cases where the concentration levels are so far away from the level of the NAAQS (either substantially higher or lower) that it would not matter if the data are excluded or not, the same NAAQS determination would result. The EPA has considered these issues and in general believes that it would still be acceptable for one agency to use data for comparison to the NAAQS, while another agency does not, even if it's the same method used in adjacent air agency networks.

On the issue of grouping sites for purposes of allowing monitors that are not collocated to be included when recommending a method should not be compared to the NAAQS, the EPA believes that it is not necessary to provide specific details on what criteria are necessary to group sites as air agencies are in the best position to determine a recommendation of when such sites should or should not be grouped. However, to illustrate examples of possible ways to group sites, the air agency could take into account factors such as whether the sites are all in either a rural or urban location, since urban locations tend to be impacted more directly by fresh emissions which are known to be more volatile, or whether there is consistency in the climate for the sites of interest as might be the case for sites near a large water body or at a high altitude. The EPA will consider these issues when evaluating air agency requests for approval.

The EPA is finalizing its proposal to allow each air agency to specify its intention to use or not use data from continuous $PM_{2.5}$ FEMs that are eligible for comparison to the NAAQS as part of their annual monitoring network plan due to the applicable EPA Region Office by July 1 each year where adequate FRM data are available. The EPA's approval of an annual monitoring network plan [236] as a whole, or in part, will constitute concurrence with an air agency's recommendation to use or not use data from continuous $PM_{2.5}$ FEMs as eligible for comparison to the NAAQS, unless otherwise noted in the approval of the plan. The absence of an air agency statement specifying a position on use of data from a continuous $PM_{2.5}$ FEM for comparison to the NAAQS will be interpreted as meaning that all such data are applicable for comparison to the NAAQS following the provisions in Part 50, Appendix N on data handling and Part 58 on the monitoring requirements. In finalizing this decision the EPA will ensure, as proposed, that air agencies can identify already collected data from $PM_{2.5}$ continuous FEMs that should not be used for comparison to the NAAQS. After considering comments in support of allowing additional retrospective assessments, the EPA is also finalizing an approach of allowing for the continued use of retrospective assessments to inform when already collected data should not be compared to the NAAQS, if there has been a significant change in the assessment of that data from previous years.

c. Revoking $PM_{10-2.5}$ Speciation Requirements at NCore Sites

The EPA proposed 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. $PM_{10-2.5}$ mass monitoring commenced on January 1, 2011 as part of the nationwide startup of the NCore network (U.S. EPA, 2011a, p. 1–15).

As part of the process to further define appropriate techniques for $PM_{10-2.5}$ 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). 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 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 implement a small pilot monitoring project to evaluate the available monitoring and analytical technologies.

The EPA pilot monitoring project was completed in 2011, with plans to analyze the data and prepare a final report on findings and recommendations in 2013. At that time, the EPA will consider what $PM_{10-2.5}$ speciation sampling techniques, analytical methodologies, and monitoring design strategies would be most appropriate as part of a potential nation-wide monitoring deployment. Such a deployment could be based on the NCore multi-pollutant framework or some other strategy that allows flexibility and targets measurements in areas with higher levels of coarse particles.

All comments received from air agencies and multi-state organizations were supportive of the removal of the $PM_{10-2.5}$ speciation requirement.

A few industry commenters raised concerns about the availability of $PM_{10-2.5}$ speciation data for research purposes. One environmental group opposed revoking the $PM_{10-2.5}$ speciation requirement and expressed the need for $PM_{10-2.5}$ data to support health effects research and future regulatory efforts.

The EPA has considered the comments from air agencies that were all supportive of revoking the requirement, as well as the industry and environmental groups concerns that $PM_{10-2.5}$ speciation data will not be available for research. In considering these comments, the EPA recognizes the importance of efforts to develop and evaluate speciation monitoring approaches for $PM_{10-2.5}$ given that there is relatively little information available on the chemical and biological composition of $PM_{10-2.5}$ and on the health effects associated with the various components (U.S. EPA, 2009a, section 2.3.4). Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations with health effects across locations is difficult to characterize (U.S. EPA, 2009a, section 6.5.2.3). However, the EPA believes that until a final report on the findings from the pilot study is completed in 2013 and the results of the study can be considered, $PM_{10-2.5}$ speciation is not ready for nationwide deployment. Therefore, the EPA is finalizing its decision to revoke the $PM_{10-2.5}$ speciation requirement at NCore stations. Given the continued importance of characterizing $PM_{10-2.5}$ species, and given that ongoing and future research will likely further

[236] Approval of an annual monitoring network plan is subject to approval of the EPA Regional Administrator as provided for in § 58.10(a)(2).

inform the development of speciation methods, the appropriateness of requiring speciation monitoring for $PM_{10-2.5}$ will be revisited in future reviews.

d. Measurements for the Proposed New $PM_{2.5}$ Visibility Index NAAQS

The EPA proposed requirements for sampling of $PM_{2.5}$ chemical speciation in states with large CBSAs. However, as explained in section VI, the EPA is not finalizing the proposed secondary $PM_{2.5}$ visibility index NAAQS and therefore is not finalizing the proposed monitoring changes associated with that standard.

4. Revisions to the Quality Assurance Requirements for SLAMS, SPMs, and PSD

a. Quality Assurance Weight of Evidence

The EPA proposed to use a weight-of-evidence approach for determining whether the quality of data is appropriate for regulatory decision-making purposes. While the EPA believes that it is essential to require a minimum set of checks and procedures in appendix A to support the successful implementation of a quality system, the success or failure of any one check or series of checks should not preclude the EPA from determining that data are of acceptable quality to be used for regulatory decision-making purposes. Accordingly, the EPA proposed to include additional wording in appendix A to clarify the role that appendix A generated data quality indicators have in the overall quality system that supports ambient air monitoring activities.

The EPA received eight comments on the weight of evidence approach with the majority of commenters endorsing the approach. One commenter felt that the ''paragraph, as written, undermines the importance of the quality control/quality assurance system dictated in Part 58.'' Some that supported the approach also provided a word of caution that ''while a common sense approach to the assessment of quality data is important, minimum requirements are necessary to ensure scientifically-defensible data is being used in decision making''. The EPA agrees with the commenter's points that data should be subject to a minimum set of requirements for data collection, reporting and quality. In developing the weight of evidence approach, the EPA is not attempting to diminish the requirements of appendix A but rather ensure that other elements of a quality system that air agencies implement and are documented in their QAPP can also be used when judging whether data are valid for a particular monitoring objective. While the EPA considers the appendix A requirements the minimum for reporting, it is not the only data that the EPA and the air agencies use to judge quality. Therefore, if an appendix A requirement for some reason is not complete, the EPA concludes that it should not necessarily be the sole reason to declare the data invalid or unusable. One commenter who felt that the approach may be appropriate also suggested that the language of the proposal was vague and may weaken the ability of air monitoring agencies to validate their own data and instead allows the EPA to make decisions regarding data validity. In the majority of cases when the quality of ambient air data is called into question, the EPA Regions and air agencies work together and reach consensus on data usability. The EPA agrees that the air agencies know more about their data and it is the air agencies responsibility to certify the data as valid. In most cases, the EPA and the air agencies will be in agreement on the validity and usability of this data. However, since the EPA is responsible for making final regulatory decisions concerning the NAAQS, in rare cases it may ultimately have to make a validity decision that the air agencies may not agree with. After consideration of the general support received, the EPA will finalize the language as proposed. For the reasons explained above, the EPA concludes that this will not undermine the quality assurance system, but rather strengthen it.

A few commenters, although supporting the weight of evidence approach, also commented that appendix A minimum requirements should not only apply to all air quality data collected by state, local, and tribal agencies, but also to ''secondary'' data collected by other monitoring efforts. The EPA understands that this term is used by these commenters to either represent the Chemical Speciation and IMPROVE Network data being used to calculate light extinction for the secondary $PM_{2.5}$ visibility index NAAQS, or for criteria pollutant data collected by entities other than the state, local or tribal monitoring organizations. The EPA agrees with the comments that the appendix A requirements must apply to the CSN and IMPROVE data, if the data were being used for comparison to the secondary NAAQS, and included the term ''$PM_{2.5}$ CSN'' to refer to both networks. However, since as explained in Section VI, the secondary $PM_{2.5}$ visibility index NAAQS is not being finalized, the EPA will be removing any text related to the CSN and IMPROVE requirements from appendix A. If the term is being used by commenters to refer to criteria pollutant data collected by entities other than the state, local or tribal monitoring organizations then the appendix A requirements, as has always been the case, apply to those monitors.

b. Quality Assurance Requirements for the Chemical Speciation Network

The EPA proposed to include requirements for flow rate verifications and flow rate audits for the $PM_{2.5}$ CSN. Air agencies currently perform these audits even though they are not currently required. Thus, although they would be considered a new requirement, they are not new implementation activities. In addition, the CSN already includes six collocated sites which the EPA proposes to include in the 40 CFR part 58 appendix A requirements. The EPA proposed that PSD sites would not be required to collocate a second set of instruments for speciated $PM_{2.5}$ mass monitoring.

There were no comments that specifically addressed the addition of collocation and flow rate requirements in appendix A for the chemical speciation network (CSN). Since these flow rates have historically been included in the Agencies' CSN Network Quality Assurance Project Plan and implemented for many years, air agencies may not have considered them any additional burden on the program. However, as explained in Section VI, the secondary $PM_{2.5}$ visibility index NAAQS is not being finalized; therefore, the EPA will not include these QA requirements into appendix A since the networks will not produce data to be used for NAAQS decisions.

c. Waivers for Maximum Allowable Separation of Collocated $PM_{2.5}$ Samplers and Monitors

The EPA proposed to allow waivers, when approved by the EPA Regional Administrator, for collocation of $PM_{2.5}$ samplers and monitors of up to 10 meters so long as the site is at a neighborhood scale or larger. The EPA proposed to allow waivers for the maximum allowable distance associated with collocated $PM_{2.5}$ samplers and monitors. Ensuring $PM_{2.5}$ continuous FEMs and $PM_{2.5}$ FRMs meet collocation requirements (i.e., 1 to 4 meters for $PM_{2.5}$ samplers with flow rates of less than 200 liters/minute) can be challenging, since in some cases multiple instruments, FEMs installed in the shelter and FRMs installed on a platform, are being sited at the same station. The EPA believes that instruments spaced farther apart could be maintained within the operational precision of the instruments, especially at sites located at larger scales of representation (e.g., neighborhood scale and larger).

All comments received responded in support of the requirement allowing up to 10 meter horizontal spacing for sites at a neighborhood or larger scale of representation. The EPA received no negative comments on this part of the proposal. During stakeholder presentations of the proposal, the EPA received a verbal comment that air agencies were also having difficulty meeting the one meter vertical criteria since $PM_{2.5}$ FEMs are typically housed in shelters with inlets extending through shelter roofs while the collocated FRM monitors are placed outside, usually on platforms somewhat lower to the ground. After considering this comment, and further discussion with EPA Office of Research and Development on spacing requirements, the agency will amend the appendix A requirements to allow for a 1–3 meter vertical spacing which may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation. In addition, the language will be amended to allow for waiver approvals during annual network plan approval processes. Alternatively, the existing waiver provision outlined in paragraph 10 of Appendix E may be used.

5. Revisions to Probe and Monitoring Path Siting Criteria

a. Near-Road Component to the $PM_{2.5}$ Monitoring Network

The EPA proposed that the probe and siting criteria for the near-road component of the $PM_{2.5}$ monitoring network design follow the same probe and siting criteria as the NO_2 near-road monitoring sites. These requirements would provide that the monitoring probe be sited ''* * * as near as practicable to the outside nearest edge of the traffic lanes of the target road segments; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment'' (section 6.4 of appendix E to 40 CFR part 58).

The EPA received comments from several stakeholders on the probe and siting criteria for $PM_{2.5}$ monitors in the near-road environment. One public health group offered detailed comments on the probe and siting criteria for $PM_{2.5}$ monitors in near-road environments. While the commenter offered support for collocating the $PM_{2.5}$ monitors with NO_2 monitors in the near-road environment, there was concern expressed regarding allowing monitors at sites of more than 15 meters from the traffic corridor which is the source of the air quality concern. The commenter points out that the EPA's existing rules for siting localized hot spot sites in areas of highest concentration require sites at microscale locations which provide for a distance of no more than 15 meters from a major roadway. Several air agencies offered consistent comments that the inlet of the $PM_{2.5}$ monitors should be the same as that of the near-roadway NO_2 monitors; however, one of the commenters suggested that the requirements for distance to the nearest vertical wall or obstruction should match the requirements for current micro and middle scale installations of $PM_{2.5}$ monitors. The concern expressed is that a wall or obstruction may disrupt the normal downwind flow across a roadway.

In reviewing comments on probe and monitoring path criteria for $PM_{2.5}$ monitors in near road environments, and whether to make any changes, the EPA has several issues to consider. One of the most important things to consider is what the intended network design of these monitors should be. As stated in the proposal our goal is to ''better understand the health impacts of these (near-road $PM_{2.5}$) exposures,'' that a number of monitoring objectives can be supported by having near-road $PM_{2.5}$ monitors, and that while it might be that the location of maximum concentration of $PM_{2.5}$ exposure from near-roadway sources might differ from the maximum location of NO_2 or other pollutants, we proposed to require that the near-road $PM_{2.5}$ monitors be collocated with the planned NO_2 monitors. The EPA did not propose to change the distance from obstructions for $PM_{2.5}$ monitors in its proposal.

As we stated in the proposal, the planned NO_2 monitors are using several relevant factors that are also relevant for siting of $PM_{2.5}$ (e.g., average annual daily traffic and fleet mix [accounting for heavy duty vehicles] by road segment) and that significant thought and review are going into the design of the near-road stations. Therefore, the EPA is not persuaded that we should provide any additional constraints to the siting of the station (i.e., the distance from the roadway) than is already provided for in the NO_2 near-road monitor probe and monitoring path siting criteria. The EPA is concerned that additional constraints (i.e., to require sites within 15 meters of the road), might have some advantages, but also might unnecessarily eliminate otherwise useful near-road locations that on balance might be a better candidate location.

The EPA recognizes that there may be cases where the physical location of a near-road monitoring station is farther than 15 meters, but no greater than 50 meters from the roadway, but such cases are presumed to still be the most useful location for the siting of the NO_2 monitors, which we then proposed to collocate with $PM_{2.5}$. Regardless of the actual distance of the inlet for the $PM_{2.5}$ monitor at the near-road monitoring station, so long as it is collocated with the approved near-road station for NO_2 and meets existing criteria, the EPA will consider this site to be appropriate as a near-road $PM_{2.5}$ monitoring station. As explained in the proposal, there are a number of reasons to collect multi-pollutant data in the near-road environment. The EPA believes that these sites will be sufficient as representative maximum concentration sites for NO_2 and $PM_{2.5}$ in the near-road environment. As noted above, where an air agency believes a different location is a more appropriate site for a near-road $PM_{2.5}$ monitor, the EPA can use its discretion in approving a deviation from the $PM_{2.5}$ monitoring requirements as already exists in the network design criteria. A deviation would be appropriate for consideration where, for example, a state provides quantitative evidence demonstrating that peak ambient $PM_{2.5}$ concentrations would occur in a near-road location which meets siting criteria but is not a near-road NO_2 monitoring site. Such deviations are to be approved by the Regional Administrator as described in section 4.7.1 of Appendix D to part 58.

While it is still desirable for the near-road stations to be as close to the road as practical, there may be differences in the scale of representation of the near-road $PM_{2.5}$ monitor from one location to another, while the NO_2 near-road monitors are at the same scale of representation (i.e., micro-scale) in different locations. This is a result of the scale of representation being based on the pollutant at a location and not the location alone. Therefore, in cases where the station is 20 meters from a major road, the NO_2 measurement may still be micro-scale, while the $PM_{2.5}$ measurement would be middle-scale if the average daily traffic count were sufficiently large enough.[237] If a site with both measurements were 10 meters

[237] See Table E–1 in Appendix E to Part 58 for defining the scale of representation of a PM sampler based on its distance to the nearest traffic lane and average daily traffic count.

from a major road they would both be expected to be micro-scale sites.

In considering the comment on distance from obstructions, the EPA notes that a monitoring station with multiple measurements is effectively considered collocated for those measurements, even though the actual location of the inlets is slightly different from each other within the station. For example, a gas monitor (e.g., for carbon monoxide) may be pulling ambient air from a manifold with an inlet located on one part of a station roof, while a PM monitor is pulling air directly from its inlet located a few meters away on the same roof. The EPA believes it is appropriate and consistent with the public comment above on distance from obstructions to maintain the existing requirements for distance from obstructions on a pollutant by pollutant basis, even if they are different for $PM_{2.5}$ and NO_2 monitors that will be at the same station. Air agencies will need to consider these distances from obstructions for each pollutant inlet probe (i.e., >1 meter for NO_2 monitors and >2 meters for $PM_{2.5}$ monitors) in locating monitors at the station.

The EPA is maintaining the existing probe and siting criteria for $PM_{2.5}$ monitors; however, we are finalizing the provision that the required near-road component of the $PM_{2.5}$ monitoring network design shall be collocated with a required NO_2 monitor at near-road monitoring station. These near-road NO_2 monitoring stations are to be sited ''* * * as near as practicable to the outside nearest edge of the traffic lanes of the target road segments; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment'' (section 6.4 of appendix E to 40 CFR part 58). The EPA is retaining the existing requirement that $PM_{2.5}$ inlets, including those at near road stations, must be >2 meters from obstructions.

b. CSN Network

As explained in Section VI, the EPA is not finalizing the proposed secondary standard based on a $PM_{2.5}$ visibility index and therefore will not be finalizing probe and siting criteria associated with the use of CSN measurements.

c. Reinsertion of Table E–1 to Appendix E

The EPA proposed to reinsert table E–1 to appendix E of 40 CFR part 58. This table presents the minimum separation distance between roadways and probes or monitoring paths for monitoring neighborhood and urban scale ozone (O_3) and oxides of nitrogen (NO, NO_2, NO_X, NO_y). This table was inadvertently removed during a previous CFR revision process.

The only comments received on this topic were supportive of the reinsertion of table E–1; therefore, the EPA is finalizing the reinsertion of this table, unchanged from its prior iteration, back into the CFR.

6. Additional Ambient Air Monitoring Topics

a. Annual Monitoring Network Plan and Periodic Assessment

In October of 2006, the EPA finalized new requirements for each state, or where applicable, local agency to perform and submit to their EPA Regional Offices an Assessment of the Air Quality Surveillance System (40 CFR 58.10). This assessment is required every five years. The first required five year assessments were due to EPA Regional Offices by July 1, 2010. The assessments are intended to provide a comprehensive look at each monitoring agency's ambient air monitoring network to ensure that the network is meeting the minimum monitoring objectives defined in appendix D to 40 CFR part 58, whether new sites are needed, whether existing sites are no longer needed and can be terminated, and whether new technologies are appropriate for incorporation into the ambient air monitoring network.[238]

Since each agency has completed its first required five-year assessment, and several monitoring rule requirements have either been added or changed since this requirement was added in 2006, the EPA thought it was appropriate to review this requirement and solicit comment on any possible changes the EPA should consider that may improve the usefulness of the assessments. Specifically, the EPA solicited comment on ways to either streamline or add additional criteria for future assessments.

The EPA also proposed to remove references to ''community monitoring zones'' and ''spatial averaging'' in the annual monitoring network plans due to EPA Regional Offices by July 1 of each year. The Agency proposed to remove these references since, as discussed in section VII.A.2 above, the EPA proposed to remove all references to the spatial averaging option throughout 40 CFR part 50 appendix N. Consistent with these changes, the EPA also proposed to remove references to community monitoring zones under the annual monitoring network plans described in 40 CFR 58.10.

The EPA received comments from several air agencies on the five year assessments. Most comments on the five year assessments focused on the type and usefulness of assessment tools made available to air agencies during the last review. Of specific note were concerns that assessment tools used to evaluate networks on a regional or national basis do not provide the spatial resolution necessary to adequately assess state networks on a scale most useful to air agencies. This is especially true when attempting to evaluate smaller scale monitoring or pollutant gradients associated with near-road and source oriented monitoring. Suggestions for improvement identified the need for the EPA to work closely with air agencies early in the next cycle of assessments (due in 2015) so that any tools developed can be of benefit to the questions air agencies need to address for their programs. The EPA did not receive any comments on removing references to community monitoring zones specifically as it pertains to their listing in the annual monitoring network plans described in 40 CFR 58.10.[239]

The EPA took comment on potential improvements to the five year assessments. All the recommendations received focused on the types of assessments to perform and ensuring that the EPA works closely with air agencies so that assessments will be of benefit to the air agencies. No specific recommendations were made to add or remove any of the requirements of the five year assessments and consequently the EPA is not making any changes. The EPA intends to work with air agencies to ensure future tools are as helpful as practicable.

Consistent with the decision to end the practice of spatial averaging, the EPA is finalizing the removal of language that references ''community monitoring zones'' and ''spatial averaging'' in the annual monitoring network plans due to EPA Regional Offices by July 1 of each year.

b. Operating Schedules

The EPA generally requires $PM_{2.5}$ SLAMS to operate on at least a 1-day-in-3 sampling schedule, unless a reduced sampling frequency is approved such as might be the case with

[238] The EPA provides a link to these assessments on EPA's Web site at: *http://www.epa.gov/ttn/amtic/plans.html.* A detailed description of the requirements for the assessments is described in 40 CFR 58.10.

[239] Comments on the substantive question of whether to revoke references to community monitoring zones were addressed in section VIII.B.1.

a site that has a collocated continuous operating $PM_{2.5}$ monitor.[240] However, in the 2006 monitoring rule amendments, the EPA finalized a new requirement for the operating schedule of $PM_{2.5}$ SLAMS sites (40 CFR 58.12). The new requirement stated that sites with a design value within plus or minus five percent of the 24-hour $PM_{2.5}$ NAAQS must have an FRM or FEM operating on a daily sampling schedule. This requirement was included to minimize any statistical error associated with the form of the 24-hour $PM_{2.5}$ NAAQS (i.e., the 98th percentile). In section III.F, the Administrator is finalizing revisions to the level of the primary annual $PM_{2.5}$ NAAQS. Accordingly, possible changes to sampling frequency requirements were also considered.

The EPA had previously considered how sample frequency affects the Data Quality Objectives in a consultation with the CASAC AAMMS in September of 2005 (70 FR 51353 to 51354, August 30, 2005). As a result of that consultation, the EPA proposed (71 FR 2710 to 2808, January 17, 2006) and finalized (71 FR 61236 to 61328, October 17, 2006) changes to the sample frequency requirements as part of the monitoring rule changes in 2006. In that work, the EPA demonstrated that having a higher sample count is generally more useful to minimize uncertainty for a percentile standard than an annual average. Given the decision to strengthen the primary annual $PM_{2.5}$ NAAQS and the known burden of performing daily sampling using the filter-based samplers that are still a mainstay in monitoring agency networks, the issue of needing daily sampling for sites that have design values close to the level of the 24-hour $PM_{2.5}$ standard was reconsidered if the site already has a design value above the level of the primary annual $PM_{2.5}$ NAAQS.

In a related issue, since the EPA finalized the requirement for daily sampling at sites within 5 percent of the 24-hour $PM_{2.5}$ NAAQS in 2006, there has been confusion over the procedures for adjusting sample frequencies, where necessary, to account for variations in year-to-year design values. Therefore, the EPA proposed to revise this requirement in the following ways: (1) The EPA proposed that monitors would only be required to operate on a daily schedule if their 24-hour design values were within five percent of the 24-hour $PM_{2.5}$ NAAQS and the site had a design value that was not above the level of the annual $PM_{2.5}$ NAAQS. (2) The EPA proposed that review of data for purposes of determining applicability of this requirement at a minimum be included in each agency's annual monitoring network plan described in 40 CFR 58.10 based on the three most recent years of ambient data that were certified as of the May 1 annual deadline. However, monitoring agencies may request changes to sample frequency at any time of the year by submitting such a request to their applicable EPA Regional Office. Changes in sampling frequency are expected to take place by January 1 of the following year. Increased sampling is expected to be conducted for at least three years, unless a reduction in sampling frequency has been approved in a subsequent annual monitoring network plan or otherwise approved by the Regional Administrator.

Comments received on the sample frequency requirements for $PM_{2.5}$ were from air agencies, who were generally supportive of the EPA's proposed approach.

The EPA is finalizing its proposal to modify the sample frequency requirements for triggering daily sampling so that only those areas with 24-hour design values within five percent of the 24-hour $PM_{2.5}$ NAAQS and where the design value site is not above the level of the annual $PM_{2.5}$ NAAQS would be required to operate on a daily sample frequency. The EPA is also finalizing all other aspects of this part of the proposal.

c. Data Reporting and Certification for CSN and IMPROVE Data

The EPA is not finalizing its proposal on minor changes to reporting and certification of data associated with CSN and IMPROVE networks since as explained in Section VI, EPA is not finalizing a secondary standard to support visibility impairment that would have used CSN and IMPROVE data.

d. Requirements for Archiving Filters

The EPA proposed to extend the requirement for archival of $PM_{2.5}$, PM_{10}, and $PM_{10\text{-}2.5}$ filters from manual low-volume samplers (samplers with a flow rate of less than 200 liters/minute) at SLAMS from one year after data collection to five years after data collection. The archive of low-volume PM filters is an important resource for on-going research and development of emission control strategies and for use in health and epidemiology research. During a workshop on Ambient Air Quality Monitoring and Health Research in 2008, retaining filters for laboratory analysis was identified as a key recommendation to provide daily measurements of metals and elements (U.S. EPA, 2008d, pp. 17 to 21). The EPA's previous requirement of one-year is not sufficiently long for retrospective analysis of important episodes and for use in long-term epidemiology research. Since initially requiring filter archival of low-volume PM filters in 1997, the EPA has always recommended longer archiving of filters and most agencies are already doing so. However, a small number of agencies have reported discarding older filters, despite the minimal cost of storing these filters. Since cold storage of a large number of filters may be cost prohibitive and of little benefit in retaining key aerosol species in the x-ray fluorescence (XRF) analyses, the EPA proposed to minimize the costs of retaining filters by only requiring cold storage during the first year after sample collection.

All comments received on this issue were from air agencies, which were largely supportive of such a change to this requirement. One air agency did report that it would present a hardship to store filters for such a long period of time as they did not have the room to support such a requirement.

The EPA is finalizing the requirement for archival of $PM_{2.5}$, PM_{10}, and $PM_{10\text{-}2.5}$ filters from manual low-volume samplers (samplers with a flow rate of less than 200 liters/minute) at SLAMS for a minimum of five years after data collection, with cold storage only required for the first 12 months of archiving. The EPA will work closely with air agencies through its EPA Regional Offices and laboratories to support any air agency unable to store filters for the new five year requirement.

IX. Clean Air Act Implementation Requirements for the PM NAAQS

This section of the preamble discusses the general approach for air agencies[241] to meet certain CAA requirements for implementing the revised primary annual $PM_{2.5}$ NAAQS as part of the revised suite of NAAQS for PM. In accordance with CAA section 107(d), the PM NAAQS revisions trigger a process under which states must and tribes may make recommendations to the Administrator regarding area designations, and the EPA will take final action on those designations. Under section 110 of the CAA and related provisions, states are also required to submit, for the EPA's

[240] All NCore stations must operate on at least a one-in-three day sample frequency for filter-based PM sampling.

[241] This and all subsequent references to ''air agency'' are meant to include state, local and tribal agencies responsible for the implementation of a $PM_{2.5}$ control program.

approval, SIPs that provide for the attainment and maintenance of the revised NAAQS through control programs directed at sources of direct $PM_{2.5}$ and precursor emissions. If a state fails to adopt and implement the required SIPs by the time periods provided in the CAA, the EPA has responsibility under the CAA to adopt a Federal Implementation Plan (FIP) to assure that areas attain the NAAQS in an expeditious manner. Additionally, emissions sources and air agencies must address the revised PM NAAQS in the context of preconstruction air permitting requirements and the transportation conformity and general conformity processes.

In addition to today's revisions to the primary annual $PM_{2.5}$ NAAQS, the EPA is taking final action on a PSD implementation provision. To facilitate timely implementation of the PSD requirements resulting from the revised NAAQS, which would otherwise become applicable to all PSD permit applications upon the effective date of this final PM NAAQS rule, the EPA is finalizing a grandfathering provision for pending permit applications. This final rule incorporates revisions to the PSD regulations that provide for grandfathering of PSD permit applications that have been determined to be complete on or before December 14, 2012 or for which public notice of a draft permit or preliminary determination has been published as of the effective date of today's revised $PM_{2.5}$ NAAQS. Accordingly, for projects eligible under the grandfathering provision, sources must meet the requirements associated with the prior primary annual $PM_{2.5}$ NAAQS rather than the revised primary annual $PM_{2.5}$ NAAQS.

The EPA also proposed to implement a surrogacy approach for addressing PSD requirements associated with the proposed distinct secondary visibility index NAAQS. As described in section VI, the EPA is not finalizing a distinct secondary visibility index standard at this time and therefore the proposed surrogacy approach for implementing such a standard under the PSD program is unnecessary. Additionally, as discussed in section IV, today's final rule does not include any changes to the existing PM_{10} NAAQS. Accordingly, this section of the preamble does not include any discussion of implementation specifically related to the PM_{10} NAAQS.

Under the schedule in section 107(d)(1) of the CAA, as confirmed in this action, state Governors and tribes, if they choose, are required to submit their initial designation recommendations for the revised primary annual $PM_{2.5}$ NAAQS to the EPA no later than 1 year following promulgation of the revised NAAQS (i.e., by December 13, 2013). The EPA will provide designation guidance to air agencies shortly after today's final NAAQS rule to assist them in formulating their designation recommendations. The EPA intends to complete initial designations for the revised primary annual $PM_{2.5}$ NAAQS by December 12, 2014 using available air quality data from the current $PM_{2.5}$ monitoring networks.

In addition to describing the PSD grandfathering provision being finalized in today's rule and responding to associated public comments, this section of the preamble describes the EPA's future plans for addressing the remaining aspects of implementation, such as infrastructure SIP submittals and nonattainment area planning. In the proposed rule, the EPA solicited preliminary comment on some of the issues that the Agency anticipates will need to be addressed in future guidance or regulatory actions related to implementation of the revised $PM_{2.5}$ NAAQS. The EPA received comments on a few of these issues and, as explained in greater detail later in this section, the EPA either has considered or will consider, as appropriate, all substantive comments received as future guidance and proposed rules are developed.

A. Designation of Areas

1. Overview of Clean Air Act Designations Requirements

After the EPA establishes or revises a NAAQS, the CAA requires the EPA and states to take steps to ensure that the new or revised NAAQS is met. The first step, known as the initial area designations, involves identifying areas of the country that either meet or do not meet the new or revised NAAQS along with the nearby areas contributing to violations. Section 107(d)(1) of the CAA states that, ''By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109, the Governor of each state shall * * * submit to the Administrator a list of all areas (or portions thereof) in the State'' that designates those areas as nonattainment, attainment, or unclassifiable.[242] Section 107(d)(1)(B)(i) further provides, ''Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) * * * as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations.'' The term ''promulgation'' has been interpreted by the courts with respect to the NAAQS to be signature and widespread dissemination of a rule. By no later than 120 days prior to promulgating designations, the EPA is required to notify states of any intended modifications to their recommendations, including area boundaries, that the EPA may deem necessary. States then have an opportunity to demonstrate why the EPA's intended modification is inappropriate. Whether or not a state provides a recommendation, the EPA must timely promulgate the designation that it deems appropriate. While section 107 of the CAA specifically addresses states, the EPA intends to follow the same process for tribes that choose to make a recommendation to the extent practicable, pursuant to section 301(d) of the CAA regarding tribal authority, and the Tribal Authority Rule (63 FR 7254, February 12, 1998). To provide clarity and consistency in doing so, the EPA issued a 2011 guidance memorandum on working with tribes during the designations process (Page, 2011).

2. Proposed Designations Schedules

When the EPA proposed the new and revised PM NAAQS on June 29, 2012, the EPA indicated an intention to follow the standard 2-year schedule for initial area designations for both the revised primary annual $PM_{2.5}$ standard and the proposed secondary PM visibility index standard, noting that promulgating initial area designations for these standards on the same schedule would provide early regulatory certainty for states. Under this approach, the EPA intended to complete initial designations for both the revised primary annual $PM_{2.5}$ NAAQS and the secondary PM visibility index NAAQS by December 2014 using available air quality data from the current $PM_{2.5}$ and speciation monitoring networks using the most recent 3 consecutive years of certified air quality monitoring data (i.e., most likely data from 2011–2013).

[242] While the CAA says ''designating'' with respect to the Governor's list, in the full context of the CAA section it is clear that the Governor actually makes a recommendation to which the EPA must respond via a specified process if the EPA does not accept it.

The EPA's June 29, 2012 notice proposed new requirements for establishing near-road $PM_{2.5}$ monitors in certain cities (section VIII.B.3.b.i of the proposal) and new requirements for each state with a CBSA over 1 million in population to add or relocate an existing CSN (or IMPROVE) monitoring site in at least one of its CBSAs to collect speciated $PM_{2.5}$ data to support implementation of the proposed secondary standard to address visibility impairment (section VIII.A.2 of the proposal). The EPA anticipated that 3 consecutive years of air quality data from any near-road monitoring sites or newly placed CSN (or IMPROVE) $PM_{2.5}$ speciated monitoring site would not be available until 2018. The timing for both of these proposed monitoring changes would preclude the use of the collected data in initial area designations, and therefore, the EPA stated in the proposal that initial area designations would not take into account monitoring data from any newly established near-road monitoring sites, nor from newly established speciation monitoring sites.

3. Comments and Responses

The EPA received numerous comments on the proposed designations schedules from states, state organizations, local air pollution control agencies, regional organizations, industry, environmental organizations, and health-related organizations. Most commenters expressed support for a standard 2-year schedule for initial area designations for the primary annual standard. Several commenters also encouraged the EPA to consider an additional year for initial area designations associated with the proposed secondary PM visibility index standard due to the lag in obtaining data from speciation monitoring networks, the variability in monitored relative humidity data, and the ''unique'' nature of the proposed secondary standard. For the reasons stated in section VI.D.2, the Administrator has decided not to establish the proposed distinct secondary standard to address visibility impairment, and therefore, the EPA will not promulgate initial area designations for a secondary PM visibility index standard. Because data are currently available from numerous existing $PM_{2.5}$ mass monitoring sites to determine compliance with the revised primary annual $PM_{2.5}$ NAAQS, the EPA believes it is appropriate to pursue a standard 2-year schedule for initial area designations for the primary annual $PM_{2.5}$ NAAQS.

The EPA also received numerous comments related to the use of data from the proposed new near-road monitors in the designations process. Several commenters asked the EPA to clarify whether these data will be used if available for initial area designations. Others asked the EPA to provide guidance related to establishing boundaries for areas containing violating near-road monitors. One commenter suggested that the EPA conduct dispersion modeling around transportation facilities in accordance with the EPA's transportation conformity hotspot modeling guidance and use concentrations to determine attainment status for designations process. This same commenter also supported using modeling for unmonitored areas, e.g., communities near roadways.

As previously stated, the EPA does not believe that data from the new near-road monitors will be available for the EPA to consider within the timeframe for initial area designation provided by the CAA. Section 107(d)(1)(B) of the CAA requires the EPA to designate areas no later than 2 years following promulgation of a new or revised NAAQS, or by December 2014. (The CAA provides the Agency an additional third year from promulgation should there be insufficient information on which to make compliance determinations). For initial area designations for the primary annual $PM_{2.5}$ NAAQS, the EPA relies exclusively on monitoring data to identify areas to be designated nonattainment due to violations of the standards and then uses other information to identify areas contributing to violations in those areas. *See Catawba County* v. *EPA,* 571 F.3d 12–13 (D.C. Cir. 2009). As indicated in the proposal, the initial set of near-roadway $PM_{2.5}$ monitors will be fully deployed by January 2015, with the requisite 3 years of air quality data available in 2018.[243] The EPA intends to proceed with initial area designations using 3 years of consecutive air quality data from the existing, area-wide FRM/FEM/ARM $PM_{2.5}$ monitoring sites to complete designations by December 2014. Consistent with previous area designations processes used in informing boundary decisions, the EPA would then analyze a variety of area-specific information[244] in determining which nearby areas contribute to a violation. As previously indicated, the EPA relies on monitoring data to identify areas to be designated nonattainment due to violations of the standards and does not intend to conduct or use dispersion modeling around transportation facilities or in unmonitored areas to determine whether an area is violating the primary annual $PM_{2.5}$ NAAQS for purposes of establishing nonattainment areas as this is not required by the statute. *See Catawba County* v. *EPA,* 571 F.3d 12–13 (D.C. Cir. 2009). The EPA intends to address the use of area-specific information and the boundary setting process, including the presumptive starting area boundary, in the designation guidance to the states, expected to be available shortly after promulgation of the PM NAAQS.

4. Intended Designations Schedules

In this final rule, the EPA is setting a revised, more protective primary annual $PM_{2.5}$ NAAQS. After considering the public comments and for the reasons discussed above, the EPA intends to designate areas for the primary annual $PM_{2.5}$ NAAQS on a 2-year schedule from signature of this final PM NAAQS rule, as prescribed in CAA section 107.[245] Under the schedule in section 107(d)(1) of the CAA, as confirmed in this action, state Governors and tribes, if they choose, are required to submit their initial designation recommendations for the revised primary annual $PM_{2.5}$ NAAQS to the EPA no later than 1 year following promulgation of the revised NAAQS (i.e., by December 13, 2013). These recommendations should be based on air quality data from the years 2010 to 2012. If the EPA intends to make any modifications to a state's or tribe's recommendations, the EPA is required to notify the state or tribe no later than 120 days prior to finalizing the designation; this would be no later than August 14, 2014. States and tribes will then have an opportunity to demonstrate why the EPA's intended modification is inappropriate before the EPA makes the final designation decisions. Prior to the EPA's signing a final rule by December 12, 2014, promulgating the initial area

[243] The remainder of the near-road monitors in CBSAs with populations between 1 million but less than 2.5 million will be deployed by January 1, 2017.

[244] The EPA has used area-specific information to support boundary determinations by evaluating factors such as air quality data, emissions and emissions-related data, meteorology, geography/topography, and existing jurisdictional boundaries. This may include, as appropriate, information from non-FRM/FEM/ARM monitors and air quality modeling, where available, to help define an appropriate boundary for areas contributing to FRM/FEM/ARM-based monitored violations.

[245] While the EPA intends to make every effort to designate areas for the primary annual $PM_{2.5}$ NAAQS on a 2-year schedule, the EPA recognizes that new information may later arise that justifies the need for additional time, up to 1 additional year available based on insufficiency of data, to complete the process. Any subsequent change to the designations schedule would be announced.

designations for the 2012 primary annual $PM_{2.5}$ NAAQS, data from 2013 may be available. If so, the EPA's designations decisions will be based on air quality data from the years 2011 to 2013. States and tribes may update their recommendations when these new data become available.

In the proposal, the EPA stated its intention to provide technical information and guidance to states shortly after promulgation of the NAAQS to assist states and tribes in the development of their designation recommendations. The EPA understands that developing recommendations on appropriate nonattainment area boundaries is a significant effort for states, especially for states with little or no experience in $PM_{2.5}$ air quality planning. Therefore, the EPA plans to assist states throughout the designations process on technical and policy-related issues through outreach efforts that will provide information and data sources relevant to making designations decisions. The EPA will include such information for the revised primary annual $PM_{2.5}$ NAAQS on the general $PM_{2.5}$ designations Web site at *http://www.epa.gov/pmdesignations.* The EPA also encourages states and tribes to consult with their EPA regional office as they develop their area recommendations.

B. Section 110(a)(2) Infrastructure SIP Requirements

The proposal described the CAA requirements for air quality management infrastructure SIPs that states must submit to the EPA within 3 years after promulgation of a new or revised primary standard. As discussed in the proposal, while the CAA allows the EPA to set a shorter time for submission of these SIPs, the EPA does not currently intend to do so. In the proposal, the EPA solicited comment on infrastructure SIP submittal timing, in addition to ''all aspects'' of infrastructure SIPs, for the Agency to consider in developing future guidance. The EPA received comments recommending that the EPA provide states an additional 18 months to submit SIPs for any revised secondary standard, but because the Agency is not revising the secondary NAAQS in this rule, the issue of whether or not to allow states extra time to submit infrastructure SIPs for the secondary NAAQS is now moot. The EPA received several comments on other aspects of infrastructure SIPs, which are being considered in the development of a forthcoming guidance document on section 110 infrastructure SIP requirements that will apply to all NAAQS, including the revised $PM_{2.5}$ NAAQS. In addition, the EPA may issue supplemental infrastructure SIP guidance specific to the revised $PM_{2.5}$ NAAQS if needed.

C. Implementing the Revised Primary Annual $PM_{2.5}$ NAAQS in Nonattainment Areas

In the proposal, the EPA described the basic CAA requirements that govern SIP submittals for nonattainment areas (77 FR 38890, June 29, 2012 at 39019–21). The Agency did not propose any particular approach for implementing any revised $PM_{2.5}$ standards, but rather indicated its intent to carry out a notice-and-comment rulemaking to propose and issue a final implementation rule that would spell out the implementation requirements for the revised primary annual $PM_{2.5}$ NAAQS and the revised monitoring regulations. The EPA acknowledges that several states and industry groups commented on the need for the EPA to issue an implementation rule, either in proposed or final form, simultaneous with this final PM NAAQS rule. Other commenters commented that the EPA should consult with states and local air agencies to develop the future implementation rule and to do so expeditiously, while another state commenter requested that the EPA commit to firm deadlines for issuing the future implementation rule and guidance related to infrastructure SIPs, among other things.

The EPA acknowledges states' need for timely guidance on how to implement the revised NAAQS. However, due to the number of unique and complex issues associated with the PM NAAQS proposal and uncertainty about the outcome of the final NAAQS, the EPA is not able to propose an implementation rule or finalize any aspect of the implementation program beyond the PSD grandfathering provision discussed later in this section at this time. Because we agree that it is beneficial to engage with air agencies early in the rule development process, however, we have initiated such discussions to inform the upcoming proposed rule. The EPA intends to finalize the implementation rule around the time the initial area designations process is finalized.

One particular implementation-related issue that the EPA sought preliminary comment on in the proposal was the concept of a transition period during which any changes in monitoring requirements would not affect attainment plans and maintenance plans for the 1997 and 2006 $PM_{2.5}$ NAAQS. The EPA received a range of comments both in support of and in opposition to such a concept. Upon further analysis of the potential effect of monitoring requirement changes, and in consideration of comments received, we believe that it will not be necessary to provide for such a transition period in the future implementation rule because the changes in monitoring requirements included in this final rule would not automatically affect attainment plans and maintenance plans for the 1997 or 2006 $PM_{2.5}$ NAAQS. Specifically, there are currently approximately ten $PM_{2.5}$ air quality monitors that have been identified as not comparable to the annual standards as part of the annual state monitoring plan revision process. If a state chooses to revise the status of one of these monitors in order to make it comparable to the annual standards because it is determined to be representative of many other similar locations, it would propose a change in status for that monitor in the next revision of the state $PM_{2.5}$ monitoring plan (state revisions are due in June of each year). The EPA would then review and take action on the state's proposed change. The EPA believes that the monitoring plan revision process provides adequate procedural steps for identifying which monitors are to be comparable to the annual $PM_{2.5}$ standards. Thus for this reason, there is no need to include any ''transition period'' in a future rule.

The EPA appreciates the input received from commenters on implementation issues and will take it into consideration as we continue to work with air agencies to develop our proposed implementation rule. In developing the future implementation rule proposal, the EPA also plans to address any potential impact of the monitoring requirement changes being finalized in this rule, particularly on attainment planning and development of attainment demonstrations by states, and in doing so, we will consider the preliminary comments received on this topic.

D. Prevention of Significant Deterioration and Nonattainment New Source Review Programs for the Revised Primary Annual $PM_{2.5}$ NAAQS

The CAA requires states to include SIP provisions that address the preconstruction review of new stationary sources and the modification of existing sources. The preconstruction review of each new and modified source generally applies on a pollutant-specific basis and the requirements for each pollutant vary depending on whether the area is designated attainment (or unclassifiable) or nonattainment for that pollutant. Parts C and D of title I of the CAA contain specific requirements for the preconstruction review and permitting of new major stationary sources and major modifications, referred to as the PSD program and the nonattainment new source review (NNSR) program, respectively. Collectively, those permit requirements are commonly referred to as the ''major NSR program'' because of their applicability to new major stationary sources and major modifications.

Today's final rule revising the primary annual $PM_{2.5}$ NAAQS will affect PSD permitting requirements as of the effective date of today's final rule, March 18, 2013, which is also the effective date of the revised $PM_{2.5}$ NAAQS. In addition, certain NNSR permitting requirements related to the revised $PM_{2.5}$ NAAQS will take effect on and after the effective date of any nonattainment area designation for $PM_{2.5}$. In order to minimize potential delays for pending PSD permit applications and to provide a reasonable transition, the EPA is finalizing a grandfathering provision for PSD permit applications that have reached a specified milestone in the permitting process. This final rule incorporates revisions to the PSD regulations that provide for grandfathering of PSD permit applications for which the reviewing authority has determined the application to be complete on or before December 14, 2012 or for which the reviewing authority has first published public notice that a draft permit or preliminary determination for the permit has been issued prior to the effective date of today's revised PM NAAQS. Accordingly, projects eligible under the grandfathering provision must meet the requirements associated with the prior primary annual $PM_{2.5}$ NAAQS rather than the revised primary annual $PM_{2.5}$ NAAQS. As discussed in more detail in the following sections, the EPA is not now making any changes to the $PM_{2.5}$ increments, nor are we revising any of the screening tools that are now used to implement the major NSR program for $PM_{2.5}$. These screening tools include the significant emission rate (''SER''), used as a threshold for determining whether a given project is subject to major NSR permitting requirements under both PSD and NNSR; the significant impact levels (''SILs''), used to determine the scope of the required air quality analysis that must be carried out in order to demonstrate that the source's emissions will not cause or contribute to a violation of any NAAQS or increment under the PSD program; and the significant monitoring concentration (''SMC''), a screening tool used to determine whether it may be appropriate to exempt a proposed source from the requirement to collect preconstruction ambient monitoring data as part of the required air quality analysis.

1. Prevention of Significant Deterioration

The PSD requirements set forth under part C (sections 160 through 169) of the CAA apply to new major stationary sources and major modifications locating in areas designated as ''attainment'' or ''unclassifiable'' with respect to the NAAQS for a particular pollutant. The EPA regulations addressing the statutory requirements under part C for a PSD permit program can be found at 40 CFR 51.166 (containing the PSD requirements for an approved SIP) and 40 CFR 52.21 (the federal PSD permit program). For PSD, a ''major stationary source'' is one with the potential to emit 250 tons per year (tpy) or more of any air pollutant, unless the source or modification is classified under a list of 28 source categories contained in the statutory definition of ''major emitting facility'' in section 169(1) of the CAA. For those 28 listed source categories, a ''major stationary source'' is one with the potential to emit 100 tpy or more of any air pollutant. A ''major modification'' is a physical change or a change in the method of operation of an existing major stationary source that results in a significant emissions increase and a significant net emissions increase of a regulated NSR pollutant. Under PSD, new major sources and major modifications must apply best available control technology (BACT) for each applicable pollutant and conduct an air quality analysis to demonstrate that the proposed source or project will not cause or contribute to a violation of any NAAQS or PSD increments (*see* CAA section 165(a)(3); 40 CFR 51.166(k); 40 CFR 52.21(k)). PSD requirements also include in appropriate cases an analysis of potential adverse impacts on Class I areas (*see* sections 162 and 165 of the CAA).

PSD permitting requirements generally first became applicable to $PM_{2.5}$ in 1997, on the effective date of the NAAQS for $PM_{2.5}$ (Seitz, 1997). The EPA's regulations define the term ''regulated NSR pollutant'' to include any pollutant for which a NAAQS has been promulgated or that is otherwise identified as a constituent or precursor to a NAAQS pollutant (40 CFR 51.166(b)(49); 40 CFR 52.21(b)(50)).[246] In addition, on May 16, 2008, the EPA amended its regulations to identify certain $PM_{2.5}$ precursors (SO_2 and NO_X) as regulated NSR pollutants and adopt other provisions, such as a significant emissions rate for $PM_{2.5}$, to facilitate implementation of PSD and NNSR program requirements for $PM_{2.5}$ (73 FR 28321).[247] Air agencies were required to revise their SIPs by May 16, 2011, to incorporate the required elements of the 2008 final rule.

On October 20, 2010, the EPA again amended the PSD regulations at 40 CFR 51.166 and 52.21 to add PSD increments as well as two screening tools for $PM_{2.5}$—SILs and SMC (75 FR 64864). The October 2010 final rule became effective on December 20, 2010. The EPA indicated that the SILs and SMC for $PM_{2.5}$, while useful tools for program implementation, are not considered mandatory elements of an approvable SIP; thus, no schedule was imposed on states for addressing those screening tools in their PSD rules. For the portions of the rule that addressed the PSD increments for $PM_{2.5}$, states were required to submit the necessary SIP revisions (at least as stringent as the PSD requirements at 40 CFR 51.166) to the EPA for approval within 21 months from the date on which the EPA promulgated the new $PM_{2.5}$ increments—by July 20, 2012. The schedule for developing and submitting the revisions specifically for the adoption of new PSD increments in state PSD programs is prescribed by the CAA section 166(b). As of October 20, 2011, sources for which PSD permits have been issued pursuant to the federal PSD program at 40 CFR 52.21 have been required, where applicable, to determine their impact on the $PM_{2.5}$ increments.

The PSD program currently regulates emissions of PM using several indicators of particles, including ''particulate matter emissions'' (as regulated under various new source performance standards under 40 CFR part 60), ''PM_{10} emissions,'' and ''$PM_{2.5}$ emissions.'' The latter two emission indicators are designed to be consistent

[246] Under various provisions of the CAA, PSD requirements are applicable to each pollutant subject to regulation under the CAA, excluding hazardous air pollutants. The definition of ''regulated NSR pollutant'' also includes pollutants subject to any standard under section 111 of the CAA or any Class I or II substance subject to title VI of the CAA.

[247] It should be noted that on October 25, 2012, the definition of ''regulated NSR pollutant'' was revised to remove the requirement that condensable PM be included when considering ''particulate matter emissions.'' Accordingly, the definition now requires condensable PM to be counted for PM_{10} emissions and $PM_{2.5}$ emissions, and for ''particulate matter emissions'' only when required by the applicable New Source Performance Standard or SIP. (*See* 77 FR 65107.)

with the ambient air indicators for PM that the EPA currently uses to define the PM NAAQS. As already noted, the PSD program also limits $PM_{2.5}$ concentrations by regulating emissions of gaseous pollutants that result in the secondary formation of particulate matter. Those pollutants, known as $PM_{2.5}$ precursors, generally include SO_2 and NO_X.

In addition to the NAAQS revisions contained in today's final rule, the EPA is finalizing certain clarifications to the existing monitoring regulations codified at 40 CFR 58.30 (Special considerations for data comparisons to the NAAQS). These clarifications are presented in detail in section VIII.B.2 of this preamble. The monitoring regulations provide a basis for determining whether specific monitoring sites are comparable to specific NAAQS. By extension, the EPA has also used the principles for making these determinations for monitoring sites to guide permitting authorities in assessing the comparability of specific receptor locations involved in PSD air quality analyses. Receptors are used in PSD modeling analyses to predict potential air quality impacts in the vicinity of the proposed new or modified facility and in some cases also at more distant Class I areas. Since the EPA interprets the regulation at 40 CFR 58.30 to apply in this context, the EPA will continue to use the principles in the revised regulations in guiding PSD modeling analysis design. Accordingly, the EPA recommends that specific receptor locations used in PSD air quality analyses are evaluated consistent with the final monitoring regulations, as amended by today's rule.

a. Transition Provision (Grandfathering)

i. Proposal

As discussed previously in this preamble, today's final rule establishes a revised level of the primary annual $PM_{2.5}$ NAAQS.[248] Longstanding EPA policy interprets the CAA and 40 CFR 52.21(k)(1) and 51.166(k)(1) to generally require that PSD permit applications include a demonstration that new major stationary sources and major modifications will not cause or contribute to a violation of any NAAQS that is in effect as of the date the PSD permit is issued (Page, 2010a; Seitz, 1997). Thus, as a result of today's final rule, any proposed major new and modified sources with permits pending at the time the $PM_{2.5}$ NAAQS changes take effect would be expected to demonstrate compliance with the revised standard, absent some type of transition provision exempting such applications from the new requirements.

In order to provide for a reasonable transition into the new PSD permitting requirements that will result from the revision of the primary annual $PM_{2.5}$ NAAQS (primarily the requirement to demonstrate that emissions will not cause or contribute to a violation of the revised NAAQS) and the changes to the monitoring requirements discussed earlier, the EPA proposed to add a grandfathering provision to the federal PSD program codified at 40 CFR 52.21 that would apply to certain PSD permit applications that are pending on the effective date of the revised $PM_{2.5}$ NAAQS. Specifically, the EPA proposed to amend the federal PSD regulations at 40 CFR 52.21 to grandfather pending permit applications for which the Administrator or delegated air agency has published a public notice on the draft permit prior to the effective date of the revised $PM_{2.5}$ NAAQS. Qualifying applications could continue being processed in accordance with the PSD requirements applicable to the pre-existing suite of PM NAAQS at the time the public notice on the draft permit was first published. The EPA also proposed that air agencies that issue PSD permits under their own SIP-approved PSD permit program should have the discretion to ''grandfather'' proposed PSD permits in the same manner under these same circumstances. Thus, the EPA also proposed to revise section 40 CFR 51.166 to provide a comparable exemption applicable to SIP-approved PSD programs.

In the preamble to the proposal, the EPA provided a detailed rationale and legal basis for the proposed grandfathering provision, also citing examples in which the EPA previously recognized that the CAA provides discretion for the EPA to grandfather PSD permit applications from requirements that become applicable while the application is pending (45 FR 52683, Aug. 7, 1980; 52 FR 24672, July 1, 1987; U.S. EPA, 2011c, pp. 54 to 61). In summary, when read in combination, sections 165(a)(3), 165(c) and 301[249] of the CAA provide the EPA with the discretion to promulgate regulations to grandfather pending permit applications from having to address a revised NAAQS where necessary to achieve a balance between the CAA objectives in order to protect the NAAQS on the one hand, and to avoid delays in processing PSD permit applications on the other. The EPA has also construed section 160(3) of the CAA, which states that a purpose of the PSD program is to ''insure that economic growth will occur in a manner consistent with the preservation of existing clean air resources,'' to call for a balancing of economic growth and protection of air quality (70 FR 59582, Oct. 12, 2005 at 59587 to 59588). The reasoning of those prior EPA actions is also applicable to the promulgation of revised PM NAAQS.

In developing the proposed grandfathering provision, the EPA considered whether such a provision should include a sunset clause. A sunset clause would add a time limit beyond which an otherwise eligible permit application would no longer be grandfathered from specified new PSD permitting requirements. Consistent with past grandfathering actions described above, the EPA did not propose to include a sunset clause for the proposed grandfathering provision.

ii. Comments and Responses

The majority of commenters, including all industry and state agency representatives, supported the EPA's proposal to adopt a grandfathering provision based on the purpose and rationale described in the preamble to the proposal. These commenters agreed that grandfathering certain pending PSD permit applications was reasonable to balance the CAA objectives to protect the NAAQS on one hand, and to avoid delays in processing PSD permit applications on the other. They also agreed grandfathering provides a reasonable transition into the PSD requirements associated with the revised NAAQS. Industry commenters also indicated that such a provision was important to economic growth and recovery, and was consistent with the purposes of the PSD program, i.e., to ensure that economic growth will occur in a manner consistent with preservation of air quality. Several state commenters pointed out that finalizing the revised $PM_{2.5}$ NAAQS without a grandfathering provision would result

[248] The EPA is also revising the form of the annual primary standard by removing the option for spatial averaging. However, this provision has played no role in PSD so its removal has no implications for PSD.

[249] Section 165(a)(3) of the CAA generally requires that no major emitting facility may be constructed unless the owner or operator demonstrates that emissions from construction or operation of such facility will not cause or contribute to a violation of any NAAQS or PSD increment. Section 165(c) of the CAA requires that the EPA grant or deny any completed permit application not later than one year after the date of filing of such complete application. Section 301 of the CAA authorizes the EPA to prescribe such regulations as are necessary to carry out the functions under the CAA.

in a significant additional resource burden on both permit applicants and air agencies, which would have to reopen pending permit applications that have reached advanced stages in processing to address the revised standard. The commenters further noted that there would likely be little if any environmental benefit afforded by such a process. One state agency commenter performed a preliminary review of recent PSD permitting actions and determined that in all cases, the proposed primary annual $PM_{2.5}$ standard would not have led to tighter permit restrictions or reduced emissions, and that a re-noticing of the preliminary permit decisions would accomplish nothing more than to change the margins of compliance. In other words, re-noticing would have led to project delays with no reduction in $PM_{2.5}$ impacts.

Four environmental group commenters (one representing a coalition of a health advocacy group and several environmental groups) opposed the proposed grandfathering provision based either on concerns about further delay in implementation of the revised PM NAAQS or on a position that the proposed grandfathering provision exceeds the EPA's statutory authority and is unlawful. Commenters challenging the EPA's legal authority to implement the proposed grandfathering provision contended that CAA sections 165 and 301 do not confer any authority on the EPA to grandfather PSD permit applications. The commenters asserted that CAA section 165(a) forecloses the EPA's proposed approach, specifically citing CAA section 165(a)(3)(B) which provides that no major emitting facility ''may be constructed'' unless the facility's owner or operator demonstrates emissions from the facility will not cause or contribute to the violation of ''any * * * national ambient air quality standard in any air quality control region.'' These commenters further claimed that because Congress limited the applicability of the new PSD requirements in several ways, including specific grandfathering relief for sources constructed before the enactment of the 1977 Amendments to the CAA, the EPA is not authorized to waive otherwise applicable statutory requirements (citing *Andrus* v. *Glover Constr. Co.,* 446 U.S 608, 616–17 (1980)).

A subset of commenters also stated that the EPA's proposed grandfathering approach undermines the policy choices made by Congress in adopting the PSD program that (1) it is preferable to prevent air pollution from becoming a problem in the first place, and (2) controls should be installed when new sources are being constructed rather than as retrofits on existing sources.

One commenter asserted that there is no conflict between CAA sections 165(a) and 165(c) as the EPA had implied; therefore, there is no need for the EPA to invoke the regulatory authority of CAA section 301. This commenter also concluded that the EPA's rationale of balancing of economic growth and the protection of air quality pursuant to CAA section 160(3) was unlawful, and that the EPA had not adequately explained the considerations it sought to balance and how the proposal would achieve its goals. The same commenter questioned the EPA's authority to leverage principles of equity and fairness in proposing the grandfathering provision. The commenter also objected to the EPA's rationale for choosing the public notice date of a draft permit as the milestone triggering the grandfathering provision, stating that the approach was contrary to statute because it would deprive interested persons of their statutory right to comment on elements of the application related to the current NAAQS.

The EPA does not agree with the interpretations of the CAA offered by the commenters opposing the proposed grandfathering provision. The EPA has previously exercised this discretion to establish grandfathering provisions in regulations. Indeed, the EPA has done so where provisions of the CAA contradict each other, citing the authority under section 301(a)(1) ''to set transitional rules which accommodate reasonably the purpose and concerns behind the two contradictory provisions'' (45 FR 52676, August 7, 1980 at 52683). Furthermore, the EPA has noted and continues to recognize that even in the absence of a conflict between sections of the Act, ''EPA would have the authority under section 301(a)(1) to exempt those projects in order to phase-in new requirements on a reasonable schedule.'' *Id.* at 52683 n. 5.

There is a conflict or tension between certain provisions of the CAA that the EPA must reconcile in situations where the ability of air agencies to complete action on a permit application within the statutory one-year deadline is likely to be impeded if a new or revised NAAQS becomes applicable during the permit application review process. We do not agree with the commenters' arguments to the contrary. The CAA does not provide clear direction concerning how the EPA should apply section 165(a)(3) of the Act to NAAQS that become effective in circumstances where efforts to update a permit application to address the new or revised NAAQS would be time consuming and impede compliance with the CAA obligation to take action on the application within one year after the completeness determination. Since Congress has not precisely spoken to this issue, the EPA has the discretion to apply a permissible interpretation of the Act that balances the requirements in the Act to make a decision on a permit application within one year and to ensure that new and modified sources will only be authorized to construct after showing they can meet the substantive permitting criteria. *Chevron, U.S.A., Inc.* v. *Natural Res. Def. Council, Inc.,* 467 U.S. 837, 843–44 (1984).

Targeted grandfathering applicable to a specific NAAQS does not waive the statutory requirements in section 165(a)(3), as some commenters assert. Rather, the grandfathering provision makes clear which NAAQS are covered by this provision of the Act when it is applied to a permit application that has reached a specific stage in the review process (i.e., the date the application is determined to be complete or the first date of publication of a public notice on the draft permit or preliminary determination) before a specified date. Grandfathering resolves the question of how the EPA and other permitting authorities should interpret and apply section 165(a)(3) of the Act in the case of today's PM NAAQS revisions considering the requirement of section 165(c) of the Act that reviewing authorities make a decision on a permit application within one year of the date the application was determined complete. This is not a question of whether section 165(a)(3) applies; it is a question of which NAAQS this requirement should cover in the case of a pending PSD permit.

The EPA agrees that as a general rule, section 165(a)(3) applies to ''any NAAQS'' that is effective as of the date a final PSD permit is initially issued (before any administrative appeal proceeding commences). However, these provisions cannot be read in isolation and should be construed in the context of other provisions in section 165 of the Act, such as section 165(c). Since the EPA is required to give effect to all provisions of the Act, in those circumstances where a strict reading of sections 165(a)(3) would frustrate congressional intent that the EPA and other implementing air agencies act in a timely manner, the Agency has the discretion to interpret the reach of section 165(a)(3) to be limited to particular NAAQS that were proposed or effective prior to significant milestones in the permitting process.

Thus, the EPA does not agree with the view expressed by some commenters that section 165(a)(3) must be read strictly in all circumstances to apply to all NAAQS in effect on the date the EPA issues a final permit decision, regardless of other circumstances or other requirements of the CAA. Such a reading fails to acknowledge or give meaning to section 165(c) of the Act. Legislative history illustrates congressional intent to avoid delays in permit processing. S. Rep. No. 94–717, at 26 (1976) (''nothing could be more detrimental to the intent of this section and the integrity of this Act than to have the process encumbered by bureaucratic delay'').

The EPA is also not persuaded that the presence of a grandfathering provision in section 168(b) precludes the EPA from establishing grandfathering exemptions in other circumstances. The commenter's reference to the Supreme Court's observation that when ''Congress expressly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied in the absence of evidence of a contrary legislative intent,'' *Andrus,* 446 U.S. at 616–17, is not persuasive here. The Court applied this principle in a circumstance where there was a provision of law ''expressly relating to contracts of the sort at issue here.'' *Id.* These are not the circumstances here. Section 168(b) of the Act does not expressly relate to the application of PSD permitting requirements to an application pending at the time of the promulgation of a new or revised NAAQS. Section 168(b) exempted facilities that were subject to permitting requirements under an earlier version of the PSD program created solely by the EPA regulation prior to the enactment of section 165 of the CAA and other provisions that expressly authorized and established the requirements of the PSD permitting program applicable today. This exemption operated to continue existing requirements for certain sources after a fundamental change in the statutory and regulatory regime under which such sources were required to obtain authorization to construct or modify major stationary sources of air pollutants. Such an exemption does not expressly relate to the incorporation of a new requirement into the PSD program, under existing statutory authority, when the EPA promulgates a regulation that creates such a requirement. In this case, the EPA is not grandfathering permit applications from the general prohibition in section 165(a) against commencing construction in the absence of a permit issued ''in accordance with the requirements of this part.'' The CAA does not contain any express exemptions to the phrase ''the requirements of this part'' or from section 165(a)(3) of the Act that apply when the EPA promulgates a new or revised NAAQS. Furthermore, section 168(b) applied to sources that had commenced construction before new provisions of the CAA were enacted, whereas the grandfathering that the EPA proposed for purposes of the revised PM NAAQS is applicable to changes in regulatory requirements prior to the issuance of a permit. Thus, the adoption of a one-time grandfather provision upon enactment of the statutory PSD program is clearly different from grandfathering when the EPA promulgates a new or revised NAAQS, which the Act does not address. The fact that Congress expressly enumerated an exemption in section 168 intended to ease transition upon enactment of the PSD provisions in the Act does not constrain the Agency with respect to offering reasonable transitional exemption provisions when EPA regulations create new PSD program requirements under those statutory provisions.

The EPA agrees that the PSD program is based on the goals of preventing air pollution and installing controls when new sources are being constructed, but section 160(3) of the Act also states that a purpose of the PSD program is to ''insure that economic growth will occur in a manner consistent with the preservation of existing clean air resources.'' The EPA continues to construe this provision to call for a balancing of economic growth and protection of air quality. *See* 70 FR 59582, October 12, 2005 at 59587–88. Legislative history illustrates Congressional intent to avoid a moratorium on construction and delays in permit processing. The House Committee report describes how ''the committee went to extraordinary lengths to assure that this legislation and the time needed to develop and implement regulations would not cause current construction to be halted or clamp even a temporary moratorium on planned industrial and economic development.'' H.R. Rep. No. 95–294, 95th Cong., 1st Sess., at 171 (1977). As an illustration of the lengths to which the committee went, the report lists five elements of the legislation, including the following statement: ''To prevent disruption of present or planned sources, the committee has authorized extensive 'grandfathering' of both existing and planned sources.'' *Id.* Furthermore, the Senate Committee report specifically discusses concerns about delays in program implementation. S. Rep. No. 94–717, at 26 (1976) (''nothing could be more detrimental to the intent of this section and the integrity of this Act than to have the process encumbered by bureaucratic delay'').

In the 1980 PSD regulation, the EPA sought to strike a balance between competing goals of the CAA (45 FR 52683). The EPA explained that delaying certain construction ''by imposing new PSD requirements could frustrate economic development'' and noted that the grandfathered projects ''have a relatively minor effect on air quality.'' *Id.* As a result, the EPA adopted a grandfathering provision that ''would strike a rough balance between the benefits and costs of applying PSD to those projects.'' *Id.* Although the EPA used issuance of permits previously required under the SIP in that case to determine eligibility for grandfathering, this precedent does not preclude the EPA from using another milestone in the permit process to determine eligibility in order to strike the appropriate balance in a different situation. The interests behind section 165 include both protection of air quality and timely decision-making on pending permit applications. The EPA is seeking here to balance the requirements in the Act to make a decision on a permit application within one year and to ensure that new and modified sources will only be authorized to construct after showing they can meet the substantive permitting criteria.

Moreover, this action is not based on an assertion of equitable power to disregard or override law, but rather on an interpretation of our statutory authority. In so doing, the EPA has in this case determined which regulatory requirements are covered by the statutory requirements that apply to an application that has reached a specified milestone when the regulatory requirement was established. The EPA does not dispute that administrative agencies only have the powers conferred by statute. However, the EPA may interpret the statutory requirements consistent with Congressional intent and exercise its discretion in a thoughtful way in doing so. Thus, while an administrative agency in the executive branch does not have the equitable powers of a court, this does not necessarily mean an administrative agency cannot interpret its statutory authority to achieve equitable outcomes consistent with Congressional intent.

Based on the foregoing, the EPA believes it has adequately explained its consideration of the CAA requirements related to both NAAQS protection and timely decision-making on permit applications in designing the proposed grandfathering provision. As described below, the EPA is finalizing a grandfathering provision that applies to two categories of PSD permit applications: (1) Those that the reviewing authority has determined to be complete on or before December 14, 2012, or (2) those for which the reviewing authority has first published a public notice that a draft permit or preliminary determination had been prepared prior to the effective date of the revised PM NAAQS. In the proposal, the EPA proposed to grandfather only the latter category, based on publication of a public notice on a draft permit or preliminary determination by the effective date of the final PM NAAQS. However, as described later in this section, based on consideration of public comments received on the proposal, the EPA decided to augment the grandfathering provision to include applications that had been determined to be complete on or before December 14, 2012, the date of signature of the final rule. Permit applications qualifying under the final grandfathering provision must demonstrate that a qualifying new or modified source will not cause or contribute to a violation of the $PM_{2.5}$ NAAQS and increments in effect as of the date the permit application is determined to be complete by the reviewing authority or as of the date the reviewing authority first publishes public notice of the draft permit or preliminary determination, depending on which prong of the grandfathering provision is applicable.

The grandfathering provision does not apply to any other applicable PSD requirements related to $PM_{2.5}$. Sources with projects qualifying under the grandfathering provision will be required to install BACT for $PM_{2.5}$ emissions, demonstrate that project emissions will not cause or contribute to a violation of the PSD increments for $PM_{2.5}$ or the $PM_{2.5}$ NAAQS in effect at the time the permit application is determined to be complete or the public notice is first published on the draft permit or preliminary determination, and address Class I and additional impacts in accordance with the PSD regulatory requirements. Accordingly, the EPA does not expect that the grandfathering provision being finalized in today's rule will result in significantly different air quality impacts than would occur absent any type of grandfathering or transition provision. One commenter has submitted an analysis to support this conclusion.

As described in the proposal and some of the comments received from state agencies, if the EPA and other reviewing authorities were to require permit applicants to demonstrate that they will not cause or contribute to a violation of the revised PM NAAQS after the public comment period has begun, this would unduly delay the processing of the permit application by potentially requiring an additional public comment period and increased demand on the limited resources of the reviewing authority. The EPA disagrees with commenters who contend that grandfathering is contrary to statute because it would preclude public comment on elements of the application related to the current NAAQS. With respect to an application grandfathered under the new provisions provided by today's rule, interested persons will have the opportunity to comment on all aspects of PSD review for $PM_{2.5,}$ including the air quality impacts associated with the revised NAAQS that became effective after the application was determined to be complete or after a public notice was published on the draft permit or preliminary determination, depending on which prong of the grandfathering provision applies. Section 165(a)(2) of the CAA and section 51.166(q)(2)(v) require an opportunity for the public to comment on ''the air quality impact of the source'' and ''other appropriate considerations.'' The grandfathering provision does not necessarily take away the ability of the public to comment on the impact the source may have on the revised NAAQS (including the standard proposed several months earlier) or the discretion of the permitting authority to consider these comments. However, as provided by the grandfathering provision established today in the EPA's PSD regulations, a permit applicant is not required to complete an analysis after the date of the applicable grandfathering milestone to demonstrate that it will not cause or contribute to a violation of the NAAQS that became effective after that date to obtain a permit. Thus, consistent with CAA section 165(a)(2), ''the required analysis'' will have ''been conducted in accordance with regulation promulgated by the Administrator'' and made available for public comment.

Several of the commenters supporting the proposed grandfathering provision in general recommended that the EPA establish the grandfathering milestone as the date that a complete permit application is submitted (or that a submitted permit application is deemed complete by the reviewing agency) rather than the publication date of public notice for a draft permit or preliminary determination as proposed. These commenters pointed out the significant level of effort, resources and time involved in preparing all of the information necessary for a complete permit application, including a BACT analysis, air quality analysis, additional impacts analyses, and a Class I area impact analysis. They claimed that it would be unfair to establish a grandfathering milestone past the complete application date because the processes and timeframes involved in generating the draft permit or preliminary determination materials and publishing the public notice are largely out of the control of the permit applicant and vary from agency to agency. They further stated that requiring reevaluation of a proposed project to assess impacts with respect to the revised NAAQS after a permit application has been deemed complete would result in significant additional cost and delay. One industry commenter pointed out that the EPA's proposed grandfathering approach could place considerable pressure on permit authorities to expedite review of publication of draft permits or decisions before adequate internal review was completed, which could result in subsequent withdrawal of the permit. Several commenters cited prior EPA grandfathering provisions that relied upon that milestone, including the 1987 PM_{10} NAAQS (52 FR 24672, July 1, 1987) and the 1988 NO_2 increments (53 FR 40656, October 17, 1998), and contended that the EPA had not justified the use of an alternative date for purposes of the proposed revisions to the $PM_{2.5}$ NAAQS.

Some state commenters also indicated that the proposed draft permit public notice date milestone could result in additional resource burden on the agency to expedite completion of draft permit packages and process public notices. Other state commenters supported the EPA's proposed draft permit or preliminary determination public notice date as the appropriate grandfathering eligibility milestone, indicating that this approach would provide states and industry certainty on the NAAQS demonstration required during the $PM_{2.5}$ NAAQS transition period.

The EPA acknowledges the comments raising concerns about an approach based solely on the public notice milestone date, and agrees that they warrant consideration of a different milestone date. Further, we agree that an alternate milestone for grandfathering based on the date a permit application is determined complete would address many of these concerns. Therefore, the EPA has modified its proposed approach to address these concerns. In particular, the EPA agrees with commenters that a substantial portion of the level of effort, resource investment, and time involved in the PSD permit process occurs during the process of preparing a PSD permit application and obtaining a completeness determination from the reviewing authority. Of particular importance is the issue of the time delay and the effect on permitting authorities to meet permit issuance deadlines, as previously noted. Commenters have persuaded the EPA that reevaluation of a proposed project to assess impacts with respect to the revised NAAQS after a permit application has been deemed complete would result in significant additional delay, thus frustrating the statutory requirement to complete action on a permit application within one year of the completeness date.

We also agree with commenters that after the permit application completeness determination stage in the permitting process, the applicant must have completed all of the required technical demonstrations (including a BACT analysis, air quality analysis, additional impacts analyses, and Class I area impact analyses), and that the final stages of the permitting process prior to public notice (i.e., developing the draft permit or preliminary determination, developing supporting materials and publishing the public notice) are under the control of the permitting authority. Given the variable practices and timelines of permitting authorities in processing these final steps between permit application completeness and publication of a public notice on the draft permit or preliminary determination pointed out by commenters, we agree that the proposed grandfathering approach could result in inequitable and burdensome outcomes in some circumstances.

The EPA has therefore concluded based on public comments that it should add an additional grandfathering milestone to avoid substantial additional burden and delay for permit applications that have reached a stage in the review process by which significant resources have been expended to complete fundamental PSD analyses and demonstrations that would have to be redone. After a PSD permit application has been determined complete, it may be time consuming for the applicant to amend its permit application to address new or revised NAAQS promulgated after that date. The time required to both amend the application and review the amended application would impose unreasonable additional burden and delay upon the applicant and the reviewing authority. As a result, if the EPA and other reviewing authorities were to require permit applicants to demonstrate that they will not cause or contribute to a violation of the revised PM NAAQS after the permit application is determined to be complete, or any later stage in the permitting process, this would unduly delay the processing of the permit application and place increased demand on the limited resources of the reviewing authority at a time when it should be focused on preparing the draft permit and supporting materials, preparing a public notice, considering public comments and preparing a final permit decision in order to conclude its review of a permit application in a timely manner.

The EPA also agrees with commenters' concerns that the proposed grandfathering approach, based solely on the date of publication of a public notice on a draft permit or preliminary determination, could in some cases result in pressure on permitting authorities to expedite review of publication of draft permits, resulting in additional burden on such permitting authorities and other potential adverse consequences. We note that expediting review is consistent with the requirement of section 165(c) of the CAA to process permit applications in a timely manner. We also observe that using the milestone of a completeness determination to determine eligibility for grandfathering could simply shift this pressure back to the stage in which a permitting authority is reviewing an application to determine if it is complete. A significant distinction, however, is that the one-year deadline for completing action on a permit does not begin to run until the date that a permit application is determined complete.

Based on the comments received and the EPA's consideration of those comments described above, the EPA has decided to modify the proposed grandfathering approach by adding a second category of applications to the proposed qualifying criteria. Specifically, the EPA is finalizing a grandfathering provision that extends grandfathering to permit applications that the reviewing authority has determined, on or before December 14, 2012 (the signature date of the final rule), to be complete. We are adding this category to our originally proposed category: Permit applications for which the permitting authority has first published a public notice that the draft permit or preliminary determination has been prepared prior to the effective date of the revised PM NAAQS.

We are adding eligibility criteria rather than wholly replacing what we proposed for two reasons. First, the EPA understands that there may be some permitting authorities that do not issue formal determinations that an application is complete. Applications in these jurisdictions that may in fact have been complete and far enough along in the review process that a public notice could be issued before the effective date of the revised NAAQS could be significantly delayed if the EPA removed the eligibility criteria based on the publication of the public notice. Second, given that the EPA proposed to establish eligibility for grandfathering based on the timing of the public notice, some permitting authorities and applicants may have anticipated that they had more time to take action to qualify for grandfathering and may have not acted as promptly as they could have to submit additional information or make a completeness determination. Retaining the proposed eligibility criteria avoids prejudice to parties that may have relied on the proposed rule in such a manner.

For the second eligibility criterion added in this final rule, the EPA chose to use the date an application is determined complete, as requested by several commenters. In several existing provisions in sections 51.166(i) and 52.21(i) of the EPA's regulations, a pending application was able to quality for grandfathering if it was submitted before the applicable date but subsequently determined complete after that date. However, this historic approach can be cumbersome to implement and can lead to inconsistent implementation and potential abuse. These concerns stem from the fact that there is a time lag between submittal and the completeness determination during which there are typically additional data requests by the permitting authority and supplemental application material submittals by the applicant. Therefore, it can be difficult to determine the specific date that the submitted application actually became complete; since this date could range from the initial submittal date, through a number of supplemental submittal dates, to the date the permitting authority formally determines the application to be complete. The EPA has chosen to use the date an application is determined complete because this date is easier to identify and apply. For PSD permits issued under 40 CFR 52.21, the EPA's regulations in 40 CFR part 124 define the effective date of an application as the date the permitting authority notifies the applicant that the application is complete. 40 CFR 124.3(f).

The EPA chose to base the second eligibility criterion on the date this rule has been signed by the Administrator to avoid creating pressure on permitting authorities to determine applications complete. Such pressure could lead to premature findings of completeness and grandfathering of a larger number of applications than is warranted to avoid undue delays, thus increasing the air quality impact of the grandfathering provision. Notably, the one-year deadline for completing action on a permit does not begin to run until the date that a permit application is determined complete. While Congress desired timely action on a permit application, the statute gives permitting authorities leeway to ensure they have all the necessary information to proceed expeditiously on a permit application before the clock starts running. The goal of protecting air quality can thus be fulfilled without compromising Congressional intent for timely action by conducting a careful review of an application to determine that it is complete. Applications that have not yet been determined complete may be supplemented to ensure the proposed source does not cause or contribute to a violation of the revised NAAQS without compromising compliance with the one-year deadline in section 165(c). The EPA thus selected the signature date of the final rule to ensure the integrity of completeness determinations issued after the rule is signed and to limit the number of additional sources eligible for grandfathering.

The final grandfathering provision appropriately balances the objectives of CAA section 165 to protect air quality and ensure timely decision-making on permit applications, while also addressing concerns about resource burdens raised by commenters. In addition, as pointed out by commenters, the final grandfathering provision also provides an approach that is more consistent with prior EPA grandfathering actions, e.g., in the 1987 PM_{10} NAAQS, wherein the EPA selected the date of application completeness for grandfathering projects from requirements associated with the new NAAQS.

Regarding the need for a sunset clause for the grandfathering provision, the majority of commenters supported, as proposed, not including such a clause, and no commenters specifically recommended that a sunset clause be established. Commenters pointed out that permit applicants and reviewing authorities already have strong incentives to issue final permits in a timely manner following the public notice stage, and that a sunset clause would not add any meaningful incentive to expedite the permitting process, rather potentially causing additional delays. One commenter stated that permitting authorities have ample discretion, which they routinely use, to refuse to issue a draft permit if additional information is requested during a comment period or the agency itself wants additional information following publication of a draft permit or preliminary determination. The same commenter indicated that permitting authorities also have sufficient discretion to reopen permit proceedings if they consider information in an application to be stale.

The EPA agrees with commenters that the addition of a sunset clause to the proposed grandfathering provision would not add meaningful additional incentive for sources or permitting authorities to expedite permitting processes. The EPA also agrees that a sunset clause could in fact result in further delays for permit actions that qualify for the proposed grandfathering provision in circumstances where unrelated and not reasonably avoidable factors cause final permit issuance to lapse beyond the sunset date. In such cases, the already delayed permit action would necessarily be further delayed to address PSD permitting requirements associated with the revised $PM_{2.5}$ NAAQS, potentially triggering a domino effect of newly applicable requirements. As such, the EPA believes a sunset clause would diminish the value of the grandfathering provision and likely introduce additional complexities in relation to specific permit actions.

A few industry commenters suggested, as an alternative to our proposed approach, that the EPA should effectively grandfather PSD permit actions from meeting requirements associated with the revised PM NAAQS by extending the effective date of the NAAQS by one year. These commenters argued that such an approach is preferable because it would address potential concerns about the inability of state agencies to implement the proposed grandfathering provision prior to rule adoption and SIP approval. Several industry groups and representatives also commented that the EPA should not eliminate state discretion to grandfather individual permits even without an express exemption.

The EPA disagrees with extending the effective date of the revised PM NAAQS by one year because this approach would entirely defer the important health benefits associated with the revised PM NAAQS. Further, as discussed in the proposal, the EPA does not anticipate any issues related to implementation of the grandfathering provision in SIP approved state/local jurisdictions. The EPA proposed and is finalizing a revision to 40 CFR 51.166 to provide a comparable exemption applicable to SIP-approved PSD programs, and air agencies that issue PSD permits under an EPA-approved PSD permit program should have the discretion to ''grandfather'' proposed PSD permits consistent with these final rule provisions. Even absent an express grandfathering provision in state rules, states have the discretion to permit grandfathering consistent with the federal regulations if the particular state's laws and regulations may be interpreted to provide such discretion.[250] However, state SIPs may not be less stringent than federal requirements. Accordingly, the EPA believes that such discretion must be limited to applying grandfathering consistent with the federal rule provisions.

iii. Final Action

For the reasons articulated above, the EPA is finalizing a grandfathering provision under the PSD regulations that provides that qualifying sources and modifications shall not be required to demonstrate that their proposed emissions will not cause or contribute to a violation of the revised primary annual $PM_{2.5}$ NAAQS but instead shall demonstrate that such emissions will not cause or contribute to the $PM_{2.5}$ NAAQS in effect on the date the reviewing authority determines the permit application to be complete or the date the public notice on the draft permit or preliminary determination is first published, depending on which prong of the grandfathering provision is applicable. Under the final

[250] In one extraordinary case where the EPA had not previously adopted a grandfathering provision in regulations and had significantly exceeded the deadline in section 165(c) of the CAA, the EPA has taken the position that it may grandfather a specific source through adjudication, thus interpreting its regulations, as well as other authorities, to allow grandfathering in that extraordinary circumstance (U.S. EPA, 2011c, pp. 67 to 71). Although grandfathering without a specific exemption in regulations was justified based on the particular facts in that specific instance, the preferred approach is to enable grandfathering through express regulatory exemptions of the type being finalized in this action (U.S. EPA, 2011c, p. 68).

grandfathering provision, qualifying sources and modifications are those for which the reviewing authority has determined that the permit application is complete on or before December 14, 2012 or the permitting authority has first published a public notice that a draft permit or preliminary determination has been prepared prior to the effective date of today's final revisions to the PM NAAQS.[251] The relevant public notice requirements for EPA and delegated agency issued permits are those in 40 CFR 124.10(c)(2), and the corresponding provisions for implementation-plan approved agency permits are those in 40 CFR 51.166(q)(2)(iii). The grandfathering provision is being incorporated into the regulations at 40 CFR 52.21 and 51.166 to provide the same transition for the EPA, delegated jurisdictions, and implementation plan-approved jurisdictions. The EPA is not establishing a sunset date for this grandfathering provision.

b. Modeling Tools and Guidance Applicable to the Revised Primary Annual $PM_{2.5}$ NAAQS

Today's final rule revising the level of the primary annual $PM_{2.5}$ NAAQS from 15.0 μg/m^3 to 12.0 μg/m^3 generally will require proposed new major stationary sources and modifications to take these changes into account as part of the required air quality analysis to demonstrate that the proposed emissions increase will not cause or contribute to a violation of the PM NAAQS. Upon the effective date of today's final revisions to the PM NAAQS, proposed new major stationary sources and major modifications that are not grandfathered from the new requirements (as described in section IX.D.1.a) will be required to demonstrate compliance with the suite of PM NAAQS, including the revised primary annual $PM_{2.5}$ NAAQS.

PSD applicants are currently required to demonstrate compliance with the existing primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS and will need to consider the impact of their proposed emissions increases on the revised primary annual $PM_{2.5}$ NAAQS. To assist sources and permitting authorities in carrying out the required air quality analysis for $PM_{2.5}$ under the existing standards, the EPA issued, on March 23, 2010, a guidance memorandum that recommends certain interim procedures to address the fact that compliance with the 24-hour $PM_{2.5}$ NAAQS is based on a particular statistical form, and that there are technical complications associated with the ability of existing models to estimate the impacts of secondarily formed $PM_{2.5}$ resulting from emissions of $PM_{2.5}$ precursors (Page, 2010b). For the latter issue, the EPA recommended that special attention be given to the evaluation of monitored background air quality data, since such data readily account for the contribution of both primary and secondarily formed $PM_{2.5}$ from existing sources affecting the area.

To provide more detail and to address potential issues associated with the modeling of direct and precursor emissions of $PM_{2.5}$, the EPA is now developing additional permit modeling guidance that will recommend appropriate technical approaches for conducting a $PM_{2.5}$ NAAQS compliance demonstration, which includes more adequate accounting for contributions from secondary formation of ambient $PM_{2.5}$ resulting from a proposed new or modified source's precursor emissions. To this end, the EPA discussed this draft guidance in March 2012 at the EPA's 10th Modeling Conference.[252] Based on its review of comments received through the conference and further technical analyses, the EPA intends to issue final guidance by the end of calendar year 2012, prior to the effective date of today's final PM NAAQS revisions.

The EPA also received a number of industry and state comments on the $PM_{2.5}$ NAAQS proposal related to $PM_{2.5}$ air quality impact analyses and associated existing modeling tools and procedures. In general, commenters identified the lack of approved air quality modeling tools and procedures to predict the impacts of single source emissions on $PM_{2.5}$ concentration in ambient air as well as limitations associated with existing $PM_{2.5}$ modeling tools and guidance. Commenters recommended the EPA address these existing issues and provide updated guidance through an open stakeholder process and preferably through notice-and-comment rulemaking. As described above, the EPA intends to issue revised $PM_{2.5}$ modeling guidance prior to the effective date of today's revised PM NAAQS to assist permit applicants and reviewing authorities in performing required air quality impact analyses. The EPA expects that this revised guidance will address all or most of the remaining issues related to $PM_{2.5}$ air quality impact demonstrations under the PSD program, at least on an interim basis, until the EPA takes additional steps to improve existing regulatory models and procedures. To that end, the EPA is also pursuing regulatory updates to the Guideline on Air Quality Models (40 CFR part 51 Appendix W) to formalize new models and techniques as appropriate. The EPA recently granted a petition for rulemaking to specifically evaluate whether to incorporate into the Guideline new analytical techniques or models for secondary $PM_{2.5}$ (McCarthy, 2012). The EPA anticipates that this rulemaking will be proposed by the end of calendar year 2014 or early in calendar year 2015.

c. PSD Screening Tools: Significant Emissions Rates, Significant Impact Levels, and Significant Monitoring Concentration

The EPA has historically allowed the use of screening tools to help facilitate the implementation of the NSR program by reducing the permit applicant's burden and streamlining the permitting process for circumstances where emissions or concentrations could be considered *de minimis.* These screening tools, which all provide *de minimis* thresholds of some kind, include SERs, SILs, and a SMC. The EPA promulgated a SER for $PM_{2.5}$ in the 2008 final rule on NSR implementation as part of the first phase of NSR amendments to address $PM_{2.5}$ (74 FR 28333, May 16, 2008). The $PM_{2.5}$ SER is used to determine whether any proposed major stationary source or major modification will emit sufficient amounts of $PM_{2.5}$ to require review under the PSD program.[253] Under the terms of the existing EPA regulations, the applicable SER for $PM_{2.5}$ is 10 tpy of direct $PM_{2.5}$ emissions (including condensable PM) and, for precursors, 40 tpy of SO_2 and 40 tpy of NO_X emissions. 40 CFR 51.166(b)(23); 40 CFR 52.21(b)(23). This SER applies to permitting requirements based on both the annual and 24-hour $PM_{2.5}$ NAAQS. The SERs are pollutant-specific but not specific to the averaging

[251] There may be application completeness determinations or draft permits/preliminary determinations for which a public notice was issued prior to October 20, 2011, which is the date that $PM_{2.5}$ increments became applicable requirements for any newly issued federal PSD permits under 40 CFR 52.21. It is not the EPA's intention that the final grandfathering provision should relieve such a permit from the requirement to demonstrate compliance with those new $PM_{2.5}$ increments, for which the EPA did not adopt any grandfathering provisions but deferred implementation in accordance with the requirements of the CAA.

[252] The presentation on this draft guidance was posted on the EPA Web site at: *http://www.epa.gov/ttn/scram/10thmodconf.htm.*

[253] The PSD rules provide that a source that would emit major amounts of any regulated NSR pollutant must undergo review for that pollutant as well as any other regulated NSR pollutant that the source would emit in significant amounts.

time of any NAAQS for a particular pollutant.

Once it is determined that emissions resulting from the proposed new source or modification are significant for $PM_{2.5}$, the permit applicant must complete an air quality analysis. 40 CFR 51.166(m)(1)(i); 40 CFR 52.21(m)(1)(i). The SIL helps to determine the scope of the required air quality analysis that must be carried out in order to demonstrate that the source's emissions will not cause or contribute to a violation of any NAAQS or increment. The EPA promulgated SILs for $PM_{2.5}$ in 2010 under a final rule that established increments, SILs, and a SMC for $PM_{2.5}$ (75 FR 64864, October 20, 2010 at 64890 to 64894).

Historically, the EPA and other permitting authorities have allowed permit applicants to determine the scope of analysis required to satisfy section 165(a)(3) of the CAA by modeling their proposed emissions increase to predict ambient air quality impacts associated with that emissions increase, and by comparing this predicted increase in ambient concentration of $PM_{2.5}$ to the applicable SIL, which is also expressed as an ambient $PM_{2.5}$ concentration over a prescribed averaging time consistent with the NAAQS and increments. The EPA notes that the current $PM_{2.5}$ SILs are the subject of a petition that challenges the EPA's legal authority under the CAA to develop and implement those SILs, and also alleges that the $PM_{2.5}$ SILs established by the EPA have not been adequately demonstrated to represent *de minimis* values. *Sierra Club* v. *EPA, No. 10–1413* (D.C. Cir. filed Dec. 17, 2010). In the course of this litigation, the EPA has recognized the need to correct the text addressing the use of the $PM_{2.5}$ SILs in the PSD regulations (40 CFR 51.166(k)(2); 40 CFR 52.21(k)(2)), and the EPA has asked the court to vacate and remand those provisions so that the EPA may correct them. However, the EPA does not believe this corrective action would preclude appropriate use of the $PM_{2.5}$ SILs in the interim. The EPA has not asked the court to vacate the SILs in section 51.165(b) of its regulations. Furthermore, SILs that are not reflected in rules may be used if the permitting record provides adequate support that the values reflect a *de minimis* impact on air quality, consistent with the principles described in EPA memoranda establishing interim SILs for the one-hour SO_2 and NO_2 NAAQS.[254] The revisions to the primary annual $PM_{2.5}$ NAAQS do not affect the continued used of the $PM_{2.5}$ SILs.

Finally, the SMC, also measured as an ambient pollutant concentration (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. Like the $PM_{2.5}$ SILs, the SMC was challenged by the Sierra Club in the same petition, and is currently under review by the Court.

In the proposal, the EPA did not propose any changes to the existing $PM_{2.5}$ SERs, SILs and SMC, but solicited preliminary comment on whether any such changes would be appropriate. The EPA also indicated that any changes to the $PM_{2.5}$ screening values would be addressed in a subsequent rulemaking that would specifically address various PSD implementation issues.

The EPA received several comments from industry and state agencies regarding the existing PSD screening tools and the potential need to adjust associated values based on the revised primary annual $PM_{2.5}$ NAAQS. The majority of these commenters supported retaining the existing SERs, SILs and SMC for $PM_{2.5}$ (and $PM_{2.5}$ precursors in the case of the SERs), indicating that there was no compelling technical reason for revision based on the proposed revision to the primary $PM_{2.5}$ NAAQS. One industry commenter indicated that there might be a need to revise the annual $PM_{2.5}$ SILs based on the approach used in establishing the current value. However, this commenter and others recommended that any revisions to the PSD screening levels for $PM_{2.5}$ be accomplished through a separate notice-and-comment rulemaking. Several state commenters that supported retention of the current $PM_{2.5}$ SILs also urged the EPA to provide guidance on the use of those existing SILs.

One set of collaborative comments from health and environmental advocacy groups stated that the EPA's proposal to leave in place the PSD screening tools adopted with the previous PM NAAQS had no rational basis and was contrary to statutory requirements. These commenters claimed that the EPA has no statutory authority to establish SILs and SMC for $PM_{2.5}$, which is the subject of current litigation in *Sierra Club* v. *EPA,* No. 10–1413 (D.C. Cir. filed Dec. 17, 2010). The EPA's argument in support of the existing PSD screening tools is contained in a brief filed in that case, which is included in the docket for the final rule. *Id.,* Brief of Respondent at 26–56 (June 26, 2012). These same commenters and one additional collaborative comment letter from academic researchers also stated that the EPA should revise the current $PM_{2.5}$ SERs, SILs and SMC to reflect the revised NAAQS and true *de minimis* levels.

The EPA did not propose to make and is not finalizing any changes to the existing $PM_{2.5}$ SERs, SILs and SMC as part of this final rule. The EPA intends to consider the need for any future changes to these values in light of today's revision of the primary annual $PM_{2.5}$ NAAQS and considering public comments received. The EPA will address any changes to the $PM_{2.5}$ SERs, SILs and SMC in a subsequent PSD implementation rulemaking if deemed necessary or appropriate. The EPA will determine the need for, and develop such rulemaking expeditiously, and any such forthcoming rulemaking will provide an additional opportunity for public comment on specific proposed revisions to the PSD screening tool values for $PM_{2.5}$. Until any rulemaking to amend existing regulations is completed, permitting decisions should continue to be based on the SERs for $PM_{2.5}$ (and its precursors) and the SILs and SMC for $PM_{2.5}$ in existing regulations.

d. PSD Increments

Section 166(a) of the CAA requires the EPA to promulgate ''regulations to prevent the significant deterioration of air quality'' for pollutants covered by the NAAQS. Among other things, the EPA has implemented this requirement through promulgation of PSD increments. The EPA promulgated $PM_{2.5}$ increments in 2010 to prevent significant air quality deterioration with regard to the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS (75 FR 64864, October 20, 2010). The revision to the primary annual $PM_{2.5}$ NAAQS raises the question of whether

[254] Page, 2010c; Page, 2010d. The EPA provided similar advice before it finalized the proposed $PM_{2.5}$ SILs (Page, 2010b). *See* also, *In re Mississippi Lime Co.,* PSD Permit Appeal 11–01, Slip. Op. at 34–41 (EAB August 9, 2011) and U.S. EPA, 2012d.

the EPA should consider revising the annual $PM_{2.5}$ increments. The EPA does not interpret section 166(a) of the Act to require that the EPA revise existing increments whenever the EPA revises a NAAQS for the same pollutant and averaging time,[255] but the Agency interprets the Act to afford the EPA the discretion to do so. In the proposal, the EPA did not propose to revise the $PM_{2.5}$ increments. In the meantime, the current $PM_{2.5}$ increments remain in effect, and PSD permitting should continue pursuant to the current increments, with a minimum of disruption to the permitting process when the revised NAAQS take effect.

The EPA received few comments on whether there was any need or justification to revise the existing PSD increments for $PM_{2.5}$. Industry and state agency commenters generally supported retaining the existing increments. Commenters again recommended that any revisions to the PSD increments for $PM_{2.5}$ be accomplished through a separate notice-and-comment rulemaking.

The EPA did not propose to make and is not finalizing any changes to the existing PSD increments for $PM_{2.5}$ as part of this final rule. The EPA will consider whether it is appropriate to propose any revised PSD increments for $PM_{2.5}$ in the future. Any such forthcoming rulemaking will provide an additional opportunity for public comment on specific proposed revisions to the PSD increments for $PM_{2.5}$. Until any rulemaking to amend existing regulations is completed, permitting decisions should continue to be based on the PSD increments for $PM_{2.5}$ in existing regulations.

e. Other PSD Transition Issues

Several industry commenters expressed concern that a permitting problem would result from the fact that, upon promulgation of the revised $PM_{2.5}$ NAAQS, ambient air quality monitoring data would show that for some areas, $PM_{2.5}$ concentrations exceed the revised NAAQS, although those areas would not be formally designated as ''nonattainment'' until a later date pursuant to the designation process provided by the CAA. The commenters noted that sources locating in such areas would be required to obtain a PSD permit in order to construct or modify, but could not do so because the requirement that the new or modified source must demonstrate that it will not cause or contribute to a NAAQS violation, even though the area would technically already be in nonattainment. The commenters further noted that once the nonattainment designation is made, section 173 of the Act provides a nonattainment area permit program that specifies conditions under which a permit will be issued, including obtaining offsetting reductions in emissions rather than demonstrating through modeling or other analysis that the source will not cause or contribute to a violation of the NAAQS as required in PSD. Thus, the commenters urged the EPA to offer an interim approach that would avoid the imposition of an effective construction ban on such areas until such time as the nonattainment area designations and the nonattainment NSR offset requirements are in place instead of the PSD requirements. Some of the commenters specifically requested that the EPA provide either a surrogacy approach based on showing compliance with the pre-existing annual $PM_{2.5}$ NAAQS or a PSD offset approach to avoid a construction moratorium in such areas.

The commenters are correct in that areas already in violation of the revised annual $PM_{2.5}$ NAAQS upon the effective date of such NAAQS may not be formally designated nonattainment for two years or potentially longer in accordance with the statutory procedures for promulgating such area designations. In addition, it is the EPA's longstanding policy that new and revised NAAQS must be implemented through the permitting process as of the NAAQS effective date (except for earlier projects that would qualify for any EPA-authorized grandfathering). Accordingly, new major stationary sources and major modifications for which permits will be issued on or after the effective date of the revised annual $PM_{2.5}$ NAAQS must comply with the PSD requirement to demonstrate compliance with that and any other applicable NAAQS.

We disagree, however, with the commenters' conclusion that such circumstances will result in ''the imposition of an effective construction ban on such areas.'' First, as already described, the EPA is promulgating a grandfathering provision that allows certain proposed new and modified sources to proceed with the permit process based on the requirements that were in effect previously, provided the permitting authority either has determined on or before December 14, 2012 that the permit application is complete or has proposed the permit (i.e., the draft permit or preliminary determination has been noticed for public comment) prior to the date the revised PM standards become effective, which is 60 days after publication in the **Federal Register**. The grandfathering provision thus will enable some sources to avoid issues associated with potential violations of the revised annual $PM_{2.5}$ NAAQS.

Second, for those sources that are not eligible to be grandfathered under the new provision, permitting authorities have the discretion to consider offsetting emissions reductions at other sources as part of a demonstration that an individual source seeking a permit will not cause or contribute to violation of the NAAQS. See, Page (2010c). The EPA has historically recognized in regulations and through other actions that sources applying for PSD permits may utilize offsets as part of the required PSD demonstration, even though the PSD provisions of the Clean Air Act do not expressly reference offsets in the same manner as the nonattainment NSR provisions of the Act. See, In re *Interpower of New York, Inc.,* 5 E.A.D. 130, 141 (EAB 1994) (describing an EPA Region 2 PSD permit that relied in part on offsets to demonstrate the source would not cause or contribute to a violation of the NAAQS).

Existing EPA regulations provide a procedure by which major stationary sources and major modifications locating in an area designated as attainment or unclassifiable for any NAAQS, and found to cause or contribute to a NAAQS violation in any area, may utilize offsets to address such adverse impacts and ultimately be issued a permit. *See* 40 CFR 51.165(b). Specifically, paragraph (b)(3) of those regulations provides that the required permit program may include a provision allowing a proposed major source or major modification to reduce the impact of its emissions on air quality by obtaining sufficient emissions reductions to, at a minimum, compensate for its adverse ambient impact where the source or modification would otherwise cause or contribute to a violation of any NAAQS. On October 20, 2010, the EPA amended the requirements at 40 CFR 51.165(b) to define a significant impact with regard to the $PM_{2.5}$ NAAQS. *See* 75 FR 64864 at 64902.

As noted by some of the commenters, the EPA addressed this same issue in 1987 when it promulgated a new set of NAAQS for PM_{10} and revised 40 CFR 51.165(b) of the regulations. *See* 52 FR 24672 (July 1, 1987) at 24684, 24686–87,

[255] A United States District Court has upheld the EPA's interpretation. *See* Order Granting Defendant's Motion to Dismiss Mandatory Duty Claim, *Wildearth Guardians* v. *Jackson,* Case No. 11–cv–5651–YGR (N.D. Cal. May 7, 2012). An appeal of this decision is now pending with the United States Court of Appeals for the Ninth Circuit.

24698. For PM_{10}, the EPA made it clear that when a proposed PSD source was found to cause or contribute to violation of the PM_{10} NAAQS, the source would be required satisfy the requirements of 40 CFR 51.165(b) ''to obtain, at a minimum, sufficient PM_{10} emission offsets to compensate for the source's ambient impact in the area of the violation.'' Such offsets were considered to satisfy the ''cause or contribute to'' language under section 165(a)(3)(B) of the CAA. *Id.* at 24698.[256] In response to comments concerning the appropriate criteria for applying this offset requirement for PSD purposes, the EPA also stated that any emissions offsets used for PSD purposes must meet applicability criteria that are at least as stringent as the offset criteria set forth in the nonattainment NSR requirements for offsets under 40 CFR 51.165(a)(3). *Id.* at 24684.

We continue to believe that the 40 CFR 51.165(a)(3) criteria provide the most appropriate guide for determining the creditability of PSD offsets, including any offsets obtained to satisfy the PSD requirements for the revised $PM_{2.5}$ NAAQS prior to any anticipated designation of any area as nonattainment with that NAAQS. Since the purpose for using offsets in PSD is to show that additional emissions from the proposed construction will not cause or contribute to a violation, the EPA has not codified a requirement that such offsets necessarily must meet the same criteria that apply to offsets under the nonattainment NSR program. In fact, the EPA has previously observed that, in the context of PSD, it may not be necessary for a permit applicant to fully offset the proposed emissions increase if an emissions reduction of lesser quantity will be sufficient to mitigate the proposed source's adverse air quality impact on a modeled violation. Page (2010c); 44 FR 3274, January 16, 1979, at 3278 (''Although full emission offsets are not required, such a source must obtain emission offsets sufficient to compensate for its air quality impact where the violation occurs.''). This may be particularly true where anticipated reductions from existing air quality regulations may mitigate the impacts of a proposed source's emissions by the time the source begins operating in an area that is expected to be designated nonattainment. This would need to be evaluated on a case-by-case basis. To the extent that any permit applicants may experience difficulties making the NAAQS compliance showing required to obtain a PSD permit in areas and as set forth in the Memorandum noted above, the EPA is committed to working with permitting authorities and applicants to identify ways to apply offsets under the PSD program as necessary to meet PSD requirements.

[256] In 1980, the EPA had determined that the statutory requirement under CAA section 165(a)(3)(B), providing that a proposed new or modified PSD source must demonstrate that it will not cause or contribute to a violation of any NAAQS, taken together with the requirements of section 110(a)(2)(D) of the CAA required all major stationary sources locating outside a nonattainment area but causing or contributing to a NAAQS violation to reduce the impact on air quality so as to assure attainment and maintenance of the NAAQS. In a footnote, the EPA further indicated that this offset requirement must apply to sources causing or contributing to a newly discovered NAAQS violation until the area is designated nonattainment. *See* 45 FR 31307 (May 13, 1980) at 31310. In this 1980 rule, EPA adopted section 51.18(k), which was later renumbered section 51.165(b). EPA revised 51.165(b) in 1987 to expressly authorize an offset program to meet the requirements of section 110(a)(2)(D)(i), but this provision may also be interpreted to apply to section 165(a)(3)(B) of the CAA, consistent with EPA's reading of section 51.18(k) in 1980.

2. Nonattainment New Source Review

Part D of Title I of the CAA pertains to the preconstruction review and permitting requirements for new major stationary sources and major modifications locating in areas designated ''nonattainment'' for a particular pollutant. Those requirements are commonly referred to as the NNSR program. The EPA regulations for the NNSR program are contained at 40 CFR 51.165, 52.24 and part 51, appendix S.

For NNSR, ''major stationary source'' is generally defined as a source with the potential to emit at least 100 tpy or more of a pollutant for which an area has been designated ''nonattainment.'' The NNSR program applies only to pollutants for which the EPA has promulgated NAAQS. Because the EPA has defined the PM NAAQS, and has established area designations for PM, in terms of two separate indicators—PM_{10} and $PM_{2.5}$—each indicator is regulated separately for purposes of NNSR applicability. That is, for PM_{10}, a ''major stationary source'' for NNSR applicability generally is a source that is located in a PM_{10} nonattainment area and has the potential to emit at least 100 tpy of PM_{10} emissions.[257] For $PM_{2.5}$, a ''major stationary source'' for NNSR applicability is a source that is located in a $PM_{2.5}$ nonattainment area and has the potential to emit at least 100 tpy of direct $PM_{2.5}$ (''$PM_{2.5}$ emissions'') or any individual precursor of $PM_{2.5}$.

[257] In some cases, however, the CAA and the EPA's regulations define ''major stationary source'' for nonattainment area NSR in terms of a lower emissions rate dependent on the pollutant. For PM_{10}, for example, a source having the potential to emit at least 70 tpy of PM_{10} is considered ''major'' if the source is located in a nonattainment area classified as a ''Serious Area.''

For a major modification, the NNSR regulations rely upon SERs described previously in the PSD discussion in section IX.D.1. For NNSR, a major modification is a physical change or a change in the method of operation of an existing stationary source that is major for the nonattainment pollutant and results in a significant emissions increase and a significant net emissions increase of that nonattainment pollutant or any individual precursor of that pollutant. As described earlier, the EPA will be evaluating the existing SERs for $PM_{2.5}$ and $PM_{2.5}$ precursors, and will determine whether there is any basis for proposing changes to any of the existing values. Any decision to propose changing the existing SERs in a future rulemaking would also apply to their use in the NNSR program requirements.

The EPA has designated nonattainment areas for the existing primary annual and 24-hour $PM_{2.5}$ NAAQS independently, and the EPA also approves redesignations to attainment separately for the two averaging periods. Thus, an area may be nonattainment for the annual standard and unclassifiable/attainment or attainment for the 24-hour standard. In the proposal, the EPA indicated that no formal policy has yet been developed to address this situation, but that the EPA presently believes that it is reasonable to require that only NNSR (and not PSD) applies for $PM_{2.5}$ in any area that is nonattainment for either averaging period.[258] The same situation would have existed with respect to the proposed secondary visibility index standard, had the EPA elected to finalize such a standard. Accordingly, the EPA indicated in the proposal that it intends to address this issue in a future NSR rulemaking, but invited preliminary comment on whether it is appropriate to apply the NNSR program requirements for any pollutant that is designated nonattainment for at least one averaging period or at least one primary or secondary NAAQS for a particular pollutant.

New major stationary sources or major modifications that trigger NNSR based on $PM_{2.5}$ emissions (or emissions of a $PM_{2.5}$ precursor) in a $PM_{2.5}$ nonattainment area must install technology that meets the lowest achievable emission rate (LAER); secure appropriate emissions reductions to offset the proposed emissions increases;

[258] However, transportation conformity requirements discussed in section IX.E below are dependent upon the averaging period(s) for which an area is designated nonattainment.

and perform other analyses as required under section 173 of the CAA. Following the promulgation of any revised NAAQS for $PM_{2.5}$, some new nonattainment areas for $PM_{2.5}$ may result. Where a state does not have any NNSR program or the current NNSR program does not apply to $PM_{2.5}$, that state will be required to submit the necessary SIP revisions to ensure that new major stationary sources and major modifications for $PM_{2.5}$ undergo preconstruction review pursuant to the NNSR program. Under section 172(b) of the CAA, the Administrator may provide states up to 3 years from the effective date of nonattainment area designations to submit the necessary SIP revisions meeting the applicable NNSR requirements. Nevertheless, permits issued to sources in nonattainment areas must satisfy the applicable requirements for nonattainment areas as of the effective date of the specific nonattainment designation; therefore, states whose existing NNSR program requirements, if any, cannot be interpreted to apply to the revised primary annual $PM_{2.5}$ NAAQS at that time will be allowed to issue the necessary permits in accordance with the applicable nonattainment permitting requirements contained in the Emissions Offset Interpretative Ruling at 40 CFR part 51, appendix S, which would apply to the revised $PM_{2.5}$ NAAQS upon its effective date (*see* 73 FR 38321, May 16, 2008 at 28340). The EPA did not propose any type of $PM_{2.5}$ grandfathering provision at this time for purposes of NNSR.

Several industry commenters recommended that the EPA establish a grandfathering provision for NNSR as was proposed under the PSD program. A subset of these commenters recommended that grandfathering be accomplished by establishing an effective date for designations one year after initial publication in the **Federal Register**. However, no commenters provided any rationale or supporting basis for such a grandfathering provision or the underlying need for a transition into NNSR permitting for the revised $PM_{2.5}$ NAAQS.

The EPA disagrees with commenters that recommended a grandfathering provision for NNSR requirements associated with the revised $PM_{2.5}$ NAAQS. As described in the proposal, the timetable for adopting new provisions under a state's NNSR program will not apply with regard to the revised NAAQS for $PM_{2.5}$ until such time that an area is designated nonattainment for a particular standard. Major NSR permits for $PM_{2.5}$ issued in areas newly designated as nonattainment for the revised primary annual $PM_{2.5}$ NAAQS must, as of the effective date of such designation, meet the applicable NNSR requirements for $PM_{2.5}$ (Seitz, 1991). As such, there may be cases where applicants with PSD permit applications for $PM_{2.5}$ in progress will be required to revise their applications to address NNSR requirements for a newly designated $PM_{2.5}$ nonattainment area, and such revisions could result in additional resource burden and permit delays. However, the EPA believes at this time that such cases will be very limited, and in addition there is a substantial lead time between the effective date of the revised $PM_{2.5}$ NAAQS and the effective date of any associated new nonattainment designations for permit applicants and air agencies to anticipate when the NNSR requirements will apply. Therefore, the EPA is not inclined at this time to pursue a rulemaking to establish a grandfathering provision for the revised $PM_{2.5}$ NAAQS under the NNSR program. The EPA will independently, and in consultation with other reviewing authorities, work with permit applicants on specific projects requiring additional measures to achieve a workable transition into NNSR permitting requirements. The EPA will also continue to consider whether regulatory grandfathering may become necessary for NNSR, and if determined to be, will undertake any such action as part of a subsequent NSR implementation rulemaking with additional opportunity for public comment.

A few industry and state commenters addressed the issue of potential dual review (applying NNSR and PSD simultaneously) based on distinct designations for separate averaging times of the $PM_{2.5}$ NAAQS. These commenters generally agreed with the EPA's conclusion that it was reasonable to apply only the NNSR permitting requirements to such situations and not PSD. Regarding the issue of potential dual review for multiple averaging times of the $PM_{2.5}$ NAAQS, since the proposal, the EPA has determined that existing regulations resolve this issue in favor of the conclusion suggested in the proposed rule. Based on the express terms of existing regulations, only the NNSR permit requirements, and not PSD, apply for the pollutant $PM_{2.5}$ in cases where the area is designated nonattainment for at least one averaging time of the $PM_{2.5}$ NAAQS. The federal PSD regulations provide that the PSD requirements (the requirements of paragraphs (j) through (r) of each section) ''do not apply to a major stationary source or major modification *with respect to a particular pollutant* if the owner or operator demonstrates that, as to that pollutant, the source or modification is located in an area designated as nonattainment under section 107 of the Act.'' 40 CFR 52.21(i)(2) and 40 CFR 51.166(i)(2) (emphasis added). Thus, this provision expressly excludes from PSD any pollutant for which an area is designated nonattainment, without reference to a particular averaging period. For a number of years, it was the EPA's practice to establish a single designation in an area for a particular pollutant. Accordingly, if the area was not meeting the NAAQS for a particular averaging period, the area was designated nonattainment—even though the area was likely meeting the NAAQS for one or more averaging periods for the same pollutant. The EPA's statement in the proposal that we had not yet established a policy on the dual review question for $PM_{2.5}$ was based on the fact that we had only recently begun establishing designations for each averaging time in the case of the $PM_{2.5}$ NAAQS. However, at the time of the proposal, the EPA had not closely examined the applicability of the language in sections 51.166(i)(2) and 52.21(i)(2) in this context. After closer inspection prompted by the comments on this issue, we do not read these provisions to authorize application of PSD to a pollutant when an area may be designated nonattainment for a particular averaging time, while also designated attainment or unclassifiable for a different averaging time for the same pollutant.

As proposed, the EPA is not finalizing any changes under the NNSR program regulations as part of this final NAAQS rule. The EPA will consider the need for any changes to the NNSR program provisions and will implement any such changes as part of a future NSR implementation rule and/or guidance.

E. Transportation Conformity Program

Transportation conformity is required under CAA section 176(c) to ensure that transportation plans, transportation improvement programs (TIPs) and federally supported highway and transit projects will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. Transportation conformity applies to areas that are designated nonattainment and maintenance for transportation-related criteria pollutants: Carbon monoxide, ozone, NO_2, and $PM_{2.5}$, and PM_{10}. Transportation conformity for any revised NAAQS for $PM_{2.5}$ does not apply until 1 year after the effective date of the nonattainment designation for that revised NAAQS (*see* CAA section 176(c)(6) and 40 CFR 93.102(d)). The EPA's Transportation Conformity Rule (40 CFR part 51, subpart T, and 40 CFR part 93, subpart A) establishes the criteria and procedures for determining whether transportation activities conform to the SIP. The EPA is not making any changes to the transportation conformity rule in this rulemaking. The EPA notes that the transportation conformity rule already addresses the $PM_{2.5}$ and PM_{10} NAAQS. The EPA will review whether there is a need to issue new or revised transportation conformity guidance in light of this final rule. In developing new or revised guidance the EPA will consider the comments related to implementation of the transportation conformity rule that were received in response to the proposal.

As discussed in section VIII above, the EPA finalized certain clarifying changes to $PM_{2.5}$ air quality monitoring regulations. These changes are designed to align different elements of the monitoring regulations for consistency.

Due to these changes to the monitoring regulations, the EPA will update its guidance on conformity quantitative $PM_{2.5}$ hot-spot analyses as appropriate to make it consistent with the revised monitoring requirements (U.S. EPA, 2010j). The EPA intends that the current quantitative $PM_{2.5}$ hot-spot guidance continues to apply to any quantitative $PM_{2.5}$ hot-spot analysis that was begun before the effective date of these revisions to the monitoring regulations. Revised guidance for quantitative $PM_{2.5}$ hot-spot analyses would apply to any quantitative $PM_{2.5}$ hot-spot analysis begun after the effective date of the revised monitoring regulations. Nonattainment and maintenance areas are encouraged to use their interagency consultation processes to determine whether an analysis for a given project was started before the effective date of changes to the monitoring requirements. Applying the current guidance to $PM_{2.5}$ analyses that had begun before the effective date of changes to the monitoring regulations is consistent with how the conformity rule and guidance address the transitional period for new emissions factor models or local planning assumptions (40 CFR 93.110(a) and 93.111(b) and (c)). In both of those cases, analyses begun before the new model or data became available can be completed using the data and/or model that were available when the analyses began. The EPA rules allow this in order to conserve state resources by not making transportation planning agencies redo analyses simply because a model has been revised, new data have become available, or in this case, the EPA has revised its regulations for $PM_{2.5}$ monitoring.

F. General Conformity Program

General conformity is required by CAA section 176(c). This section requires that actions by federal agencies do not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. General conformity applies to any federal action (e.g., funding, licensing, permitting, or approving), other than projects that are Federal Highway Administration (FHWA)/ Federal Transit Administration (FTA) projects as defined in 40 CFR 93.101 (which are covered under transportation conformity described above), if the action takes place in a nonattainment or maintenance area for ozone, PM, NO_2, carbon monoxide, lead, or SO_2. General conformity also applies to a federal highway and transit project if it does not involve either Title 23 or 49 funding, but does involve FHWA or FTA approval such as is required for a connection to an Interstate highway or for a deviation from applicable design standards per 40 CFR 93.101. (The FHWA and FTA actions described here as not subject to general conformity are subject to transportation conformity.) General conformity for the revised PM NAAQS will not apply until 1 year after the effective date of a nonattainment designation for that NAAQS. The EPA's General Conformity Rule (40 CFR 93.150 to 93.165) establishes the criteria and procedures for determining if a federal action conforms to the SIP. With respect to the revised PM NAAQS, federal agencies are expected to continue to estimate emissions for conformity analyses in the same manner as they are estimated for conformity analyses for the 1997 and 2006 p.m. NAAQS. The EPA's existing general conformity regulations include the basic requirement that a federal agency's general conformity analysis be based on the latest and most accurate emissions estimation techniques available (40 CFR 93.159(b)), and the EPA expects that this same principle will be followed for analyses needed for these revised PM NAAQS. When updated and improved emissions estimation techniques become available, the EPA expects the federal agency to use those techniques. With this final rule, the EPA is making no changes to the general conformity rule as it already addresses the $PM_{2.5}$ and PM_{10} NAAQS. As noted in the proposal, the EPA will review the need to issue guidance describing how the current conformity rule applies in nonattainment and maintenance areas for the final revised primary annual $PM_{2.5}$ NAAQS.

X. Statutory and Executive Order Reviews

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

Under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), this action is an ''economically significant regulatory action'' because it is likely to have an annual effect on the economy of $100 million or more. The $100 million threshold can be triggered by either costs or benefits, or a combination of them. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations have been documented in the docket for this action.

The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in *Regulatory Impact Analysis for the Final Revisions to the National Ambient Air Quality Standards for Particulate Matter,* EPA 452/R–12–003. A copy of the analysis is available in Docket No. EPA–HQ–OAR–2010–0955.

The estimates in the RIA are associated with the revised standard and alternative standard levels (in µg/m³) of the primary annual $PM_{2.5}$ standards including: 13, 12, and 11. Table 4 provides a summary of the estimated costs, monetized benefits, and net benefits associated with full attainment of these alternative standards.

TABLE 4—TOTAL COSTS, MONETIZED BENEFITS AND NET BENEFITS IN 2020 (MILLIONS OF 2010$) FULL ATTAINMENT [a]

Alternative $PM_{2.5}$ annual standards (μg/m³)	Total costs [b]		Monetized benefits [d]		Net benefits	
	3% Discount rate [c]	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate [d]	7% Discount rate
13	$11 to $100	$11 to $100	$1,300 to $2,900	$1,200 to $2,600	$1,200 to $2,900	$1,100 to $2,600
12	$53 to $350	$53 to $350	$4,000 to $9,100	$3,600 to $8,200	$3,700 to $9,000	$3,300 to $8,100
11	$320 to $1,700	$320 to $1,700	$13,000 to $29,000	$12,000 to $26,000	$11,000 to $29,000	$10,000 to $26,000

[a] These estimates reflect incremental emissions reductions from an analytical baseline that gives an "adjustment " to the San Joaquin and South Coast areas in California for NO_X emissions reductions expected to occur between 2020 and 2025, when those areas are expected to demonstrate attainment with the revised standards. Full benefits of the revised standards in those two areas will not be realized until 2025.

[b] The two cost estimates do not represent lower and upper bound estimates, but represent estimates generated by two different methodologies. The lower estimate is generated using the fixed-cost methodology, which assumes that technological change and innovation will result in the availability of additional controls by 2020 that are similar in cost to the higher end of the cost range for current, known controls. The higher estimate is generated using the hybrid methodology, which assumes that while additional controls may become available by 2020, they become available at an increasing cost and the increasing cost varies by geographic area and by degree of difficulty associated with obtaining the needed emissions reductions.

[c] Due to data limitations, we were unable to discount compliance costs for all sectors at 3%. See section 7.2.2 of the RIA for additional details on the data limitations. As a result, the net benefit calculations at 3% were computed by subtracting the costs at 7% from the monetized benefits at 3%.

[d] The reduction in premature deaths each year accounts for over 90% of total monetized benefits. Mortality risk valuation assumes discounting over the SAB-recommended 20-year segmented lag structure. Not all possible benefits or disbenefits are quantified and monetized in this analysis. B is the sum of all unquantified benefits. Data limitations prevented us from quantifying these endpoints, and as such, these benefits are inherently more uncertain than those benefits that we were able to quantify. The range of benefits reflects the range of the central estimates from two mortality cohort studies (i.e., Krewski *et al.* (2009) to Lepeule *et al.* (2012)).

B. Paperwork Reduction Act

The information collection requirements in this final rule have been submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The information collection requirements are not enforceable until OMB approves them. The Information Collection Request (ICR) document prepared by the EPA for these revisions to part 58 has been assigned EPA ICR number 0940.26. The information collected under 40 CFR part 53 (e.g., test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the NAAQS in 40 CFR part 50 will meet the design, performance, and/or comparability requirements for designation as an FRM or FEM. The EPA does not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with PM_{10}, $PM_{2.5}$, or $PM_{10\text{-}2.5}$ FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 0940.24). As such, no change in the burden estimate for 40 CFR part 53 has been made as part of this rulemaking.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The amendments finalized in this rule will revise the network design requirements for $PM_{2.5}$ monitoring sites, resulting in the movement of 21 monitors to established near-road monitoring stations by January 1, 2015. The incremental burden associated with moving these 21 monitors that are required in 40 CFR part 58 (this is a one-time cost of relocating the monitors) is $28,570. Burden is defined at 5 CFR 1320.3(b). State, local, and Tribal entities are eligible for state assistance grants provided by the federal government under the CAA which can be used for monitors and related activities. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, the EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA–HQ–OAR–2007–0492. Submit any comments related to the ICR to the EPA and OMB. Send comments to the EPA at the Air and Radiation Docket and Information Center Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket and Information Center Docket is (202) 566–1742. An electronic version of the public docket is available at *www.regulations.gov.* Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after January 15, 2013, a comment to OMB is best assured of having its full effect if OMB receives it by February 14, 2013.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of particulate matter in ambient air as required by section 109 of the CAA. *See also American Trucking Associations* v. *EPA.* 175 F.3d at 1044–45 (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for state, local, or tribal governments or the private sector. The action imposes no enforceable duty on any state, local or tribal governments or the private sector beyond those duties already established in the CAA. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA.

This action is also not subject to the requirements section 205 of the UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This action imposes no new expenditure or enforceable duty on any state, local, or tribal governments or the private sector, and the EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

Furthermore, in setting a NAAQS, the EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards although such factors may be considered to a degree in the development of state plans to implement the standards. *See also American Trucking Associations* v. *EPA,* 175 F. 3d at 1043 (noting that because the EPA is precluded from considering costs of implementation in establishing NAAQS, preparation of a Regulatory Impact Analysis pursuant to the Unfunded Mandates Reform Act would not furnish any information which the court could consider in reviewing the NAAQS). The EPA acknowledges, however, that any corresponding revisions to associated SIP requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively, might result in such effects. Accordingly, the EPA will address, as appropriate, unfunded mandates if and when it proposes any revisions to 40 CFR parts 51 or 58.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the states regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, the EPA is mandated to establish and review NAAQS; however, CAA section 116 preserves the rights of states to establish more stringent requirements if deemed necessary by a state. Furthermore, this final rule does not impact CAA section 107 which establishes that the states have primary responsibility for implementation of the NAAQS. Finally, as noted in section D (above) on UMRA, this rule does not impose significant costs on state, local, or Tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this action.

However, as also noted in section D (above) on UMRA, the EPA recognizes that states will have a substantial interest in this rule and any corresponding revisions to associated air quality surveillance requirements, 40 CFR part 58.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires the EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This rule concerns the establishment of national standards to address the health and welfare effects of particulate matter. Historically, the EPA's definition of ''tribal implications'' has been limited to situations in which it can be shown that a rule has impacts on the tribes' ability to govern or implications for tribal sovereignty. Based on this historic definition, this action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), i.e. because it does not have a substantial direct effect on one or more Indian tribes, since tribes are not obligated to adopt or implement any NAAQS. Nevertheless, we were aware that many tribes would be interested in this rule and we undertook a number of outreach activities to inform tribes about the PM NAAQS review and offered to two consultations with tribes.

Although Executive Order 13175 does not apply to this rule, the EPA undertook a consultation process including: Prior to proposal on March 29, 2012 we sent letters to tribal leadership inviting consultation on the rule and then sent a second round of letters offering consultation after the proposal was issued on June 29, 2012. No tribe requested a formal consultation with the EPA. We conducted outreach and information calls to tribal environmental staff on May 9, 2012; June 15, 2012; and August 1, 2012. We also participated on the National Tribal Air Association call on June 28, 2012.

As a result we received comments from the National Tribal Air Association, the Southern Ute Mountain Ute Tribe, and the Navajo Nation EPA. In general, these tribal organizations were supportive of the EPA's proposal.

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

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of PM exposures on children. The protection offered by these standards is especially important for children because childhood represents a lifestage associated with increased susceptibility to PM-related health effects. Because children have been identified as an at-risk population, we have carefully evaluated the environmental health effects of exposure to PM pollution among children. Discussions of the results of the evaluation of the scientific evidence and policy considerations pertaining to children are contained in sections III.B, III.D, III.E, IV.B, and IV.C of this preamble. The revised primary $PM_{2.5}$ NAAQS discussed above will provide greater public health protection, including increased protection for at-risk populations such as children.

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

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this action concerns the review of the NAAQS for PM. The action does not prescribe specific pollution control strategies by which these ambient standards will be met. Such strategies are developed by states on a case-by-case basis, and the EPA cannot predict whether the control options selected by states will include regulations on energy suppliers, distributors, or users.

I. National Technology Transfer and Advancement Act

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

This final rulemaking involves technical standards for environmental monitoring and measurement. Specifically, the EPA proposes to retain the indicators for fine ($PM_{2.5}$) and coarse (PM_{10}) particles. The indicator for fine particles is measured using the Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere (appendix L to 40 CFR part 50), which is known as the $PM_{2.5}$ FRM, and the indicator for coarse particles is measured using the Reference Method for the Determination of Particulate Matter as PM_{10} in the Atmosphere (appendix J to 40 CFR part 50), which is known as the PM_{10} FRM.

To the extent feasible, the EPA employs a Performance-Based Measurement System (PBMS), which does not require the use of specific, prescribed analytic methods. The PBMS is defined as a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner. It is intended to be more flexible and cost effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. Though the FRM defines the particular specifications for ambient monitors, there is some variability with regard to how monitors measure PM, depending on the type and size of PM and environmental conditions. Therefore, it is not practically possible to fully define the FRM in performance terms to account for this variability. Nevertheless, our approach in the past has resulted in multiple brands of monitors being approved as FRM for PM, and we expect this to continue. Also, the FRMs described in 40 CFR part 50 and the equivalency criteria described in 40 CFR part 53, constitute a performance-based measurement system for PM, since methods that meet the field testing and performance criteria can be approved as FEMs. Since finalized in 2006 (71 FR, 61236, October 17, 2006) the new field and performance criteria for approval of $PM_{2.5}$ continuous FEMs has resulted in the approval of six approved FEMs.[259] In summary, for measurement of $PM_{2.5}$ and PM_{10}, the EPA relies on both FRMs and FEMs, with FEMs relying on a PBMS approach for their approval. The EPA is not precluding the use of any other method, whether it constitutes a voluntary consensus standard or not, as long as it meets the specified performance criteria.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

The EPA maintains an ongoing commitment to ensure environmental justice for all people, regardless of race, color, national origin, or income. Ensuring environmental justice means not only protecting human health and the environment for everyone, but also ensuring that all people are treated fairly and are given the opportunity to participate meaningfully in the development, implementation, and enforcement of environmental laws, regulations, and policies. We conducted an outreach and information call with environmental justice organizations on August 9, 2012.

The EPA has identified potential disproportionately high and adverse effects on minority and/or low-income populations related to $PM_{2.5}$ exposures. In addition, the EPA has identified persons from lower socioeconomic strata as an at-risk population for PM-related health effects. As a result, the EPA has carefully evaluated the potential impacts on low-income and minority populations as discussed in section III.E.3.a of this preamble. Based on this evaluation and consideration of public comments on the proposal, the EPA is eliminating the spatial averaging provisions as part of the form of the primary annual $PM_{2.5}$ standard to avoid potential disproportionate impacts on at-risk populations. The Agency expects this final rule will lead to the establishment of uniform NAAQS for PM. The Integrated Science Assessment and Policy Assessment contain the evaluation of the scientific evidence and policy considerations that pertain to these populations. These documents are available as described in the Supplementary Information section of this preamble and copies of all documents have been placed in the public docket for this action.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal**

[259] A list of designated reference and equivalent methods is available on EPA's Web site at: *http://www.epa.gov/ttn/amtic/criteria.html.*

Register. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective March 18, 2013.

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List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 51

Environmental protection, Administrative practices and procedures, Air pollution control, Intergovernmental relations.

40 CFR Part 52

Environmental protection, Administrative practices and procedures, Air pollution control, Incorporation by reference, Intergovernmental relations.

40 CFR Part 53

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: December 14, 2012.

Lisa P. Jackson,

Administrator.

For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

■ 1. The authority citation for part 50 continues to read as follows:

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

■ 2. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (e.g., micrograms per cubic meter) other than for particulate matter ($PM_{2.5}$) standards contained in §§ 50.7, 50.13, and 50.18, and lead standards contained in § 50.16 shall be corrected to a reference temperature of 25 (deg) C and a reference pressure of 760 millimeters of mercury (1,013.2 millibars). Measurements of $PM_{2.5}$ for purposes of comparison to the standards contained in §§ 50.7, 50.13, and 50.18, and of lead for purposes of comparison to the standards contained in § 50.16 shall be reported based on actual ambient air volume measured at the actual ambient temperature and pressure at the monitoring site during the measurement period.

■ 3. Table 1 in § 50.14(c)(2)(vi) is revised to read as follows:

§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.

* * * * *

(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/m^3) Promulgated October 17, 2006.	2004–2006	October 1, 2007	April 15, 2008.
Ozone/8-Hr Standard (0.075 ppm) Promulgated March 12, 2008.	2005–2007	June 18, 2009	June 18, 2009.
	2008	June 18, 2009	June 18, 2009.
	2009	60 days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first.	60 days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first.
NO_2/1-Hr Standard (100 ppb) Promulgated February 9, 2010.	2008	July 1, 2010	January 22, 2011.
	2009	July 1, 2010 [a]	January 22, 2011.
	2010	April 1, 2011	July 1, 2011.
SO_2/1-Hr Standard (75 ppb) Promulgated June 22, 2010.	2008	October 1, 2010	June 1, 2011.
	2009	October 1, 2010	June 1, 2011.
	2010	June 1, 2011	June 1, 2011.
	2011	60 days after the end of the calendar quarter in which the event occurred or March 31, 2012, whichever date occurs first.	60 days after the end of the calendar quarter in which the event occurred or March 31, 2012, whichever date occurs first.
$PM_{2.5}$/Primary Annual Standard (12 µg/m^3) Promulgated December 14, 2012.	2010 and 2011	July 1, 2013	December 12, 2013.
	2012	July 1, 2013 [a]	December 12, 2013.
	2013	July 1, 2014 [a]	August 1, 2014.

[a] This date is the same as the general schedule in 40 CFR 50.14.

Note: The table of revised deadlines *only* applies to data EPA will use to establish the initial area designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by the EPA for redesignations to attainment.

* * * * *

■ 4. Add § 50.18 to read as follows:

§ 50.18 National primary ambient air quality standards for $PM_{2.5}$.

(a) The national primary ambient air quality standards for $PM_{2.5}$ are 12.0 micrograms per cubic meter (µg/m^3) annual arithmetic mean concentration and 35 µg/m^3 24-hour average concentration measured in the ambient air as $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) by either:

(1) A reference method based on appendix L to this part and designated in accordance with part 53 of this chapter; or

(2) An equivalent method designated in accordance with part 53 of this chapter.

(b) The primary annual $PM_{2.5}$ standard is met when the annual arithmetic mean concentration, as determined in accordance with appendix N of this part, is less than or equal to 12.0 µg/m^3.

(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/m^3.

■ 5. Appendix N to part 50 is revised to read as follows:

Appendix N to Part 50—Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$

1.0 General

(a) This appendix explains the data handling conventions and computations necessary for determining when the national ambient air quality standards (NAAQS) for $PM_{2.5}$ are met, specifically the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS specified in § 50.7, 50.13, and 50.18. $PM_{2.5}$ is defined, in general terms, as particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers. $PM_{2.5}$ mass concentrations are measured in the ambient air by a Federal Reference Method (FRM) based on appendix L of this part, as applicable, and designated in accordance with part 53 of this chapter; or by a Federal Equivalent Method (FEM) designated in accordance with part 53 of this chapter; or by an Approved Regional Method (ARM) designated in accordance with part 58 of this chapter. Only those FRM, FEM, and ARM measurements that are derived in accordance with part 58 of this chapter (i.e., that are deemed ''suitable'') shall be used in comparisons with the $PM_{2.5}$ NAAQS. The data handling and computation procedures to be used to construct annual and 24-hour

NAAQS metrics from reported $PM_{2.5}$ mass concentrations, and the associated instructions for comparing these calculated metrics to the levels of the $PM_{2.5}$ NAAQS, are specified in sections 2.0, 3.0, and 4.0 of this appendix.

(b) Decisions to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, are made according to the requirements and process deadlines specified in §§ 50.1, 50.14 and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

Annual mean refers to a weighted arithmetic mean, based on quarterly means, as defined in section 4.4 of this appendix.

The *Air Quality System (AQS)* is EPA's official repository of ambient air data.

Collocated monitors refers to two or more air measurement instruments for the same parameter (e.g., $PM_{2.5}$ mass) operated at the same site location, and whose placement is consistent with § 53.1 of this chapter. For purposes of considering a combined site record in this appendix, when two or more monitors are operated at the same site, one monitor is designated as the ''primary'' monitor with any additional monitors designated as ''collocated.'' It is implicit in these appendix procedures that the primary monitor and collocated monitor(s) are all deemed suitable for the applicable NAAQS comparison; however, it is not a requirement that the primary and monitors utilize the same specific sampling and analysis method.

Combined site data record is the data set used for performing calculations in appendix N. It represents data for the primary monitors augmented with data from collocated monitors according to the procedure specified in section 3.0(d) of this appendix.

Creditable samples are daily values in the combined site record that are given credit for data completeness. The number of creditable samples (cn) for a given year also governs which value in the sorted series of daily values represents the 98th percentile for that year. Creditable samples include daily values collected on scheduled sampling days and valid make-up samples taken for missed or invalidated samples on scheduled sampling days.

Daily values refer to the 24-hour average concentrations of $PM_{2.5}$ mass measured (or averaged from hourly measurements in AQS) from midnight to midnight (local standard time) from suitable monitors.

Data substitution tests are diagnostic evaluations performed on an annual $PM_{2.5}$ NAAQS design value (DV) or a 24-hour $PM_{2.5}$ NAAQS DV to determine if those metrics, which are judged to be based on incomplete data in accordance with 4.1(b) or 4.2(b) of this appendix shall nevertheless be deemed valid for NAAQS comparisons, or alternatively, shall still be considered incomplete and not valid for NAAQS comparisons. There are two data substitution tests, the ''minimum quarterly value'' test and the ''maximum quarterly value'' test.

Design values (DVs) are the 3-year average NAAQS metrics that are compared to the NAAQS levels to determine when a monitoring site meets or does not meet the NAAQS, calculated as shown in section 4. There are two separate DVs specified in this appendix:

(1) The 3-year average of $PM_{2.5}$ annual mean mass concentrations for each eligible monitoring site is referred to as the ''*annual $PM_{2.5}$ NAAQS DV*''.

(2) The 3-year average of annual 98th percentile 24-hour average $PM_{2.5}$ mass concentration values recorded at each eligible monitoring site is referred to as the ''*24-hour (or daily) $PM_{2.5}$ NAAQS DV*''.

Eligible sites are monitoring stations that meet the criteria specified in § 58.11 and § 58.30 of this chapter, and thus are approved for comparison to the annual $PM_{2.5}$ NAAQS. For the 24-hour $PM_{2.5}$ NAAQS, all site locations that meet the criteria specified in § 58.11 are approved (i.e., eligible) for NAAQS comparisons.

Extra samples are non-creditable samples. They are daily values that do not occur on scheduled sampling days and that cannot be used as make-up samples for missed or invalidated scheduled samples. Extra samples are used in mean calculations and are included in the series of all daily values subject to selection as a 98th percentile value, but are not used to determine which value in the sorted list represents the 98th percentile.

Make-up samples are samples collected to take the place of missed or invalidated required scheduled samples. Make-up samples can be made by either the primary or the collocated monitor. Make-up samples are either taken before the next required sampling day or exactly one week after the missed (or voided) sampling day.

The *maximum quarterly value data substitution test* substitutes actual ''high'' reported daily $PM_{2.5}$ values from the same site (specifically, the highest reported non-excluded quarterly value(s) (year non-specific) contained in the combined site record for the evaluated 3-year period) for missing daily values.

The *minimum quarterly value data substitution test* substitutes actual ''low'' reported daily $PM_{2.5}$ values from the same site (specifically, the lowest reported quarterly value(s) (year non-specific) contained in the combined site record for the evaluated 3-year period) for missing daily values.

98th percentile is the smallest daily value out of a year of $PM_{2.5}$ mass monitoring data below which no more than 98 percent of all daily values fall using the ranking and selection method specified in section 4.5(a) of this appendix.

Primary monitors are suitable monitors designated by a state or local agency in their annual network plan (and in AQS) as the default data source for creating a combined site record for purposes of NAAQS comparisons. If there is only one suitable monitor at a particular site location, then it is presumed to be a primary monitor.

Quarter refers to a calendar quarter (e.g., January through March).

Quarterly data capture rate is the percentage of scheduled samples in a calendar quarter that have corresponding valid reported sample values. Quarterly data capture rates are specifically calculated as the number of creditable samples for the quarter divided by the number of scheduled samples for the quarter, the result then multiplied by 100 and rounded to the nearest integer.

Scheduled $PM_{2.5}$ samples refers to those reported daily values which are consistent with the required sampling frequency (per § 58.12 of this chapter) for the primary monitor, or those that meet the special exception noted in section 3.0(e) of this appendix.

Seasonal sampling is the practice of collecting data at a reduced frequency during a season of expected low concentrations.

Suitable monitors are instruments that use sampling and analysis methods approved for NAAQS comparisons. For the annual and 24-hour $PM_{2.5}$ NAAQS, suitable monitors include all FRMs, and all FEMs/ARMs except those specific continuous FEMs/ARMs disqualified by a particular monitoring agency network in accordance with § 58.10(b)(13) and approved by the EPA Regional Administrator per § 58.11(e) of this chapter.

Test design values (TDV) are numerical values that used in the data substitution tests described in sections 4.1(c)(i), 4.1(c)(ii) and 4.2(c)(i) of this appendix to determine if the $PM_{2.5}$ NAAQS DV with incomplete data are judged to be valid for NAAQS comparisons. There are two TDVs: TDV_{min} to determine if the NAAQS is not met and is used in the ''minimum quarterly value'' data substitution test and TDV_{max} to determine if the NAAQS is met and is used in the ''maximum quarterly value'' data substitution test. These TDV's are derived by substituting historically low or historically high daily concentration values for missing data in an incomplete year(s).

Year refers to a calendar year.

2.0 Monitoring Considerations

(a) Section 58.30 of this chapter provides special considerations for data comparisons to the annual $PM_{2.5}$ NAAQS.

(b) Monitors meeting the network technical requirements detailed in § 58.11 of this chapter are suitable for comparison with the NAAQS for $PM_{2.5}$.

(c) Section 58.12 of this chapter specifies the required minimum frequency of sampling for $PM_{2.5}$. Exceptions to the specified sampling frequencies, such as seasonal sampling, are subject to the approval of the EPA Regional Administrator and must be documented in the state or local agency Annual Monitoring Network Plan as required in § 58.10 of this chapter and also in AQS.

3.0 Requirements for Data Use and Data Reporting for Comparisons With the NAAQS for $PM_{2.5}$

(a) Except as otherwise provided in this appendix, all valid FRM/FEM/ARM $PM_{2.5}$ mass concentration data produced by suitable monitors that are required to be submitted to AQS, or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in the DV calculations. Generally, EPA will only use such data if they have been certified by the reporting organization (as prescribed by § 58.15 of this chapter); however, data not certified by the reporting organization can nevertheless be used, if the deadline for certification has passed and EPA judges the data to be complete and accurate.

(b) $PM_{2.5}$ mass concentration data (typically collected hourly for continuous instruments and daily for filter-based instruments) shall be reported to AQS in micrograms per cubic meter (µg/m³) to at least one decimal place. If concentrations are reported to one decimal place, additional digits to the right of the tenths decimal place shall be truncated. If concentrations are reported to AQS with more than one decimal place, AQS will truncate the value to one decimal place for NAAQS usage (i.e., for implementing the procedures in this appendix). In situations where suitable $PM_{2.5}$ data are available to EPA but not reported to AQS, the same truncation protocol shall be applied to that data. In situations where $PM_{2.5}$ mass data are submitted to AQS, or are otherwise available, with less precision than specified above, these data shall nevertheless still be deemed appropriate for NAAQS usage.

(c) Twenty-four-hour average concentrations will be computed in AQS from submitted hourly $PM_{2.5}$ concentration data for each corresponding day of the year and the result will be stored in the first, or start, hour (i.e., midnight, hour '0') of the 24-hour period. A 24-hour average concentration shall be considered valid if at least 75 percent of the hourly averages (i.e., 18 hourly values) for the 24-hour period are available. In the event that less than all 24 hourly average concentrations are available (i.e., less than 24, but at least 18), the 24-hour average concentration shall be computed on the basis of the hours available using the number of available hours within the 24-hour period as the divisor (e.g., 19, if 19 hourly values are available). Twenty-four-hour periods with seven or more missing hours shall also be considered valid if, after substituting zero for all missing hourly concentrations, the resulting 24-hour average daily value is greater than the level of the 24-hour $PM_{2.5}$ NAAQS (i.e., greater than or equal to 35.5 µg/m³). Twenty-four hour average $PM_{2.5}$ mass concentrations that are averaged in AQS from hourly values will be truncated to one decimal place, consistent with the data handling procedure for the reported hourly (and also 24-hour filter-based) data.

(d) All calculations shown in this appendix shall be implemented on a site-level basis. Site level concentration data shall be processed as follows:

(1) The default dataset for $PM_{2.5}$ mass concentrations for a site shall consist of the measured concentrations recorded from the designated primary monitor(s). All daily values produced by the primary monitor are considered part of the site record; this includes all creditable samples and all extra samples.

(2) Data for the primary monitors shall be augmented as much as possible with data from collocated monitors. If a valid daily value is not produced by the primary monitor for a particular day (scheduled or otherwise), but a value is available from a collocated monitor, then that collocated value shall be considered part of the combined site data record. If more than one collocated daily value is available, the average of those valid collocated values shall be used as the daily value. The data record resulting from this procedure is referred to as the ''combined site data record.''

(e) All daily values in a combined site data record are used in the calculations specified in this appendix; however, not all daily values are given credit towards data completeness requirements. Only creditable samples are given credit for data completeness. Creditable samples include daily values in the combined site record that are collected on scheduled sampling days and valid make-up samples taken for missed or invalidated samples on scheduled sampling days. Days are considered scheduled according to the required sampling frequency of the designated primary monitor with one exception. The exception is, if a collocated continuous FEM/ARM monitor has a more intensive sampling frequency than the primary FRM monitor, then samples contributed to the combined site record from that continuous FEM/ARM monitor are always considered scheduled and, hence, also creditable. Daily values in the combined site data record that are reported for nonscheduled days, but that are not valid make-up samples are referred to as extra samples.

4.0 Comparisons With the Annual and 24-Hour $PM_{2.5}$ NAAQS

4.1 Annual $PM_{2.5}$ NAAQS

(a) The primary annual $PM_{2.5}$ NAAQS is met when the annual $PM_{2.5}$ NAAQS DV is less than or equal to 12.0 µg/m³ at each eligible monitoring site. The secondary annual $PM_{2.5}$ NAAQS is met when the annual $PM_{2.5}$ NAAQS DV is less than or equal to 15.0 µg/m³ at each eligible monitoring site.

(b) Three years of valid annual means are required to produce a valid annual $PM_{2.5}$ NAAQS DV. A year meets data completeness requirements when quarterly data capture rates for all four quarters are at least 75 percent. However, years with at least 11 creditable samples in each quarter shall also be considered valid if the resulting annual mean or resulting annual $PM_{2.5}$ NAAQS DV (rounded according to the conventions of section 4.3 of this appendix) is greater than the level of the applicable primary or secondary annual $PM_{2.5}$ NAAQS. Furthermore, where the explicit 75 percent data capture and/or 11 sample minimum requirements are not met, the 3-year annual $PM_{2.5}$ NAAQS DV shall still be considered valid if it passes at least one of the two data substitution tests stipulated below.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 4.1(b) of this appendix and thus would normally not be useable for the calculation of a valid annual $PM_{2.5}$ NAAQS DV, the annual $PM_{2.5}$ NAAQS DV shall nevertheless be considered valid if one of the test conditions specified in sections 4.1(c)(i) and 4.1(c)(ii) of this appendix is met.

(i) An annual $PM_{2.5}$ NAAQS DV that is above the level of the NAAQS can be validated if it passes the minimum quarterly value data substitution test. This type of data substitution is permitted only if there are at least 30 days across the three quarters of the three years under consideration (e.g., collectively, quarter 1 of year 1, quarter 1 of year 2 and quarter 1 of year 3) from which to select the quarter-specific low value. Data substitution will be performed in all quarter periods that have less than 11 creditable samples.

Procedure: Identify for each deficient quarter (i.e., those with less than 11 creditable samples) the lowest reported daily value for that quarter, looking across those three months of all three years under consideration. If after substituting the lowest reported daily value for a quarter for (11 − cn) daily values in the matching deficient quarter(s) (i.e., to bring the creditable number for those quarters up to 11), the procedure yields a recalculated annual $PM_{2.5}$ NAAQS test DV (TDV_{min}) that is greater than the level of the standard, then the annual $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the annual $PM_{2.5}$ NAAQS is deemed to have been violated in that 3-year period.

(ii) An annual $PM_{2.5}$ NAAQS DV that is equal to or below the level of the NAAQS can be validated if it passes the maximum quarterly value data substitution test. This type of data substitution is permitted only if there is at least 50 percent data capture in each quarter that is deficient of 75 percent data capture in each of the three years under consideration. Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture. If any quarter has less than 50 percent data capture then this substitution test cannot be used.

Procedure: Identify for each deficient quarter (i.e., those with less than 75 percent but at least 50 percent data capture) the highest reported daily value for that quarter, excluding state-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, looking across those three quarters of all three years under consideration. If after substituting the highest reported daily $PM_{2.5}$ value for a quarter for all missing daily data in the matching deficient quarter(s) (i.e., to make those quarters 100 percent complete), the procedure yields a recalculated annual $PM_{2.5}$ NAAQS test DV (TDV_{max}) that is less than or equal to the level of the standard, then the annual $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the annual $PM_{2.5}$ NAAQS is deemed to have been met in that 3-year period.

(d) An annual $PM_{2.5}$ NAAQS DV based on data that do not meet the completeness criteria stated in 4(b) and also do not satisfy the test conditions specified in section 4(c), may also be considered valid with the approval of, or at the initiative of, the EPA Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the daily values that are available, and nearby concentrations in determining whether to use such data.

(e) The equations for calculating the annual $PM_{2.5}$ NAAQS DVs are given in section 4.4 of this appendix.

4.2 Twenty-four-hour $PM_{2.5}$ NAAQS

(a) The primary and secondary 24-hour $PM_{2.5}$ NAAQS are met when the 24-hour $PM_{2.5}$ NAAQS DV at each eligible monitoring site is less than or equal to 35 μg/m³.

(b) Three years of valid annual $PM_{2.5}$ 98th percentile mass concentrations are required to produce a valid 24-hour $PM_{2.5}$ NAAQS DV. A year meets data completeness requirements when quarterly data capture rates for all four quarters are at least 75 percent. However, years shall be considered valid, notwithstanding quarters with less than complete data (even quarters with less than 11 creditable samples, but at least one creditable sample must be present for the year), if the resulting annual 98th percentile value or resulting 24-hour NAAQS DV (rounded according to the conventions of section 4.3 of this appendix) is greater than the level of the standard. Furthermore, where the explicit 75 percent quarterly data capture requirement is not met, the 24-hour $PM_{2.5}$ NAAQS DV shall still be considered valid if it passes the maximum quarterly value data substitution test.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 4.2(b) of this appendix and thus would normally not be useable for the calculation of a valid 24-hour $PM_{2.5}$ NAAQS DV, the 24-hour $PM_{2.5}$ NAAQS DV shall nevertheless be considered valid if the test conditions specified in section 4.2(c)(i) of this appendix are met.

(i) A $PM_{2.5}$ 24-hour mass NAAQS DV that is equal to or below the level of the NAAQS can be validated if it passes the maximum quarterly value data substitution test. This type of data substitution is permitted only if there is at least 50 percent data capture in each quarter that is deficient of 75 percent data capture in each of the three years under consideration. Data substitution will be performed in all quarters that have less than 75 percent data capture but at least 50 percent data capture. If any quarter has less than 50 percent data capture then this substitution test cannot be used.

Procedure: Identify for each deficient quarter (i.e., those with less than 75 percent but at least 50 percent data capture) the highest reported daily $PM_{2.5}$ value for that quarter, excluding state-flagged data affected by exceptional events which have been approved for exclusion by the Regional Administrator, looking across those three quarters of all three years under consideration. If, after substituting the highest reported daily maximum $PM_{2.5}$ value for a quarter for all missing daily data in the matching deficient quarter(s) (i.e., to make those quarters 100 percent complete), the procedure yields a recalculated 3-year 24-hour NAAQS test DV (TDV_{max}) less than or equal to the level of the standard, then the 24-hour $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the 24-hour $PM_{2.5}$ NAAQS is deemed to have been met in that 3-year period.

(d) A 24-hour $PM_{2.5}$ NAAQS DV based on data that do not meet the completeness criteria stated in section 4(b) of this appendix and also do not satisfy the test conditions specified in section 4(c) of this appendix, may also be considered valid with the approval of, or at the initiative of, the EPA Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the daily values that are available, and nearby concentrations in determining whether to use such data.

(e) The procedures and equations for calculating the 24-hour $PM_{2.5}$ NAAQS DVs are given in section 4.5 of this appendix.

4.3 Rounding Conventions. For the purposes of comparing calculated $PM_{2.5}$ NAAQS DVs to the applicable level of the standard, it is necessary to round the final results of the calculations described in sections 4.4 and 4.5 of this appendix. Results for all intermediate calculations shall not be rounded.

(a) Annual $PM_{2.5}$ NAAQS DVs shall be rounded to the nearest tenth of a μg/m³ (decimals x.x5 and greater are rounded up to the next tenth, and any decimal lower than x.x5 is rounded down to the nearest tenth).

(b) Twenty-four-hour $PM_{2.5}$ NAAQS DVs shall be rounded to the nearest 1 μg/m³ (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

4.4 Equations for the Annual $PM_{2.5}$ NAAQS.

(a) An annual mean value for $PM_{2.5}$ is determined by first averaging the daily values of a calendar quarter using equation 1 of this appendix:

Equation 1

$$\overline{X}_{q,y} = \frac{1}{n_q} \sum_{i=1}^{n_q} X_{i,q,y}$$

Where:

$\bar{X}_{q,y}$ = the mean for quarter q of the year y;

n_q = the number of daily values in the quarter; and

$x_{i\ q,y}$ = the i^{th} 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 n^{th} largest value (e.g., for the range of 101 to 150, the 98th percentile value would be the third highest value in the sorted series of daily values.

TABLE 1

Annual number of creditable samples for year y (cn_y)	The 98th percentile for year y ($P_{0.98,y}$), is the n^{th} maximum 24-hour average value for the year where n is the listed number
1 to 50	1
51 to 100	2
101 to 150	3
151 to 200	4
201 to 250	5
251 to 300	6
301 to 350	7
351 to 366	8

(b) The 24-hour $PM_{2.5}$ NAAQS DV is then calculated by averaging the annual 98th percentiles using equation 4 of this appendix: $P_{0.98,y}$

Equation 4

$$\overline{P}_{0.98} = \frac{1}{3}\sum_{y=1}^{3} P_{0.98,y}$$

Where:

$\bar{P}_{0.98}$ = the 24-hour $PM_{2.5}$ NAAQS DV; and

$P_{0.98,\,y}$ = the annual 98th percentile for year y

(c) The 24-hour $PM_{2.5}$ NAAQS DV is rounded according to the conventions in section 4.3 of this appendix before a comparison with the level of the primary and secondary 24-hour NAAQS are made.

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 6. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671*q*.

Subpart I—[Amended]

■ 7. In § 51.166, add paragraph (i)(10) to read as follows:

§ 51.166 Prevention of significant deterioration of air quality.

* * * * *

(i) * * *

(10) The plan may provide that the requirements of paragraph (k)(1) of this section shall not apply to a stationary source or modification with respect to the national ambient air quality standards for $PM_{2.5}$ in effect on March 18, 2013 if:

(i) The reviewing authority has determined a permit application subject to this section to be complete on or before December 14, 2012. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ in effect at the time the reviewing authority determined the permit application to be complete; or

(ii) The reviewing authority has first published before March 18, 2013 a public notice of a preliminary determination for the permit application subject to this section. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ in effect at the time of first publication of a public notice on the preliminary determination.

* * * * *

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 9. In § 52.21, add paragraph (i)(11) to read as follows:

§ 52.21 Prevention of significant deterioration of air quality.

* * * * *

(i) * * *

(11) The requirements of paragraph (k)(1) of this section shall not apply to a stationary source or modification with respect to the national ambient air quality standards for $PM_{2.5}$ in effect on March 18, 2013 if:

(i) The Administrator has determined a permit application subject to this section to be complete on or before December 14, 2012. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ in effect at the time the Administrator determined the permit application to be complete; or

(ii) The Administrator has first published before March 18, 2013 a public notice that a draft permit subject to this section has been prepared. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ in effect on the date the Administrator first published a public notice that a draft permit has been prepared.

* * * * *

PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

■ 10. The authority citation for part 53 continues to read as follows:

Authority: Section 301(a) of the CAA (42 U.S.C. sec. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

■ 11. In § 53.9, revise paragraph (c) to read as follows:

§ 53.9 Conditions of designation.

* * * * *

(c) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10\text{-}2.5}$ sampler offered for sale as part of an FRM or FEM shall function within the limits of the performance specifications referred to in § 53.20(a), § 53.30(a), § 53.35, § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).

* * * * *

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

■ 12. The authority citation of part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7405, 7410, 7414, 7601, 7611, 7614, and 7619.

■ 13. Section 58.1 is amended by adding in alphabetical order a definition for ''Area-wide'' and by removing the definition for ''Community monitoring zone (CMZ)'' to read as follows:

§ 58.1 Definitions.

* * * * *

Area-wide means all monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro- or middle-scale that are representative of many such locations in the same CBSA.

* * * * *

■ 14. Section 58.10 is amended as follows:
■ a. By revising paragraph (a)(2).
■ b. By adding paragraph (a)(8).
■ c. By adding paragraph (b)(13).
■ d. By revising paragraph (c).
■ e. By revising paragraph (d).

§ 58.10 Annual monitoring network plan and periodic network assessment.

(a) * * *

(2) Any annual monitoring network plan that proposes SLAMS network modifications (including new monitoring sites, new determinations that data are not of sufficient quality to be compared to the NAAQS, and changes in identification of monitors as suitable or not suitable for comparison against the annual $PM_{2.5}$ NAAQS) is subject to the approval of the EPA Regional Administrator, who shall provide opportunity for public comment and shall approve or disapprove the plan and schedule within 120 days. If the State or local agency has already provided a public comment opportunity on its plan and has made no changes subsequent to that comment opportunity, and has submitted the received comments together with the plan, the Regional Administrator is not required to provide a separate opportunity for comment.

* * *

(8)(i) A plan for establishing near-road $PM_{2.5}$ monitoring sites in CBSAs having 2.5 million or more persons, in accordance with the requirements of appendix D to this part, shall be submitted as part of the annual monitoring network plan to the EPA Regional Administrator by July 1, 2014. The plan shall provide for these required monitoring stations to be operational by January 1, 2015.

(ii) A plan for establishing near-road $PM_{2.5}$ monitoring sites in CBSAs having 1 million or more persons, but less than 2.5 million persons, in accordance with the requirements of appendix D to this part, shall be submitted as part of the annual monitoring network plan to the EPA Regional Administrator by July 1, 2016. The plan shall provide for these required monitoring stations to be operational by January 1, 2017.

(b) * * *

(13) The identification of any $PM_{2.5}$ FEMs and/or ARMs used in the monitoring agency's network where the data are not of sufficient quality such that data are not to be compared to the NAAQS. For required SLAMS where the agency identifies that the $PM_{2.5}$ Class III FEM or ARM does not produce data of sufficient quality for comparison to the NAAQS, the monitoring agency must ensure that an operating FRM or filter-based FEM meeting the sample frequency requirements described in § 58.12 or other Class III $PM_{2.5}$ FEM or ARM with data of sufficient quality is operating and reporting data to meet the network design criteria described in appendix D to this part.

(c) The annual monitoring network plan must document how state and local agencies provide for the review of changes to a $PM_{2.5}$ monitoring network that impact the location of a violating $PM_{2.5}$ monitor. The affected state or local agency must document the process for obtaining public comment and include any comments received through the public notification process within their submitted plan.

(d) The state, or where applicable local, agency shall perform and submit to the EPA Regional Administrator an assessment of the air quality surveillance system every 5 years to determine, at a minimum, if the network meets the monitoring objectives defined in appendix D to this part, whether new sites are needed, whether existing sites are no longer needed and can be terminated, and whether new technologies are appropriate for incorporation into the ambient air monitoring network. The network assessment must consider the ability of existing and proposed sites to support air quality characterization for areas with relatively high populations of susceptible individuals (e.g., children with asthma), and, for any sites that are being proposed for discontinuance, the effect on data users other than the agency itself, such as nearby states and tribes or health effects studies. The state, or where applicable local, agency must submit a copy of this 5-year assessment, along with a revised annual network plan, to the Regional Administrator. The assessments are due every five years beginning July 1, 2010.

* * * * *

■ 15. Section 58.11 is amended by adding paragraph (e) to read as follows:

§ 58.11 Network technical requirements.

* * * * *

(e) State and local governments must assess data from Class III $PM_{2.5}$ FEM and ARM monitors operated within their network using the performance criteria described in table C–4 to subpart C of part 53 of this chapter, for cases where the data are identified as not of sufficient comparability to a collocated FRM, and the monitoring agency requests that the FEM or ARM data should not be used in comparison to the NAAQS. These assessments are required in the monitoring agency's annual monitoring network plan described in § 58.10(b) for cases where the FEM or ARM is identified as not of sufficient comparability to a collocated FRM. For these collocated $PM_{2.5}$ monitors the performance criteria apply with the following additional provisions:

(1) The acceptable concentration range (Rj), $\mu g/m^3$ may include values down to 0 $\mu g/m^3$.

(2) The minimum number of test sites shall be at least one; however, the number of test sites will generally include all locations within an agency's network with collocated FRMs and FEMs or ARMs.

(3) The minimum number of methods shall include at least one FRM and at least one FEM or ARM.

(4) Since multiple FRMs and FEMs may not be present at each site; the precision statistic requirement does not apply, even if precision data are available.

(5) All seasons must be covered with no more than thirty-six consecutive months of data in total aggregated together.

(6) The key statistical metric to include in an assessment is the bias (both additive and multiplicative) of the $PM_{2.5}$ continuous FEM(s) compared to a collocated FRM(s). Correlation is required to be reported in the assessment, but failure to meet the correlation criteria, by itself, is not cause to exclude data from a continuous FEM monitor.

■ 16. Section 58.12 is amended by revising paragraph (d)(1)(iii) and by removing and reserving paragraph (f)(2) to read as follows:

§ 58.12 Operating schedules.

* * * * *

(d) * * *

(1) * * *

(iii) Required SLAMS stations whose measurements determine the 24-hour design value for their area and whose data are within plus or minus 5 percent of the level of the 24-hour $PM_{2.5}$ NAAQS must have an FRM or FEM operate on a daily schedule if that area's design value for the annual NAAQS is less than the level of the annual $PM_{2.5}$ standard. A continuously operating FEM or ARM $PM_{2.5}$ monitor satisfies this requirement unless it is identified in the monitoring agency's annual monitoring network plan as not appropriate for comparison to the NAAQS.

* * * * *

(f) * * *

(2) [Reserved]

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■ 17. Section 58.13 is amended by adding paragraph (f) to read as follows:

§ 58.13 Monitoring network completion.

* * * * *

(f) $PM_{2.5}$ monitors required in near-road environments as described in appendix D to this part, must be physically established and operating under all of the requirements of this part, including the requirements of appendices A, C, D, and E to this part, no later than:

(1) January 1, 2015 for $PM_{2.5}$ monitors in CBSAs having 2.5 million persons or more; or

(2) January 1, 2017 for $PM_{2.5}$ monitors in CBSAs having 1 million or more, but less than 2.5 million persons.

■ 18. Section 58.16 is amended by revising paragraphs (a) and (f) to read as follows:

§ 58.16 Data submittal and archiving requirements.

(a) The state, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO_2; CO; O_3; NO_2; NO; NOy; NO_X; Pb-TSP mass concentration; Pb-PM_{10} mass concentration; PM_{10} mass concentration; $PM_{2.5}$ mass concentration; for filter-based $PM_{2.5}$ FRM/FEM the field blank mass, sampler-generated average daily temperature, and sampler-generated average daily pressure; chemically speciated $PM_{2.5}$ mass concentration data; $PM_{10-2.5}$ 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, including destructive analyses if necessary, at the request of EPA or to provide information to state and local agencies on particulate matter composition. Other Federal agencies may request access to filters for purposes of supporting air quality management or community health—such as biological assay—through the applicable EPA Regional Administrator. The filters shall be archived according to procedures approved by the Administrator, which shall include cold storage of filters after post-sampling laboratory analyses for at least 12 months following field sampling. The EPA recommends that particulate matter filters be archived for longer periods, especially for key sites in making NAAQS-related decisions or for supporting health-related air pollution studies.

* * * * *

■ 19. Section 58.20 is amended by revising paragraph (c) to read as follows:

§ 58.20 Special purpose monitors (SPM).

* * * * *

(c) All data from an SPM using an FRM, FEM, or ARM which has operated for more than 24 months are eligible for comparison to the relevant NAAQS, subject to the conditions of §§ 58.11(e) and 58.30, unless the air monitoring agency demonstrates that the data came from a particular period during which the requirements of appendix A, appendix C, or appendix E to this part were not met, subject to review and EPA Regional Office approval as part of the annual monitoring network plan described in § 58.10.

* * * * *

■ 20. The heading for Subpart D is revised to read as follows:

Subpart D—Comparability of Ambient Data to the NAAQS

■ 21. Section 58.30 is amended by revising paragraph (a) to read as follows:

§ 58.30 Special considerations for data comparisons to the NAAQS.

(a) *Comparability of* $PM_{2.5}$ *data.* The primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS are described in part 50 of this chapter. Monitors that follow the network technical requirements specified in § 58.11 are eligible for comparison to the NAAQS subject to the additional requirements of this section. $PM_{2.5}$ measurement data from all eligible monitors are comparable to the 24-hour $PM_{2.5}$ NAAQS. $PM_{2.5}$ measurement data from all eligible monitors that are representative of area-wide air quality are comparable to the annual $PM_{2.5}$ NAAQS. Consistent with appendix D to this part, section 4.7.1, when micro- or middle-scale $PM_{2.5}$ monitoring sites collectively identify a larger region of localized high ambient $PM_{2.5}$ concentrations, such sites would be considered representative of an area-wide location and, therefore, eligible for comparison to the annual $PM_{2.5}$ NAAQS. $PM_{2.5}$ measurement data from monitors that are not representative of area-wide air quality but rather of relatively unique micro-scale, or localized hot spot, or unique middle-scale impact sites are not eligible for comparison to the annual $PM_{2.5}$ NAAQS. $PM_{2.5}$ measurement data from these monitors are eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. For example, if a micro- or middle-scale $PM_{2.5}$ monitoring site is adjacent to a unique dominating local $PM_{2.5}$ source, then the $PM_{2.5}$ measurement data from such a site would only be eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. Approval of sites that are suitable and sites that are not suitable for comparison with the annual $PM_{2.5}$ NAAQS is provided for as part of the annual monitoring network plan described in § 58.10.

* * * * *

■ 22. Appendix A to part 58 is amended as follows:

■ a. By redesignating the existing introductory paragraph in section 1 as paragraph (b) in section 1, and revising newly redesignated paragraph (b).

■ b. By adding paragraph (a) to section 1.

■ c. By revising paragraphs 3.2.5.6, and 3.2.6.3.

■ d. By revising Table A–1.

The revisions and additions read as follows:

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *

1. * * *

(a) Each monitoring organization is required to implement a quality system that provides sufficient information to assess the quality of the monitoring data. The quality system must, at a minimum, include the specific requirements described in this appendix of this subpart. Failure to conduct or pass a required check or procedure, or a series of required checks or procedures, does not by itself invalidate data for regulatory decision making. Rather, monitoring agencies and EPA shall use the checks and procedures required in this appendix in combination with other data quality information, reports, and similar documents showing overall compliance with part 58. Accordingly, EPA and monitoring agencies shall use a ''weight of evidence'' approach when determining the suitability of data for regulatory decisions. The EPA reserves the authority to use or not use monitoring data submitted by a monitoring organization when making regulatory decisions based on the EPA's assessment of the quality of the data. Generally, consensus built validation templates or validation criteria already approved in Quality Assurance Project Plans (QAPPs) should be used as the basis for the weight of evidence approach.

(b) This appendix specifies the minimum quality system requirements applicable to SLAMS air monitoring data and PSD data for the pollutants SO_2, NO_2, O_3, CO, Pb, $PM_{2.5}$, PM_{10} and $PM_{10\text{-}2.5}$ submitted to EPA. This appendix also applies to all SPM stations using FRM, FEM, or ARM methods which also meet the requirements of appendix E of this part, unless alternatives to this appendix for SPMs have been approved in accordance with § 58.11(a)(2). Monitoring organizations are encouraged to develop and maintain quality systems more extensive than the required minimums. The permit-granting authority for PSD may require more frequent or more stringent requirements. Monitoring organizations may, based on their quality objectives, develop and maintain quality systems beyond the required minimum. Additional guidance for the requirements reflected in this appendix can be found in the ''Quality Assurance Handbook for Air Pollution Measurement Systems'', Volume II (see reference 10 of this appendix) and at a national level in references 1, 2, and 3 of this appendix.

* * * * *

3.2.5* * *

3.2.5.6 The two collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference. A waiver allowing up to 10 meters horizontal distance and up to 3 meters vertical distance (inlet to inlet) between a primary and collocated sampler may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation. This waiver may be approved during the annual network plan approval process. Calibration, sampling, and analysis must be the same for all the collocated samplers in each agency's network.

* * * * *

3.2.6 * * *

3.2.6.3 The two collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference. A waiver allowing up to 10 meters horizontal distance and up to 3 meters vertical distance (inlet to inlet) between a primary and a collocated sampler may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation taking into consideration safety, logistics, and space availability. This waiver may be approved during the annual network plan approval process. Calibration, sampling, and analysis must be the same for all the collocated samplers in each agency's network.

* * * * *

TABLE A–1 OF APPENDIX A TO PART 58—DIFFERENCE AND SIMILARITIES BETWEEN SLAMS AND PSD REQUIREMENTS

Topic	SLAMS	PSD
Requirements	1. The development, documentation, and implementation of an approved quality system.	Same as SLAMS.
	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.

* * * * *

■ 23. Appendix D to part 58 is amended as follows:

■ a. By revising paragraphs 4.7.1(b) and 4.7.1(c)(1).

■ b. By removing paragraph 4.7.5.

■ c. By removing and reserving paragraph 4.8.2.

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

4.7.1 * * *

(b) Specific Design Criteria for $PM_{2.5}$. The required monitoring stations or sites must be sited to represent area-wide air quality. These sites can include sites collocated at PAMS. These monitoring stations will typically be at neighborhood or urban-scale; however, micro-or middle-scale $PM_{2.5}$ monitoring sites that represent many such locations throughout a metropolitan area are considered to represent area-wide air quality.

(1) At least one monitoring station is to be sited at neighborhood or larger scale in an area of expected maximum concentration.

(2) For CBSAs with a population of 1,000,000 or more persons, at least one $PM_{2.5}$ monitor is to be collocated at a near-road NO_2

station required in section 4.3.2(a) of this appendix.

(3) For areas with additional required SLAMS, a monitoring station is to be sited in an area of poor air quality.

(4) Additional technical guidance for siting $PM_{2.5}$ monitors is provided in references 6 and 7 of this appendix.

(c) * * *

(1) *Micro-scale.* This scale would typify areas such as downtown street canyons and traffic corridors where the general public would be exposed to maximum concentrations from mobile sources. In some circumstances, the micro-scale is appropriate for particulate sites. SLAMS sites measured at the micro-scale level should, however, be limited to urban sites that are representative of long-term human exposure and of many such microenvironments in the area. In general, micro-scale particulate matter sites should be located near inhabited buildings or locations where the general public can be expected to be exposed to the concentration measured. Emissions from stationary sources such as primary and secondary smelters, power plants, and other large industrial processes may, under certain plume conditions, likewise result in high ground level concentrations at the micro-scale. In the latter case, the micro-scale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Data collected at micro-scale sites provide information for evaluating and developing hot spot control measures.

* * * * *

4.8 * * *

4.8.2 [Reserved]

* * * * *

■ 24. Appendix E to part 58 is amended as follows:

■ a. By adding table E–1 to paragraph 6 above paragraph 6.1.

■ b. By revising table E–4.

Appendix E to Part 58—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

* * * * *

6. * * *

TABLE E–1 TO APPENDIX E OF PART 58—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES OR MONITORING PATHS FOR MONITORING NEIGHBORHOOD AND URBAN SCALE OZONE (O_3) AND OXIDES OF NITROGEN (NO, NO_2, NO_X, NO_y)

Roadway average daily traffic, vehicles per day	Minimum distance [1] (meters)	Minimum distance [1 2] meters)
≤ 1,000	10	10
10,000	10	20
15,000	20	30
20,000	30	40
40,000	50	60
70,000	100	100
≥ 110,000	250	250

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2] Applicable for ozone monitors whose placement has not already been approved as of December 18, 2006.

* * * * *

11. * * *

TABLE E–4 OF APPENDIX E TO PART 58—SUMMARY OF PROBE AND MONITORING PATH SITING CRITERIA

Pollutant	Scale (maximum monitoring path length, meters)	Height from ground to probe, inlet or 80% of monitoring path [1] (meters)	Horizontal and vertical distance from supporting structures [2] to probe, inlet or 90% of monitoring path[1] (meters)	Distance from trees to probe, inlet or 90% of monitoring path [1] (meters)	Distance from roadways to probe, inlet or monitoring path [1] (meters)
SO_2 [3 4 5 6]	Middle (300 m) Neighborhood Urban, and Regional (1 km).	2–15	>1	>10	N/A.
CO [4 5 7]	Micro [downtown or street canyon sites], micro [near-road sites], middle (300 m) and Neighborhood (1 km).	2.5–3.5; 2–7; 2–15	>1	>10	2–10 for downtown areas or street canyon microscale; ≤50 for near-road microscale; see Table E–2 of this appendix for middle and neighborhood scales.
O_3 [3 4 5]	Middle (300 m) Neighborhood, Urban, and Regional (1 km).	2–15	>1	>10	*See* Table E–1 of this appendix for all scales.
NO_2 [3 4 5]	Micro (Near-road [50–300 m]).	2–7 (micro);	>1	>10	≤50 for near-road microscale.
	Middle (300 m)	2–15 (all other scales).			
	Neighborhood, Urban, and Regional (1 km).				*See* Table E–1 of this appendix for all other scales.
Ozone precursors (for PAMS) [3 4 5].	Neighborhood and Urban (1 km).	2–15	>1	>10	*See* Table E–4 of this appendix for all scales.
PM, Pb [3 4 5 6 8]	Micro, Middle, Neighborhood, Urban and Regional.	2–7 (micro); 2–7 (middle $PM_{10-2.5}$); 2–7 for near-road; 2–15 (all other scales).	>2 (all scales, horizontal distance only).	>10 (all scales)	2–10 (micro); *see* Figure E–1 of this appendix for all other scales. ≤50 for near-road.

N/A—Not applicable.

[1] Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring, middle, neighborhood, urban, and regional scale NO_2 monitoring, and all applicable scales for monitoring SO_2, O_3, and O_3 precursors.

[2] When probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.

[3] Should be greater than 20 meters from the dripline of tree(s) and must be 10 meters from the dripline when the tree(s) act as an obstruction.

[4] Distance from sampler, probe, or 90 percent of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the sampler, probe, or monitoring path. Sites not meeting this criterion may be classified as middle scale (*see* text).

[5] Must have unrestricted airflow 270 degrees around the probe or sampler; 180 degrees if the probe is on the side of a building or a wall.

[6] The probe, sampler, or monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.

[7] For micro-scale CO monitoring sites, the probe must be >10 meters from a street intersection and preferably at a midblock location.

[8] Collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference, unless a waiver is in place as approved by the Regional Administrator pursuant to section 3 of Appendix A.

* * * * *

■ 25. Appendix G to part 58 is amended as follows:
■ a. By revising section 9.
■ b. By revising section 10.
■ c. By revising paragraphs 12.1 introductory text and 12.1.a, and table 2.
■ d. By revising section 13.

Appendix G to Part 58—Uniform Air Quality Index (AQI) and Daily Reporting

* * * * *

9. How does the AQI relate to air pollution levels?

For each pollutant, the AQI transforms ambient concentrations to a scale from 0 to 500. The AQI is keyed as appropriate to the national ambient air quality standards (NAAQS) for each pollutant. In most cases, the index value of 100 is associated with the numerical level of the short-term standard (i.e., averaging time of 24-hours or less) for each pollutant. The index value of 50 is associated with the numerical level of the annual standard for a pollutant, if there is one, at one-half the level of the short-term standard for the pollutant, or at the level at which it is appropriate to begin to provide guidance on cautionary language. Higher categories of the index are based on increasingly serious health effects and increasing proportions of the population that are likely to be affected. The index is related to other air pollution concentrations through linear interpolation based on these levels. The AQI is equal to the highest of the numbers corresponding to each pollutant. For the purposes of reporting the AQI, the sub-indexes for PM_{10} and $PM_{2.5}$ are to be considered separately. The pollutant responsible for the highest index value (the reported AQI) is called the ''critical'' pollutant.

10. What monitors should I use to get the pollutant concentrations for calculating the AQI?

You must use concentration data from State/Local Air Monitoring Station (SLAMS) or parts of the SLAMS required by 40 CFR 58.10 for each pollutant except PM. For PM, calculate and report the AQI on days for which you have measured air quality data (e.g., from continuous $PM_{2.5}$ monitors required in Appendix D to this part). You may use PM measurements from monitors that are not reference or equivalent methods (for example, continuous PM_{10} or $PM_{2.5}$ monitors). Detailed guidance for relating non-approved measurements to approved methods by statistical linear regression is referenced in section 13 below.

* * * * *

12. How do I calculate the AQI?

i. The AQI is the highest value calculated for each pollutant as follows:

a. Identify the highest concentration among all of the monitors within each reporting area and truncate as follows:

(1) Ozone—truncate to 3 decimal places
$PM_{2.5}$—truncate to 1 decimal place
PM_{10}—truncate to integer
CO—truncate to 1 decimal place
SO_2—truncate to integer
NO_2—truncate to integer

(2) [Reserved]

* * * * *

TABLE 2—BREAKPOINTS FOR THE AQI

These breakpoints							Equal these AQI's	
O_3 (ppm) 8-hour	O_3 (ppm) 1-hour[1]	$PM_{2.5}$ (µg/m^3) 24-hour	PM_{10} (µg/m^3) 24-hour	CO (ppm) 8-hour	SO_2 (ppb) 1-hour	NO_2 (ppb) 1-hour	AQI	Category
0.000–0.059	....	0.0–12.0	0–54	0.0–4.4	0–35	0–53	0–50	Good.
0.060–0.075	....	12.1–35.4	55–154	4.5–9.4	36–75	54–100	51–100	Moderate.
0.076–0.095	0.125–0.164	35.5–55.4	155–254	9.5–12.4	76–185	101–360	101–150	Unhealthy for Sensitive Groups.
0.096–0.115	0.165–0.204	[3] 55.5–150.4	255–354	12.5–15.4	[4] 186–304	361–649	151–200	Unhealthy.
0.116–0.374	0.205–0.404	[3] 150.5–250.4	355–424	15.5–30.4	[4] 305–604	650–1249	201–300	Very Unhealthy.
([2])	0.405–0.504	[3] 250.5–350.4	425–504	30.5–40.4	[4] 605–804	1250–1649	301–400	Hazardous.
([2])	0.505–0.604	[3] 350.5–500.4	505–604	40.5–50.4	[4] 805–1004	1650–2049	401–500	

[1] Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI based on 1-hour ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index value may be calculated, and the maximum of the two values reported.
[2] 8-hour O^3 values do not define higher AQI values (≥301). AQI values of 301 or greater are calculated with 1-hour O_3 concentrations.
[3] If a different SHL for $PM_{2.5}$ is promulgated, these numbers will change accordingly.
[4] 1-hr SO_2 values do not define higher AQI values (≥ 200). AQI values of 200 or greater are calculated with 24-hour SO_2 concentrations.

* * * * *

13. What additional information should I know?

The EPA has developed a computer program to calculate the AQI for you. The program prompts for inputs, and it displays all the pertinent information for the AQI (the index value, color, category, sensitive group, health effects, and cautionary language). The EPA has also prepared a brochure on the AQI that explains the index in detail (The Air Quality Index), Reporting Guidance (Technical Assistance Document for the Reporting of Daily Air Quality—the Air Quality Index (AQI)) that provides associated health effects and cautionary statements, and Forecasting Guidance (Guideline for Developing an Ozone Forecasting Program) that explains the steps necessary to start an air pollution forecasting program. You can download the program and the guidance documents at *www.airnow.gov.* Reference for relating non-approved PM measurements to approved methods (Eberly, S., T. Fitz-Simons, T. Hanley, L. Weinstock., T. Tamanini, G. Denniston, B. Lambeth, E. Michel, S. Bortnick. Data Quality Objectives (DQOs) For Relating Federal Reference Method (FRM) and Continuous $PM_{2.5}$ Measurements to Report an Air Quality Index (AQI). U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA–454/B–02–002, November 2002) can be found on the Ambient Monitoring Technology Information Center

(AMTIC) Web site, *http://www.epa.gov/ttnamti1/.*

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