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6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

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

[EPA-HQ-OAR-2007-0492; FRL-9682-9]

RIN 2060-AO47

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Based on its review of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the EPA proposes to make revisions to the primary and secondary NAAQS for PM to provide requisite protection of public health and welfare, respectively, and to make corresponding revisions to the data handling conventions for PM and ambient air monitoring, reporting, and network design requirements. The EPA also proposes revisions to the prevention of significant deterioration (PSD) permitting program with respect to the proposed NAAQS revisions. With regard to primary standards for fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), the EPA proposes to revise the annual $PM_{2.5}$ standard by lowering the level to within a range of 12.0 to 13.0 micrograms per cubic meter ($\mu g/m^3$), so as to provide increased protection against health effects associated with long- and short-term exposures (including premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease) and to retain the 24-hour $PM_{2.5}$ standard. The EPA proposes changes to the Air Quality Index (AQI) for $PM_{2.5}$ to be consistent with the proposed primary $PM_{2.5}$ standards. With regard to the primary standard for particles generally less than or equal to 10 μm in diameter (PM_{10}), the EPA proposes to retain the current 24-hour PM_{10} standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10-2.5}$). With regard to the secondary PM standards, the EPA proposes to revise the suite of secondary PM

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

DATES: Comments must be received on or before August 31, 2012.

Public Hearings: The EPA intends to hold public hearings on this proposed rule in July 2012. These will be announced in a separate *Federal Register* notice that provides details, including specific dates, times, addresses, and contact information for these hearings.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2007-0492 by one of the following methods:

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

Instructions: Direct your comments to Docket ID No. EPA-HQ-OAR-2007-0492. The EPA's policy is that all comments received will be included in the public docket without change and may be

made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website 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 e-mail comment directly to the EPA without going through www.regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at http://www.epa.gov/epahome/dockets.htm.

Docket: All documents in the docket are listed on the www.regulations.gov website. 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 website. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and may be viewed, with prior arrangement, at the EPA Docket Center. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public

Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Ms. Beth M. Hassett-Sipple, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C504-06, Research Triangle Park, NC 27711; telephone: (919) 541-4605; fax: (919) 541-0237; email: hassett-sipple.beth@epa.gov

SUPPLEMENTARY INFORMATION:

General Information

What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to the EPA through www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, *Federal Register* date and page number).
- Follow directions – the agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.

- Describe any assumptions and provide any technical information and/or data that you used.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

Availability of Related Information

A number of the documents that are relevant to this rulemaking are available through EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) website 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* (US EPA, 2008a), available at http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html, the *Integrated Science Assessment for Particulate Matter* (US 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* (US EPA, 2010a), available at http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html, the *Particulate Matter Urban-Focused Visibility Assessment* (US 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* (US EPA, 2011a), available at http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pa.html. These and other related documents are also available for inspection and copying in the EPA docket identified above.

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I. Executive Summary

A. Purpose of this Regulatory Action

Sections 108 and 109 of the Clean Air Act (CAA) govern the establishment, review, and revision, as appropriate, of the national ambient air quality standards (NAAQS) to protect public health and welfare. The CAA requires periodic review of the air quality criteria – the science upon which the standards are based – and the standards themselves. This proposed rulemaking is being done pursuant to

these statutory requirements. The schedule for this proposed rule is set out in a court order.

In 2006, the EPA completed the last review of the PM NAAQS. In that review, the EPA took three principal actions: (1) With regard to fine particles (generally referring to particles less than or equal to 2.5 micrometers (µm) in diameter, $PM_{2.5}$), at that time, the EPA revised the level of the primary 24-hour $PM_{2.5}$ standard from 65 to 35 $\mu g/m^3$ 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. (3) The EPA also revised the secondary standards to be identical in all respects to the primary standards.

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

This review was initiated in June 2007. Between 2007 and 2011, EPA prepared draft and final Integrated Science Assessments, Risk and Exposure Assessments, and Policy Assessments. Multiple drafts of all of these documents were subject to review by the public and peer reviewed by EPA's Clean Air Scientific Advisory Committee (CASAC). This proposed rulemaking is the next step in the review process.

In this rulemaking, the EPA proposes to make revisions to the suite of primary and secondary standards for PM to provide increased protection of public health and welfare. We also discuss EPA's

current perspectives on implementation issues related to the proposed revisions to the PM NAAQS. The EPA proposes revisions to the Prevention of Significant Deterioration (PSD) permitting regulations to address the proposed changes in the primary and secondary PM NAAQS. The EPA also proposes an approach for implementing the PSD program specifically for the proposed secondary standard. The EPA is also proposing to update the Air Quality Index (AQI) for $PM_{2.5}$ and to make changes in the data handling conventions for PM and ambient air monitoring, reporting, and network design requirements to correspond with the proposed changes to the standards.

B. Summary of Major Provisions

With regard to the primary standards for fine particles, EPA proposes to revise the annual $PM_{2.5}$ standard by lowering the level from 15.0 to within a range of 12.0 to 13.0 $\mu g/m^3$ so as to provide increased protection against health effects associated with long- and short-term exposures. The EPA proposes to retain the level (35 $\mu g/m^3$) and the form (98th percentile) of the 24-hour $PM_{2.5}$ standard to provide supplemental protection against health effects associated with short-term exposures. This proposed action would provide increased protection for children, older adults, persons with pre-existing heart and lung disease, and other at-risk populations against an array of $PM_{2.5}$-related adverse health effects that include premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease. The EPA also proposes to eliminate spatial averaging provisions as part of the form of the annual standard to avoid potential disproportionate impacts on at-risk populations.

The proposed changes to the primary annual $PM_{2.5}$ standard are within the range that CASAC advised the Agency to consider. These changes are based on an integrative assessment of an extensive body of new scientific evidence, which substantially strengthens what was known about $PM_{2.5}$-related health effects in the last review, including extended analyses of key epidemiological studies, and evidence of health effects observed at lower ambient $PM_{2.5}$ concentrations, including effects in areas that likely met the current standards. The proposed changes also reflect consideration of a quantitative risk

assessment that estimates public health risks likely to remain upon just meeting the current and various alternative standards. Based on this information, the Administrator proposes to conclude that the current primary $PM_{2.5}$ standards are not requisite to protect public health with an adequate margin of safety, as required by the CAA, and that the proposed revisions are warranted to provide the appropriate degree of increased public health protection. The EPA solicits comment on all aspects of the proposed primary $PM_{2.5}$ standards.

With regard to the primary standard for coarse particles, EPA proposes to retain the current 24-hour PM_{10} standard, with a level of 150 $\mu g/m^3$ and a one-expected exceedance form, to continue to provide protection against effects associated with short-term exposure to $PM_{10\text{-}2.5}$, including premature mortality and increased hospital admissions and emergency department visits. In reaching this decision, the Administrator proposes to conclude that the available health evidence and air quality information for $PM_{10\text{-}2.5}$, taken together with the considerable uncertainties and limitations associated with that information, suggests that the degree of public health protection provided against short-term exposures to $PM_{10\text{-}2.5}$ does not need to be increased beyond that provided by the current PM_{10} standard. The Administrator welcomes the public's views on these approaches to considering and accounting for the evidence and its limitations and uncertainties.

With regard to the secondary PM standards, the EPA proposes to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment. More specifically, the EPA proposes to establish a secondary standard defined in terms of a $PM_{2.5}$ visibility index, which would use speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction, similar to the Regional Haze Program; a 24-hour averaging time; a 90th percentile form, averaged over 3 years; and a level set at one of two options – either 30 deciviews (dv) or 28 dv. The EPA also proposes to rely upon the existing Chemical Speciation Network (CSN) to provide appropriate monitoring data for calculating $PM_{2.5}$ visibility index values.

The proposed secondary standard is based on the long-standing science characterizing the

contribution of PM, especially fine particles, to visibility impairment and on air quality analyses, with consideration also given to a reanalysis of public perception surveys regarding people's stated preferences regarding acceptable and unacceptable visual air quality. Based on this information, the Administrator proposes to conclude that the current secondary $PM_{2.5}$ standards are not sufficiently protective of the public welfare with respect to visual air quality. The EPA solicits comment on all aspects of the proposed secondary standard.

To address other non-visibility welfare effects including ecological effects, effects on materials, and climate impacts, the EPA proposes to retain the current suite of secondary PM standards generally, while proposing to revise only the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging consistent with this proposed change to the primary annual $PM_{2.5}$ standard.

The proposed revisions to the PM NAAQS would trigger a process under which states (and tribes, if they choose) will make recommendations to the Administrator regarding designations, identifying areas of the country that either meet or do not meet the proposed new or revised NAAQS for $PM_{2.5}$. States will also review, modify and supplement their existing state implementation plans. The proposed NAAQS revisions would affect the applicable air permitting requirements and the transportation conformity and general conformity processes. This notice provides background information for understanding the implications of the proposed NAAQS revisions for these implementation processes and describes and requests comment on EPA's current perspectives on implementation issues. In addition, the EPA proposes to revise its PSD regulations to provide limited grandfathering from the requirements that result from the revised PM NAAQS for permit applications for which the public comment period has begun when the revised PM NAAQS take effect. The EPA also proposes to implement a surrogate approach that would provide a mechanism for permit applicants to demonstrate that they will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index NAAQS. It is the EPA's intention to finalize any time-sensitive revisions to its PSD regulations at the same time as any new or revised NAAQS are finalized.

With regard to implementation-related activities, the EPA intends to promulgate rules or develop guidance related to NAAQS implementation on a schedule that provides timely clarity to the states, tribes, and other parties responsible for NAAQS implementation. The EPA solicits comment on all implementation aspects during the public comment period for this notice and will consider these comments as it develops future rulemaking or guidance, as appropriate.

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

C. Costs and Benefits

In setting the NAAQS, the EPA may not consider the costs of implementing the standards. This was confirmed by the Supreme Court in *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001), as discussed in section II.A of this notice. As has traditionally been done in NAAQS rulemaking, the EPA has conducted a Regulatory Impact Analysis (RIA) to provide the public with information on the potential costs and benefits of attaining several alternative $PM_{2.5}$ standards. In NAAQS rulemaking, the RIA is done for informational purposes only, and the proposed decisions on the NAAQS in this rulemaking are not in any way based on consideration of the information or analyses in the RIA. The RIA fulfills the requirements of Executive Orders 13563 and 12866. The summary of the RIA, which is discussed in more detail below in section X.A, estimates benefits ranging from $88 million to $220 million (for 13.0 $\mu g/m^3$) and from $2.3 billion to $5.9 billion per year (for 12.0 $\mu g/m^3$) in 2020 and costs ranging from $2.9 million (for 13.0 $\mu g/m^3$) to $69 million (for 12.0 $\mu g/m^3$) per year.

II. Background

A. Legislative Requirements

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

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the

[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."

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 sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *See Lead Industries Association v. EPA*, 647 F.2d at 1161-62; *Whitman v. American Trucking Associations*, 531 U.S. 457, 495 (2001).

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

2d at 1185.

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

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

1. Previous PM NAAQS Reviews

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

In 1971, the EPA established NAAQS for PM based on the original air quality criteria document (DHEW, 1969; 36 FR 8186, April 30, 1971). The reference method specified for determining attainment of the original standards was the high-volume sampler, which collects PM up to a nominal size of 25 to 45 µm (referred to as total suspended particles or TSP). The primary standards (measured by the indicator TSP) were 260 $\mu g/m^3$, 24-hour average, not to be exceeded more than once per year, and 75

[3] Lists of CASAC members and of members of the CASAC PM Review Panel are available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CommitteesandMembership?OpenDocument.
[4] Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes, such that the indicator for a PM NAAQS has historically been defined in terms of particle size ranges.

$\mu g/m^3$, annual geometric mean. The secondary standard was 150 $\mu g/m^3$, 24-hour average, not to be exceeded more than once per year.

In October 1979, the EPA announced the first periodic review of the criteria and NAAQS for PM, and significant revisions to the original standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In that decision, the EPA changed the indicator for PM from TSP to PM_{10}, the latter including particles with an aerodynamic diameter less than or equal to a nominal 10 µm, which delineates thoracic particles (i.e., that subset of inhalable particles small enough to penetrate beyond the larynx to the thoracic region of the respiratory tract). The EPA also revised the primary standards by: (1) replacing the 24-hour TSP standard with a 24-hour PM_{10} standard of 150 $\mu g/m^3$ with no more than one expected

Table 1. Summary of National Ambient Air Quality Standards Promulgated for PM 1971-2006[5]

Final Rule	Indicator	Averaging Time	Level	Form
1971 36 FR 8186 April 30, 1971	TSP	24-hour	260 μg/m^3 (primary) 150 μg/m^3 (secondary)	Not to be exceeded more than once per year
		Annual	75 μg/m^3 (primary)	Annual average
1987 52 FR 24634 July 1, 1987	PM_{10}	24-hour	150 μg/m^3	Not to be exceeded more than once per year on average over a 3-year period
		Annual	50 μg/m^3	Annual arithmetic mean, averaged over 3 years
1997 62 FR 38652 July 18, 1997	$PM_{2.5}$	24-hour	65 μg/m^3	98th percentile, averaged over 3 years[6]
		Annual	15.0 μg/m^3	Annual arithmetic mean, averaged over 3 years[7,8]
	PM_{10}	24-hour	150 μg/m^3	Initially promulgated 99th percentile, averaged over 3 years; when 1997 standards for PM_{10} were vacated, the form of 1987 standards remained in place (not to be exceeded more than once per year on average over a 3-year period)
		Annual	50 μg/m^3	Annual arithmetic mean, averaged over 3 years
2006 71 FR 61144 October 17, 2006	$PM_{2.5}$	24-hour	35 μg/m^3	98th percentile, averaged over 3 years[6]
		Annual	15.0 μg/m^3	Annual arithmetic mean, averaged over 3 years[7,9]
	PM_{10}	24-hour	150 μg/m^3	Not to be exceeded more than once per year on average over a 3-year period

[5] When not specified, primary and secondary standards are identical.
[6] The level of the 24-hour standard is defined as an integer (zero decimal places) as determined by rounding. For example, a 3-year average 98th percentile concentration of 35.49 μg/m^3 would round to 35 μg/m^3 and thus meet the 24-hour standard and a 3-year average of 35.50 μg/m^3 would round to 36 and, hence, violate the 24-hour standard (40 CFR part 50, appendix N).
[7] The level of the annual standard is defined to one decimal place (i.e., 15.0 μg/m^3) as determined by rounding. For example, a 3-year average annual mean of 15.04 μg/m^3 would round to 15.0 μg/m^3 and, thus, meet the annual standard and a 3-year average of 15.05 μg/m^3 would round to 15.1 μg/m^3 and, hence, violate the annual standard (40 CFR part 50, appendix N).
[8] The level of the standard was to be compared to measurements made at sites that represent "community-wide air quality" recording the highest level, or, if specific requirements were satisfied, to average measurements from multiple community-wide air quality monitoring sites ("spatial averaging").
[9] The EPA tightened the constraints on the spatial averaging criteria by further limiting the conditions under which some areas may average measurements from multiple community-oriented monitors to determine compliance (*See* 71 FR 61165 to 61167, October 17, 2006).

exceedance per year; and (2) replacing the annual TSP standard with a PM_{10} standard of 50 μg/m^3, annual arithmetic mean. The secondary standard was revised by replacing it with 24-hour and annual PM_{10} standards identical in all respects to the primary standards. The revisions also included a new reference method for the measurement of PM_{10} in the ambient air and rules for determining attainment of the new standards. On judicial review, the revised standards were upheld in all respects. *Natural Resources Defense Council v. EPA*, 902 F. 2d 962 (D.C. Cir. 1990).

In April 1994, the EPA announced its plans for the second periodic review of the criteria and NAAQS for PM, and promulgated significant revisions to the NAAQS in 1997 (62 FR 38652, July 18, 1997). Most significantly, the EPA determined that although the PM NAAQS should continue to focus on thoracic particles (PM_{10}), the fine and coarse fractions of PM_{10} should be considered separately. New standards were added, using $PM_{2.5}$ as the indicator for fine particles. The PM_{10} standards were retained for the purpose of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or $PM_{10-2.5}$).[10] The EPA established two new $PM_{2.5}$ standards: an annual standard of 15 μg/m^3, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple monitors sited to represent community-wide air quality[11]; and a 24-hour standard of 65 μg/m^3, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor[12] within an area. Also, the EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and rules for determining attainment of the new standards. To continue to address thoracic coarse particles, the annual PM_{10} standard was retained, while the form, but not the level, of the 24-hour

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

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

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

PM_{10} standard was revised to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by making them identical in all respects to the primary standards.

Following promulgation of the revised PM NAAQS in 1997, petitions for review were filed by a large number of parties, addressing a broad range of issues. In May 1998, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit issued an initial decision that upheld EPA's decision to establish fine particle standards, holding that "the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards." *American Trucking Associations v. EPA*, 175 F. 3d 1027, 1055-56 (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 EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding, in part, that PM_{10} is a "poorly matched indicator for coarse particulate pollution" because it includes fine particles. Id. at 1053-55. Pursuant to the court's decision, the EPA removed the vacated 1997 PM_{10} standards from the CFR (69 FR 45592, July 30, 2004) and deleted the regulatory provision [at 40 CFR section 50.6(d)] that controlled the transition from the pre-existing 1987 PM_{10} standards to the 1997 PM_{10} standards. The pre-existing 1987 PM_{10} standards remained in place (65 FR 80776, December 22, 2000). The court also upheld EPA's determination not to establish more stringent secondary standards for fine particles to address effects on visibility (175 F. 3d at 1027).

More generally, the panel held (over a strong dissent) that EPA's approach to establishing the level of the standards in 1997, both for the PM and for the ozone NAAQS promulgated on the same day, effected "an unconstitutional delegation of legislative authority." Id. at 1034-40. Although the panel stated that "the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable," it remanded the rule to the EPA, stating that when the EPA considers these factors for potential non-threshold pollutants "what EPA lacks is any determinate

criterion for drawing lines" to determine where the standards should be set. Consistent with EPA's long-standing interpretation and 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 EPA's request for rehearing en banc, with five judges dissenting. Id. at 13. Both sides filed cross appeals on these issues to the United States Supreme Court, which granted certiorari. In February 2001, the Supreme Court issued a unanimous decision upholding EPA's position on both the constitutional and cost issues. *Whitman v. American Trucking Associations*, 531 U.S. 457, 464, 475-76. On the constitutional issue, the Court held that the statutory requirement that NAAQS be "requisite" to protect public health with an adequate margin of safety sufficiently cabined EPA's discretion, affirming EPA's approach of setting standards that are neither more nor less stringent than necessary. The Supreme Court remanded the case to the Court of Appeals for resolution of any remaining issues that had not been addressed in that court's earlier rulings. Id. at 475-76. In March 2002, the Court of Appeals rejected all remaining challenges to the standards, holding under the statutory standard of review that EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not "arbitrary and capricious." *American Trucking Associations v. EPA*, 283 F. 3d 355, 369-72 (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, 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 (US 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," US EPA, 2005). In conjunction with their review of the Staff Paper, CASAC provided advice to the Administrator on revisions to the PM NAAQS (Henderson, 2005a). In particular, most CASAC PM Panel members favored revising the level of the primary 24-hour $PM_{2.5}$ standard in the range of 35 to 30 μg/m^3 with a 98th percentile form, in concert with revising the level of the primary annual $PM_{2.5}$ standard in the range of 14 to 13 μg/m^3 (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/m^3; (2) revising the form, but not the level, of the primary annual $PM_{2.5}$ standard by tightening the constraints on the use of spatial averaging; (3) replacing the primary 24-hour PM_{10} standard with a 24-hour standard defined in terms of a new indicator, $PM_{10-2.5}$, this proposed indicator 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/m^3 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.[13] Subsequent to the proposal,

[13] In recognition of an alternative view expressed by most members of the CASAC PM Panel, the Agency also solicited comments on a subdaily (4- to 8-hour averaging time) secondary $PM_{2.5}$ standard to address visibility impairment, considering alternative standard levels within a range of 20 to 30 μg/m^3 in conjunction with a form within a range of the 92nd to 98th percentile (71 FR 2685, January 17, 2006).

CASAC provided additional advice to the EPA in a letter to the Administrator requesting reconsideration of CASAC's recommendations for both the primary and secondary $PM_{2.5}$ standards as well as the standards for thoracic coarse particles (Henderson, 2006a).

On October 17, 2006, the EPA promulgated revisions to the PM NAAQS to provide increased protection of public health and welfare (71 FR 61144). With regard to the primary and secondary standards for fine particles, the EPA revised the level of the primary 24-hour $PM_{2.5}$ standard to 35 $\mu g/m^3$, retained the level of the primary annual $PM_{2.5}$ standard at 15 $\mu g/m^3$, and revised the form of the primary annual $PM_{2.5}$ standard by adding further constraints on the optional use of spatial averaging. The EPA revised the secondary standards for fine particles by making them identical in all respects to the primary standards. With regard to the primary and secondary standards for thoracic coarse particles, the EPA retained the level and form of the 24-hour PM_{10} standard (such that the standard remained at a level of 150 $\mu g/m^3$ with a one-expected exceedance form), and revoked the annual PM_{10} standard. The EPA also established a new Federal Reference Method (FRM) for the measurement of $PM_{10-2.5}$ in the ambient air (71 FR 61212-13). Although the standards for thoracic coarse particles were not defined in terms of a $PM_{10-2.5}$ indicator, the EPA adopted a new FRM for $PM_{10-2.5}$ to facilitate consistent research on $PM_{10-2.5}$ air quality and health effects and to promote commercial development of Federal Equivalent Methods (FEMs) to support future reviews of the PM NAAQS (71 FR 61212/2).

Following issuance of the final rule, CASAC articulated its concern that "EPA's final rule on the NAAQS for PM does not reflect several important aspects of the CASAC's advice" (Henderson et al., 2006b, p. 1). With regard to the primary $PM_{2.5}$ annual standard, CASAC expressed serious concerns regarding the decision to retain the level of the standard at 15 $\mu g/m^3$. Specifically, CASAC stated, "It is the CASAC's consensus scientific opinion that the decision to retain without change the annual $PM_{2.5}$ standard does not provide an 'adequate margin of safety… requisite to protect the public health' (as required by the Clean Air Act), leaving parts of the population of this country at significant risk of adverse health effects from exposure to fine PM" (Henderson et al., 2006b, p. 2). Furthermore, CASAC

pointed out that its' recommendations "were consistent with the mainstream scientific advice that EPA received from virtually every major medical association and public health organization that provided their input to the Agency" (Henderson et al., 2006b, p. 2).[14] With regard to EPA's final decision to retain the 24-hour PM_{10} standard for thoracic coarse particles, CASAC had mixed views with regard to the decision to retain the 24-hour standard and the continued use of PM_{10} as the indicator of coarse particles, while also recognizing the need to have a standard in place to protect against effects associated with short-term exposures to thoracic coarse particles (Henderson et al., 2006b, p. 2). With regard to EPA's final decision to revise the secondary $PM_{2.5}$ standards to be identical in all respects to the revised primary $PM_{2.5}$ standards, CASAC expressed concerns that its advice to establish a distinct secondary standard for fine particles to address visibility impairment was not followed and emphasized "that continuing to rely on primary standard to protect against all PM-related adverse environmental and welfare effects assures neglect, and will allow substantial continued degradation, of visual air quality over large areas of the country" (Henderson et al, 2006b, p. 2).

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

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

requisite protection from both short- and long-term exposures to fine particles, including protection for at-risk populations such as children. *American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 520-27 (D.C. Cir. 2009). With regard to the standards for PM_{10}, the court upheld EPA's decisions to retain the 24-hour PM_{10} standard to provide protection from thoracic coarse particle exposures and to revoke the annual PM_{10} standard. *American Farm Bureau Federation v. EPA*, 559 F. 3d at 533-38. With regard to the secondary $PM_{2.5}$ standards, the court remanded the standards to the EPA because the Agency's decision was "unreasonable and contrary to the requirements of section 109(b)(2)" of the CAA. The court further concluded that the EPA failed to adequately explain why setting the secondary PM standards identical to the primary standards provided the required protection for public welfare, including protection from visibility impairment. *American Farm Bureau Federation v. EPA*, 559 F. 3d at 528-32.

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

3. Current PM NAAQS Review

The EPA initiated the current review of the air quality criteria for PM in June 2007 with a general call for information (72 FR 35462, June 28, 2007). In July 2007, the EPA held two "kick-off" workshops on the primary and secondary PM NAAQS, respectively (72 FR 34003 to 34004, June 20, 2007).[15] These workshops provided an opportunity for a public discussion of the key policy-relevant issues around which the EPA would structure this PM NAAQS review and the most meaningful new science that would be available to inform our understanding of these issues.

Based in part on the workshop discussions, the EPA developed a draft Integrated Review Plan outlining the schedule, process, and key policy-relevant questions that would guide the evaluation of the

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

air quality criteria for PM and the review of the primary and secondary PM NAAQS (US 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 (US EPA, 2008a) incorporated comments from CASAC (Henderson, 2008) and the public on the draft plan as well as input from senior Agency managers.[16,17]

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

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[16] The process followed in this review varies from the NAAQS review process described in section 1.1 of the Integrated Review Plan (US EPA, 2008a). On May 21, 2009, EPA Administrator Jackson called for key changes to the NAAQS review process including reinstating a policy assessment document that contains staff analyses of the scientific bases for alternative policy options for consideration by senior Agency management prior to rulemaking. In conjunction with this change, EPA will no longer issue a policy assessment in the form of an advance notice of proposed rulemaking (ANPR) as discussed in the Integrated Review Plan (US EPA, 2008a, p. 3). For more information on the overall process followed in this review including a description of the major elements of the process for reviewing NAAQS see Jackson (2009).

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

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, US EPA, 2009c,d; 74 FR 11580, March 18, 2009). These planning documents outlined the scope and approaches that staff planned to use in conducting quantitative assessments as well as key issues that would be addressed as part of the assessments. In designing and conducting the initial health risk and visibility impact assessments, the Agency considered CASAC comments (Samet 2009a,b) on the Scope and Methods Plans made during an April 2009 consultation (74 FR 7688, February 19, 2009) as well as public comments. Two draft assessment documents, *Risk Assessment to Support the Review of the $PM_{2.5}$ Primary National Ambient Air Quality Standards: External Review Draft*, September 2009 (US EPA, 2009e) and *Particulate Matter Urban-Focused Visibility Assessment - External Review Draft,* September 2009 (US EPA, 2009f) were reviewed by CASAC and the public at a meeting held on October 5 and 6, 2009 (74 FR 46586, September 10, 2009). Based on CASAC (Samet 2009c,d) and public comments, OAQPS staff revised these draft documents and released second draft assessment documents (US 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," US EPA, 2010a) and *Particulate Matter Urban-Focused Visibility Assessment – Final Document*, July 2010 (henceforth, "Visibility Assessment," US EPA, 2010b) (75 FR 39252, July 8, 2010).

Based on the scientific and technical information available in this review as assessed in the Integrated Science Assessment and Risk and Exposure Assessments, EPA staff prepared a Policy Assessment. The Policy Assessment is intended to help "bridge the gap" between the relevant scientific information and assessments and the judgments required of the Administrator in reaching decisions on the NAAQS (Jackson, 2009, attachment, p. 2). *American Farm Bureau Federation v. EPA*¸559 F. 3d at 521. The Policy Assessment is not a decision document; rather it presents EPA staff conclusions related to the broadest range of policy options that could be supported by the currently available information. A preliminary draft Policy Assessment (US EPA, 2009g) was released in September 2009 for informational purposes and to facilitate discussion with CASAC at the October 5 and 6, 2009 meeting on the overall structure, areas of focus, and level of detail to be included in the Policy Assessment. CASAC's comments on this preliminary draft were considered in developing a first draft PA (US 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 (US EPA, 2010f; 75 FR 39253, July 8, 2010) based on CASAC (Samet, 2010c) and public comments on the first draft Policy Assessment. The second draft document was reviewed by CASAC at a meeting on July 26 and 27, 2010 (75 FR 32763, June 9, 2010). CASAC (Samet, 2010d) and public comments on the second draft Policy Assessment were considered by EPA staff in preparing a final Policy Assessment titled *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards*, April, 2011 (US EPA, 2011a; 76, FR 22665, April 22, 2011). This document includes final staff conclusions on the adequacy of the current PM standards and alternative standards for consideration.

The schedule for the rulemaking in this review is subject to a court order in a lawsuit filed in

February 2012 by a group of plaintiffs who alleged that EPA had failed to perform its mandatory duty, under section 109(d)(1), to complete a review of the PM NAAQS within the period provided by statute. The court order, entered on June 2, 2012 and amended on June 6, 2012, provides that EPA will sign, for publication, a notice of proposed rulemaking concerning its review of the PM NAAQS no later than June 14, 2012.

The EPA is aware that a number of new scientific studies on the health effects of PM have been published since the mid-2009 cutoff date for inclusion in the Integrated Science Assessment. As in the last PM NAAQS review, the EPA intends to conduct a provisional review and assessment of any significant new studies published since the close of the Integrated Science Assessment, including studies that may be submitted during the public comment period on this proposed rule in order to ensure that, before making a final decision, the Administrator is fully aware of the new science that has developed since 2009. In this provisional assessment, the EPA will examine these new studies in light of the literature evaluated in the Integrated Science Assessment. This provisional assessment and a summary of the key conclusions will be placed in the rulemaking docket.

Today's action presents the Administrator's proposed decisions on the current PM standards. Throughout this preamble there are a number of conclusions, findings, and determinations that are part of the rationales for the decisions proposed by the Administrator. They are referred to throughout as "provisional" conclusions, findings, and determinations to reflect that they are not intended to be final or conclusive but rather proposals for public comment. The EPA invites general, specific, and technical comments on all issues involved with this proposal, including all such proposed decisions and provisional conclusions, findings, and determinations.

C. Related Control Programs to Implement PM Standards

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110 of the CAA, and related provisions, states are to submit, for EPA's approval, state implementation plans (SIPs) that provide for the

attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the PSD program (CAA sections 160 to 169). In addition, Federal programs provide for nationwide reductions in emissions of PM and other air pollutants through the Federal motor vehicle and motor vehicle fuel control program under title II of the Act (CAA sections 202 to 250) which involves controls for emissions from mobile sources and controls for the fuels used by these sources, and new source performance standards for stationary sources under section 111 of the CAA.

Currently, there are 55 areas in the U.S. (with a population of more than 100 million) that are designated as nonattainment for either the annual or 24-hour $PM_{2.5}$ standards. Regarding the 1997 $PM_{2.5}$ standards, the EPA designated 39 nonattainment areas in 2005. Regarding the 2006 24-hour $PM_{2.5}$ standard, the EPA designated 31 areas in 2009 and added one area in 2010. Sixteen areas are currently designated as nonattainment for both the 1997 and 2006 $PM_{2.5}$ standards. With regard to the PM_{10} NAAQS, 45 areas (with a population of more than 25 million) are currently designated as nonattainment. Upon any revisions to the PM NAAQS, the EPA would work with the states to conduct a new area designation process. Upon designation of new nonattainment areas, certain states would then be required to develop SIPs to attain the standards. In developing their attainment plans, states would first take into account projected emission reductions from federal and state rules that have been already adopted at the time of plan submittal. A number of significant emission reduction programs that will lead to reductions of PM and its precursors are in place today or are expected to be in place by the time any new SIPs will be due. Examples of such rules include the Transport Rule for electric generating units, regulations for onroad and nonroad engines and fuels, the utility and industrial boilers toxics rules, and various other programs already adopted by states to reduce emissions from key emissions sources. States would then evaluate the level of additional emission reductions needed for each nonattainment area to attain the standards "as expeditiously as practicable," and adopt new state regulations as

appropriate. Section IX includes additional discussion of designation and implementation issues associated with any revised PM NAAQS.

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

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

In developing this proposal, the Administrator recognizes that the CAA requires her to reach a public health policy judgment as to what standards would be requisite to protect public health with an adequate margin of safety, based on scientific evidence and technical assessments that have inherent uncertainties and limitations. This judgment requires making reasoned decisions as to what weight to place on various types of evidence and assessments, and on the related uncertainties and limitations. Thus, in selecting standards to propose, and subsequently in selecting the final standards, the Administrator is seeking not only to prevent fine particle concentrations that have been demonstrated to be harmful but also to prevent lower fine particle concentrations that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

As discussed below, a substantial amount of new research has been conducted since the close of the science assessment in the last review of the $PM_{2.5}$ NAAQS (US EPA, 2004), with important new information coming from epidemiological studies, in particular. This body of evidence includes hundreds of new epidemiological studies conducted in many countries around the world. In its assessment of the evidence judged to be most relevant to making decisions on elements of the primary $PM_{2.5}$ standards, the EPA has placed greater weight on U.S. and Canadian studies using $PM_{2.5}$ measurements, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.[18]

The newly available research studies as well as the earlier body of scientific evidence presented and assessed in the Integrated Science Assessment have undergone intensive scrutiny through multiple layers of peer review and opportunities for public review and comment. In developing this proposed rule, the EPA has drawn upon an integrative synthesis of the entire body of evidence between exposure to ambient fine particles and a broad range of health endpoints (US EPA, 2009a, Chapters 2, 4, 5, 6, 7, and 8) focusing on those health endpoints for which the Integrated Science Assessment concludes that there is a *causal* or *likely causal relationship* with long- or short-term $PM_{2.5}$ exposures. The EPA has also considered health endpoints for which the Integrated Science Assessment concludes there is evidence *suggestive of a causal relationship* with long-term $PM_{2.5}$ exposures in taking into account potential impacts on at-risk populations[19] and in considering alternative standard levels that provide protection with an appropriate margin of safety.

The EPA has also drawn upon a quantitative risk assessment based upon the scientific evidence described and assessed in the Integrated Science Assessment. These analyses, discussed in the Risk

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

[19] In this proposal, the term "at-risk" is the broadly encompassing term used for groups with specific factors that increase the risk of PM-related health effects in a population. In the Integrated Science Assessment, as discussed in section III.B.3 below, the term "susceptibility" was used broadly to recognize populations at greater risk.

Assessment (US EPA, 2010a) and Policy Assessment (US EPA, 2011a, chapter 2), have also undergone intensive scrutiny through multiple layers of peer review and opportunities for public review and comment.

Although important uncertainties remain in the qualitative and quantitative characterizations of health effects attributable to ambient fine particles, the review of this information has been extensive and deliberate. This intensive evaluation of the scientific evidence and quantitative assessments has provided an adequate basis for regulatory decision making at this time.

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

In presenting the rationale for the proposed revisions of the primary $PM_{2.5}$ standards, this section begins with a summary of the approaches used in setting the initial primary $PM_{2.5}$ NAAQS in 1997 and in reviewing those standards in 2006 (section III.A.1). The D.C. Circuit Court of Appeals remand of the primary annual $PM_{2.5}$ standard in 2009 is discussed in section III.A.2. Taking into consideration this history, section II.A.3 describes EPA's general approach used in the current review for considering the need to retain or revise the current suite of fine particle standards. Section III.B summarizes the body of scientific evidence supporting the rationale for the proposed decisions, including key health endpoints associated with long- and short-term exposures to ambient fine particles. This overview includes a discussion of at-risk populations and potential $PM_{2.5}$-related impacts on public health. Section III.C outlines the approach taken by the EPA to assess health risks associated with exposure to ambient $PM_{2.5}$, including a discussion of key uncertainties and limitations associated with these analyses. Section III.D

discusses the scientific evidence, air quality, risk-based information; CASAC advice; and the Administrator's proposed decisions related to the adequacy of the current standards. Section III.E discusses the scientific evidence, air quality, and risk-based information; CASAC advice; and the Administrator's proposed decisions related to alternative standards. Section III.F summarizes the Administrator's proposed decisions with regard to the primary $PM_{2.5}$ NAAQS.

A. Background

There are currently two primary $PM_{2.5}$ standards providing public health protection from effects associated with fine particle exposures. The annual standard is set at a level of 15.0 $\mu g/m^3$, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple monitors sited to represent community-wide air quality. The 24-hour standard is set at a level of 35 $\mu g/m^3$, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area.

The past and current approaches for reviewing the primary $PM_{2.5}$ standards described below are all based most fundamentally on using information from epidemiological studies to inform the selection of PM standards that, in the Administrator's judgment, protect public health with an adequate margin of safety. Such information can be in the form of air quality distributions over which health effect associations have been observed, or in the form of concentration-response functions that support quantitative risk assessment. However, evidence- and risk-based approaches using information from epidemiological studies to inform decisions on $PM_{2.5}$ standards are complicated by the recognition that no population threshold, below which it can be concluded with confidence that $PM_{2.5}$-related effects do not occur, can be discerned from the available evidence. As a result, any general approach to reaching decisions on what standards are appropriate necessarily requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards. This includes consideration of how to weigh the uncertainties in the reported associations across the distributions of $PM_{2.5}$ concentrations in the studies and the uncertainties in quantitative estimates of risk.

Such approaches are consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

1. General Approach Used in Previous Reviews

The general approach used to translate scientific information into standards used in the previous reviews focused on consideration of alternative standard levels that were somewhat below the long-term mean $PM_{2.5}$ concentrations reported in epidemiological studies (US EPA, 2011a, section 2.1.1). This approach recognized that the strongest evidence of $PM_{2.5}$-related associations occurs at concentrations near the long-term (i.e., annual) mean.

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

The EPA considered the epidemiological evidence and data on air quality relationships to set an annual $PM_{2.5}$ standard that was intended to be the “generally controlling” standard; i.e., the primary

means of lowering both long- and short-term ambient concentrations of $PM_{2.5}$.[20] In conjunction with the annual standard, the EPA also established a 24-hour $PM_{2.5}$ standard to provide supplemental protection against days with high peak concentrations, localized "hotspots," and risks arising from seasonal emissions that might not be well controlled by a national annual standard (62 FR 38669/3).

In 2006, the EPA used a different evidence-based approach to assess the appropriateness of the levels of the 24-hour and annual $PM_{2.5}$ standards (US EPA, 2011a, section 2.1.1.2). Based on an expanded body of epidemiological evidence that was stronger and more robust than that available in the 1997 review, including both short- and long-term exposure studies, the EPA decided that using evidence of effects associated with periods of exposure that were most closely matched to the averaging time of each standard was the most appropriate public health policy approach for evaluating the scientific evidence to inform selecting the level of each standard. Thus, the EPA relied upon evidence from the short-term exposure studies as the principal basis for revising the level of the 24-hour $PM_{2.5}$ standard from 65 to 35 $\mu g/m^3$ to protect against effects associated with short-term exposures. The EPA relied upon evidence from long-term exposure studies as the principal basis for retaining the level of the annual $PM_{2.5}$ standard at 15 $\mu g/m^3$ 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

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

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 US 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, not considered in the court's review and decision.

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

With respect to protection from long-term exposure to fine particles, the court found that the EPA failed to adequately explain how the primary annual $PM_{2.5}$ standard provided an adequate margin of safety for children and other at-risk populations. The court found that the EPA did not provide a reasonable explanation of why certain morbidity studies, including a study of children in Southern California showing lung damage associated with long-term $PM_{2.5}$ exposure (Gauderman et.al, 2000) and

a multi-city study (24-Cities Study) evaluating decreased lung function in children associated with long-term $PM_{2.5}$ exposures (Raizenne et al., 1996), did not warrant a more stringent annual $PM_{2.5}$ standard. Id. at 522-23. Specifically, the court found that:

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

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

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

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

This review is based on an assessment of a much expanded body of scientific evidence, more extensive air quality data and analyses, and a more comprehensive quantitative risk assessment relative to the information available in past reviews, as presented and assessed in the Integrated Science Assessment and Risk Assessment and discussed in the Policy Assessment. As a result, EPA's general

approach to reaching conclusions about the adequacy of the current suite of $PM_{2.5}$ standards and potential alternative standards that are appropriate to consider is broader and more integrative than in past reviews. Our general approach also reflects consideration of the issues raised by the court in its remand of the primary annual $PM_{2.5}$ standard, since decisions made in this review, and the rationales for those decisions, will comprise the Agency's response to the remand.

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

The Policy Assessment concludes it is most appropriate to consider the protection against $PM_{2.5}$-related mortality and morbidity effects, associated with both long- and short-term exposures, afforded by the annual and 24-hour standards taken together, as was done in the 1997 review, rather than to consider each standard separately, as was done in the 2006 review (US EPA, 2011a, section 2.1.3).[21] As the EPA recognized in 1997, there are various ways to combine two standards to achieve an appropriate degree of public health protection. The extent to which these two standards are interrelated in any given area depends in large part on the relative levels of the standards, the peak-to-mean ratios that characterize air quality patterns in an area, and whether changes in air quality designed to meet a

[21] By utilizing this approach, the Agency would also be responsive to the remand of the 2006 standard. As noted in section III.A.2, the D.C. Circuit, in remanding the 2006 primary annual $PM_{2.5}$ standard, concluded that the Administrator had failed to adequately explain why an annual standard was sufficiently protective in the absence of consideration of the long-term mean $PM_{2.5}$ concentrations in short-term exposure studies as well, and likewise had failed to explain why a 24-hour standard was sufficiently protective in the absence of consideration of the effect of an annual standard on reducing the overall distribution of 24-hour average $PM_{2.5}$ concentrations. 559 F. 3d at 520-24.

given suite of standards are likely to be of a more regional or more localized nature.

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

In considering the currently available evidence, the Policy Assessment recognizes that the short-term exposure studies are primarily drawn from epidemiological studies that associated variations in area-wide health effects with monitor(s) that measured the variation in daily $PM_{2.5}$ concentrations over the course of several years. The strength of the associations in these data is demonstrably in the numerous "typical" days within the air quality distribution, not in the peak days. See also 71 FR 61168, October 17, 2006 and *American Farm Bureau Federation v EPA*, 559 F. 3d at 523, 524 (making the same point). The quantitative risk assessments conducted for this and previous reviews demonstrate the same point, that is, much, if not most of the aggregate risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low-to mid-range, below the peak 24-hour concentrations (US EPA, 2011a, section 2.2.2; US EPA, 2010a, section 3.1.2.2). In addition, there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations.[22] For these reasons, strategies that focus primarily on reducing peak days are less likely to achieve reductions in the $PM_{2.5}$ concentrations

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

that are most strongly associated with the observed health effects.

Furthermore, a policy approach that focuses on reducing peak exposures would most likely result in more uneven public health protection across the U.S. by either providing inadequate protection in some areas or overprotecting in other areas (US EPA, 2010a, section 5.2.3). This is because reductions based on control of peak days are less likely to control the bulk of the air quality distribution, as discussed above.

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

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

The Policy Assessment's consideration of the protection afforded by the current and alternative suites of standards focuses on $PM_{2.5}$-related health effects associated with long-term exposures for which the magnitude of quantitative estimates of risks to public health generated in the risk assessment

is appreciably larger in terms of overall incidence and percent of total mortality or morbidity effects than for short-term $PM_{2.5}$-related effects. Nonetheless, the EPA also considers effects and estimated risks associated with short-term exposures. In both cases, the Policy Assessment places greatest weight on health effects that have been judged in the Integrated Science Assessment to have a causal or likely causal relationship with $PM_{2.5}$ exposures, while also considering health effects judged to be suggestive of a causal relationship or evidence that focuses on specific at-risk populations. The Policy Assessment places relatively greater weight on statistically significant associations that yield relatively more precise effect estimates and that are judged to be robust to confounding by other air pollutants. In the case of short-term exposure studies, the Policy Assessment places greatest weight on evidence from large multi-city studies, while also considering associations in single-city studies.

In translating information from epidemiological studies into the basis for reaching staff conclusions on the adequacy of the current suite of standards, the Policy Assessment considers a number of factors (US EPA, 2011a, section 2.2). As an initial matter, the Policy Assessment considers the extent to which the currently available evidence and related uncertainties strengthens or calls into question conclusions from the last review regarding associations between fine particle exposures and health effects. The Policy Assessment also considers evidence on at-risk populations and potential impacts on such populations. Further, the Policy Assessment explores the extent to which $PM_{2.5}$-related health effects have been observed in areas where air quality distributions extend to lower levels than previously reported or in areas that would likely have met the current suite of standards.

In translating information from epidemiological studies into the basis for reaching staff conclusions on alternative standard levels for consideration (US EPA, 2011a, sections 2.1.3 and 2.3.4), the Policy Assessment first recognizes the absence of discernible thresholds in the concentration-response functions from long- and short-term $PM_{2.5}$ exposure studies (US EPA, 2011a, section 2.4.3).[23]

[23] The epidemiological studies evaluated in the Integrated Science Assessment that examined the shape of concentration-response relationships and the potential presence of a threshold focused on

In the absence of any discernible thresholds, the Agency's general approach for identifying appropriate standard levels for consideration involves characterizing the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in epidemiological studies. In so doing, the Policy Assessment recognizes that there is no single factor or criterion that comprises the "correct" approach, but rather there are various approaches that are reasonable to consider for characterizing the confidence in the associations and the limitations and uncertainties in the evidence. Identifying the implications of various approaches for reaching conclusions on the range of alternative standard levels that is appropriate to consider can help inform decisions to either retain or revise the standards. Final decisions will necessarily also take into account public health policy judgments as to the degree of health protection that is to be achieved.

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

The approach that most directly addresses this issue considers studies that present confidence intervals around concentration-response relationships, and in particular, analyses that average across multiple concentration-response models rather than considering a single concentration-response model.[24]

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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 (US EPA, 2009a, sections 6.5, 6.2.10.10 and 7.6). Overall, the Integrated Science Assessment concludes that the studies evaluated support the use of a no-threshold, log-linear model but recognizes that "additional issues such as the influence of heterogeneity in estimates between cities, and the effect of seasonal and regional differences in PM on the concentration-response relationship still require further investigation" (US EPA, 2009a, section 2.4.3).

[24] This is distinct from confidence intervals around concentration-response relationships that are related to the magnitude of effect estimates generated at specific $PM_{2.5}$ concentrations (i.e., point-wise confidence intervals) and that are relevant to the precision of the effect estimate across the air quality

The Policy Assessment explores the extent to which such analyses have been published for studies of health effects associated with long- or short-term $PM_{2.5}$ exposures. Such analyses could potentially be used to characterize a concentration below which uncertainty in a concentration-response relationship substantially increases or is judged to be indicative of an unacceptable degree of uncertainty about the existence of a continuing concentration-response relationship. The Policy Assessment concludes that identifying this area of uncertainty in the concentration-response relationship could be used to inform identification of alternative standard levels that are appropriate to consider.

Further, the Policy Assessment explores other approaches that consider different statistical metrics from epidemiological studies. The Policy Assessment first takes into account the general approach used in previous PM reviews which focused on consideration of alternative standard levels that were somewhat below the long-term mean $PM_{2.5}$ concentrations reported in epidemiological studies.[25] This approach recognizes that the strongest evidence of $PM_{2.5}$-related associations occurs at concentrations near the long-term (i.e., annual) mean. In using this approach, the Policy Assessment places greatest weight on those long- and short-term exposure studies that reported statistically significant associations with mortality and morbidity effects.

In extending this approach, the Policy Assessment also considers information beyond a single statistical metric of $PM_{2.5}$ concentrations (i.e., the mean) to the extent such information is available. In so doing, the Policy Assessment employs distributional statistics (i.e., statistical characterization of an entire distribution of data) to identify the broader range of $PM_{2.5}$ concentrations that had the most influence on the calculation of relative risk estimates in epidemiological studies. Thus, the Policy Assessment considers the range of $PM_{2.5}$ concentrations where the data analyzed in the study (i.e., air

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distribution, rather than to our confidence in the existence of a continuing concentration-response relationship across the entire air quality distribution on which a reported association was based.

[25] Epidemiological studies typically report $PM_{2.5}$ concentrations averaged across the available ambient monitors. For multi-city studies, this metric reflects concentrations averaged across one or more ambient monitors within each area included in a given study and then averaged across study areas for an overall study mean $PM_{2.5}$ concentration. This is consistent with the epidemiological evidence considered in other NAAQS reviews.

quality and population-level data, as discussed below) are most concentrated, specifically, the range of $PM_{2.5}$ concentrations around the long-term mean over which our confidence in the associations observed in the epidemiological studies is greatest. The Policy Assessment then focuses on the lower part of this range to characterize where in the distributions the data become appreciably more sparse and, thus, where our understanding of the associations correspondingly becomes more uncertain. The Policy Assessment recognizes there is no one percentile value within a given distribution that is the most appropriate or "correct" way to characterize where our confidence in the associations becomes appreciably lower. The Policy Assessment concludes that the range from the 25th to 10th percentiles is a reasonable range to consider as a region where we have appreciably less confidence in the associations observed in epidemiological studies.[26]

In considering distributional statistics from epidemiological studies, the final Policy Assessment focused on two types of population-level metrics that CASAC advices are most useful to consider in identifying the $PM_{2.5}$ concentrations most influential in generating the health effect estimates reported in the epidemiological studies.[27] Consistent with CASAC advice, the most relevant information is the distribution of health events (e.g., deaths, hospitalizations) occurring within a study population in relation to the distribution of $PM_{2.5}$ concentrations. However, in recognizing that access to health event

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

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

data can be restricted, as discussed in section III.E.4.b below, the Policy Assessment also considers the number of study participants within each study area as an appropriate surrogate for health event data.

The Policy Assessment recognizes that an approach considering analyses of confidence intervals around concentration-response functions is intrinsically related to an approach that considers different distributional statistics. Both of these approaches could be employed to identify the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in epidemiological studies.

In applying these approaches, the Policy Assessment considers $PM_{2.5}$ concentrations from long- and short-term $PM_{2.5}$ exposure studies using composite monitor distributions.[28] For multi-city studies, this distribution reflects concentrations averaged across one or more ambient monitors within each area included in a given study and then averaged across study areas for an overall study mean $PM_{2.5}$ concentration. Beyond considering air quality concentrations based on composite monitor distributions, the second draft Policy Assessment also considered $PM_{2.5}$ concentrations based on measurements at the monitor within each area that records the highest concentration (i.e., maximum monitor) (US EPA, 2010f, sections 2.1.3 and 2.3.4.1).[29] Although the second draft Policy Assessment discussed whether consideration of alternative annual standard levels should be based on composite or maximum monitor distributions, the final Policy Assessment, consistent with CASAC advice (Samet, 2010d, p. 3), concluded that it is most reasonable to place more weight on an approach based on composite monitor distributions, which represent the $PM_{2.5}$ concentrations typically presented and used in epidemiological

[28] Using the term "composite monitor" does not imply that the EPA can identify one monitor that represents the air quality evaluated in a specific study area. Rather, as noted above, the composite monitor concentration represents the average concentration across one or more monitors within each area included in a given study and then averaged across study areas for an overall study mean $PM_{2.5}$ concentration.

[29] The maximum monitor distribution is relevant because it is generally used to determine whether a given standard is met in an area and the extent to which ambient $PM_{2.5}$ concentrations need to be reduced in order to bring an area into attainment with the standard. However, maximum monitor distributions represent a far less robust metric than composite monitor distributions for consideration of alternative annual standard levels in part because they are available for only a few epidemiological studies.

analyses and which provide a direct link between $PM_{2.5}$ concentrations and the observed health effects reported in both long- and short-term exposure studies (US EPA, 2011a, p. 2-13).

In reaching staff conclusions on alternative standard levels that are appropriate to consider, the Policy Assessment also includes a broader consideration of the uncertainties related to the concentration-response relationships from multi-city, long- and short-term exposure studies. Most notably, these uncertainties relate to our currently limited understanding of the heterogeneity of relative risk estimates in areas across the country. This heterogeneity may be attributed, in part, to the potential for different components within the mix of ambient fine particles to differentially contribute to health effects observed in the studies and to exposure-related factors (US EPA, 2011a, pp. 2-25 to 2-26). The limitations and uncertainties associated with the currently available scientific evidence, including the availability of fewer studies toward the lower range of alternative annual standard levels being considered in this proposal, are further discussed in section III.B.2 below.

The Policy Assessment recognizes that the level of protection afforded by the NAAQS relies both on the level and the form of the standard. The Policy Assessment concludes that a policy approach that uses data based on composite monitor distributions to identify alternative standard levels, and then compares those levels to concentrations at maximum monitors to determine if an area meets a given standard, inherently has the potential to build in some margin of safety (US EPA, 2011a, p. 2-14).[30] This conclusion is consistent with CASAC's comments on the second draft Policy Assessment, in which CASAC expressed its preference for focusing on an approach using composite monitor distributions

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

"because of its stability, and for the additional margin of safety it provides" when "compared to the maximum monitor perspective" (Samet, et al., 2010d, pp. 2 to 3).

In reaching staff conclusions on alternative 24-hour standard levels that are appropriate to consider for setting a 24-hour standard intended to supplement the protection afforded by a generally controlling annual standard, the Policy Assessment considered currently available short-term $PM_{2.5}$ exposure studies. The evidence from these studies informs our understanding of the protection afforded by the suite of standards against effects associated with short-term exposures. In considering the short-term exposure studies, the Policy Assessment evaluates both the distributions of 24-hour $PM_{2.5}$ concentrations, with a focus on the 98th percentile concentrations to match the form of the current 24-hour $PM_{2.5}$ standard, to the extent such data were available, as well as the long-term mean $PM_{2.5}$ concentrations reported in these studies. In addition to considering the epidemiological evidence, the Policy Assessment also considers air quality information based on county-level 24-hour and annual design values[31] to understand the policy implications of the alternative standard levels supported by the underlying science. In particular, the Policy Assessment considers the extent to which different combinations of alternative annual and 24-hour standards would support the policy goal of focusing on a generally controlling annual standard in conjunction with a 24-hour standard that would provide supplemental protection. Based on the evidence-based considerations outlined above, the Policy Assessment develops integrated conclusions with regard to alternative suites of standards, including both annual and 24-hour standards that are appropriate to consider in this review based on the currently available evidence and air quality information. In so doing, the Policy Assessment discusses the roles that each standard might be expected to play in the protection afforded by alternative suites of standards.

Beyond these evidence-based considerations, the Policy Assessment also considers the quantitative risk estimates and the key observations presented in the Risk Assessment. This assessment

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

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

The Policy Assessment conclusions related to the primary $PM_{2.5}$ standards reflect an understanding of both evidence-based and risk-based considerations to inform two overarching questions related to: (1) the adequacy of the current suite of $PM_{2.5}$ standards and (2) potential alternative standards, if any, that are appropriate to consider in this review to protect against effects associated with both long- and short-term exposures to fine particles. In addressing these broad questions, the discussions included in the Policy Assessment were organized around a series of more specific questions reflecting different aspects of each overarching question (US EPA, 2011a, chapter 2, Figure 2-1). When evaluating the health protection afforded by the current or any alternative suites of standards considered, the Policy Assessment takes into account the four basic elements of the NAAQS: the indicator, averaging time, form, and level. The general approach for reviewing the primary $PM_{2.5}$ standards described above provides a comprehensive basis to help inform the judgments required of the Administrator in reaching decisions about the current and potential alternative primary fine particle

standards and in responding to the remand of the 2006 primary annual $PM_{2.5}$ standard.

B. Health Effects Related to Exposure to Fine Particles

This section outlines key information contained in the Integrated Science Assessment (Chapters 2, 4, 5, 6, 7, and 8) and the Policy Assessment (Chapter 2) related to health effects associated with fine particle exposures. As was true in the last review, evidence from epidemiologic studies plays a key role in the Integrated Science Assessment's evaluation of the scientific evidence. The following sections discuss available information on the health effects associated with exposures to $PM_{2.5}$, including the nature of such health effects (section III.B.1) and associated limitations and uncertainties (section III.B.2), at-risk populations (section III.B.3), and potential $PM_{2.5}$-related impacts on public health (section III.B.4).

1. Nature of Effects

In considering the strength of the associations between long- and short-term exposures to $PM_{2.5}$ and health effects, the Policy Assessment notes that in the PM NAAQS review completed in 2006 the Agency concluded that there was "strong epidemiological evidence" for linking long-term $PM_{2.5}$ exposures with cardiovascular-related and lung cancer mortality and respiratory-related morbidity and for linking short-term $PM_{2.5}$ exposures with cardiovascular-related and respiratory-related mortality and morbidity (US EPA, 2004, p. 9-46; US EPA, 2005, p. 5-4). Overall, the epidemiological evidence supported "likely causal associations" between $PM_{2.5}$ and both mortality and morbidity from cardiovascular and respiratory diseases, based on "an assessment of strength, robustness, and consistency in results" (US EPA, 2004, p. 9-48).[32]

In looking across the extensive new scientific evidence available in this review, our overall understanding of health effects associated with fine particle exposures has been greatly expanded (US

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

EPA, 2009a, sections 2.3.1 and 2.3.2). The currently available evidence is stronger in comparison to evidence available in the last review because of its breadth and the substantiation of previously observed health effects. A number of large multi-city epidemiological studies have been conducted throughout the U.S., including extended analyses of studies that were important to inform decision-making in the last review. These studies have reported consistent increases in morbidity and/or mortality related to ambient $PM_{2.5}$ concentrations, with the strongest evidence reported for cardiovascular-related effects. In addition, the findings of new toxicological and controlled human exposure studies greatly expand and provide stronger support for a number of potential biologic mechanisms or pathways for cardiovascular and respiratory effects associated with long- and short-term PM exposures (US EPA, 2009a, p 2-17; chapter 5; Figures 5-4 and 5-5).

With regard to causal inferences described in the Integrated Science Assessment, the Policy Assessment notes that since the last review, the Agency has developed a more formal framework for reaching causal determinations that draws upon the assessment and integration of evidence from across epidemiological, controlled human exposure, and toxicological studies, and the related uncertainties, that ultimately influence our understanding of the evidence (US EPA, 2011a, p. 2-18; US EPA, 2009a, section 1.5). This framework employs a five-level hierarchy that classifies the overall weight of evidence and causality using the following categorizations: causal relationship, likely to be a causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (US EPA, 2009a, Table 1-3).[33]

Using this causal framework, the Integrated Science Assessment concludes that the collective evidence is largely consistent with past studies and substantially strengthens what was known about fine particles in the last review to reach the conclusion that a causal relationship exists between both long-

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

and short-term exposures to $PM_{2.5}$ and mortality and cardiovascular effects including cardiovascular-related mortality. The Integrated Science Assessment also concludes that the collective evidence continues to support a likely causal relationship between long- and short-term $PM_{2.5}$ exposures and respiratory effects, including respiratory-related mortality. Further, the Integrated Science Assessment concludes that the currently available evidence is suggestive of a causal relationship between long-term $PM_{2.5}$ exposures and other health effects, including developmental and reproductive effects (e.g., low birth weight, infant mortality) and carcinogenic, mutagenic, and genotoxic effects (e.g., lung cancer mortality) (US EPA, 2009a, sections 2.3.1 and 2.6; Table 2-6; US EPA, 2011a, Table 2-1).

a. Health Effects Associated with Long-term $PM_{2.5}$ Exposures

With regard to mortality, the Integrated Science Assessment concludes that newly available evidence significantly strengthens the link between long-term exposure to $PM_{2.5}$ and mortality, while providing indications that the magnitude of the $PM_{2.5}$-mortality association may be larger than previously estimated (US EPA, 2009a, sections 7.2.10, 7.2.11, and 7.6.1; Figures 7-6 and 7-7). A number of large U.S. cohort studies have been published since the last review, including extended analyses of the American Cancer Society (ACS) and Harvard Six Cities studies (US EPA, 2009a, pp 7-84 to 7-85; Figure 7-6; Krewski et al., 2009; Pope et al., 2004; Jerrett et al., 2005; Laden et al., 2006). In addition, new long-term $PM_{2.5}$ exposure studies evaluating mortality impacts in additional cohorts are now available (US EPA, 2009a, section 7.6). For example, the Women's Health Initiative (WHI) Observational Study reported effects of $PM_{2.5}$ on cardiovascular-related mortality in post-menopausal women with no previous history of cardiac disease (Miller et al., 2007). The $PM_{2.5}$ effect estimate in this study remained positive and statistically significant in a multi-pollutant model that included gaseous co-pollutants as well as coarse particles. In addition, multiple studies observed $PM_{2.5}$-associated mortality among older adults using Medicare data (Eftim et al., 2008; Zeger et al., 2007, 2008). Collectively, these new studies, along with evidence available in the last review, provide consistent and stronger evidence

of associations between long-term exposure to $PM_{2.5}$ and mortality (U.S. EPA, 2009a, sections 2.3.1 and 7.6).

The strength of the causal relationship between long-term $PM_{2.5}$ exposure and mortality also builds upon new studies providing evidence of improvement in community health following reductions in ambient fine particles. Pope et al. (2009) documented the population health benefits of reducing ambient air pollution by correlating past reductions in ambient $PM_{2.5}$ concentrations with increased life expectancy. These investigators reported that reductions in ambient fine particles during the 1980s and 1990s account for as much as 15 percent of the overall improvement in life expectancy in 51 U.S. metropolitan areas, with the fine particle reductions reported to be associated with an estimated increase in mean life expectancy of approximately 5 to 9 months (US EPA, 2009a, p. 7-95; Pope et al., 2009). An extended analysis of the Harvard Six Cities study found that as cities cleaned up their air, locations with the largest reductions in $PM_{2.5}$ saw the largest improvements in reduced mortality rates, while those with the smallest decreases in $PM_{2.5}$ concentrations saw the smallest improvements (Laden et al., 2006). Another extended follow-up to the Harvard Six Cities study investigated the delay between changes in ambient $PM_{2.5}$ concentrations and changes in mortality (Schwartz et al., 2008) and reported that the effects of changes in $PM_{2.5}$ were seen within the 2 years prior to death (US EPA, 2009a, p. 7-92; Figure 7-9).

With regard to cardiovascular effects, several new studies have examined the association between cardiovascular effects and long-term $PM_{2.5}$ exposures in multi-city studies conducted in the U.S. and Europe. The Integrated Science Assessment concludes that the strongest evidence comes from recent studies investigating cardiovascular-related mortality. This includes evidence from a number of large, multi-city U.S. long-term cohort studies including extended follow-up analyses of the ACS and Harvard Six Cities studies, as well as the WHI study (US EPA, 2009a, sections 7.2.10 and 7.6.1; Krewski et al., 2009; Pope et al., 2004; Laden et al., 2006; Miller et al., 2007). Pope et al. (2004) reported a positive association between mortality and long-term $PM_{2.5}$ exposure for a number of specific

cardiovascular diseases, including ischemic heart disease, dysrhythmia, heart failure, and cardiac arrest (US EPA, 2009a, p. 7-84; Figure 7-7). Krewski et al. (2009) provides further evidence for mortality related to ischemic heart disease associated with long-term $PM_{2.5}$ exposure (US EPA, 2009a, p. 7-84, Figure 7-7).

With regard to cardiovascular-related morbidity associated with long-term $PM_{2.5}$ exposures, studies were not available in the last review. Recent studies, however, have provided new evidence linking long-term exposure to $PM_{2.5}$ with cardiovascular outcomes that has "expanded upon the continuum of effects ranging from the more subtle subclinical measures to cardiopulmonary mortality" (US EPA, 2009a, p. 2-17). In the current review, studies are now available that evaluated a number of endpoints ranging from subtle indicators of cardiovascular health to serious clinical events associated with coronary heart disease and cardiovascular and cerebrovascular disease.[34] The most important new evidence comes from the WHI study which provides evidence of nonfatal cardiovascular events including both coronary and cerebrovascular events (Miller et al., 2007; US EPA, 2009a, sections 7.2.9 and 7.6.1). Toxicological studies provide supportive evidence that the cardiovascular morbidity effects observed in long-term exposure epidemiological studies are biologically plausible and coherent with studies of cardiovascular-related mortality as well as with studies of cardiovascular-related effects associated with short-term exposures to $PM_{2.5}$, as described below (US EPA, 2009a, p 7-19).

With regard to respiratory effects, the Integrated Science Assessment concludes that extended analyses of studies available in the last review as well as new epidemiological studies conducted in the U.S. and abroad provide stronger evidence of respiratory-related morbidity associated with long-term $PM_{2.5}$ exposure. The strongest evidence for respiratory-related effects available in this review is from studies that evaluated decrements in lung function growth, increased respiratory symptoms, and asthma

[34]Coronary and cerebrovascular events include myocardial infarction, coronary artery revascularization (e.g., bypass graft, angioplasty, stent, atherectomy), congestive heart failure and stroke.

development (U.S. EPA, 2009a, sections 2.3.1.2, 7.3.1.1, and 7.3.2.1).[35] Specifically, extended analyses of the Southern California Children's Health Study provide evidence that clinically important deficits in lung function[36] associated with long-term exposure to $PM_{2.5}$ persist into early adulthood (U.S. EPA, 2009a, p. 7-27; Gauderman et al., 2004). Additional analyses of the Southern California Children's Health Study cohort reported an association between long-term $PM_{2.5}$ exposure and bronchitic symptoms (US EPA, 2009a, p. 7-23 to 24; McConnell et al., 2003) that remained positive in co-pollutant models, with the $PM_{2.5}$ effect estimates increasing in magnitude in some models and decreasing in others, and a strong modifying effect of $PM_{2.5}$ on the association between lung function and asthma incidence (US EPA, 2009, 7-24; Islam et al., 2007). The outcomes observed in these more recent reports from the Southern California Children's Health Study, including evaluation of a broader range of endpoints and longer follow-up periods, were larger in magnitude and more precise than previously reported. Supporting these results are new longitudinal cohort studies conducted by other researchers in varying locations using different methods (US EPA, 2009a, section 7.3.9.1). New evidence from a U.S. cohort of cystic fibrosis patients provided evidence of association between long-term $PM_{2.5}$ exposures and exacerbations of respiratory symptoms resulting in hospital admissions or use of home intravenous antibiotics (US EPA, 2009a, p. 7-25; Goss et al., 2004).

Toxicological studies provide coherence and biological plausibility for the respiratory effects observed in epidemiological studies (US EPA, 2009a, p. 7-42). For example, pre- and postnatal exposure to ambient levels of urban particles has been found to affect lung development in an animal model (US EPA, 2009a, section 7.3.2.2; p. 7-43). This finding is important because impaired lung

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[35] Supporting evidence comes from studies "that observed associations between long-term exposure to PM_{10} and an increase in respiratory symptoms and reductions in lung function growth in areas where PM_{10} is dominated by $PM_{2.5}$" (US EPA, 2009a, p. 2-12).

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

development is one mechanism by which PM exposure may decrease lung function growth in children (US EPA, 2009a, p. 2-12; section 7.3).

With regard to respiratory-related mortality associated with long-term $PM_{2.5}$ exposure, the Integrated Science Assessment concludes that "when deaths due to respiratory causes are separated from all-cause (nonaccidental) and cardiopulmonary deaths, there is limited and inconclusive evidence for an effect of $PM_{2.5}$ on respiratory mortality, with one large cohort study finding a reduction in deaths due to respiratory causes associated with reduced $PM_{2.5}$ concentrations, and another large cohort study finding no $PM_{2.5}$ associations with respiratory mortality" (US EPA, 2009a, p. 7-41). The extended follow-up of the Harvard Six Cities study reported a positive but statistically non-significant association between long-term $PM_{2.5}$ exposure and respiratory-related mortality (Laden et al., 2006), whereas Pope et al. (2004) found no association in the ACS cohort (US EPA, 2009a, p. 7-84). There is emerging but limited evidence for an association between long-term $PM_{2.5}$ exposure and respiratory mortality in post-neonatal infants where long-term exposure was considered as approximately one month to one year (US EPA, 2009a, pp. 7-54 to 7-55). Emerging evidence of short- and long-term exposure to $PM_{2.5}$ and respiratory morbidity and infant mortality provide some support for the weak respiratory-related mortality effects observed.

Beyond effects considered to have causal or likely causal relationships with long-term $PM_{2.5}$ exposure as discussed above, the following health outcomes are classified in the Integrated Science Assessment as having evidence suggestive of a causal relationship with long-term $PM_{2.5}$ exposure: (1) reproductive and developmental effects and (2) cancer, mutagenicity, and genotoxicity effects (US EPA, 2009a, Table 2-6). With regard to reproductive and developmental effects, the Integrated Science Assessment notes, "[e]vidence is accumulating for $PM_{2.5}$-related effects on low birth weight and infant mortality, especially due to respiratory causes during the post-neonatal period" (US EPA, 2009a, p. 2-13). New evidence available in this review reports significant associations between exposure to $PM_{2.5}$ during pregnancy and lower birth weight and infant mortality, with less consistent evidence for pre-term

birth and intrauterine growth restriction. (US EPA, 2009a, section 7.4). The Integrated Science Assessment further notes that "[i]nfants and fetal development processes may be particularly vulnerable to PM exposure, and although the physical mechanisms are not fully understood, several hypotheses have been proposed involving direct effects on fetal health, altered placenta function, or indirect effects on the mother's health" (US EPA, 2009a, section 7.4.1). Although toxicological studies provide some evidence that supports an association between long-term $PM_{2.5}$ exposure and adverse reproductive and developmental outcomes, there is "little mechanistic information or biological plausibility for an association between long-term PM exposure and adverse birth outcomes (e.g., low birth weight, infant mortality)" (US EPA, 2009a, p. 2-13).

With regard to cancer, mutagenic and genotoxic effects, "[m]ultiple epidemiologic studies have shown a consistent positive association between $PM_{2.5}$ and lung cancer mortality, but studies have generally not reported associations between $PM_{2.5}$ and lung cancer incidence" (US EPA, 2009a, p. 2-13 and sections 2.3.1.2 and 7.5; Table 7-7; Figures 7-6 and 7-7). The extended follow-up to the ACS study reported an association between long-term $PM_{2.5}$ exposure and lung cancer mortality (US EPA, 2009a, p. 7-71; Krewski et al., 2009) as did the extended follow-up to the Harvard Six Cities study when considering the entire 25-year follow-up period (Laden et al., 2006). There is some evidence, primarily from *in vitro* studies, providing biological plausibility for the PM-lung cancer relationships observed in epidemiological studies (US EPA, 2009a, p. 7-80), although in vivo toxicological studies of carcinogenicity generally reported mixed results (US EPA, 2009a, section 7.5).

b. Health Effects Associated with Short-term $PM_{2.5}$ Exposures

In considering effects associated with short-term $PM_{2.5}$ exposure, the body of currently available scientific evidence has been expanded greatly by the publication of a number of new multi-city, time-series studies that have used uniform methodologies to investigate the effects of short-term fine particle exposures on public health. This body of evidence provides a more expansive data base and considers multiple locations representing varying regions and seasons that provide evidence of the influence of

climate and air pollution mixes on $PM_{2.5}$-associated health effects. These studies provide more precise estimates of the magnitude of effects associated with short-term $PM_{2.5}$ exposure than most smaller-scale single-city studies that were more commonly available in the last review (US EPA 2009a, chapter 6).

With regard to mortality, new U.S. and Canadian multi-city and single-city $PM_{2.5}$ exposure studies have found generally consistent positive associations between short-term $PM_{2.5}$ exposures and cardiovascular- and respiratory-related mortality as well as all-cause (non-accidental) mortality (US EPA, 2009a, sections 2.3.1.1, 6.2.11 and 6.5.2.2; Figures 6-26, 6-27, and 6-28). In an analysis of the National Morbidity, Mortality, and Air Pollution Study (NMMAPS) data, Dominici et al. (2007) reported associations between fine particle exposures and all-cause and cardiopulmonary-related mortality (US EPA, 2009a, p. 6-175, Figure 6-26). In a study of 112 U.S. cities, Zanobetti and Schwartz (2009) reported positive associations (in 99 percent of the cities) and frequently statistically significant associations (in 55 percent of the cities) between short-term $PM_{2.5}$ exposure and total (non-accidental) mortality (US EPA, 2009a, pp 6-176 to 6-179; Figures 6-23 and 6-24).[37] A Canadian 12-city study (Burnett et al., 2004) is generally consistent with an earlier Canadian 8-city study (Burnett and Goldberg, 2003). Both studies reported a positive and statistically significant association between short-term $PM_{2.5}$ exposure and mortality (US EPA, 2009a, p 6-182, Figure 2-1), although the influence of nitrogen dioxide (NO_2) and limited $PM_{2.5}$ data for several years during the study period somewhat diminished the findings reported in the 12-city study. In addition to these multi-city studies, evidence from available single-city studies suggests that gaseous copollutants do not confound the $PM_{2.5}$-mortality association (US EPA, 2009a, section 2.3.1.1). Collectively, these studies provide generally consistent and much stronger evidence for $PM_{2.5}$-associated mortality than the evidence available in the last review (US EPA, 2011a, p.2-24).

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

With regard to cardiovascular effects, new multi-city as well as single-city short-term $PM_{2.5}$ exposure studies conducted since the last review support a largely positive and frequently statistically significant association between short-term exposure to $PM_{2.5}$ and cardiovascular-related morbidity and mortality, substantiating prior findings. For example, among a multi-city cohort of older adults participating in the Medicare Air Pollution Study (MCAPS), investigators reported evidence of a positive association between short-term $PM_{2.5}$ exposures and hospital admissions related to cardiovascular outcomes (US EPA, 2009a, pp. 6-57 to 58; Dominici et al, 2006a; Bell et al, 2008). The strongest evidence for cardiovascular effects has been observed predominantly for hospital admissions and emergency department visits for ischemic heart disease and congestive heart failure, and cardiovascular-related mortality (US EPA, 2009a, Figure 2-1, p. 6-79, sections 6.2.10.3, 6.2.10.5, and 6.2.11; Bell et al., 2008; Dominici et al., 2006a; Tolbert et al., 2007; Zanobetti and Schwartz, 2009). In studies that evaluated the potential for confounding using co-pollutant models, $PM_{2.5}$ effect estimates for cardiovascular-related hospital admissions and emergency department visits generally remained positive, with the magnitude of $PM_{2.5}$ effect estimates increasing in some models and decreasing in others (US EPA, 2009a, Figure 6-5). Furthermore, these findings are supported by a recent study of a multi-city cohort of women participating in the WHI study that reported a positive but statistically nonsignificant association between short-term exposure to $PM_{2.5}$ and electrocardiogram measures of myocardial ischemia (Zhang et al., 2009).

In focusing on respiratory effects, the strongest evidence from short-term $PM_{2.5}$ exposure studies has been observed for respiratory-related emergency department visits and hospital admissions for chronic obstructive pulmonary disease (COPD) and respiratory infections (US EPA, 2009a, sections 2.3.1.1 and 6.3.8.3; Figures 2-1 and 6-13; Dominici et al., 2006a). In studies that employed co-pollutant models to evaluate the potential for confounding, $PM_{2.5}$ effect estimates for respiratory-related hospital admissions and emergency department visits generally remained positive, with the magnitude of $PM_{2.5}$ effect estimates increasing in some models and decreasing in others (US EPA, 2009a, Figure 6-15).

Evidence for $PM_{2.5}$-related respiratory effects has also been observed in panel studies, which indicate associations with respiratory symptoms, pulmonary function, and pulmonary inflammation among asthmatic children (US EPA, 2009a, p. 2-10). Although not consistently observed, some controlled human exposure studies have reported small decrements in various measures of pulmonary function following controlled exposures to $PM_{2.5}$ (US EPA, 20009a, p. 2-10). Furthermore, the comparatively larger body of toxicological evidence since the last review is coherent with the evidence from epidemiological and controlled human exposure studies that examined short-term exposures to $PM_{2.5}$ and respiratory effects (US EPA, 2009a, section 6.3.10.1).

c. Summary

In considering the extent to which newly available scientific evidence strengthens or calls into question evidence of associations identified in the last review between ambient fine particle exposures and health effects, the Policy Assessment recognizes that much progress has been made in assessing some key uncertainties related to our understanding of health effects associated with long- and short-term exposure to $PM_{2.5}$. As briefly discussed above as well as in the more complete discussion of the evidence as presented and assessed in the Integrated Science Assessment, the Policy Assessment notes that the newly available information combined with information available in the last review provides substantially stronger confidence in a causal relationship between long- and short-term exposures to $PM_{2.5}$ and mortality and cardiovascular effects. In addition, the newly available evidence reinforces and expands the evidence supporting a likely causal relationship between long- and short-term exposure to $PM_{2.5}$ and respiratory effects. The body of scientific evidence is somewhat expanded but is still limited with respect to associations between long-term $PM_{2.5}$ exposures and developmental and reproductive effects as well as cancer, mutagenic, and genotoxic effects. The Integrated Science Assessment concludes that these data provides evidence that is suggestive of a causal relationship for these effects. Thus, the Policy Assessment concludes there is stronger and more consistent and coherent support for associations between long- and short-term $PM_{2.5}$ exposure and a broader range of health outcomes than

was available in the last review, providing the basis for fine particle standards at least as protective as the current $PM_{2.5}$ standards.

2. Limitations and Uncertainties Associated with the Currently Available Evidence

With respect to understanding the nature and magnitude of $PM_{2.5}$-related risks, the Policy Assessment recognizes that important uncertainties remain in the current review (US EPA, 2011a, p. 2-25). Epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in responses both within and between cities and geographic regions within the U.S. In particular, the Policy Assessment notes that there are challenges with interpreting differences in health effects observed in the eastern versus western parts of the U.S., including evaluating effects stratified by seasons.[38] This heterogeneity may be attributed, in part, to differences in the fine particle composition or related to exposure measurement error.

In considering the relationships between PM composition and health effects, the ISA notes that the scientific evidence continues to evolve and concludes that, while many constituents of PM can be linked with differing health effects, the evidence is not yet sufficient to allow differentiation of those constituents or sources that may be more closely related to specific health outcomes (US EPA, 2009a, p. 2-17). In particular, based on assessing the body of available evidence, the ISA notes that (1) cardiovascular effects have been linked with elemental carbon as well as with $PM_{2.5}$ from crustal sources, traffic, and wood smoke/vegetative burning; (2) respiratory effects have been linked with secondary sulfate $PM_{2.5}$ as well as with $PM_{2.5}$ from crustal/soil/road dust and traffic sources; and (3) a few studies have reported associations between total mortality and secondary sulfate/long-range transport, traffic, and salt. While specific $PM_{2.5}$ constituents have been linked with various $PM_{2.5}$-related health effects in a small number of studies, research continues to focus on the identification of specific constituents or sources that may be most closely related to specific $PM_{2.5}$-related health outcomes.

[38] Seasonal differences in effects may be related to $PM_{2.5}$ composition as well as regional differences in climate and infrastructure that may affect time spent outdoors or indoors, housing characteristics including air conditioning usage, and differences in baseline incidence rates (US EPA, 2009a, p. 3-182).

Exposure measurement error is also an important source of uncertainty (US EPA, 2009a, section 3.8.6). Variability in the associations observed across $PM_{2.5}$ epidemiological studies may be due in part to exposure error related to measurement-related issues, the use of central fixed-site monitors to represent population exposure to $PM_{2.5}$, models used in lieu of or to supplement ambient measurements, and our limited understanding of factors that may influence exposures (e.g., topography, the built environment, climate, source characteristics, ventilation usage, personal activity patterns, photochemistry). As noted in the Integrated Science Assessment, exposure measurement error can introduce bias and increased uncertainty in associated health effect estimates (US EPA, 2009a, p. 2-17).

In addition, where $PM_{2.5}$ and other pollutants (e.g., ozone, nitrogen dioxide, and carbon monoxide) are correlated, it can be difficult to distinguish the effects of the various pollutants in the ambient mixture (i.e., co-pollutant confounding).[39] As noted above, although short-term studies of cardiovascular and respiratory hospital admissions and emergency department visits generally reported that $PM_{2.5}$ effect estimates remained positive, the magnitude of those effect estimates increased in some models and decreased in others. In addition, although evidence from single-city studies available in the last review suggests that gaseous copollutants do not confound the $PM_{2.5}$-related mortality association (US EPA, 2004, section 8.4.3.3), a conclusion that is supported by studies that examined the PM_{10}-mortality relationship (US EPA, 2009a, p. 6-182 and 6-201), many recent U.S. multi-city studies have not analyzed multipollutant models. While uncertainties and limitations still remain in the available health effects evidence, the Administrator judges the currently available scientific data base to be stronger and more consistent than in previous reviews providing a strong basis for decision making in this review.

3. At-Risk Populations

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

In identifying population groups or lifestages at greatest risk for health risk from a specific pollutant, the terms susceptibility, vulnerability, sensitivity, and at-risk are commonly employed. The definition for these terms sometimes varies, but in most instances "susceptibility" refers to biological or intrinsic factors (e.g., lifestage, gender, preexisting disease/conditions) while "vulnerability" refers to nonbiological or extrinsic factors (e.g., socioeconomic factors). However, factors included in the terms "susceptibility" and "vulnerability" are intertwined and are difficult to distinguish. In the Integrated Science Assessment, the term "susceptibility" has been used broadly to recognize populations that have a greater likelihood of experiencing effects related to ambient PM exposure[40], such that use of the term "susceptible populations" in the Integrated Science Assessment is used as a term that encompasses factors related both to susceptibility and vulnerability.[41] In the development of a more recent Integrated Science Assessment, the Agency is using the term "at-risk" groups to more broadly define the populations with characteristics that increase the risk of pollutant-related health effects (US EPA, 2011d, p. 8-1). Therefore, in this proposal, the term "at-risk" is the broadly encompassing term used for groups with specific factors that increase the risk of PM-related health effects in a population. At-risk populations could exhibit a greater risk of PM-related health effects than the general population for a number of reasons including: being affected by lower concentrations of PM, experiencing a larger health impact at a given PM concentration or being exposed to higher PM concentrations than the general population. Given the heterogeneity of individual responses to PM exposures, the severity of the health

[40] Although studies have primarily used exposures to PM_{10} or $PM_{2.5}$, the available evidence suggests that the identified factors also increase risk from $PM_{10-2.5}$ (US EPA, 2009a, section 8.1.8).
[41] The term "susceptible population" is defined in the Integrated Science Assessment as "[P]opulations that have a greater likelihood of experiencing health effects related to exposure to an air pollutant (e.g., PM) due to a variety of factors including, but not limited to: genetic or developmental factors, race, gender, lifestage, lifestyle (e.g., smoking status and nutrition) or preexisting disease; as well as population-level factors that can increase an individual's exposure to an air pollutant (e.g., PM) such as socioeconomic status [SES], which encompasses reduced access to health care, low educational attainment, residential location, and other factors (US EPA, 2009a, p. 8-1).

effects experienced by an at-risk population may be much greater than that experienced by the population at large.

As summarized below and presented in more detail in chapter 8 of the Integrated Science Assessment and section 2.2.1 of the Policy Assessment, the currently available epidemiological and controlled human exposure evidence expands our understanding of previously identified at-risk populations (i.e., children, older adults, and individuals with pre-existing heart and lung disease) and supports the identification of additional at-risk populations (e.g., persons with lower socioeconomic status, genetic differences) (US EPA, 2009a, section 2.4.1, Table 8-2). In addition, toxicological studies provide underlying support for the biological mechanisms that potentially lead to increased susceptibility to PM-related health effects (US EPA, 2009a, sections 2.4.1 and 8.1.8).

Two different lifestages have been associated with increased risk to PM-related health effects: childhood (i.e., less than 18 years of age) and older adulthood (i.e., 65 years of age and older). Childhood represents a lifestage where susceptibility to PM exposures may be related to the following observations: children spend more time outdoors; children have greater activity levels than adults; children have exposures resulting in higher doses per body weight and lung surface area; and the developing lung is prone to damage, including irreversible effects, from environmental pollutants as it continues to develop through adolescence (US EPA, 2009a, section 8.1.1.2). Older adults represent a lifestage where susceptibility to PM-associated health effects may be related to the higher prevalence of pre-existing cardiovascular and respiratory diseases found in this age group compared to younger age groups as well as the gradual decline in physiological processes that occur as part of the aging process (US EPA, 2009a, section 8.1.1.1). In addition, accumulating evidence suggests that the developing fetus may also represent an additional lifestage that is at greater risk to PM exposures (US EPA, 2009a, sections 2.3.1.2 and 7.4).

With regard to mortality, recent epidemiological studies have continued to find that older adults are at greater risk of all-cause (non-accidental) mortality associated with short-term exposure to both

$PM_{2.5}$ and PM_{10}, providing consistent and stronger evidence of effects in this at-risk population compared to the last review (US EPA, 2009a, Figure 7-7, section 8.1.1.1, Zeger et al., 2008). Evidence is accumulating for $PM_{2.5}$-related infant mortality, especially due to respiratory causes during the post-neonatal period (US EPA, 2009a, sections 2.3.1.2 and 7.4).

With regard to morbidity effects, currently available studies provide evidence that older adults have heightened responses, especially for cardiovascular-related effects, and children have heightened responses for respiratory-related effects (US EPA, 2009a, p. 2-23). In considering respiratory-related effects in children associated with long-term PM exposures, the Policy Assessment recognizes that our understanding of effects on lung development has been strengthened based on newly available evidence that is consistent and coherent across different study designs, locations, and research groups (US EPA, 2011a, p. 2-28). The strongest evidence comes from the extended follow-up for the Southern California Children's Health Study which includes several new studies that report positive associations between long-term exposure to $PM_{2.5}$ and respiratory morbidity, particularly for such endpoints as lung function growth, respiratory symptoms (e.g., bronchitic symptoms), and respiratory disease incidence (US EPA, 2009a, section 7.3; McConnell et al, 2003; Gauderman et al., 2004; Islam et al., 2007). These analyses provide evidence that $PM_{2.5}$-related effects persist into early adulthood and are more robust and larger in magnitude than previously reported. With regard to respiratory effects in children associated with short-term exposures to $PM_{2.5}$, currently available studies provide stronger evidence of respiratory-related hospitalizations with larger effect estimates observed among children. In addition, reductions in lung function (i.e., FEV_1) and increases in respiratory symptoms and medication use associated with PM exposures have been reported among asthmatic children (US EPA, 2009a, sections 6.3.1, 6.3.2.1, and 8.4.9).

A number of health conditions have been found to put individuals at greater risk for adverse effects following exposure to PM. The currently available evidence confirms and strengthens evidence in the last review that individuals with underlying cardiovascular and respiratory diseases are more

susceptible to PM exposures (US EPA, 2009a, section 8.1.6; US EPA, 2011a, section 2.2.1). There is also emerging evidence that people with diabetes, who are at risk for cardiovascular disease, as well as obese individuals, may have increased susceptibility to PM exposures (US EPA, 2009a, section 8.1.6.4). As discussed in section 8.1.6 of the Integrated Science Assessment, this body of evidence includes findings from epidemiological and human clinical studies that associations with mortality or morbidity are greater in those with pre-existing conditions, and also includes evidence from toxicological studies using animal models of cardiopulmonary disease.

Stronger evidence is available in this review than the last indicating that people from lower socioeconomic strata are an at-risk population relative to PM exposures (US EPA, 2009a, section 8.1.7; US EPA, 2011a, section 2.2.1). Persons with lower socioeconomic status (SES)[42] have been generally found to have a higher prevalence of pre-existing diseases; limited access to medical treatment; and increased nutritional deficiencies, which can increase this population's risk to PM-related effects.

Investigation of potential genetic susceptibility has provided evidence that individuals with specific genetic differences are more susceptible to PM-related effects (US EPA, 2009a, pp. 8-7 to 8-9). More research is needed to better understand the relationship between genetic effects and potential susceptibility to PM-related effects (US EPA, 2011a, p. 2-109).

In summary, there are several at-risk populations that may be especially susceptible or vulnerable to PM-related effects. These groups include those with preexisting heart and lung diseases, specific genetic differences, and lower socioeconomic status as well as the lifestages of childhood and older adulthood. Evidence for PM-related effects in these at-risk populations has expanded and is stronger than previously observed. There is emerging, though still limited, evidence for additional potentially at-risk populations, such as those with diabetes, people who are obese, pregnant women, and the developing fetus. The available evidence does not generally allow distinctions to be drawn between the

[42] Socioeconomic status is a composite measure that usually consists of economic status, measured by income; social status measured by education; and work status measured by occupation (US EPA, 2009a, p. 8-14).

PM indicators in terms of whether populations are more at-risk to a particular size fraction (i.e., $PM_{2.5}$ and $PM_{10-2.5}$).

4. Potential $PM_{2.5}$-related Impacts on Public Health

The population potentially affected by $PM_{2.5}$ is large. In addition, large subgroups of the U.S. population have been identified as at-risk populations as described in section III.B.3. While individual effect estimates from epidemiological studies may be small in size, the public health impact of the mortality and morbidity associations can be quite large. In addition, it appears that mortality risks are not limited to the very frail. Taken together, these results suggest that exposure to ambient $PM_{2.5}$ concentrations can have substantial public health impacts.

With regard to at-risk populations in the United States, approximately 7 percent of adults (approximately 16 million adults) and 9 percent of children (approximately 7 million children) have asthma (US EPA 2009a, Table 8-3; CDC, 2008[43]). In addition, approximately 4 percent of adults have been diagnosed with chronic bronchitis and approximately 2 percent with emphysema (US EPA, 2009a, Table 8-3). Approximately 11 percent of adults have been diagnosed with heart disease, 6 percent with coronary heart disease, 23 percent with hypertension, and 8 percent with diabetes (US EPA, 2009a, Table 8-3). In addition, approximately 3 percent of the U.S. adult population has suffered a stroke (US EPA, 2009a, Table 8-3). Therefore, large portions of the United States population are in groups that may be at increased risk to health effects associated with exposures to ambient $PM_{2.5}$. The size of the potentially at-risk population suggests that exposure to ambient $PM_{2.5}$ has significant impact on public health in the United States.

C. Quantitative Characterization of Health Risks

1. Overview

In this review, the quantitative risk assessment builds on the approach used and lessons learned

[43]For percentages, see http://www.cdc.gov/ASTHMA/nhis/06/table4-1.htm. For population estimates, see http://www.cdc.gov/ASTHMA/nhis/06/table3-1.htm.

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

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

2. Summary of Design Aspects

Based on a review of the evidence presented and assessed in the Integrated Science Assessment and criteria for selecting specific health effect endpoints discussed in the Risk Assessment (US EPA, 2010a, section 3.3.1), the following broad categories of health endpoints were included in the quantitative risk assessment: (1) all-cause, ischemic heart disease-related, cardiopulmonary-related, and lung cancer-related mortality associated with long-term $PM_{2.5}$ exposure; (2) non-accidental,

cardiovascular-related, and respiratory-related mortality associated with short-term $PM_{2.5}$ exposure; and (3) cardiovascular-related and respiratory-related hospital admissions and asthma-related emergency department visits associated with short-term $PM_{2.5}$ exposure. The evidence available for these selected health effect endpoints generally focused on the entire population, although some information was available to support analyses that considered differences in estimated risk for at-risk populations including older adults and persons with pre-existing cardiovascular and respiratory diseases (US EPA, 2010a, p. 3-29). The quantitative risk assessment estimates risks for various health effects in 15 urban study areas. The selection of urban study areas was based on a number of criteria including: (1) consideration of urban study areas evaluated in the last PM risk assessment; (2) consideration of locations evaluated in key epidemiological studies; (3) preference for locations with relatively elevated annual and/or 24-hour $PM_{2.5}$ monitored concentrations; and (4) preference for including locations from different regions across the country, reflecting potential differences in $PM_{2.5}$ sources, composition, and potentially other factors which might impact $PM_{2.5}$-related risk (US EPA, 2010a, section 3.3.2). Based on the results of several analyses examining the representativeness of these 15 urban study areas in the broader national context, the Risk Assessment concludes that these study areas are generally representative of urban areas in the U.S. likely to experience relatively elevated levels of risk related to ambient $PM_{2.5}$ exposure with the potential for better characterization at the higher end of that distribution (US EPA, 2011a, p. 2-42; US EPA, 2010a, section 4.4, Figure 4-17).[44]

In order to estimate the incidence of a particular health effect associated with recent ambient conditions in a specific urban study area attributable to $PM_{2.5}$ exposures, as well as the change in incidence corresponding to a given change in $PM_{2.5}$ concentrations resulting from simulating just

[44] The representativeness analysis also showed that the 15 urban study areas do not capture areas with the highest baseline morality risks or the oldest populations (both of which can result in higher $PM_{2.5}$-related mortality estimates). However, some of the areas with the highest values for these attributes have relatively low $PM_{2.5}$ concentrations (e.g., urban areas in Florida) and, consequently, the Risk Assessment concludes failure to include these areas in the set of urban study areas is unlikely to exclude high $PM_{2.5}$-risk locations (US EPA, 2010a, section 4.4.1).

meeting current or alternative $PM_{2.5}$ standards, three elements are required (US EPA, 2010a, section 3.1.1, Figures 3-2 and 3-3). These elements are: (1) air quality information (including recent air quality data for $PM_{2.5}$ from ambient monitors for the selected location, estimates of background $PM_{2.5}$ concentrations appropriate for that location, and a method for adjusting the recent data to reflect patterns of air quality estimated to occur when the area just meets a given set of $PM_{2.5}$ standards); (2) relative risk-based concentration-response functions that provide an estimate of the relationship between the health endpoints of interest and ambient $PM_{2.5}$ concentrations; and (3) baseline health effects incidence rates and population data, which are needed to provide an estimate of the incidence of health effects in an area before any changes in $PM_{2.5}$ air quality.[45]

The Risk Assessment includes a core set of risk estimates supplemented by an alternative set of risk results generated using single-factor and multi-factor sensitivity analyses. The core set of risk estimates was developed using the combination of modeling elements and input data sets identified in the Risk Assessment as having higher confidence relative to inputs used in the sensitivity analyses. The results of the sensitivity analyses provide information to evaluate and rank the potential impacts of key sources of uncertainty on the core risk estimates (US EPA, 2010a, sections 3.5 and 4.3, Table 4-3). In addition, the sensitivity analyses represent a set of reasonable alternatives to the core set of risk estimates that fall within an overall set of plausible risk estimates surrounding the core estimates (US EPA, 2010a, section 4.3.2).

Recent air quality was characterized for the 15 urban study areas based on 24-hour $PM_{2.5}$ concentrations measured for 3 years (i.e., 2005, 2006, and 2007) as described in section 3.2.1 of the Risk

[45] Incidence rates express the occurrence of a disease or event (e.g., death, hospital admission) in a specific period of time, usually per year. Rates are expressed either as a value per population group (e.g., the number of cases in Philadelphia County) or a value per number of people (e.g., the number of cases per 10,000 residents in Philadelphia County), and may be age- and/or sex-specific. Incidence rates vary among geographic areas due to differences in populations characteristics (e.g., age distribution) and factors promoting illness (e.g., smoking rates, air pollution concentrations). The baseline incidence rate provides an estimate of the incidence rate (i.e., number of cases of the health effect per year, usually per 10,000 or 100,000 general population) in the assessment location unrelated to changes in ambient $PM_{2.5}$ concentrations in that location (US EPA, 2010a, section 3.4).

Assessment. Different methodologies were then used to simulate conditions for just meeting the current or alternative $PM_{2.5}$ standards (US EPA, 2010a, section 3.2.3). This included using the single rollback approach used in the risk assessment conducted for the last review which reflects a uniform regional pattern of reductions in ambient $PM_{2.5}$ concentrations across monitors (i.e., proportional rollback approach). The proportional rollback approach was used in generating the core risk estimates (US EPA, 2010a, section 3.2.3.1). In sensitivity analyses, the Risk Assessment also applied two alternative rollback approaches (i.e., hybrid and locally-focused rollback approaches)[46] to better characterize potential variability in the way air quality in urban areas responds to programs put in place to meet the current or alternative $PM_{2.5}$ standards. In considering the three rollback approaches collectively, the proportional and locally-focused methods are approaches that are more likely to represent "bounding" scenarios related to the spatial pattern of future reductions in ambient $PM_{2.5}$ concentrations. In contrast, the hybrid approach, in principle, reflects a more plausible or representative rollback strategy since it: (1) reflects consideration for site-specific information regarding larger $PM_{2.5}$ sources and their potential impact on source-oriented monitors and (2) combines elements of more locally-focused and regionally-focused patterns of reductions (US EPA, 2010a, section 3.2.3).

The peak-to-mean ratio of ambient $PM_{2.5}$ concentrations within a study area informs the type of rollback approach used to simulate just meeting the current or alternative suites of standards to determine the magnitude of the reduction in annual mean $PM_{2.5}$ concentrations for that study area and consequently the degree of risk reduction.[47] For example, study areas with relatively high peak-to-mean ratios are likely to have greater estimated risk reductions for the current suite of standards (depending on

[46] The hybrid rollback approach involves a combination of an initial step of a more localized reduction in ambient $PM_{2.5}$ concentrations at source-oriented monitors followed by a regional pattern of reduction across all monitors in a study area (US EPA, 2010a, section 3.2.3.2). The locally-focused rollback approach involves a focused reduction of concentrations only at those monitors exceeding the current or alternative 24-hour standard levels (US EPA, 2010a, section 3.2.3.3).

[47] The peak-to-mean ratio of ambient $PM_{2.5}$ concentrations also has a direct bearing on whether the 24-hour or annual standard will be the generally controlling standard for a particular study area, with higher peak-to-mean ratios generally being associated with locations where the 24-hour standard is likely the controlling standard.

the combination of 24-hour and annual design values), and such locations can be especially sensitive to the type of rollback approach used, with the proportional rollback approach resulting in notably greater estimated risk reduction compared with the locally-focused rollback approach. In contrast, study areas with lower peak-to-mean ratios typically experience greater risk reductions when simulating just meeting the current or alternative annual-standard level than with simulating just meeting the current or alternative 24-hour standard level (again depending on the combination of 24-hour and annual design values). In addition, the type of rollback approach used will tend to have less of an impact on the magnitude of risk reductions for study areas with lower peak-to-mean ratios. Consideration of these two factors helps to inform an understanding of the nature and pattern of estimated risk reductions and risk remaining upon simulation of just meeting the current and alternative suites of standards across the urban study areas (US EPA, 2010a, section 5.2.1).

The concentration-response functions used in the risk assessment were based on findings from epidemiological studies that have relied on fixed-site, population-oriented, ambient monitors as a surrogate for actual ambient $PM_{2.5}$ exposures. The risk assessment addresses risks attributable to anthropogenic sources and activities (i.e., risk associated with concentrations above policy-relevant background).[48] This approach of estimating risks in excess of background was judged to be more relevant to policy decisions regarding ambient air quality standards than risk estimates that include effects potentially attributable to $PM_{2.5}$ concentrations that are not associated with North American anthropogenic emissions.

In modeling risk associated with long- and short-term $PM_{2.5}$ exposures, the Risk Assessment

[48] Policy-relevant background estimates used in the risk assessment model were based on information presented in the Integrated Science Assessment (US EPA, 2009a, section 3.7, Table 3-23) and discussed in the Risk Assessment (US EPA, 2010a, section 3.2.2). These values were generated based on a combination of Community Multiscale Air Quality model (CMAQ) and Goddard Earth Observing System (GEOS)-Chem modeling (US EPA, 2009a, section 3.7.1.2; US EPA, 2010a, section 3.2.2).

initially focused on selecting concentration-response functions from multi-city studies.[49] Concentration-response functions from two single-city studies provided coverage for additional health effect endpoints (i.e., emergency department visits for cardiovascular and/or respiratory effects) associated with short-term $PM_{2.5}$ exposures (US EPA, 2010a, p. 3-37).

With regard to modeling risks associated with long-term $PM_{2.5}$ exposure, concentration-response functions used in the risk model are all based on cohort studies, in which a cohort of individuals is followed over time. In the core analysis, estimated premature mortality risk associated with long-term $PM_{2.5}$ concentrations used concentration-response functions from the extended ACS study (Krewski et al., 2009). This study had a number of advantages including: analyses that expanded upon previous publications presenting evaluations of the ACS long-term cohort study and extending the follow-up period to eighteen years; a rigorous examination of different model forms for estimating effect estimates; coverage for a range of ecological variables (e.g., social, economic, and demographic factors) which allowed for consideration of whether these factors confound or modify the relationship between $PM_{2.5}$ exposure and mortality; and updated and expanded data sets on incidence and exposure (US EPA, 2010a, p 2-9 and 3-38).

As discussed in section III.B.3, persons of lower socioeconomic status have been identified as an at-risk population. The ACS study cohort does not provide representative coverage for persons of lower-socioeconomic status and, thus, the Risk Assessment concludes that using the concentration-response functions from this study may result in risk estimates that are biased low (US EPA, 2010a, p. 5-7). Therefore, concentration-response functions from a reanalysis of the Harvard Six Cities study (Krewski et al., 2000) were used in a sensitivity analysis to better support generalizing the results of the risk

[49] As noted in section 3.3.3 of the Risk Assessment, multi-city studies have a number of advantages over single-city studies including: increased statistical power providing effect estimates with relatively greater precision and reduced problems with publication bias (i.e., in which studies with statistically insignificant or negative results are less likely to get published than those with positive and/or statistically significant results).

assessment across the broader national population.[50]

While being mindful that the use of concentration-response functions from Krewski et al. (2009) introduces potential for low bias in the core risk estimates, the Policy Assessment also recognizes many strengths of this study and reasons for its continued use for generating the core risk estimates, including: consideration of a large number of metropolitan statistical areas, inclusion of two time periods for the air quality data which allowed us to consider different exposure windows, and analysis of a wide range of concentration-response function models. Therefore, the Risk Assessment concludes that concentration-response functions obtained from this study had the greatest overall support and were appropriate to incorporate in the core risk model (US EPA, 2010a, p. 3-38).

In the core analysis, for modeling health endpoints associated with long-term exposure, the Risk Assessment concluded that modeling risks down to policy-relevant background would require substantial extrapolation of the estimated concentration-response functions below the range of the data on which they were estimated (i.e., the lowest measured levels reported in the epidemiological studies were substantially above policy-relevant background). Therefore, the Risk Assessment concluded it was most appropriate in the core analysis to estimate risk only down to the lowest measured level to avoid introducing additional uncertainty into the analysis (US EPA, 2010a, 3-1 to 3-3).[51] A sensitivity analysis comparing the impact of estimated risks down to policy-relevant background rather than down to the lowest measured level (US EPA, 2010a, section 3.5.4.1) used annual estimates of policy-relevant background values for specific geographic regions (US EPA, 2010a, section 3.2.2, Table 3-2).

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[50] As noted in the last review, the ACS study population has persons generally representative of a higher SES (e.g., higher educational status) relative to the Harvard Six Cities study population (12 percent versus 28 percent of the cohort had less than a high school education, respectively) (US EPA, 2004, p. 8-118). The Policy Assessment concludes that the Harvard Six Cities study cohort may provide a more representative sample of the broader national population than the ACS study cohort (US EPA, 2011a, p. 2-40).

[51] To provide consistency for the different concentration-response functions selected from the long-term exposure studies, and, in particular, to avoid the choice of lowest measured levels unduly influencing the results of the risk assessment, the Risk Assessment concluded it was appropriate to select a single lowest measured level – 5.8 $\mu g/m^3$ from the later exposure period evaluated in Krewski et al. (2009) -- to use in estimating risks associated with long-term $PM_{2.5}$ exposures (US EPA, 2010a, p 3-3).

With regard to modeling risks associated with short-term $PM_{2.5}$ exposure, concentration-response functions from two time-series studies were selected as the primary studies to support the core analysis. Concentration-response functions from Zanobetti and Schwartz (2009) were used in estimating premature non-accidental, cardiovascular-related, and respiratory-related mortality. Concentration-response functions from Bell et al. (2008) were used in estimating cardiovascular-related and respiratory-related hospital admissions. In addition, concentration-response functions from two single-city studies were used to estimate emergency department visits for cardiovascular and/or respiratory illnesses associated with short-term $PM_{2.5}$ exposure (Tolbert et al., 2007; Ito et al., 2007; US EPA, 2010a, p. 3-37).

For modeling health endpoints associated with short-term $PM_{2.5}$ exposure, the Risk Assessment estimates risk down to policy-relevant background exclusively using quarterly values to represent the appropriate block of days within a simulated year (US EPA, 2010a, section 3.2.2, Table 3-2).

To estimate the change in incidence of a health endpoint associated with a given change in $PM_{2.5}$ concentrations, information on the baseline incidence of that endpoint is needed (US EPA, 2010a, section 3.4). In calculating a baseline incidence rate to be used with a concentration-response function from a given epidemiological study, the Risk Assessment matched the counties, age grouping, and International Classification of Diseases (ICD) codes used in that study (US EPA, 2010a, section 3.4.2).

An important component of a population health risk assessment is the characterization of both uncertainty and variability.[52] The design of the risk assessment includes a number of elements to address these issues, including using guidance from the World Health Organization (WHO, 2008) as a framework for developing the approach used for characterizing uncertainty in the analyses (US EPA, 2010a, section 3.5).

The Risk Assessment considers key sources of variability that can impact the nature and

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

magnitude of risks associated with simulating just meeting current and alternative standard levels across the urban study areas (US EPA, 2010a, section 3.5.2). These sources of variability include those that contribute to differences in risk across urban study areas, but do not directly affect the degree of risk reduction associated with the simulation of just meeting current or alternative standard levels (e.g., differences in baseline incidence rates, demographics and population behavior). The Risk Assessment also focuses on factors that not only introduce variability into risk estimates across study areas, but also play an important role in determining the magnitude of risk reductions upon simulation of just meeting current or alternative standard levels (e.g., peak-to-mean ratios of ambient $PM_{2.5}$ concentrations within individual urban study areas and the nature of the rollback approach used to simulate just meeting the current or alternative standards). Key sources of potential variability that are likely to affect population risks and the degree to which they were (or were not) fully captured in the design of the risk assessment are discussed in section 3.5.2 of the Risk Assessment. These sources include: $PM_{2.5}$ composition; intra-urban variability in ambient $PM_{2.5}$ concentrations; variability in the patterns of reductions in $PM_{2.5}$ concentrations associated with different rollback approaches when simulating just meeting the current or alternative standards; co-pollutant exposures; factors related to demographic and socioeconomic status; behavioral differences across urban study areas (e.g., time spent outdoors); baseline incidence rates; and longer-term temporal variability in ambient $PM_{2.5}$ concentrations reflecting meteorological trends as well as future changes in the mix of $PM_{2.5}$ sources, including changes in air quality related to future regulatory actions (US EPA, 2010a, pp. 3-67 to 3-69).

Single and multi-factor sensitivity analyses were combined with a qualitative analysis to assess the impact of potential sources of uncertainty on the core risk estimates (US EPA, 2010a, sections 3.5.3 and 3.5.4). The quantitative sensitivity analyses informed our understanding of sources of uncertainty that may have a moderate to large impact on the core risk estimates including: (1) characterizing intra-urban population exposure in the context of epidemiology studies linking $PM_{2.5}$ to specific health effects; (2) statistical fit of the concentration-response functions for short-term exposure-related health

endpoints; (3) shape of the concentration-response functions; (4) specifying the appropriate lag structure for short-term exposure studies; (5) transferability of concentration-response functions from study locations to urban study area locations for long-term exposure-related health endpoints; (6) use of single-city versus multi-city studies in the derivation of concentration-response functions; (7) impact of historical air quality on estimates of health risk associate with long-term $PM_{2.5}$ exposures; and (8) potential variation in effect estimates reflecting compositional differences in $PM_{2.5}$ (US EPA, 2011a, section 5.1.4). In addition to identifying sources of uncertainty with a moderate to large impact on the core risk estimates, the single and multi-element sensitivity analyses also produced a set of reasonable alternative risk estimates that allowed us to place the results of the core analysis in context with regard to uncertainty and potential bias (US EPA, 2010a, section 5.1.4). The qualitative uncertainty analysis supplemented the quantitative sensitivity analyses by allowing coverage for sources of uncertainty that could not be readily included in the sensitivity analysis (US EPA, 2010a, section 3.5.3).

With respect to the long-term exposure-related mortality risk estimates[53], the most important sources of uncertainty identified in the quantitative sensitivity analyses included: selection of concentration-response functions; modeling risk down to policy-relevant background versus lowest measured level; and the choice of rollback approach used to simulate just meeting current or alternative standards (US EPA, 2011a, p. 2-39). With regard to the qualitative analysis of uncertainty, the following sources were identified as potentially having a large impact on the core risk estimates for the long-term exposure-related mortality: characterization of intra-urban population exposures; impact of historical air quality; and potential variation in effect estimates reflecting differences in $PM_{2.5}$ composition (US EPA, 2011a, p. 2-39).

Beyond characterizing uncertainty and variability, a number of design elements were included in

[53] Given increased emphasis placed in this analysis on long-term exposure-related mortality, the uncertainty analyses completed for this health endpoint category were more comprehensive than those conducted for analyses of short-term exposure-related mortality and morbidity. This reflects, to some extent, limitations in the epidemiological data available for addressing uncertainty in the latter categories (U.S.EPA, 2010a, section 3.5.4.2).

the risk assessment to increase the overall confidence in the risk estimates generated for the 15 urban study areas (US 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 (US EPA, 2010a, section 5.1.1); (2) integration of key sources of variability into the design as well as the interpretation of risk estimates (U.S.EPA, 2010a, section 5.1.2); (3) assessment of the degree to which the urban study areas are representative of areas in the U.S. experiencing higher $PM_{2.5}$-related risk (U.S.EPA, 2010a, section 5.1.3); and (4) identification and assessment of important sources of uncertainty and the impact of these uncertainties on the core risk estimates (U.S.EPA, 2010a, section 5.1.4). Two additional analyses examined potential bias and overall confidence in the risk estimates. The first analysis explored potential bias in the core risk estimates by considering a set of alternative reasonable risk estimates generated as part of a sensitivity analysis. The second analysis compared the annual mean $PM_{2.5}$ concentrations associated with simulating just meeting the current and alternative suites of standards with the air quality distribution used in deriving the concentration-response functions applied in modeling mortality risk. Greater confidence is associated with risk estimates based on simulated annual mean $PM_{2.5}$ concentrations that are within the region of the air quality distribution used in deriving the concentration-response functions where the bulk of the data reside (e.g., within one standard deviation around the long-term mean $PM_{2.5}$ concentration) (US EPA, 2011a, p. 2-38).

3. Risk Estimates and Key Observations

As discussed below, three factors figure prominently in the interpretation of the risk estimates associated with simulating just meeting the current and alternative suites of standards, including: (1) the importance of changes in annual mean $PM_{2.5}$ concentrations for a specific study area in estimating changes in risks related to both long- and short-term exposures associated with recent air quality conditions and air quality simulated to just meet the current and alternative suites of $PM_{2.5}$ standards; (2) the ratio of peak- to-mean ambient $PM_{2.5}$ concentrations in a study area; and (3) the spatial pattern of

ambient $PM_{2.5}$ reductions that result from using different approaches to simulate just meeting the current standard levels (i.e., rollback approaches). The latter two factors are interrelated and influence the degree of risk reduction estimated under the current suite of standards.

The magnitude of both long- and short-term exposure-related risk estimated to remain upon just meeting the current suite of standards is strongly associated with the simulated change in annual mean $PM_{2.5}$ concentrations. The role of annual mean $PM_{2.5}$ concentrations in driving long-term exposure-related risk estimates is intuitive given that risks are modeled using the annual mean air quality metric.[54] The fact that short-term exposure-related risk estimates are also driven by changes in long-term mean $PM_{2.5}$ concentrations is less intuitive, since changes in mean 24-hour $PM_{2.5}$ concentrations are used to estimate changes in risk for this time period.[55] Analyses show that short-term exposure-related risks are not primarily driven by the small number of days with $PM_{2.5}$ concentrations in the upper tail of the air quality distribution, but rather by the large number of days with $PM_{2.5}$ concentrations at and around the mean of the distribution (US EPA, 2010a, section 3.1.2.2). Consequently, the largest part of the estimates of short-term exposure-related risk is related to the changes in the portion of the distribution of short term $PM_{2.5}$ exposures that are well represented by changes in the annual mean. Therefore, the Policy Assessment focuses on changes in annual mean $PM_{2.5}$ concentrations to inform our understanding of patterns of both long- and short-term exposure-related risk estimates across the set of urban study

[54] As noted in section 3.2.1 of the Risk Assessment (US EPA, 2010a), estimates of long-term exposure-related mortality are actually based on an annual mean $PM_{2.5}$ concentration that is the average across monitors in a study area (i.e., based on the composite monitor distribution). Therefore, in considering changes in long-term exposure-related mortality, it is most appropriate to compare composite monitor estimates generated for a study area under each alternative suite of standards considered. The annual mean at the highest reporting monitor (i.e., based on the maximum monitor distribution) for a study area is the annual design value. The annual design value is used to determine the percent reduction in $PM_{2.5}$ concentrations required to meet a particular standard. Both types of air quality estimates are provided in Table 3-4 of the Risk Assessment (US EPA, 2010a, pp. 3-25 to 3-27).

[55] Estimates of short-term $PM_{2.5}$ exposure-related mortality and morbidity are based on composite monitor 24-hour $PM_{2.5}$ concentrations. However, similar to the case with long-term exposure-related mortality, under the current rules, it is the 98th percentile 24-hour concentration estimated at the maximum monitor (the 24-hour design value) that will determine the degree of reduction required to meet a given 24-hour standard level (US EPA, 2011a, p. 2-37).

areas evaluated in the quantitative risk assessment (US EPA, 2011a, pp. 2-36 to 2-37).

In estimating $PM_{2.5}$-related risks likely to remain upon simulation of just meeting the current annual and 24-hour standards in the 15 urban study areas, the Risk Assessment focuses on the 13 areas that would likely not have met the current suite of $PM_{2.5}$ standards based on recent air quality (2005 to 2007). These 13 areas have annual and/or 24-hour design values that are above the levels of the current standards (US EPA, 2010a, Table 3-3).[56] Based on the core risk estimates for these areas, using the proportional rollback approach, the Policy Assessment makes the following key observations regarding the magnitude of risk remaining upon simulation of just meeting the current suite of standards:

1) *Long-term exposure-related mortality risk estimated to remain upon just meeting the current standards are significant*: Premature mortality related to ischemic heart disease attributable to long-term $PM_{2.5}$ exposure was estimated to range from less than 100 to approximately 2,000 cases per year across the urban study areas. The variability in these estimates reflects, to a great extent, differences in the size of study area populations. These estimates represent from 4 to 17% of all mortality related to ischemic heart disease in a given year for the urban study areas evaluated, representing a measure of risk that takes into account differences in population size and baseline mortality rates (US EPA, 2011a, p. 2-43, Table 2-2). These estimates of risk for mortality related to ischemic heart disease associated with long-term $PM_{2.5}$ exposure would likely be in a range of thousands of deaths per year for the 15 urban study areas[57] (US EPA, 2011a, pp. 2-46 to 2-47). Based on these risk estimates for premature mortality related to ischemic heart disease alone, the Policy Assessment concludes that risks estimated to remain upon simulation of just meeting the current suite of standards are important from a public health standpoint (US EPA, 2011a, p. 2-47). The Risk Assessment also includes estimated risks for premature mortality related to cardiopulmonary effects and lung cancer, which increase the total annual incidence of mortality attributable to long-term $PM_{2.5}$ exposure (see U.S. EPA, 2010a, section 4.2.1).

2) *Short-term exposure-related mortality risk estimated to remain upon just meeting the current standards are much smaller than long-term exposure-related mortality risks*: Cardiovascular-related mortality associated with short-term $PM_{2.5}$ exposure was estimated to range from less than 10 to 500 cases per year across the urban study areas. These estimates represent approximately 1 to 2 percent of total cardiovascular-related mortality in a given year for the urban study areas evaluated (US EPA, 2011a, p. 2-43, Table 2-3). Although long- and short-term exposure-related mortality rates have similar patterns in terms of the subset of urban study areas experiencing risk reductions for the current suite of standard levels, the magnitude of risk

[56] Of the 15 urban study areas, only Dallas and Phoenix have both annual and 24-hour design values below the levels of the current standards based on 2005-2007 air quality data (US EPA, 2010a, Table 3-3).

[57] Premature mortality for all causes attributed to $PM_{2.5}$ exposure was estimated to be in a range of tens of thousands of deaths per year on a national scale based on 2005 air quality data (US EPA, 2010a, Appendix G, Table G-1).

remaining is substantially lower, up to an order of magnitude smaller, for short-term exposure-related mortality (US EPA, 2011a, p. 2-47).

3) *Short-term exposure-related morbidity risk estimated to remain upon just meeting the current standards indicate hospitalizations are significantly larger for cardiovascular-related rather than respiratory-related events and emergency department visits for asthma-related events are significant:* Cardiovascular-related hospitalizations were estimated to range from approximately 10 to 800 cases per year across the study areas, which are less than 1 percent of total cardiovascular-related hospitalizations (US EPA, 2011a, p. 2-43, Table 2-3). Respiratory-related hospital admissions attributable to short-term $PM_{2.5}$ exposure were significantly smaller than those related to cardiovascular events (US EPA, 2010a, Tables E-102 and E-111). Cardiovascular- and respiratory-related hospital admissions together ranged up to approximately 1,000 admissions per year across the urban study areas. The estimated incidence of asthma-related emergency department visits is several times larger than the estimates of cardiovascular- and respiratory-related hospital admissions (US EPA, 2011a, p. 2-47; US EPA, 2010a, Tables E-118 to E-123

4) *Substantial variability exists in the magnitude of risk remaining across urban study areas*: Estimated risks remaining upon just meeting the current suite of standards vary substantially across study areas, even when considering risks normalized for differences in population size and baseline incidence rates. This variability is a consequence of the substantial differences in the annual mean $PM_{2.5}$ concentrations across study areas that result from simulating just meeting the current standards. This is important because, as discussed above, annual mean concentrations are highly correlated with both long- and short-term exposure-related risk. The variability in annual mean $PM_{2.5}$ concentrations occurred primarily in those study areas in which the 24-hour standard was the generally controlling standard. In such areas, the variability in estimated risks across study areas was largest when regional patterns of reductions in $PM_{2.5}$ concentrations were simulated, using the proportional rollback approach, as was done in the core analysis. Less variability was observed when more localized patterns of $PM_{2.5}$ reductions were simulated using the locally-focused rollback approach, as was done in a sensitivity analysis. When simulations were done using the locally-focused rollback approach, estimated risks remaining upon just meeting the current suite of standards were appreciably larger than those estimated in the core analysis (US EPA, 2011a, p. 2-46; US EPA, 2010a, section 4.3.1.1).

5) *Simulation of just meeting the current suite of standards results in annual mean $PM_{2.5}$ concentrations well below the current standard for some study areas:* In simulating just meeting the current suite of standards, the resulting composite monitor annual mean $PM_{2.5}$ concentrations ranged from about 15 $\mu g/m^3$ (for those study areas in which the annual standard was controlling) down to as low as about 8 $\mu g/m^3$ (for those study areas in which the 24-hour standard was the generally controlling standard or the annual mean concentration was well below 15 $\mu g/m^3$ based on recent air quality) (US EPA, 2011a, p. 2-46).

Reductions in risk associated with simulating air quality to just meet alternative standard levels were also estimated in this review (US EPA, 2010a, sections 4.2.2, 5.2.2, and 5.2.3; US EPA, 2011a, section 2.3.4.2). The estimated percent of risk reductions are depicted graphically in the Policy Assessment (US 2011a, Figures 2-11 and 2-12), showing patterns of estimated risk reductions associated

with alternative suites of standards.[58] These figures also depict the level of confidence associated with the risk estimates generated for simulating just meeting the current standards as well as alternative standard levels considered. As would be expected, patterns of increasing estimated risk reductions are generally observed as either the annual or 24-hour standard, or both, are reduced over the ranges considered in the Risk Assessment. A number of the key observations regarding the magnitude of risk remaining upon simulation of just meeting the alternative suites of standards are analogous to the observations identified above for simulation of just meeting the current standards (US EPA, 2011a, pp. 2-97 to 2-100).

With regard to characterizing estimates of $PM_{2.5}$-related risk associated with simulation of alternative standards, the Policy Assessment recognizes that greater overall confidence is associated with estimates of *risk reduction* than for estimates of *absolute risk remaining* (US EPA, 2011a, p. 2-94). Furthermore, the Policy Assessment recognizes that estimates of absolute risk remaining for each of the alternative standard levels considered, particularly in the context of long-term exposure-related mortality, may be underestimated (US EPA, 2011a, p. 2-97). In addition, the Policy Assessment observes that in considering the overall confidence associated with the quantitative analyses, the Risk Assessment recognizes that: (1) substantial variability exists in the magnitude of risk remaining across urban study areas and (2) in general, higher confidence is associated with risk estimates based on $PM_{2.5}$ concentrations near the mean $PM_{2.5}$ concentrations in the underlying epidemiological studies providing the concentration-response functions.

The variability in risk is a consequence of the substantial differences in the annual mean $PM_{2.5}$ concentrations across urban study areas that result from simulating just meeting current or alternative

[58] Patterns of risk reduction across alternative annual standard levels, in terms of percent change relative to risk estimates upon simulating just meeting the current standards, are similar for all health endpoints modeled (i.e., all-cause, ischemic heart disease-related, and cardiopulmonary-related mortality). This similarity reflects the fact that the concentration-response functions used in the quantitative risk assessment are close to linear across the range of ambient $PM_{2.5}$ concentrations evaluated. However, estimated incidence will vary by health endpoint (US EPA, 2011a, pp. 2-93 to 2-94, footnote 70).

standards. As $PM_{2.5}$ concentrations decrease from the mean $PM_{2.5}$ concentrations, the Risk Assessment concludes there is decreasing confidence in the risk estimates (US EPA, 2010a, p. 5-16). As lower long-term mean $PM_{2.5}$ concentrations are simulated (i.e., ambient concentrations further from recent air quality conditions), the potential variability in such factors as the spatial pattern of ambient $PM_{2.5}$ reductions (i.e., rollback) increases, thereby introducing greater uncertainty into the simulation of composite monitor annual mean $PM_{2.5}$ concentrations, and, consequently, in the risk estimates (US EPA, 2010a, Appendix J).

Based on consideration of the composite monitor annual mean $PM_{2.5}$ concentrations involved in estimating long-term exposure-related mortality, the Risk Assessment has higher confidence in using those concentrations that generally fall well within the range of ambient $PM_{2.5}$ concentrations considered in fitting the concentration-response functions used (i.e., within one standard deviation of the mean $PM_{2.5}$ concentration reported in Krewski et al. (2009) for 1999-2000) as inputs to the risk model. For example, with the exception of one urban study area, those areas estimated to have risk reductions using alternative annual standard levels of 13 and 14 $\mu g/m^3$ had simulated composite monitor annual mean concentrations ranging from approximately 10.6 to 13.3 $\mu g/m^3$. With lower alternative annual standard levels of 12 $\mu g/m^3$ and 10 $\mu g/m^3$, the composite monitor annual mean values ranged from approximately 9.0 to 11.4 $\mu g/m^3$ and 7.6 and 8.9 $\mu g/m^3$, respectively. These concentrations are towards the lower end of the range of ACS data (in some cases approaching the lowest measured level) used in fitting the concentration-response functions, particularly for an annual standard level of 10 $\mu g/m^3$, and, thus, the Policy Assessment concludes there is less confidence in the risk estimates associated with these levels compared with those for the higher alternative annual standard levels considered (US EPA, 2011a, p. 2-99). Thus, while simulation of risks for an alternative annual standard level of 10 $\mu g/m^3$ suggests that additional risk reductions could be expected with alternative annual standards below 12 $\mu g/m^3$, the Policy Assessment recognizes that there is potentially greater uncertainty associated with these risk estimates compared with estimates generated for the higher alternative annual standard levels considered

in the quantitative risk assessment, since these estimates required simulation of relatively greater reductions in ambient $PM_{2.5}$ concentrations (US EPA, 2011a, p. 2-98).

The results of simulating alternative suites of $PM_{2.5}$ standards including a combination of alternative annual and 24-hour standard levels suggest that an alternative 24-hour standard level can produce additional estimated risk reductions beyond that provided by an alternative annual standard alone. However, the degree of estimated risk reduction provided by the alternative 24-hour standard is highly variable (US EPA, 2010a, section 4.2.2). Thus, the Risk Assessment concludes more consistent reductions in estimated risk and consequently degrees of public health protection are estimated to result from simulating just meeting the alternative annual standard levels considered (US EPA, 2010a, pp. 5-15 to 5-16). Furthermore, the Policy Assessment concludes that the urban study areas with the greatest degree of estimated reduction associated with simulating just meeting alternative 24-hour standard levels of 30 and 25 $\mu g/m^3$ also had the lowest estimated annual mean $PM_{2.5}$ concentrations, and, therefore, there was substantially lower confidence in these risk estimates (US EPA, 2011a, pp. 2-99 to 2-100).

Based on the consideration of both the qualitative and quantitative assessments of uncertainty, the Risk Assessment concludes it is unlikely that the estimated risks are over-stated, particularly for premature mortality related to long-term $PM_{2.5}$ exposures. In fact, the Policy Assessment and Risk Assessment conclude that the core risk estimates for this category of health effects may well be biased low based on consideration of alternative model specifications evaluated in the sensitivity analyses[59] (US EPA, 2011a, p. 2-41; US EPA, 2010a, p. 5-16; Figures 4-7 and 4-8). In addition, the Policy Assessment recognizes that the currently available scientific information includes evidence for a broader range of health endpoints and at-risk populations beyond those included in the quantitative risk assessment, including lung function growth and respiratory symptoms in children and reproductive and developmental effects (US EPA, 2011a, section 2.2.1).

[59] Most of the alternative model specifications supported by the currently available scientific information produced risk estimates that are higher (by up to a factor of 2 to 3) than the core risk estimates (US EPA, 2011a, pp. 2-40 and 2-41).

In considering the set of quantitative risk estimates and related uncertainties and limitations related to long- and short-term $PM_{2.5}$ exposure discussed above together with consideration of the health endpoints which could not be quantified, the Policy Assessment concludes this information provides strong evidence that risks estimated to remain upon simulating just meeting the current suite of $PM_{2.5}$ standards are important from a public health perspective, both in terms of severity and magnitude (US EPA, 2011a, p. 2-47). Furthermore, while the alternative 24-hour standard levels considered (when controlling) did result in additional estimated risk reductions beyond those estimated for alternative annual standards alone, these additional estimated reductions are highly variable, in part due to different rollback approaches. Conversely, the Risk Assessment recognizes that alternative annual standard levels, when controlling, resulted in more consistent risk reductions across urban study areas, thereby potentially providing a more consistent degree of public health protection (US EPA, 2010a, p. 5-17).

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

The initial issue to be addressed in the current review of the primary $PM_{2.5}$ standards is whether, in view of the additional information now available, the existing standards should be retained or revised. In evaluating whether it is appropriate to retain or revise the current suite of standards, the Administrator considered the scientific information from the last review and the broader body of evidence and information now available. The Administrator has taken into account both evidence- and risk-based considerations in developing conclusions on the adequacy of the current primary $PM_{2.5}$ standards. Evidence-based considerations (section III.D.1) include the assessment of epidemiological, toxicological, and controlled human exposure studies evaluating long- or short-term exposures to $PM_{2.5}$, with supporting evidence related to dosimetry and potential pathways/modes of action, as well as the integration of evidence across each of these disciplines, as assessed in the Integrated Science Assessment (US EPA, 2009a) and focus on the policy-relevant considerations as discussed in section III.B above and in the Policy Assessment (US EPA, 2011a, section 2.2.1). The risk-based considerations (section III.D.2) draw from the results of the quantitative analyses presented in the Risk Assessment (US

EPA, 2010a) and focus on the policy-relevant considerations as discussed in section III.C above and in the Policy Assessment (US EPA, 2011a, section 2.2.2). The advice received from CASAC is discussed in section III.D.3. Finally, the Administrator's proposed conclusion on the adequacy of the current $PM_{2.5}$ primary standards is provided in section III.D.4.

1. Evidence-based Considerations in the Policy Assessment

In light of the health evidence described above, specifically with regard to factors contributing to greater susceptibility to health effects associated with ambient $PM_{2.5}$ exposures, the Policy Assessment considers the extent to which the currently available scientific evidence reports associations between fine particle exposures and health effects that extend to air quality concentrations that are lower than had previously been observed or that have been observed in areas that would likely meet the current suite of $PM_{2.5}$ standards (US EPA, 2011a, section 2.2.1). As noted above, the Integrated Science Assessment concludes there is no evidence to support the existence of a discernible threshold below which effects would not occur (US EPA, 2009a, section 2.4.3).

a. Associations with Long-term $PM_{2.5}$ Exposures

With regard to associations observed in long-term $PM_{2.5}$ exposure studies, the Policy Assessment recognizes that extended follow-up analyses of the ACS and Harvard Six Cities studies provide consistent and stronger evidence of an association with mortality at lower air quality distributions than had previously been observed (US EPA, 2011a, pp. 2-31 to 2-32). The original and reanalysis of the ACS study reported positive and statistically significant effects associated with a long-term mean $PM_{2.5}$ concentration of 18.2 $\mu g/m^3$ across 50 metropolitan areas for 1979-1983 (Pope et al., 1995; Krewski et al., 2000).[60] In extended analyses, positive and statistically significant effects of approximately similar magnitude were associated with declining $PM_{2.5}$ concentrations, from an aggregate long-term mean in

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

58 metropolitan areas of 21.2 μg/m^3 in the original monitoring period (1979-1983) to 14.0 μg/m^3 for 116 metropolitan areas in the most recent years evaluated (1999-2000), with an overall average across the two study periods in 51 metropolitan areas of 17.7 μg/m^3 (Pope et al., 2002; Krewski et al., 2009). With regard to the Harvard Six Cities Study, the original and reanalysis reported positive and statistically significant effects associated with a long-term mean $PM_{2.5}$ concentration of 18.0 μg/m^3 for 1980-1985 (Dockery et al., 1993; Krewski et al., 2000). In an extended follow-up of this study, the aggregate long-term mean concentration across all years evaluated was 16.4 μg/m^3 for 1980-1988[61] (Laden et al., 2006). In an additional analysis of the extended follow-up of the Harvard Six Cities study, investigators reported that the concentration-response relationship was linear and "clearly continuing below the level" of the current annual standard (US EPA, 2009a, p. 7-92; Schwartz et al., 2008).

New cohort studies provide additional evidence of mortality associated with air quality distributions that are generally lower than those reported in the ACS and Harvard Six Cities studies, with effect estimates that were similar or greater in magnitude (US EPA, 2011a, pp. 2-32 to 2-33). The WHI study reported positive and most often statistically significant associations between long-term $PM_{2.5}$ exposure and cardiovascular-related mortality, with much larger relative risk estimates than in the ACS and Harvard Six Cities studies, as well as morbidity effects at an aggregate long-term mean $PM_{2.5}$

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

concentration of 12.9 μg/m^3 for 2000 (Miller et al., 2007).[62] Using the Medicare cohort, Eftim et al. (2008) reported somewhat higher effect estimates than in the ACS and Harvard Six Cities studies with aggregate long-term mean concentrations of 13.6 μg/m^3 and 14.1 μg/m^3, respectively, for 2000-2002. The MCAPS reported associations between long-term $PM_{2.5}$ exposure and mortality for the eastern region of the U.S. at an aggregated long-term $PM_{2.5}$ median concentration of 14.0 μg/m^3, although no association was reported for the western region with an aggregate long-term $PM_{2.5}$ median concentration of 13.1 μg/m^3 (US EPA, 2009a, p. 7-88; Zeger et al., 2008).[63] Premature mortality in children reported in a national infant mortality study as well as mortality in a cystic fibrosis cohort including both children and adults reported positive but statistically nonsignificant effects associated with long-term aggregate mean concentrations of 14.8 μg/m^3 and 13.7 μg/m^3, respectively (Woodruff et al., 2008; Goss et al., 2004).

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[62] Miller et al. (2007) studied postmenopausal women without previous cardiovascular disease in 36 study areas from 1994 to 1998, with a median follow-up period of six years. The ambient $PM_{2.5}$ monitor nearest to a study subject's residence (within 30 miles or 48 kilometers) was identified and used to assign long-term mean $PM_{2.5}$ concentrations to each subject. The annual average concentration in the year 2000 was the primary exposure measure because of the substantially increased network of monitors in that year, as compared with previous years. Miller et al. (2007) reported a long-term mean $PM_{2.5}$ concentration across study areas of 13.5 μg/m^3. This concentration was presented in the Integrated Science Assessment (US EPA, 2009a, Figure 2-2, Table 7-8) and discussed in the second draft Policy Assessment (US EPA, 2010f, Figure 2-4). In response to a request from the EPA for additional information on the air quality data used in selected epidemiological studies (Hassett-Sipple and Stanek, 2009), study investigators provided updated air quality data for the study period. The updated long-term mean $PM_{2.5}$ concentration provided by the study authors was 12.9 μg/m^3 (personal communication from Cynthia Curl, 2009; Stanek et al., 2010). The EPA notes that this updated long-term mean concentration matches the composite monitor approach annual mean calculated by staff for the year of air quality data (i.e., 2000) considered by the study investigators (Hassett-Sipple et al., 2010, Attachment A, p. 6). The updated air quality data for the Women's Health Initiative study was presented and considered in the final Policy Assessment (US EPA, 2011a, p. 2-32). The Policy Assessment notes that in comparison to other long-term exposure studies, the WHI study was more limited in that it was based on only one year of air quality data (US EPA, 2011a, p. 2-82).

[63] Zeger et al. (2008) also reported positive and statistically significant effects for the central region, with an aggregate long-term mean $PM_{2.5}$ concentration of 10.7 μg/m^3. However, in contrast to the eastern and western risk estimates, the central risk estimate increased with adjustment for COPD (used as a proxy for smoking status). Due to the potential for confounding bias influencing the risk estimate for the central region, the Policy Assessment did not focus on the results reported in the central region to inform the adequacy of the current suite of standards or alternative annual standard levels (US EPA, 2011a, p. 2-32).

With respect to respiratory morbidity effects associated with long-term $PM_{2.5}$ exposure, the across-city mean of 2-week average $PM_{2.5}$ concentrations reported in the initial Southern California Children's Health Study was approximately 15.1 μg/m^3 (Peters et al., 1999). These results were found to be consistent with results of cross-sectional analyses of the 24-Cities Study (Dockery et al., 1996; Raizenne et al., 1996), which reported a long-term cross-city mean $PM_{2.5}$ concentration of 14.5 μg/m^3. In this review, extended analyses of the Southern California Children's Health Study provide stronger evidence of $PM_{2.5}$-related respiratory effects, at lower air quality concentrations than had previously been reported, with a four-year aggregate mean concentration of 13.8 μg/m^3 across the 12 study communities (McConnell et al., 2003; Gauderman et al., 2004, US EPA, 2009a, Figure 7-4).

In also considering health effects for which the Integrated Science Assessment concludes evidence is suggestive of a causal relationship, the Policy Assessment notes a limited number of birth outcome studies that reported positive and statistically significant effects related to aggregate long-term mean $PM_{2.5}$ concentrations down to approximately 12 μg/m^3 (US EPA, 2011a, p. 2-33).

Collectively, the Policy Assessment concludes that currently available evidence provides support for associations between long-term $PM_{2.5}$ exposure and mortality and morbidity effects that extend to air quality concentrations that are lower than had previously been observed, with aggregate long-term mean $PM_{2.5}$ concentrations extending to well below the level of the current annual standard. These studies evaluated a broader range of health outcomes in the general population and in at-risk populations than were considered in the last review, and include extended follow-up for prospective epidemiological studies that were important in the last review as well as additional evidence in important new cohorts.

b. Associations with Short-term $PM_{2.5}$ Exposures

In light of the mixed findings reported in single-city, short-term exposure studies, the Policy Assessment places comparatively greater weight on the results from multi-city studies in considering the adequacy of the current suite of standards (US EPA, 2011a, pp. 2-34 to 2-35). With regard to associations reported in short-term $PM_{2.5}$ exposure studies, the Policy Assessment recognizes that long-

term mean concentrations reported in new multi-city U.S. and Canadian studies provide evidence of associations between short-term $PM_{2.5}$ exposure and mortality at similar air quality distributions than had previously been observed in an 8-cities Canadian study (Burnett and Goldberg, 2003; aggregate long-term mean $PM_{2.5}$ concentration of 13.3 $\mu g/m^3$). 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 $\mu g/m^3$ (US EPA, 2009a, Figure 6-24). Furthermore, city-specific effect estimates indicate the association between short-term exposure to $PM_{2.5}$ and total mortality and cardiovascular- and respiratory-related mortality is consistently positive for an overwhelming majority (99 percent) of the 112 cities across a wide range of air quality concentrations (long-term mean concentrations ranging from 6.6 $\mu g/m^3$ to 24.7 $\mu g/m^3$; US EPA, 2009a, Figure 6-24, p. 6-178 to 179). The EPA staff notes that for all-cause mortality, city-specific effect estimates were statistically significant for 55 percent of the 112 cities, with long-term city-mean $PM_{2.5}$ concentrations ranging from 7.8 $\mu g/m^3$ to 18.7 $\mu g/m^3$ and 24-hour $PM_{2.5}$ city-mean 98th percentile concentrations ranging from 18.4 to 64.9 $\mu g/m^3$ (personal communication with Dr. Antonella Zanobetti, 2009).[64]

With regard to cardiovascular and respiratory morbidity effects, in the first analysis of the MCAPS cohort conducted by Dominici et al. (2006a) across 204 U.S. counties, investigators reported a statistically significant association with hospitalizations for cardiovascular and respiratory diseases and short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 13.4 $\mu g/m^3$. Furthermore, a sub-analysis restricted to days with 24-hour average concentrations of $PM_{2.5}$ at or below 35 $\mu g/m^3$ 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

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

hospital admissions for cardiovascular and respiratory diseases (Dominici, 2006b).[65] In an extended analysis of the MCAPS study, Bell et al (2008) reported a positive and statistically significant increase in cardiovascular hospitalizations associated with short-term $PM_{2.5}$ exposure, in which the aggregate long-term mean $PM_{2.5}$ concentration was 12.9 $\mu g/m^3$. 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 $\mu g/m^3$, not only indicate that effects are occurring in areas that would meet the current standards but also suggest that the overall health effects observed across the U.S. are not primarily driven by the higher end of the $PM_{2.5}$ air quality distribution (Bell, 2009a, personal communication from Dr. Michelle Bell regarding air quality data for Bell et al., 2008 and Dominici et al., 2006a).

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

In evaluating the currently available scientific evidence, as summarized in section III.B, the Policy Assessment first concludes that there is stronger and more consistent and coherent support for associations between long- and short-term $PM_{2.5}$ exposures and a broad range of health outcomes than was available in the last review, providing the basis for fine particle standards at least as protective as the current $PM_{2.5}$ standards (US EPA, 2011a, p. 2-26). Having reached this initial conclusion, the Policy Assessment addresses the question of whether the available evidence supports consideration of standards

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

that are more protective than the current standards. In so doing, the Policy Assessment considers whether there is now evidence that health effect associations have been observed in areas that likely met the current suite of $PM_{2.5}$ standards. As discussed above, long- and short-term $PM_{2.5}$ exposure studies provide evidence of associations with mortality and cardiovascular and respiratory effects both at lower ambient $PM_{2.5}$ concentrations than had been observed in the previous review and at concentrations allowed by the current standards (US EPA, 2011a, p. 2-35).

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

2. Summary of Risk-based Considerations in the Policy Assessment

In addition to evidence-based consideration, the Policy Assessment also considers the extent to which health risks estimated to occur upon simulating just meeting the current $PM_{2.5}$ standards may be judged to be important from a public health perspective, taking into account key uncertainties associated with the quantitative health risk estimates. In so doing, the Policy Assessment first notes that the quantitative risk assessment addresses: (1) the core $PM_{2.5}$-related risk estimates; (2) the related uncertainty and sensitivity analyses, including additional sets of reasonable risk estimates generated to supplement the core analysis; (3) an assessment of the representativeness of the urban study areas within

a national context;[66] and (4) consideration of patterns in design values and air quality monitoring data to inform interpretation of the risk estimates, as discussed in section III.C above.

In considering the health risks estimated to remain upon simulation of just meeting the current suite of standards and considering both the qualitative and quantitative assessment of uncertainty completed as part of the assessment, the Policy Assessment concludes these risks are important from a public health standpoint (US EPA, 2011a, p. 2-47). This conclusion reflects consideration of both the severity and the magnitude of the effects. For example, the risk assessment indicates the possibility that premature deaths related to ischemic heart disease associated with long-term $PM_{2.5}$ exposure alone would likely be on the order of thousands of deaths per year in the 15 urban study areas upon simulating just meeting the current standards[67] (US EPA, 2011a, pp. 2-46 to 2-47). Moreover, additional risks are anticipated for premature mortality related to cardiopulmonary effects and lung cancer associated with long-term $PM_{2.5}$ exposure as well as mortality and cardiovascular- and respiratory-related morbidity effects (e.g., hospital admissions, emergency department visits) associated with short-term $PM_{2.5}$ exposures. Based on the consideration of both qualitative and quantitative assessments of uncertainty completed as part of the quantitative risk assessment, the Risk Assessment concludes that it is unlikely that the estimated risks are over-stated, particularly for mortality related to long-term $PM_{2.5}$ exposure, and may well be biased low based on consideration of alternative model specifications evaluated in the sensitivity analyses (US EPA, 2010a, p. 5-16; US EPA, 2011a, p. 2-41). Furthermore, the currently available scientific information summarized in section III.B above provides evidence for a broader range of health endpoints and at-risk populations beyond those included in the quantitative risk assessment (US EPA, 2011a, p. 2-47).

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

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

In considering the risks estimated to occur upon simulating just meeting the current $PM_{2.5}$ standards, the Policy Assessment concludes that these estimated risks can reasonably be judged to be important from a public health perspective and provide strong support for consideration of alternative standards that would provide increased protection beyond that afforded by the current $PM_{2.5}$ standards (US EPA, 2011a, p. 2-48).

3. CASAC Advice

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

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

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

In considering the adequacy of the current suite of $PM_{2.5}$ standards, the Administrator has considered the large body of evidence presented and assessed in the Integrated Science Assessment (US EPA, 2009a), the staff conclusions and associated rationales presented in the Policy Assessment, views expressed by CASAC, and public comments. In particular, the Administrator recognizes that the Integrated Science Assessment concludes that the results of epidemiological and experimental studies form a plausible and coherent data set that supports a causal relationship between long- and short-term

$PM_{2.5}$ exposures and mortality and cardiovascular effects, and a likely causal relationship between long- and short-term $PM_{2.5}$ exposures and respiratory effects. Moreover, the Administrator reflects that these effects have been observed at lower ambient $PM_{2.5}$ concentrations than what had been observed in the last review, including at ambient $PM_{2.5}$ concentrations in areas that likely met the current $PM_{2.5}$ NAAQS. *See American Trucking Associations v. EPA*, 283 F. 3d at 369, 376 (revision of level of existing standards justified when effects are observed in areas that meet those standards). With regard to the results of the quantitative risk assessment, the Administrator notes that the Risk Assessment concludes that the risks estimated to remain upon simulation of just meeting the current standards are important from a public health standpoint in terms of both the severity and magnitude of the effects.

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

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

1. Indicator

In initially setting standards for fine particles in 1997, the EPA concluded it was appropriate to control fine particles as a group, rather than singling out any particular component or class of fine particles. The EPA noted that community health studies had found significant associations between various indicators of fine particles, and that health effects in a large number of areas had significant mass contributions of differing components or sources of fine particles. In addition, a number of toxicological and controlled human exposure studies had reported health effects associations with high

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

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

The Policy Assessment also considers the expanded body of evidence available in this review to

consider whether there is sufficient evidence to support a separate standard for ultrafine particles[68] or whether there is sufficient evidence to establish distinct standards focused on regulating specific $PM_{2.5}$ components or a group of components associated with any source categories of fine particles (US 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 (US 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 (US 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 (US 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 (US EPA, 2009a, p. 6-127).

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

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

2009a, p. 2-22, see also section 1.5.3).

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

Collectively, in considering the body of scientific evidence available in this review, the Integrated Science Assessment concludes that the currently available evidence is suggestive of a causal relationship between short-term exposures to ultrafine particles and cardiovascular and respiratory effects. Furthermore, the Integrated Science Assessment concludes that evidence is inadequate to infer a causal relationship between short-term exposure to ultrafine particles and mortality as well as long-term exposure to ultrafine particles and all outcomes evaluated (US 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 (US EPA, 2009a, p. 2-2). Therefore, the Policy Assessment recognizes a national characterization of concentrations, temporal and spatial patterns, and trends is not possible at this time, and the availability of ambient ultrafine measurements to support health studies is extremely limited (US EPA, 2011a, p. 2-51). In general, measurements of ultrafine particles are highly dependent on monitor location and, therefore, more subject to exposure error than accumulation mode particles (US 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 (US EPA, 2009a, p. 3-89). Limited studies of ambient ultrafine particle measurements suggest these particles exhibit a high degree of spatial and temporal heterogeneity driven primarily by differences in nearby source characteristics (US 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 (US 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 (US EPA, 2009a, p. 3-84).

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

In addressing the issue of particle composition, the Integrated Science Assessment concludes that, "[f]rom a mechanistic perspective, it is highly plausible that the chemical composition of PM would be a better predictor of health effects than particle size" (US 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 (US EPA, 2009a, section 6.6).

With respect to the availability of ambient measurement data for fine particle components in this review, there are now more extensive ambient $PM_{2.5}$ speciation measurement data available through the Chemical Speciation Network (CSN) than in previous reviews (US EPA, 2011a, section 1.3.2 and Appendix B, section B.1.3). Data from the CSN provide further evidence of spatial and seasonal variation in both $PM_{2.5}$ mass and composition among cities and geographic regions (US 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 (US 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 (US 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 (US EPA, 2009a, p. 6-203).[69] The CSN provides $PM_{2.5}$ speciation measurements generally on a one-in-three or one-in-six day sampling schedule and, thus, do not capture data every day at most sites.[70]

The Policy Assessment recognizes that several new multi-city studies evaluating short-term exposures to fine particle constituents are now available. These studies continue to show an association between mortality and cardiovascular and/or respiratory morbidity effects and short-term exposures to various $PM_{2.5}$ components including nickel, vanadium, elemental carbon, organic carbon, nitrates, and sulfates (US EPA, 2011a, section 2.3.1; US 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 (US EPA, 2009a, section 7.6.2). The Policy Assessment notes the most significant new evidence is provided by a study that evaluated multiple $PM_{2.5}$ components and an indicator of traffic density in an assessment of health effects related to long-term exposure to $PM_{2.5}$ (Lipfert et al., 2006). Using health data from a cohort of U.S. military veterans and $PM_{2.5}$ measurement data from the CSN, Lipfert et al. (2006) reported positive associations between mortality and long-term exposures to nitrates, elemental carbon, nickel, and vanadium as well as traffic density and peak ozone concentrations (US EPA, 2011a, p. 2-54; US EPA, 2009a, pp. 7-89 to 7-90).

With respect to source categories of fine particles associated with a range of health endpoints, the Integrated Science Assessment reports that the currently available evidence suggests associations

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

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

between cardiovascular effects and a number of specific $PM_{2.5}$–related source categories, specifically oil combustion, wood or biomass burning, motor vehicle emissions, and crustal or road dust sources (US EPA, 2009a, section 6.6; Table 6-18). In addition, a few studies have evaluated associations between $PM_{2.5}$-related source categories and mortality. These studies include a study that reported an association between mortality and a $PM_{2.5}$ coal combustion factor (Laden et al., 2000), while other studies linked mortality to a secondary sulfate long-range transport $PM_{2.5}$ source (Ito et al., 2006; Mar et al., 2006) (US EPA, 2009a, section 6.6.2.1). There is less consistency in associations observed between sources of fine particles and respiratory health effects, which may be partially due to the fact that fewer studies have evaluated respiratory-related outcomes and measures. However, there is some evidence for $PM_{2.5}$-related associations with secondary sulfate and decrements in lung function in asthmatic and healthy adults (US EPA, 2009a, p. 6-211; Gong et al., 2005; Lanki et al., 2006). Respiratory effects relating to the crustal/soil/road dust and traffic sources of PM have been observed in asthmatic children and adults (US 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 (US EPA, 2009a, p. 6-211; Hopke et al., 2006; Ito et al., 2006; Mar et al., 2006; Thurston et al., 2005). These studies reported associations between total mortality and secondary sulfate in two cities for two different lag times. The sulfate effect was stronger for total mortality in Washington D.C. and for cardiovascular-related morality in Phoenix (US 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 (US 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 (US EPA, 2009a, pp. 6-204 and 6-211).

Collectively, in considering the currently available evidence for health effects associated with specific $PM_{2.5}$ components or groups of components associated with any source categories of fine particles as presented in the Integrated Science Assessment, the Policy Assessment concludes that additional information available in this review continues to provide evidence that many different constituents of the fine particle mixture as well as groups of components associated with specific source categories of fine particles are linked to adverse health effects (US 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" (US EPA, 2009a, p. 6-210). Assessing this information, the Integrated Science Assessment concludes that "the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes" (US EPA, 2009a, pp. 2-26 and 6-212). Therefore, the Policy Assessment concludes that the currently available evidence is not sufficient to support consideration of a separate indicator for a specific $PM_{2.5}$ component or group of components associated with any source category of fine particles. Furthermore, the Policy Assessment concludes that the evidence is not sufficient to support eliminating any component or group of components associated with any source categories of fine particles from the mix of fine particles included in the $PM_{2.5}$ indicator (US EPA, 2011a, p. 2-56).

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

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

2. Averaging Time

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

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

In considering whether the information available in this review supports consideration of different averaging times for $PM_{2.5}$ standards specifically with regard to considering a standard with an averaging time less than 24 hours to address health effects associated with sub-daily $PM_{2.5}$ exposures,

the Policy Assessment notes there continues to be a growing body of studies that provide additional evidence of effects associated with exposure periods less than 24-hours (US 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 (US EPA, 2009a, section 6.2). Because these studies have used different indicators (e.g., $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$, ultrafine particles), averaging times (e.g., 1, 2, and 4 hours), and health outcomes, it is difficult to draw conclusions about cardiovascular effects associated specifically with sub-daily exposures to $PM_{2.5}$.

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

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

With regard to health effects associated with $PM_{2.5}$ exposure across varying seasons in this review, Bell et al. (2008) reported higher $PM_{2.5}$ risk estimates for hospitalization for cardiovascular and respiratory diseases in the winter compared to other seasons. In comparison to the winter season, smaller statistically significant associations were also reported between $PM_{2.5}$ and cardiovascular morbidity for spring and autumn, and a positive, but statistically non-significant association was observed for the summer months. In the case of mortality, Zanobetti and Schwartz (2009) reported a 4-fold higher effect estimate for $PM_{2.5}$ associated mortality for the spring as compared to the winter. Taken together, these

results provide emerging but limited evidence that individuals may be at greater risk of dying from higher exposures to $PM_{2.5}$ in the warmer months and may be at greater risk of $PM_{2.5}$-associated hospitalization for cardiovascular and respiratory diseases during colder months of the year (US EPA, 2011a, p. 2-58).

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

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

3. Form

The "form" of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard. In this review, we consider whether currently available information supports consideration of alternative forms for the annual or 24-hour

$PM_{2.5}$ standards.

a. Annual Standard

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

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

In this review, as discussed in section III.B.3, there now exist more health data such that the Integrated Science Assessment has identified persons from lower socioeconomic strata as an at-risk population (US EPA, 2009a, section 8.1.7; US EPA, 2011a, section 2.2.1). Moreover, there now exist more years of $PM_{2.5}$ air quality data than were available in the last review. Consideration in the Policy Assessment of the spatial variability across urban areas that is revealed by this expanded data base has

raised questions as to whether an annual standard that allows for spatial averaging, even within specified constraints as narrowed in 2006, would provide appropriate public health protection.

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

Based upon the analysis described above, the Policy Assessment concludes that the existing constraints on spatial averaging, as modified in 2006, may be inadequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on at-risk populations of persons with lower SES levels as well as minorities. Therefore, the Policy Assessment concludes that it

is appropriate to consider revising the form of the annual $PM_{2.5}$ standard such that it does not allow for the use of spatial averaging across monitors. In doing so, the level of the annual $PM_{2.5}$ standard would be compared to measurements made at the monitoring site that represents area-wide air quality recording the highest $PM_{2.5}$ concentrations[71] (US EPA, 2011a, p. 2-60).

The CASAC agreed with staff conclusions that it is "reasonable" for the EPA to eliminate the spatial averaging provisions (Samet, 2010d, p. 2). Further, in CASAC's comments on the first draft Policy Assessment, they noted, "Given mounting evidence showing that persons with lower SES levels are a susceptible group for PM-related health risks, CASAC recommends that the provisions that allow for spatial averaging across monitors be eliminated for the reasons cited in the (first draft) Policy Assessment" (Samet, 2010c, p. 13).

In considering the Policy Assessment's conclusions based on the results of the analysis discussed above and concern over the evidence of potential disproportionate impacts on at-risk populations as well as CASAC advice, the Administrator proposes to revise the form of the annual $PM_{2.5}$ standard to eliminate the use of spatial averaging. Thus, the Administrator proposes revising the form of the annual $PM_{2.5}$ standard to compare the level of the standard with measurements from each "appropriate" monitor in an area[72] with no allowance for spatial averaging. Thus, for an area with multiple monitors, the appropriate reporting monitor with the highest design value would determine the attainment status for that area.

b. 24-Hour Standard

In 1997, the EPA established the form of the 24-hour $PM_{2.5}$ standard as the 98th percentile of 24-hour concentrations at each population-oriented monitor within an area, averaged over three years

[71] As discussed in section VIII.B.1 below, the EPA is proposing to revise several terms associated with $PM_{2.5}$ monitor placement. Specifically, the EPA is proposing to revoke the term "community-oriented" and replace it with the term "area-wide" monitoring.

[72] As discussed in section VIII.B.2.b below, the EPA proposes that $PM_{2.5}$ monitoring sites at micro- and middle-scale locations be comparable to the annual standard unless the monitoring site has been approved by the Regional Administrator as a "relatively unique micro-scale, or localized hot-spot, or unique middle-scale site."

(62 FR at 38671 to 38674, July 18, 1997). The Agency selected the 98th percentile as an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability which, when averaged over 3 years, facilitated effective health protection through the development of more stable implementation programs. By basing the form of the standard on concentrations measured at population-oriented monitoring sites, the EPA intended to provide protection for people residing in or near localized areas of elevated concentrations. In the last review, in conjunction with lowering the level of the 24-hour standard, the EPA retained this form based in part on a comparison with the 99th percentile form.[73]

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

The Agency recognizes that the selection of the appropriate form of the 24-hour standard includes maintaining adequate protection against peak 24-hour concentrations while also providing a stable target for risk management programs, which serves to provide for the most effective public health protection in the long run.[74] As in previous reviews, the EPA recognizes that a concentration-based form, compared to an exceedance-based form, is more reflective of the health risks posed by elevated pollutant concentrations because such a form gives proportionally greater weight to days when

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

[74] See *ATA III*, 283 F.3d at 374-376 which concludes that it is legitimate for the EPA to consider overall stability of the standard and its resulting promotion of overall effectiveness of NAAQS control programs in setting a standard that is requisite to protect the public health. The context for the court's discussion is identical to that here; whether to adopt a 98th percentile form for a 24-hour primary $PM_{2.5}$ standard intended to provide supplemental protection for a generally controlling annual standard.

concentrations are well above the level of the standard than to days when the concentrations are just above the level of the standard. Further, the Agency concludes that a concentration-based form, when averaged over three years, provides an appropriate balance between limiting peak pollutant concentrations and providing a stable regulatory target, thus facilitating the development of more stable implementation programs.

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

4. Level

In the last review, the EPA selected levels for the annual and the 24-hour $PM_{2.5}$ standards using evidence of effects associated with periods of exposure that were most closely matched to the averaging time of each standard. Thus, as discussed in section III.A.1, the EPA relied upon evidence from long-term exposure studies as the principal basis for selecting the level of the annual $PM_{2.5}$ standard that would protect against effects associated with long-term exposures. The EPA relied upon evidence from the short-term exposures studies as the principal basis for selecting the level of the 24-hour $PM_{2.5}$ standard that would protect against effects associated with short-term exposures. As summarized in section III.A.2 above, the 2006 decision to retain the level of the annual $PM_{2.5}$ standard at 15 $\mu g/m^3$ [75] was challenged and on judicial review, the D.C. Circuit remanded the primary annual $PM_{2.5}$ standard to the EPA, finding that EPA's explanation for its approach to setting the level of the annual standard was

[75] Throughout this section, the annual standard level is denoted as an integer value for simplicity, although, as noted above in section II.B.1, Table 1, the standard level is defined to one decimal place, such that the current standard level is 15.0 $\mu g/m^3$. Alternative standard levels discussed in this section are similarly defined to one decimal place.

inadequate.

a. Approach Used in the Policy Assessment

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

Beyond looking directly at the relevant epidemiologic evidence, the Policy Assessment considers the extent to which specific alternative $PM_{2.5}$ standard levels are likely to reduce the nature and magnitude of both long-term exposure-related mortality risk and short-term exposure-related mortality and morbidity risk (US EPA, 2011a, section 2.3.4.2; U.S.EPA, 2010a, section 4.2.2). As noted in section III.C.3 above, patterns of increasing estimated risk reductions are generally observed as either the annual or 24-hour standard, or both, are reduced below the level of the current standards (US 2011a, Figures 2-11 and 2-12; US EPA, 2010a, sections 4.2.2, 5.2.2, and 5.2.3).

Based on the quantitative risk assessment, the Policy Assessment observes, as discussed in section III.A.3, that analyses conducted for this and previous reviews demonstrate that much, if not most, of the aggregate risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low-to mid-range, below the peak 24-hour concentrations (US EPA, 2011a, p. 2-9). Furthermore, as discussed in section III.C.3, the Risk Assessment observes that alternative annual standard levels, when controlling, resulted in more

consistent risk reductions across urban study areas, thereby potentially providing a more consistent degree of public health protection (US EPA, 2010a, pp. 5-15 to 5-16). In contrast, the Risk Assessment notes that while the results of simulating alternative suites of $PM_{2.5}$ standards including different combinations of alternative annual and 24-hour standard levels suggest that an alternative 24-hour standard level can produce additional estimated risk reductions beyond that provided by an alternative annual standard alone. However, the degree of estimated risk reduction provided by alternative 24-hour standard levels is highly variable, in part due to the choice of rollback approached used (US EPA, 2010a, p. 5-17).

Therefore, the Policy Assessment concludes, consistent with CASAC advice (Samet 2010c, p. 1), that it is appropriate to set a "generally controlling" annual standard that will lower a wide range of ambient 24-hour concentrations. The Policy Assessment concludes this approach would likely reduce aggregate risks associated with both long- and short-term exposures with more consistency than a generally controlling 24-hour standard and would be the most effective and efficient way to reduce total PM_{2-5}-related population risk and so provide appropriate protection. The staff believes this approach, in contrast to one focusing on a generally controlling 24-hour standard, would likely reduce aggregate risks associated with both long- and short-term exposures with more consistency and would likely avoid setting national standards that could result in relatively uneven protection across the country due to setting standards that are either more or less stringent than necessary in different geographical areas.

The Policy Assessment recognizes that an annual standard intended to serve as the primary means for providing protection against effects associated with both long- and short-term $PM_{2.5}$ exposures cannot be expected to offer an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures. As a result, in conjunction with a generally controlling annual standard, the Policy Assessment concludes it is appropriate to consider setting a 24-hour standard to provide supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure

periods.

Based on the above considerations, the approach used in the Policy Assessment to identify alternative standard levels that are appropriate for consideration focuses on translating information from epidemiological studies into the basis for staff conclusions on levels. This approach is broader and more integrative than the general approach used by the EPA in previous reviews (see summary in section III.A.3 above; US EPA, 2011a, sections 2.1.3 and 2.3.4.1) and reflects the more extensive and stronger body of scientific evidence now available on health effects related to long- and short-term $PM_{2.5}$ exposures, a more comprehensive quantitative risk assessment, and more extensive $PM_{2.5}$ air quality data. In considering the currently available information, the Policy Assessment focuses on identifying levels for an annual standard and a 24-hour standard that, in combination, provide protection against health effects associated with both long- and short-term $PM_{2.5}$ exposures. The Policy Assessment also considers the extent to which various combinations of annual and 24-hour standards reflect setting a generally controlling annual standard with a 24-hour standard providing supplemental protection (US EPA, 2011a, sections 2.1.3, 2.3.4.1).

As discussed in the Policy Assessment, EPA staff recognizes that there is no single factor or criterion that comprises the "correct" approach for reaching conclusions on alternative standard levels for consideration, but rather there are various approaches that are reasonable to consider (US EPA, 2011a, section 2.3.4.1). In reaching conclusions in the Policy Assessment on the ranges of standard levels that are appropriate to consider, staff considered the relative weight to place on different evidence. The Policy Assessment initially focuses on long- and short-term $PM_{2.5}$ exposure studies conducted in the U.S. and Canada and places the greatest weight on health outcomes judged in the Integrated Science Assessment as having evidence to support a causal or likely causal relationship. The Policy Assessment also considers the evidence for a broader range of health outcomes judged in the Integrated Science Assessment to have evidence suggestive of a causal relationship, specifically studies that focus on effects in susceptible populations, to evaluate whether this evidence provides support for considering

lower alternative standard levels.

Several factors were taken into account in placing relative weight on the body of available epidemiological studies, for example, study characteristics, including study design (e.g., time period of air quality monitoring, control for potential confounders); strength of the study (in terms of statistical significance and precision of results); and availability of population-level and air quality distribution data. As noted above in section III.A.3, the Policy Assessment places greatest weight on information from multi-city epidemiological studies to inform staff conclusions regarding alternative annual standard levels. These studies have a number of advantages compared to single-city studies[76] that include providing representation of ambient $PM_{2.5}$ concentrations and potential health impacts across a range of diverse locations providing spatial coverage for different regions across the country, reflecting differences in $PM_{2.5}$ sources, composition, and potentially other exposure-related factors which might impact $PM_{2.5}$-related risks; lack of 'publication bias' (US EPA, 2004, p. 8-30); and consideration of larger study populations that afford the possibility of generalizing to the broader national population and provide higher statistical power than single-city studies to detect potentially statistically significant associations with relatively more precise effect estimates.

In reaching conclusions in the Policy Assessment regarding alternative 24-hour standard levels that are appropriate to consider, staff also considers relevant information from single-city short-term $PM_{2.5}$ exposure studies. Although, as discussed above, multi-city studies have greater power to detect associations and provide broader geographic coverage in comparison to single-city studies, the extent to which effects reported in multi-city short-term $PM_{2.5}$ exposure studies are associated with the specific short-term air quality in any particular location is unclear, especially when considering short-term

[76] As discussed in section III.B.1 above, the Policy Assessment recognizes that single-city studies provide ancillary evidence to multi-city studies in support of calling into question the adequacy of the current suite of standards. However, in light of the mixed findings reported in single-city short-term $PM_{2.5}$ exposure studies, and the likelihood that these results are influenced by localized events and not representative of air quality across the country, the Policy Assessment places comparatively greater weight on the results from multi-city studies in considering alternative annual and 24-hour standard levels (US EPA, 2011a, p. 2-64).

concentrations at the upper end of the air quality distribution (i.e., at the 98th percentile value) for a given study area. In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the air quality in a given study area is more straightforward. Therefore, the Policy Assessment considers the results of both multi-city and single-city short-term exposure studies to inform staff conclusions regarding alternative levels that are appropriate to consider for a 24-hour standard that is intended to provide supplemental protection in areas where the annual standard may not offer appropriate protection against the effects of all short-term exposures (US EPA, 2011a, pp. 2-62 to 2-65).

b. Consideration of the Annual Standard in the Policy Assessment

In recognizing the absence of a discernible population threshold below which effects would not occur, the Policy Assessment's general approach for identifying alternative annual standard levels that are appropriate to consider focuses on characterizing the range of $PM_{2.5}$ concentrations over which we have the most confidence in the associations reported in the epidemiological studies, and conversely where our confidence in the association becomes appreciably lower. The most direct approach to address this issue, consistent with CASAC advice (Samet, 2010c, p.10), is to consider epidemiological studies reporting confidence intervals around concentration-response relationships (US EPA, 2011a, p. 2-63). Based on a thorough search of the available evidence, the Policy Assessment identified three long-term $PM_{2.5}$ exposure studies reporting confidence intervals around concentration-response functions (i.e., Schwartz et al., 2008; Pope et al., 2002; Miller et al., 2007; US EPA, 2011a, pp. 2-65 to 2-70 and Figure 2-3).[77] In its assessment of these studies, the Policy Assessment places greater weight on analyses that averaged across multiple concentration-response models since this approach represents a more robust examination of the underlying concentration-response relationship than analyses

[77] The EPA carefully analyzed the published evidence, but was unable to identify any short-term $PM_{2.5}$ exposure studies that characterized confidence intervals around concentration-response relationships. Nor did CASAC or public comments on this issue, as addressed in their comments on the second draft Policy Assessment, identify any additional analyses.

considering a single concentration-response model. Although these analyses of long-term exposure to $PM_{2.5}$ provide information on the lack of any discernible population threshold, only Schwartz et al. (2008) conducted a multi-model analysis to characterize confidence intervals around the estimated concentration-response relationship that can help inform at what $PM_{2.5}$ concentrations we have appreciably less confidence in the nature of the underlying concentration-response relationship. Although analyses of confidence intervals associated with concentration-response relationships can help inform consideration of alternative standard levels, the Policy Assessment concludes that the single relevant analysis now available is too limited to serve as the principal basis for identifying alternative standard levels in this review (US EPA, 2011a, p. 2-70).

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

However, consistent with CASAC's comments on the second draft Policy Assessment[78] (Samet,

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

2010d, p. 2), in preparing the final Policy Assessment, EPA staff explored ways to take into account additional information from epidemiological studies, when available (Rajan et al., 2011). These analyses focused on evaluating different statistical metrics, beyond the long-term mean concentration, to characterize the range of $PM_{2.5}$ concentrations down through which staff continued to have confidence in the associations observed in epidemiological studies and below which there is a comparative lack of data such that the staff's confidence in the relationship was appreciably less. This would also be the range of $PM_{2.5}$ concentrations which has the most influence on generating the health effect estimates reported in epidemiological studies. As discussed in section III.A.3 above, the Policy Assessment recognizes there is no one percentile value within a given distribution that is the most appropriate or "correct" way to characterize where our confidence in the associations becomes appreciably lower. The Policy Assessment concludes that focusing on concentrations within the lower quartile of a distribution, such as the range from the 25th to the 10th percentile, is reasonable to consider as a region within which we begin to have appreciably less confidence in the associations observed in epidemiological studies.[79] In staff's 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 (US EPA, 2009a, p. 2-71).

As outlined in section III.A.3 above, the Policy Assessment recognizes that there are two types of population-level information to consider in identifying the range of $PM_{2.5}$ concentrations which have the most influence on generating the health effect estimates reported in epidemiological studies. The

[79] In the last review, staff believed it was appropriate to consider a level for an annual $PM_{2.5}$ standard that was somewhat below the averages of the long-term concentrations across the cities in each of the key long-term exposures studies, recognizing that the evidence of an association in any such study was strongest at and around the long-term average where the data in the study are most concentrated. For example, the interquartile range of long-term average concentrations within a study and a range within one standard deviation around the study mean were considered reasonable approaches for characterizing the range over which the evidence of association is strongest (US 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 (US EPA, 2011a, p. 2-71).

most relevant information to consider is the number of health events (e.g., deaths, hospitalizations) occurring within a study population in relation to the distribution of $PM_{2.5}$ concentrations likely experienced by study participants. However, in recognizing that access to health event data may be restricted, and consistent with advice from CASAC (Samet 2010d, p.2), EPA staff also considered the number of participants within each study area in relation to the distribution of $PM_{2.5}$ concentrations (i.e., study population data), as an appropriate surrogate for health event data.

In applying this approach, the Policy Assessment focuses on identifying the broader range of $PM_{2.5}$ concentrations which had the most influence on generating health effect estimates in epidemiological studies, as discussed in section III.A.3 above. As discussed below, in working with study investigators, EPA staff was able to obtain health event data for three large multi-city studies (Krewski et al., 2009; Zanobetti and Schwartz, 2009; Bell et al., 2008) and population data for the same three studies and one additional long-term exposure study (Miller et al., 2007); as documented in a staff memorandum (Rajan et al., 2011). For the three studies for which both health event and study population data were available, EPA staff analyzed the reliability of using study population data as a surrogate for health event data. Based on these analyses, EPA staff recognized that the $10^{th}$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).

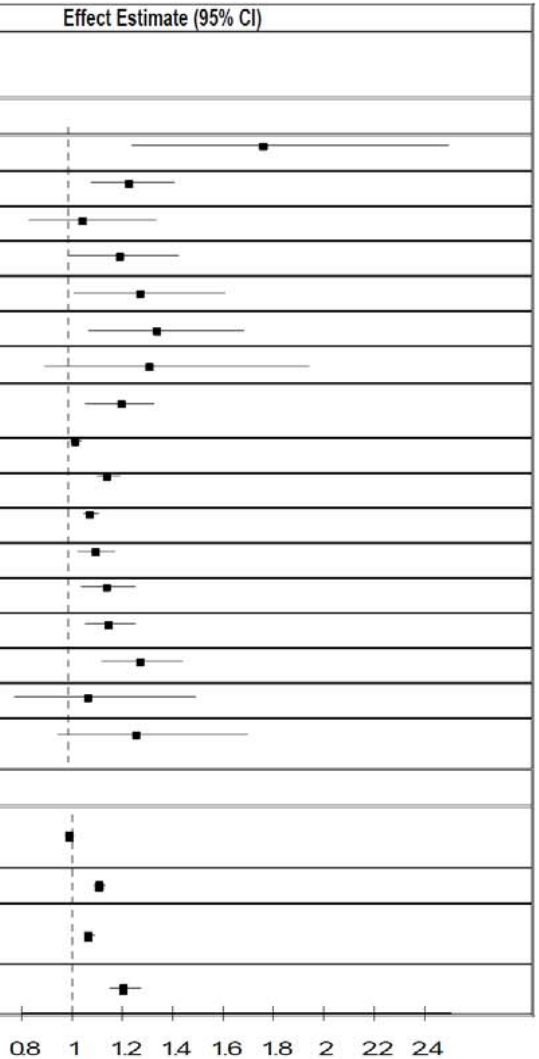
With regard to the long-term mean $PM_{2.5}$ concentrations which are relevant to the first approach, Figures 1 through 3 (US EPA, 2011a, Figures 2-4, 2-5, 2-6, and 2-8) summarize data available for multi-city, long- and short-term exposure studies that evaluated endpoints classified in the Integrated 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.[80] Figures 1 and 3 summarize the health outcomes evaluated, relative risk estimates, air quality data, and geographic scope for long- and short-term exposure studies, respectively, that evaluated mortality (evidence of a causal relationship); cardiovascular effects (evidence of a causal relationship); and respiratory effects (evidence of a likely causal relationship) in the general population, as well as in older adults, an at-risk population. Figure 2 provides this same summary information for long-term exposure studies that evaluated respiratory effects (evidence of a likely causal relationship) in children, an at-risk population, as well as developmental effects (evidence suggestive of a causal relationship). By following the general approach used in previous PM NAAQS reviews, one could consider identifying alternative standard levels that are somewhat below the long-term mean $PM_{2.5}$ concentrations reported in these epidemiological studies.

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

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

Study	Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (µg/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

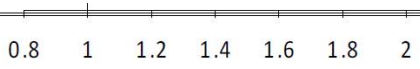


[a]Update of Miller et al. (2007) $PM_{2.5}$ data included in Curl, 2009
[b]Cohort included persons with cystic fibrosis age 6 and older, mean age: 18.4 yrs
[c]Estimated from data provided by study author (Laden, 2009)
[d]Median (IQR: Interquartile range); overall US reported median (IQR) of 13.2 µg/m^3 (11.1-14.9)

Source: US EPA, 2011a, Figure 2-4

Figure 2. Summary of Effect Estimates (per 10 µg/m^3) and Air Quality Distributions for Multi-City, Long-term $PM_{2.5}$ Exposure Studies of Children

Children								
Study	**Cite**	**Geographic Area**	**Years of Air Quality Data**	**Endpoint**	**Air Quality Data (µg/m^3)**			**Effect Estimate (95% CI)**
					Mean	**Mean – 1SD**	**Range**	
	Bell et al. (2007)	CT,MA	1998-2002	Low Birth Weight	11.9[a]	10.3		
	Liu et al. (2007)	3 Canadian cities	1985-1999	IUGR -1nd trimester	12.2	-	6.3-15	
				IUGR -2nd trimester				
				IUGR – 3rd trimester				
	Parker and Woodruff (2008)	Continental US	2000-2003	Low Birth Weight	13.5[a]	-	10.9-16.1 (IQR)	
S CA CHS	McConnell et al. (2003)	12 communities – S CA	1996-1999	Bronchitic Symptoms	13.8	6.1	6-29	
24-Cities	Dockery et al. (1996)	24 communities – US, Canada	1988-1991	Bronchitis	14.5	10.3	5.8-20.7	
	Woodruff et al. (2008)	96 US counties	1999-2002	Infant mortality	14.9[b]	--	12.0-18.6 (IQR)	



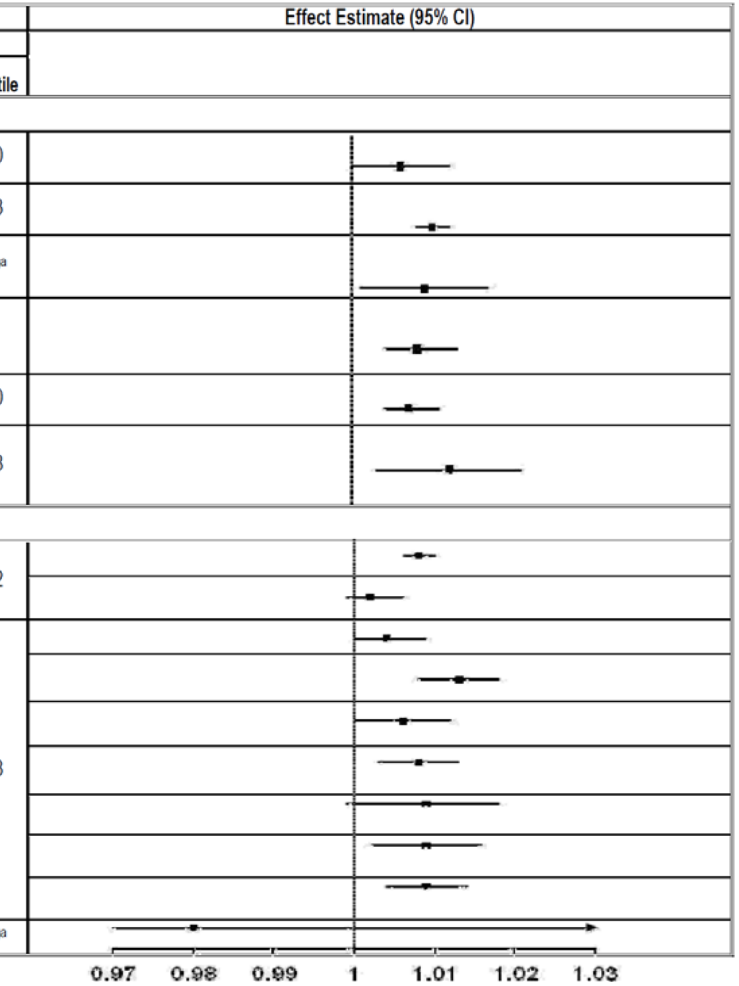
[a]Gestational mean

[b]Median for all cause mortality; median (IQR: interquartile range) for survivors = 14.8 (11.7-18.7) µg/m^3. Exposure period was first 2 months of life.

Source: US EPA, 2011a, Figure 2-5

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

Study/Cite	Geographic Area	Years of Air Quality Data	Endpoint	Air Quality Data (µg/m^3) Author Reported Data: Mean	Mean - 1SD	Range	98th percentile	Effect Estimate (95% CI)
General Population								
Burnett et al. (2004)	12 Canadian Cities	1981-1999	Nonaccidental mortality	12.8	-	-	38.0	
Zanobetti & Schwartz (2009)	112 US counties	1999-2005	Nonaccidental mortality	13.2[a]	10.3[a]	6.6-24.7	34.3	
Burnett & Goldberg (2003)	8 Canadian Cities	1986-1996	Nonaccidental mortality	13.3	3.9[b]	-	38.9[a]	
Harvard Six Cities/ Klemm and Mason (2003)	6 US cities (Northeast/ Midwest)	1979-1988	Nonaccidental mortality	14.7[c]	-	9-23 (IQR)	-	
Franklin et al. (2008)	25 US communities	2000-2005	Nonaccidental mortality	14.8[a]	-	9.9-27.4[a]	43.0	
Franklin et al. (2007)	27 US communities	1997-2002	Nonaccidental mortality	15.6[a]	-	8.8-23.9	45.8	
Older Adults/Children[d]								
MCAPS/Bell et al. (2008)	202 US counties	1999-2005	CVD HA	12.9[a]	10.2[a]	4-20	34.2	
			Resp HA					
MCAPS/Dominici et al. 2006	204 US counties	1999-2002	IHD HA	13.4[a]	10.5[a]	4-23	34.8	
			CHF HA					
			Dysrhythmia HA					
			CBVD HA					
			PVD HA					
			COPD HA					
			RTI HA					
O' Connor (2008)	7 US Cities	1998-2001	Wheeze/Cough	14.0	-	-	39.0[a]	



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

Source: US EPA, 2011a, Figure 2-6

With regard to consideration of additional information from epidemiological studies which is relevant to the second approach, EPA has compiled a summary of the range of $PM_{2.5}$ concentrations corresponding with the 25th to 10th percentiles of health event or study population data from the four multi-city studies, for which distributional statistics are available[81] (US EPA, 2011a, Figure 2-7; Rajan et al., 2011, Table 1). By considering this approach, one could focus on the range of $PM_{2.5}$ concentrations below the long-term mean ambient concentrations over which we continue to have confidence in the associations observed in epidemiological studies (e.g., above the 25th percentile) where commensurate public health protection could be obtained for $PM_{2.5}$-related effects and, conversely, identify the range in the distribution below which our confidence in the associations is appreciably less, to identify alternative annual standard levels.

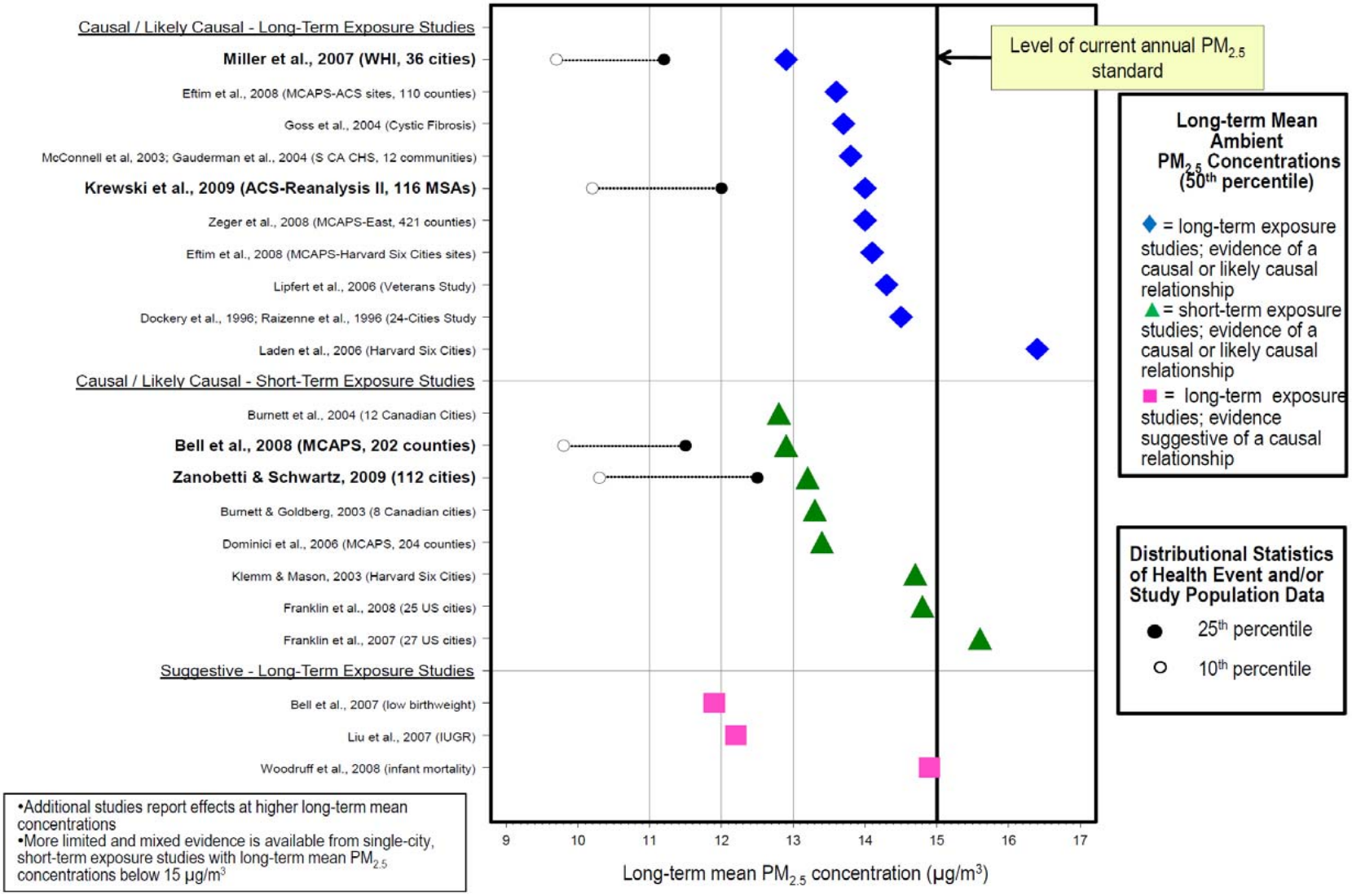
The mean $PM_{2.5}$ concentrations associated with the studies summarized in Figures 1, 2, and 3 and with the distributional statistics analyses (Rajan et al., 2011) are based on concentrations averaged across ambient monitors within each area included in a given study and then averaged across study areas to calculate an overall study mean concentration, as discussed above. As noted above in section III.A.3 and discussed in the Policy Assessment, a policy approach that uses data based on composite monitor distributions to identify alternative standard levels, and then compares those levels to concentrations at appropriate maximum monitors to determine if an area meets a given standard, inherently has the potential to build in some margin of safety (US EPA, 2011a, p. 2-14). In analyses conducted by EPA staff based on selected long- and short-term exposure studies, the Policy Assessment notes that the differences between the maximum and composite distributions were greater for studies with fewer years of air quality data (i.e., 1 to 3 years) and smaller numbers of study areas (i.e., 36 to 51 study areas). The

[81] Health event data (e.g., number of deaths, hospitalizations) occurring in a study population were obtained for three multi-city studies (Krewski et al., 2009; Zanobetti and Schwartz, 2009; Bell et al., 2008) and study population data were obtained for the same three studies and one additional study (Miller et al., 2007) (US 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.

differences in the maximum and composite monitor distribution were much smaller (i.e., generally within five percent) for studies with more years of air quality data (i.e., up to 6 years) and larger numbers of study areas (i.e., 112 to 204 study areas) (Hassett-Sipple et al., 2010; US EPA, 2010f, section 2.3.4.1). Therefore, any margin of safety that may be provided by a policy approach that uses data based on composite monitor distributions to identify alternative standard levels, and then compares those levels to concentrations at appropriate maximum monitors to determine if an area meets a given standard, will vary depending upon the number of monitors and air quality distributions within a given area. See also, section III.A.3 above.

Figure 4 summarizes statistical metrics for those studies included in Figures 1, 2, and 3 that provide evidence of statistically significant $PM_{2.5}$-related effects, which are relevant to the two approaches for translating epidemiological evidence into standard levels discussed above. The top of Figure 4 includes information for *long-term* exposure studies evaluating health outcomes classified as having evidence of a *casual* or *likely casual relationship* with $PM_{2.5}$ exposures (long-term mean $PM_{2.5}$ concentrations indicated by diamond symbols). The middle of Figure 4 includes information for *short-term* exposure studies evaluating health outcomes classified as having evidence of a *casual* or *likely casual* relationship with $PM_{2.5}$ exposures (long-term mean $PM_{2.5}$ concentrations indicated by triangle symbols). The bottom of Figure 4 includes information for *long-term* exposures studies evaluating health outcomes classified as having evidence *suggestive of a causal relationship* (long-term mean $PM_{2.5}$ concentrations indicated by square symbols). Figure 4 also summarizes the range of $PM_{2.5}$ concentrations corresponding with the 25th (indicated by solid circles) to 10th (indicated by open circles) percentiles of the health event or study population data from the four multi-city studies (highlighted in bold text) for which distributional statistics are available.

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



Source: US EPA, 2011a, Figure 2-8

In looking first at the long-term mean $PM_{2.5}$ concentrations reported in the multi-city long-term exposure studies, as summarized at the top of Figure 4, the Policy Assessment observes positive and often statistically significant associations at long-term mean $PM_{2.5}$ concentrations ranging from 16.4 to 12.9 μg/m^3 [82] (Laden et al., 2006; Lipfert et al., 2006; Krewski et al., 2009; Goss et al., 2004; Miller et al.; 2007; Zeger et al., 2008; Eftim et al., 2008; Dockery et al., 1996; McConnell et al., 2003). In considering the one long-term $PM_{2.5}$ exposure study for which health event data are available (Krewski et al., 2009), the Policy Assessment observes that the long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25th and 10th percentiles of the distribution of mortality data are 12.0 μg/m^3 and 10.2 μg/m^3, respectively (Figure 4; US EPA, 2011a, Figure 2-7; Rajan et al., 2011, Table 1). As identified above, although less directly relevant than event data, the number of participants within each study area can be used as a surrogate for health event data in relation to the distribution of $PM_{2.5}$ concentrations. The long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25th and 10th percentiles of the distribution of study participants for Miller et al. (2007) were 11.2 μg/m^3 and 9.7 μg/m^3, respectively (Figure 4; US EPA, 2011a, Figure 2-7; Rajan et al., 2011, Table 1).

In then considering information from multi-city, short-term exposure studies reporting positive and statistically significant associations with these same broad health effect categories, as summarized in the middle of Figure 4, the Policy Assessment observes positive and statistically significant associations at long-term mean $PM_{2.5}$ concentrations in a similar range of 15.6 to 12.8 μg/m^3 (Franklin et al., 2007, 2008; Klemm and Mason, 2003; Burnett and Goldberg, 2003; Zanobetti and Schwartz, 2009; Burnett et al., 2004; Bell et al., 2008; Dominici et al., 2006a; see Figure 3). In considering the two multi-city, short-term $PM_{2.5}$ exposure studies for which health event data are available, the Policy Assessment

[82] As discussed in section III.D.1.a above, the lowest long-term mean $PM_{2.5}$ concentration reported in the long-term exposure studies was based on updated air quality data for Miller et al. (2007). As noted in the Policy Assessment, these air quality data were based on only one year of ambient measurements (2000) and in comparison to other long-term exposure studies that considered multiple years of air quality data, were much more limited (US EPA, 2011a, pp. 2-81 to 2-82).

observes that the long-term mean $PM_{2.5}$ concentrations corresponding with study areas contributing to the 25th and 10th percentiles of the distribution of deaths and cardiovascular-related hospitalizations are 12.5 μg/m^3 and 10.3 μg/m^3, respectively, for Zanobetti and Schwartz (2009), and 11.5 μg/m^3 and 9.8 μg/m^3, respectively, for Bell et al. (2008) (Figure 4; US EPA, 2011a, Figure 2-7; Rajan et al., 2011, Table 1).

Taking into consideration additional studies of specific at-risk populations (i.e., children), the Policy Assessment expands its evaluation of the long-term exposure studies to include a broader range of health outcomes judged in the Integrated Science Assessment to have evidence suggestive of a causal relationship. This evidence was taken into account to evaluate whether it provides support for considering lower alternative levels than if weight were only placed on studies for which health effects have been judged in the Integrated Science Assessment to have evidence supporting a causal or likely causal relationship. The Policy Assessment makes note of a limited number of studies that provide emerging evidence for $PM_{2.5}$-related low birth weight and infant mortality, especially related to respiratory causes during the post-neonatal period. This more limited body of evidence, as summarized at the bottom of Figure 4, indicates positive and often statistically significant effects associated with long-term $PM_{2.5}$ mean concentrations in the range of 14.9 to 11.9 μg/m^3 (Woodruff et al., 2008; Liu et al., 2007; Bell et al., 2007; see Figure 2). As illustrated in Figure 2, although Parker and Woodruff (2008) did not observe an association between quarterly estimates of exposure to $PM_{2.5}$ and low birth weight in a multi-city U.S. study, other U.S. and Canadian studies did report positive and statistically significant associations between $PM_{2.5}$ and low birth weight at lower ambient concentrations (Bell et al., 2007; Liu et al., 2007).[83] There remain significant limitations (e.g., identifying the etiologically relevant time period) in the evaluation of evidence on the relationship between $PM_{2.5}$ exposures and birth

[83] As noted in section 7.4 of the Integrated Science Assessment, Parker et al. (2005) reported that over a 9-month exposure period (mean $PM_{2.5}$ concentration of 15.4 μg/m^3) a significant decrease in birth weight was associated with infants in the highest quartile of $PM_{2.5}$ exposure as compared to infants exposed in the lowest quartile.

outcomes (US EPA, 2009a, pp. 7-48 and 7-56) which should be taken into consideration in reaching judgments about how to weigh these studies of potential impacts on specific susceptible populations in considering alternative standard levels that provide protection with an appropriate margin of safety.

With respect to carcinogenicity, mutagenicity, and genotoxicity (evidence suggestive of a causal relationship), the strongest evidence currently available is from long-term prospective cohort studies that report positive associations between $PM_{2.5}$ and lung cancer mortality. At this time, the $PM_{2.5}$ concentrations reported in studies evaluating these effects generally included ambient concentrations that are equal to or greater than ambient concentrations observed in studies that reported mortality and cardiovascular and respiratory effects (US EPA, 2009a, section 7.5). Therefore, in selecting alternative standard levels appropriate to consider, the Policy Assessment noted that, in providing protection against mortality and cardiovascular and respiratory effects it is reasonable to anticipate that protection will also be provided for carcinogenicity, mutagenicity, and genotoxicity effects (US EPA, 2011a, p. 2-78).

In summarizing the currently available evidence and air quality information within the context of identifying potential alternative annual standard levels for consideration, the Policy Assessment first notes that the Integrated Science Assessment concludes there is no evidence of a discernible population threshold below which effects would not occur. Thus, health effects may occur over the full range of concentrations observed in the epidemiological studies. In the absence of any discernible thresholds, the general approach used in the Policy Assessment for identifying alternative standard levels that would provide appropriate protection against effects observed in epidemiological studies has focused on the central question of identifying the range of $PM_{2.5}$ concentrations below the long-term mean concentrations where we continue to have confidence in the associations observed in epidemiological studies.

In considering the evidence, the Policy Assessment recognizes that NAAQS are standards set so as to provide requisite protection, neither more nor less stringent than necessary to protect public health with an adequate margin of safety. This judgment, ultimately made by the Administrator, involves

weighing the strength of the evidence and the inherent uncertainties and limitations of that evidence. Therefore, depending on the weight placed on different aspects of the evidence and inherent uncertainties, considerations of different alternative standard levels could be supported.

Given the currently available evidence and considering the various approaches discussed above, the Policy Assessment concludes it is appropriate to focus on an annual standard level within a range of about 12 to 11 μg/m^3 (US EPA, 2011a, pp. 2-82, 2-101, and 2-106). As illustrated in Figure 4, a standard level of 12 μg/m^3, at the upper end of this range, is somewhat below the long-term mean $PM_{2.5}$ concentrations reported in all the multi-city, long- and short-term exposure studies that provide evidence of positive and statistically significant associations with health effects classified as having evidence of a causal or likely causal relationship, including premature mortality and hospitalizations and emergency department visits for cardiovascular and respiratory effects as well as respiratory effects in children. Further, a level of 12 μg/m^3 would reflect consideration of additional population-level information from such epidemiological studies in that it generally corresponds with approximately the 25th percentile of the available distributions of health events data in the studies for which population-level information was available.[84] In addition, a level of 12 μg/m^3 would reflect some consideration of studies that provide more limited evidence of reproductive and developmental effects, which are suggestive of a causal relationship, in that it is about at the same level as the lowest long-term mean $PM_{2.5}$ concentrations reported in such studies (see Figure 4).

Alternatively, an annual standard level of 11 μg/m^3, at the lower end of this range, is well below the lowest long-term mean $PM_{2.5}$ concentrations reported in all multi-city long- and short-term exposure studies that provide evidence of positive and statistically significant associations with health effects classified as having evidence of a causal or likely causal relationship. A level of 11 μg/m^3 would reflect

[84] As outlined in section III.A.3, the Policy Assessment considers the 25th percentile to be the start of the range of $PM_{2.5}$ concentrations below the mean within which the data become appreciably more sparse and, thus, where our confidence in the associations observed in epidemiological studies begins to become appreciably less.

placing more weight on the distributions of health event and population data, in that this level is within the range of $PM_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of all the available distributions of such data.[85] In addition, a level of 11 μg/m^3 is somewhat below the lowest long-term mean $PM_{2.5}$ concentrations reported in reproductive and developmental effects studies that are suggestive of a causal relationship. Thus, a level of 11 μg/m^3 would reflect an approach to translating the available evidence that places relatively more emphasis on margin of safety considerations than would a standard set at a higher level. Such a policy approach would tend to weigh uncertainties in the evidence in such a way as to avoid potentially underestimating $PM_{2.5}$-related risks to public health. Further, recognizing the uncertainties inherent in identifying any particular point at which our confidence in reported associations becomes appreciably less, the Policy Assessment concludes that the available evidence does not provide a sufficient basis to consider alternative annual standard levels below 11 μg/m^3 (US EPA, 2011a, p. 2-81).

The Policy Assessment also considers the extent to which the available evidence provides a basis for considering alternative annual standard levels above 12 μg/m^3. As discussed below, the Policy Assessment concludes that it could be reasonable to consider a standard level up to 13 μg/m^3 based on a policy approach that tends to weigh uncertainties in the evidence in such a way as to avoid potentially overestimating $PM_{2.5}$-related risks to public health, especially to the extent that primary emphasis is placed on long-term exposure studies as a basis for an annual standard level. A level of 13 μg/m^3 is somewhat below the long-term mean $PM_{2.5}$ concentrations reported in all but one of the long-term exposure studies providing evidence of positive and statistically significant associations with $PM_{2.5}$-related health effects classified as having a causal or likely causal relationship. As shown in Figure 4, the one long-term exposure study with a long-term mean $PM_{2.5}$ concentration just below 13 μg/m^3 is the WHI study (Miller et al., 2007). As noted in section III.D.1.a above, the Policy Assessment

[85] As discussed in section III.A.3, the Policy Assessment identifies the range from the 25th to the 10th percentiles as a reasonable range to consider, in that it is a range where we have appreciably less confidence in the associations observed in epidemiological studies (US EPA, 2011a, p. 2-12).

observes that in comparison to other long-term exposure studies, the WHI study was more limited in that it was based on only one year of air quality data (US EPA, 2011a, pp. 2-81 to 2-82). Thus, to the extent that less weight is placed on the WHI study than on other long-term exposure studies with more robust air quality data, a level of 13 $\mu g/m^3$ could be considered as being protective of long-term exposure related effects classified as having a causal or likely causal relationship. In also considering short-term exposure studies, the Policy Assessment notes that a level of 13 $\mu g/m^3$ is below the long-term mean $PM_{2.5}$ concentrations reported in most such studies, but is above the long-term means of 12.8 and 12.9 $\mu g/m^3$ reported in Burnett et al. (2004) and Bell et al. (2008), respectively. In considering these studies, the Policy Assessment finds no basis to conclude that these two studies are any more limited or uncertain than the other short-term exposure studies shown in Figures 3 and 4 (US EPA, 2011a, p. 2-82). On this basis, as discussed below, the Policy Assessment concludes that consideration of an annual standard level of 13 $\mu g/m^3$ would have implications for the degree of protection that would need to be provided by the 24-hour standard, such that taken together the suite of $PM_{2.5}$ standards would provide appropriate protection from effects on public health related to short-term exposure to $PM_{2.5}$ (US EPA, 2011a, p. 2-82).

The Policy Assessment also notes that a standard level of 13 $\mu g/m^3$ would reflect a judgment that the uncertainties in the epidemiological evidence as summarized in section III.B.2 above, including uncertainties related to the heterogeneity observed in the epidemiological studies in the eastern versus western parts of the U.S., the relative toxicity of $PM_{2.5}$ components, and the potential role of co-pollutants, are too great to warrant placing any weight on the distributions of health event and population data that extend down below the long-term mean concentrations into the lower quartile of the data. This level would also reflect a judgment that the evidence from reproductive and developmental effects studies that is suggestive of a causal relationship is too uncertain to support consideration of any lower level.

Beyond evidence-based considerations, the Policy Assessment also considered the extent to

which quantitative risk assessment supports consideration of these alternative standard levels or provides support for lower levels. In considering simulations of just meeting alternative annual standard levels within the range of 13 to 11 μg/m^3 (in conjunction with the current 24-hour standard level of 35 μg/m^3), the Policy Assessment concluded that important public health improvements are associated with risk reductions estimated for standard levels of 13 and 12 μg/m^3, noting that the level of 11 μg/m^3 was not include 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/m^3). 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/m^3, but did not provide strong support for considering lower alternative standard levels (US EPA, 2011a, pp. 2-102 to 2-103).

Taken together, the Policy Assessment concludes that consideration of alternative annual standard levels in the range of 13 to 11 μg/m^3 may be appropriate. Furthermore, the Policy Assessment concludes that the currently available evidence most strongly supports consideration of an alternative annual standard level in the range of 12 to 11 μg/m^3 (US EPA, 2011a, p. 2-82). The Policy Assessment concludes that an alternative level within the range of 12 to 11 μg/m^3 would more fully take into consideration the available information from all long- and short-term $PM_{2.5}$ exposure studies, including studies of at-risk populations, than would a higher level. This range would also reflect placing weight on information from studies that help to characterize the range of $PM_{2.5}$ concentrations over which we continue to have confidence in the associations observed in epidemiological studies, as well as the extent to which our confidence in the associations is appreciably less at lower concentrations.

c. Consideration of the 24-Hour Standard in the Policy Assessment

As recognized in section III.A.3 above, an annual standard intended to serve as the primary means for providing protection from effects associated with both long- and short-term $PM_{2.5}$ exposures

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

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

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

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

With regard to multi-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures, as summarized in Figure 3, the Policy Assessment observes an overall pattern of positive and statistically significant associations in studies with 98th percentile values averaged across study areas in the range of 45.8 to 34.2 μg/m^3 (Burnett et al., 2004; Zanobetti and Schwartz, 2009; Bell et al., 2008; Dominici et al., 2006a, Burnett and Goldberg, 2003; Franklin et al., 2008). The Policy Assessment notes that, to the extent air quality distributions were reduced to reflect just meeting the current 24-hour standard, additional protection would be anticipated for the effects observed in the three multi-city studies with 98th percentile values greater than 35 μg/m^3 (Burnett et al., 2004; Burnett and Goldberg, 2003; Franklin et al., 2008). In the three additional studies with 98th percentile values below 35 μg/m^3, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 μg/m^3, the Policy Assessment notes that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 μg/m^3, respectively (Bell et al., 2008; Zanobetti and Schwartz, 2009; Dominici et al., 2006a). To the extent that consideration is given to revising the level of the annual standard, as discussed above in section III.E.4.b, the Policy Assessment recognizes that potential changes associated with meeting such an alternative annual standard would result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures. Consequently, in considering a 24-hour standard that would work in conjunction with an annual standard to provide appropriate public health protection, the Policy Assessment notes that to the extent that the level of the annual standard is revised to within a range of 13 to 11 μg/m^3, in

particular in the range of 12 to 11 μg/m^3, additional protection would be provided for the effects observed in these multi-city studies (US EPA, 2011a, p. 2-84).

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

In reaching staff conclusions regarding alternative 24-hour standard levels that are appropriate to consider, the Policy Assessment also takes into account relevant information from single-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures. The Policy Assessment recognizes that these studies may provide additional insights regarding impacts on susceptible populations and/or on areas with isolated peak concentrations. Although, as discussed in section III.E.4.a above, multi-city studies have advantages over single-city studies in terms of statistical power to detect associations and broader geographic coverage as well as other factors such as less likelihood of publication bias, reflecting differences in $PM_{2.5}$ sources, composition, and potentially other factors that could impact $PM_{2.5}$-related effects, multi-city studies often present overall effect estimates rather than single-city effect estimates. Since short-term air quality can vary considerably across cities, the extent to which effects reported in multi-city studies are associated with short-term air quality in any particular location is uncertain, especially when considering short-term concentrations at the upper end of the distribution of daily $PM_{2.5}$ concentrations (i.e., at the 98th percentile value). In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the

air quality in a given study area is more straightforward to establish. Therefore, the Policy Assessment also considers evidence from single-city, short-term exposure studies to inform staff conclusions regarding alternative levels that are appropriate to consider for a 24-hour standard that is intended to provide supplemental protection in areas where the annual standard may not provide an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures.

As discussed above for the multi-city studies, the Policy Assessment takes into account both the 24-hour $PM_{2.5}$ concentrations in the single-city studies, focusing on the 98th percentile air quality values, as well as the long-term mean $PM_{2.5}$ concentrations. The Policy Assessment considers single-city studies conducted in areas that would likely have met the current suite of $PM_{2.5}$ standards as most useful for informing staff conclusions related to the level of the 24-hour standard (US EPA, 2011a, Figure 2-9). The Policy Assessment notes that additional single-city studies summarized in that Figure 2-9 were conducted in areas that would likely have met one but not both of the current $PM_{2.5}$ standards. To the extent changes in air quality designed to just meet the current suite of $PM_{2.5}$ standards are undertaken, one could reasonably anticipate additional public health protection will occur in these study areas. Therefore, the Policy Assessment concludes that these studies are not helpful to inform staff conclusions regarding alternative standard levels that are appropriate to consider (US EPA, 2011a, p. 2-87).

With regard to single-city studies that were conducted in areas that would likely have met both the current 24-hour and annual standards, the Policy Assessment first considers studies that reported positive and statistically significant associations. In considering this group of studies, the Policy Assessment notes Mar et al. (2003) reported a positive and statistically significant association for premature mortality in Phoenix with a long-term mean concentration of 13.5 $\mu g/m^3$ in conjunction with a 98th percentile value of 32.2 $\mu g/m^3$ (US EPA, 2011a, Figure 2-9). To the extent that consideration is given to revising the level of the annual standard, within a range of 13 to 11 $\mu g/m^3$, as discussed above, additional protection would be provided for the effects observed in this study (US EPA, 2011a, p. 2-87).

Four additional studies reported positive and statistically significant associations with 98th

percentile values within a range of 31.2 to 25.8 μg/m^3 and long-term mean concentrations within a range of 12.1 to 8.5 μg/m^3 (Delfino et al., 1997; Peters et al., 2001; Stieb et al., 2000; and Mar et al., 2004; US EPA, 2011a, Figure 2-9). Delfino et al. (1997) reported statistically significant associations between $PM_{2.5}$ and respiratory emergency department visits for older adults (greater than 64 years old) but not young children (less than 2 years old), in one part of the study period (summer 1993) but not the other (summer 1992). Peters et al. (2001) reported a positive and statistically significant association between short-term exposure to $PM_{2.5}$ (2-hour and 24-hour averaging times) and onset of acute myocardial infarction in Boston. Stieb et al. (2000) reported positive and statistically significant associations with cardiovascular- and respiratory-related emergency department visits in Saint John, Canada, in single pollutant models but not in multi-pollutant models (US EPA, 2004, pp. 8-154 and 8-252 to 8-253). Mar et al. (2004) reported a positive and statistically significant association for short-term $PM_{2.5}$ exposures in relation to respiratory symptoms among children but not adults in Spokane, however, this study had very limited statistical power because of the small number of children and adults evaluated.

The Policy Assessment also considers short-term single-city $PM_{2.5}$ exposure studies that reported positive but nonstatistically significant associations for cardiovascular and respiratory endpoints in areas that would likely have met both the current 24-hour and annual standards. The 98th percentile values reported in these studies ranged from 31.6 to 17.2 μg/m^3 and the long-term mean concentrations ranged from 13.0 to 7.0 μg/m^3 (US EPA, 2011a, Figure 2-9). These studies included consideration of cardiovascular-related mortality effects in Phoenix (Wilson et al., 2007), asthma medication use in children in Denver (Rabinovitch et al., 2006), hospital admissions for hemorrhagic and ischemic stroke in Edmonton, Canada (Villeneuve et al., 2006), and hospital admissions for ischemic stroke/transient ischemic attack in Nueces County, TX (Lisabeth et al., 2008).

Lastly, the Policy Assessment considers single-city studies conducted in areas that would likely have met both the current 24-hour and annual standards that reported null findings. The 98th percentile values reported in these studies ranged from 29.6 to 24.0 μg/m^3 and the long-term mean concentrations

ranged from 10.8 to 8.5 μg/m^3 (US EPA, 2011a, Figure 2-9). These studies reported no associations with short-term $PM_{2.5}$ exposures and cardiovascular-related hospital admissions and respiratory-related emergency department visits (Slaughter et al., 2005) and cardiovascular-related emergency department visits (Schreuder et al., 2006) in Spokane; asthma exacerbation in children in Denver (Rabinovitch et al., 2004); and hospital admissions for transient ischemic attack in Edmonton, Canada (Villeneuve et al., 2006).

Viewing the evidence as a whole, the Policy Assessment observes a limited number of single-city studies that reported positive and statistically significant associations for a range of health endpoints related to short-term $PM_{2.5}$ concentrations in areas that would likely have met the current suite of $PM_{2.5}$ standards. Many of these studies had significant limitations (e.g., limited statistical power, limited exposure data) or equivocal results (i.e., mixed results within the same study area) as briefly identified above and discussed in more detail in the Policy Assessment (US EPA, 2011a, p. 2-88). Other studies reported positive but not statistically significant results or null associations also in areas that would likely have met the current suite of $PM_{2.5}$ standards. Overall, the entire body of results from these single-city studies is mixed, particularly as 24-hour 98th percentile concentrations go below 35 μg/m^3.

Although a number of single-city studies report effects at appreciably lower $PM_{2.5}$ concentrations than multi-city short-term exposure studies, the uncertainties and limitations associated with the single-city studies were greater and, thus, the Policy Assessment concludes there is less confidence in using these studies as a basis for setting the level of a standard. Therefore, the Policy Assessment concludes that the multi-city short-term exposure studies provide the strongest evidence to inform decisions on the level of the 24-hour standard, and the single-city studies do not warrant consideration of 24-hour standard levels different from those supported by the multi-city studies (US EPA, 2011a, p. 2-88).

In addition to considering the epidemiological evidence, the Policy Assessment takes into account air quality information based on county-level 24-hour and annual design values to understand the implications of the alternative standard levels supported by the currently available scientific

evidence, as discussed in section III.E.4.b above. As discussed in section III.A.3 above, the Policy Assessment concludes that a policy goal which includes setting the annual standard to be the "generally controlling" standard in conjunction with setting the 24-hour standard to provide supplemental protection, to the extent that additional protection is warranted, is the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures, resulting in more uniform protection across the U.S than the alternative of setting the 24-hour standard to be the controlling standard. Therefore, the Policy Assessment considers the extent to which different combinations of alternative annual and 24-hour standard levels based on the evidence would support this policy goal (US EPA, 2011a, pp 2-88 to 2-91, Figure 2-10).

Using information on the relationship of the 24-hour and annual design values, the Policy Assessment examines the implications of three alternative suites of $PM_{2.5}$ standards identified as appropriate to consider based on the currently available scientific evidence, as discussed above. The Policy Assessment concludes that an alternative suite of $PM_{2.5}$ standards that would include an annual standard level of 11 or 12 $\mu g/m^3$ and a 24-hour standard with a level of 35 $\mu g/m^3$ (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 (US EPA, 2011a, pp. 2-89 to 2-91 and Figure 2-10). These Northwest counties generally represent areas where the annual mean $PM_{2.5}$ concentrations have historically been low but where relatively high 24-hour concentrations occur, often related to seasonal wood smoke emissions. Alternatively, combining an alternative annual standard of 13 $\mu g/m^3$ with a 24-hour standard of 30 $\mu g/m^3$ would result in many more areas across the country in which the 24-hour standard would likely become the controlling standard than if an alternative annual standard of 12 or 11 $\mu g/m^3$ were paired with the current level of the 24-hour standard (i.e., 35 $\mu g/m^3$).

The Policy Assessment concludes that consideration of retaining the 24-hour standard level at 35 $\mu g/m^3$ 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/m^3, this alternative would recognize additional public health protection against effects associated with short-term $PM_{2.5}$ exposures which would be provided by lowering the annual standard such that revision to the 24-hour standard would not be warranted (US EPA, 2011a, p. 2-91).

The Policy Assessment also recognizes an alternative approach to considering the evidence that provides some support for revising the level below 35 μg/m^3, perhaps as low as 30 μg/m^3 (US EPA, 2011a, p. 2-92). This alternative 24-hour standard level would be more compatible with an alternative annual standard of 13 μg/m^3 based on placing greater weight on one multi-city short-term exposure study (Bell et al., 2008) that reported positive and statistically significant effects at a 98th percentile value less than 35 μg/m^3 (i.e., 34.2 μg/m^3) in conjunction with a long-term mean concentration less than 13 μg/m^3 (i.e., 12.9 μg/m^3).

Beyond evidence-based considerations, the Policy Assessment also considered the extent to which the quantitative risk assessment supports consideration of retaining the current 24-hour standard level or provides support for lower standard levels. In considering simulations of just meeting the current 24-hour standard level of 35 μg/m^3 or alternative levels of 30 or 25 μg/m^3 (in conjunction with alternative annual standard levels within a range of 13 to 11 μg/m^3), 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/m^3). Based on this information, the Policy Assessment concluded that the quantitative risk assessment provides support for considering a 24-hour standard level of 35 or 30 μg/m^3 (in conjunction with an alternative standard level within a range of 13 to 11 μg/m^3) but does not provide strong support for considering lower alternative 24-hour standard levels (US EPA, 2011a, pp. 2-102 to 2-103).

Taken together, the Policy Assessment concludes that while it is appropriate to consider an alternative 24-hour standard level within a range of 35 to 30 μg/m^3, the currently available evidence

most strongly supports consideration for retaining the current 24-hour standard level at 35 μg/m^3 in conjunction with lowering the level of the annual standard within a range of 12 to 11 μg/m^3 (US EPA, 2011a, p. 2-92).

d. CASAC Advice

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

CASAC concluded that the range of levels presented in the second draft Policy Assessment (i.e., alternative annual standard levels within a range of 13 to 11 μg/m^3 and alternative 24-hour standard levels within a range of 35 to 30 μg/m^3) "are supported by the epidemiological and toxicological evidence, as well as by the risk and air quality information compiled" in the Integrated Science Assessment, Risk Assessment, and second draft Policy Assessment. CASAC further noted that "[a]lthough there is increasing uncertainty at lower levels, there is no evidence of a threshold (i.e., a level below which there is no risk for adverse health effects)" (Samet, 2010d, p. ii).

Although CASAC supported the alternative standard level ranges presented in the second draft Policy Assessment, it did not express support for any specific levels or combinations of standards. Rather, CASAC encouraged the EPA to develop a clearer rationale in the final Policy Assessment for staff conclusions regarding annual and 24-hour standards that are appropriate to consider, including consideration of the combination of these standards supported by the available information (Samet,

2010d, p. ii). Specifically, CASAC encouraged staff to focus on information related to the concentrations that were most influential in generating the health effect estimates in individual studies to inform alternative standard levels (Samet, 2010d, p. 2). CASAC also commented that the approach presented in the second draft Policy Assessment to identify alternative 24-hour standard levels which focused on peak-to-mean ratios was not relevant for informing the actual level (Samet 2010d, p. 4). Further, they expressed the concern that the combinations of annual and 24-hour standard levels discussed in the second draft Policy Assessment (i.e., in the range of 13 to 11 $\mu g/m^3$ for the annual standard, in conjunction with retaining the current 24-hour $PM_{2.5}$ standard level of 35 $\mu g/m^3$; alternatively, revising the level of the 24-hour standard to 30 $\mu g/m^3$ in conjunction with an annual standard level of 11 $\mu g/m^3$) "may not be adequately inclusive" and "[i]t was not clear why, for example a daily standard of 30 $\mu g/m^3$ should only be considered in combination with an annual level of 11 $\mu g/m^3$" (Samet, 2010d, p. ii). CASAC encouraged the EPA to more clearly explain its rationale for identifying the 24-hour/annual combinations that are appropriate for consideration (Samet 2010d, p. ii).

In considering CASAC's advice as well as public comment on the second draft Policy Assessment, EPA staff conducted additional analyses and modified their conclusions regarding alternative standard levels that are appropriate to consider. The staff conclusions in the final Policy Assessment (US EPA, 2011a, section 2.3.4.4) differ somewhat from the alternative standard levels discussed in the second draft Policy Assessment (US EPA, 2010f, section 2.3.4.3), upon which CASAC based its advice. Changes made in the final Policy Assessment were primarily focused on improving and clarifying the approach for translating the epidemiological evidence into a basis for staff conclusions on the broadest range of alternative standard levels supported by the available scientific information and more clearly articulating the rationale for the staff's conclusions (Wegman, 2011, pp. 1 to 2). Consistent with CASAC's advice to consider more information from epidemiological studies, the EPA analyzed additional population-level data obtained from several study investigators. In commenting on draft staff conclusions in the second draft Policy Assessment, CASAC did not have an opportunity to review the

staff analyses of distributional statistics to identify the broader range of $PM_{2.5}$ concentrations that were most influential in generating health effect estimates in epidemiological studies (Rajan et al., 2011). In addition, CASAC was not aware of the revised long-term mean $PM_{2.5}$ concentration in the WHI study as discussed in section III.D.1.a above or the staff's inclusion of that value in its evaluation of the evidence (i.e., in Figures 1 and 4 above and related discussion). The WHI study is the only long-term cohort study that provides information regarding effects classified as having evidence of a causal or likely causal relationship associated with a long-term $PM_{2.5}$ concentration below 13 $\mu g/m^3$. Furthermore, CASAC did not have an opportunity to review the staff's revised rationale for the combinations of alternative standards suggested in the final Policy Assessment.

e. Administrator's Proposed Conclusions on the Primary $PM_{2.5}$ Standard Levels

In reaching her conclusions regarding appropriate alternative standard levels to consider, the Administrator has considered the epidemiological and other scientific evidence, estimates of risk reductions associated with just meeting alternative annual and/or 24-hour standards, air quality analyses, related limitations and uncertainties and the advice of CASAC. As an initial matter, the Administrator agrees with the approach discussed in the Policy Assessment as summarized in sections III.A.3 and III.E.4.a above, and supported by CASAC, of considering the protection afforded by the annual and 24-hour standards taken together for mortality and morbidity effects associated with both long- and short-term exposures to $PM_{2.5}$. This is consistent with the approach taken in the review completed in 1997, in contrast to considering each standard separately, as was done in the review completed in 2006. Furthermore, based on the evidence and quantitative risk assessment, the Administrator provisionally concludes it is appropriate to set a "generally controlling" annual standard that will lower a wide range of ambient 24-hour concentrations, with a 24-hour standard focused on providing supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or $PM_{2.5}$-related effects that may be associated with shorter-than daily exposure periods. The Administrator provisionally concludes this approach would likely reduce aggregate risks

associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard and would be the most effective and efficient way to reduce total PM_{2-5}-related population risk.

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

The newly available scientific evidence builds upon the previous scientific data base to provide evidence of generally robust associations and to provide a basis for greater confidence in the reported associations than in the last review. The Administrator recognizes that the weight of evidence, as

evaluated in the Integrated Science Assessment, is strongest for health endpoints classified as having evidence of a causal relationship. These relationships include those between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects. She recognizes that the weight of evidence is also strong for health endpoints classified as having evidence of a likely causal relationship, which include those between long- and short-term $PM_{2.5}$ exposures and respiratory effects. In addition, the Administrator makes note of the much more limited evidence for health endpoints classified as having evidence suggestive of a causal relationship, including developmental, reproductive and carcinogenic effects.

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

Consistent with the general approach summarized in section III.A.3 above, and supported by CASAC as discussed in section III.E.4.d above, the Administrator generally agrees that it is appropriate to consider a level for an annual standard that is somewhat below the long-term mean $PM_{2.5}$ concentrations reported in long- and short-term exposure studies. In recognizing that the evidence of an association in any such study is strongest at and around the long-term average where the data in the study are most concentrated, she understands that this approach does not provide a bright line for reaching decisions about appropriate standard levels. The Administrator notes that long-term mean $PM_{2.5}$ concentrations are available for each study considered and, therefore, represent the most robust

data set to inform her decisions on appropriate annual standard levels. She also notes that the overall study mean $PM_{2.5}$ concentrations are generally calculated based on monitored concentrations averaged across monitors in each study area with multiple monitors, referred to as a composite monitor concentration, in contrast to the highest concentration monitored in study area, referred to as a maximum monitor concentration, which are used to determine whether an area meets a given standard. In considering such long-term mean concentrations, the Administrator understands that it is appropriate to consider the weight of evidence for the health endpoints evaluated in such studies in giving weight to this information.

Based on the information summarized in Figure 4 and presented in more detail in the Policy Assessment (US EPA, 2011a, chapter 2) for effects classified in the Integrated Science Assessment as having a causal or likely causal relationship with $PM_{2.5}$ exposures, the Administrator observes an overall pattern of statistically significant associations reported in studies of long-term $PM_{2.5}$ exposures with long-term mean concentrations ranging from somewhat above the current standard level of 15 $\mu g/m^3$ down to the lowest mean concentration in such studies of 12.9 $\mu g/m^3$ (in Miller et al., 2007). She observes a similar pattern of statistically significant associations in studies of short-term $PM_{2.5}$ exposures with long-term mean concentrations ranging from around 15 $\mu g/m^3$ down to 12.8 $\mu g/m^3$ (in Burnett et al., 2004). With regard to effects classified as providing evidence suggestive of a causal relationship, the Administrator observes a small number of long-term exposure studies related to developmental and reproductive effects that reported statistically significant associations with overall study mean $PM_{2.5}$ concentrations down to 11.9 $\mu g/m^3$ (in Bell et al., 2007).[86]

The Administrator also considers additional information from epidemiological studies, consistent

[86] With respect to suggestive evidence related to cancer, mutagenic, and genotoxic effects, the $PM_{2.5}$ concentrations reported in studies generally included ambient concentrations that are equal to or greater than ambient concentrations observed in studies that reported mortality and cardiovascular and respiratory effects (US 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.

with CASAC advice, to take into account the broader distribution of $PM_{2.5}$ concentrations and the degree of confidence in the observed associations over the broader air quality distribution. In considering this additional information, she understands that the Policy Assessment presented information on the 25th and 10th percentiles of the distributions of $PM_{2.5}$ concentrations available from four multi-city studies to provide a general frame of reference as to the part of the distribution within which the data become appreciably more sparse and, thus, where her confidence in the associations observed in epidemiological studies would become appreciably less. As discussed in section III.E.4.b above and summarized in Figure 4, the Administrator takes note of additional population-level data that are available for four studies (Krewski et al., 2009; Miller et al., 2007; Bell et al., 2008; Zanobetti and Schwartz, 2009), each of which report statistically significant associations with health endpoints classified as having evidence of a causal relationship. In considering the long-term $PM_{2.5}$ concentrations associated with the 25th percentile values of the population-level data for these four studies, she observes that these values range from somewhat above to somewhat below 12 $\mu g/m^3$ (Figure 4). The Administrator recognizes that these four studies represent some of the strongest evidence available within the overall body of scientific evidence and notes that three of these studies (Krewski et al., 2009; Bell et al., 2008; Zanobetti and Schwartz, 2009) were used as the basis for concentration-response functions used in the quantitative risk assessment (US EPA, 2010a, section 3.3.3). However, the Administrator also recognizes that additional population-level data are available for only these four studies and, therefore, she believes that these studies comprise a more limited data set than one based on long-term mean $PM_{2.5}$ concentrations for which data are available for all studies considered, as discussed above. In considering this information, the Administrator notes that CASAC advised that information about the long-term $PM_{2.5}$ concentrations that were most influential in generating the health effect estimates in epidemiological studies can help to inform selection of an appropriate annual standard level.

The Administrator recognizes, as summarized in section III.B.2 above, that important uncertainties remain in the evidence and information considered in this review of the primary fine

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

The Administrator is mindful that considering what standards are requisite to protect public health with an adequate margin of safety requires public health policy judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. In considering how to translate the available information into appropriate standard levels, the Administrator weighs the available scientific information and associated uncertainties and limitations. For the purpose of determining what standard levels are appropriate to propose, the Administrator recognizes, as did EPA staff in the Policy Assessment, that there is no single factor or criterion that comprises the "correct" approach to weighing the various types of available evidence and information, but rather there are various approaches that are appropriate to consider. The Administrator further recognizes that different evaluations of the evidence and other information before the Administrator could reflect placing different weight on the relative strengths and limitations of the

scientific information, and different judgments could be made as to how such information should appropriately be used in making public health policy decisions on standard levels. This recognition leads the Administrator to consider various approaches to weighing the evidence so as to identify appropriate standard levels to propose. In so doing, the Administrator encourages extensive public comment on alternative approaches to weighing the evidence and other information so as to inform her public health policy judgments before reaching final decisions on appropriate standard levels.

In considering the available information, the Administrator notes the advice of CASAC that the currently available scientific information, including epidemiological and toxicological evidence as well as risk and air quality information, provides support for considering an annual standard level within a range of 13 to 11 $\mu g/m^3$ and a 24-hour standard level within a range of 35 to 30 $\mu g/m^3$. In addition, the Administrator recognizes that the Policy Assessment concludes that the available evidence and risk-based information support consideration of annual standard levels in the range of 13 to 11 $\mu g/m^3$, and that the Policy Assessment also concludes that the evidence most strongly supports consideration of an annual standard level in the range of 12 to 11 $\mu g/m^3$. In considering how the annual and 24-hour standards work together to provide appropriate public health protection, the Administrator observes that CASAC did not express support for any specific levels or combinations of standards within in these ranges, although she recognizes that CASAC did not have an opportunity to review additional information and analyses presented in the final Policy Assessment prepared in response to CASAC's recommendations on the second draft Policy Assessment. Nor did CASAC have an opportunity to review the EPA staff's revised rationale for the combinations of alternative standards presented in the final document.

In considering the extent to which the currently available evidence and information provide support for specific standard levels within the ranges identified by CASAC and the Policy Assessment as appropriate for consideration, the Administrator initially considers standard levels within the range of 13 to 11 $\mu g/m^3$ for the annual standard. In so doing, the Administrator first considers the long-term mean

$PM_{2.5}$ concentrations reported in studies of effects classified as having evidence of a causal or likely causal relationship, as summarized in Figure 4 and discussed more broadly above. She notes that a level at the upper end of this range would be below most but not all the overall study mean concentrations from the multi-city studies of long- and short-term exposures, whereas somewhat lower levels within this range would be below all such overall study mean concentrations. In considering the appropriate weight to place on this information, the Administrator again notes that the evidence of an association in any such study is strongest at and around the long-term average where the data in the study are most concentrated, and that long-term mean $PM_{2.5}$ concentrations are available for each study considered and, therefore, represent the most robust data set to inform her decisions on appropriate annual standard levels. Further, she is mindful that this approach does not provide a bright line for reaching decisions about appropriate standard levels.

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

The Administrator also considers additional distributional analyses of population-level information that were available from four of the epidemiological studies that provide evidence of effects identified as having a causal relationship with long- or short-term $PM_{2.5}$ concentrations for annual standard levels within the same range of 13 to 11 $\mu g/m^3$. In so doing, the Administrator first notes that a level in the mid-part of this range generally corresponds with approximately the 25th percentile of the distributions of health events data available in three of these studies. The Administrator also notes that

standard levels toward the upper part of this range would reflect placing substantially less weight on this information, whereas standard levels toward the lower part of this range would reflect placing substantially more weight on this information. In considering this information, the Administrator notes that there is no bright line that delineates the part of the distribution of $PM_{2.5}$ concentrations within which the data become appreciably more sparse and, thus, where her confidence in the associations observed in epidemiological studies becomes appreciably less.

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

The Administrator also recognizes that judgments about the appropriate weight to place on any of the factors discussed above should reflect consideration not only of the relative strength of the evidence but also on the important uncertainties that remain in the evidence and information being considered in this review. The Administrator notes that the extent to which these uncertainties influence judgments about appropriate annual standard levels within the range of 13 to 11 $\mu g/m^3$ would likely be greater for standard levels in the lower part of this range which would necessarily be based on fewer available studies than would higher levels within this range.

Based on the above considerations, the Administrator concludes that it is appropriate to propose to set a level for the primary annual $PM_{2.5}$ standard within the range of 12 to 13 $\mu g/m^3$. The Administrator provisionally concludes that a standard set within this range would reflect alternative

approaches to appropriately placing the most weight on the strongest available evidence, while placing less weight on much more limited evidence and on more uncertain analyses of information available from a relatively small number of studies. Further, she provisionally concludes that a standard level within this range would reflect alternative approaches to appropriately providing an adequate margin of safety for the populations at risk for the serious health effects classified as having evidence of a causal or likely causal relationship, depending in part on the emphasis placed on margin of safety considerations. The Administrator recognizes that setting an annual standard level at the lower end of this range would reflect an approach that places more emphasis on the entire body of the evidence, including the analysis of the distribution of air quality concentrations most influential in generating health effect estimates in the studies, and on margin of safety considerations, than would setting a level at the upper end of the range. Conversely, an approach that would support a level at the upper end of this range would place more emphasis on the remaining uncertainties in the evidence to avoid potentially overestimating public health improvements, and would generally support a view that the uncertainties remaining in the evidence are too great to warrant setting a lower annual standard level.

While the Administrator recognizes that CASAC advised, and the Policy Assessment concluded, that the available scientific information provides support for considering a range that extended down to 11 $\mu g/m^3$, she concludes that proposing such an extended range would reflect a public health policy approach that places more weight on relatively limited evidence and more uncertain information and analyses than she considers appropriate at this time. Nonetheless, the Administrator solicits comment on a level down to 11 $\mu g/m^3$ as well as on approaches for translating scientific evidence and rationales that would support such a level. Such an approach might reflect a view that the uncertainties associated with the available scientific information warrant a highly precautionary public health policy response that would incorporate a large margin of safety.

The Administrator recognizes that potential air quality changes associated with meeting an annual standard set at a level within the range of 12 to 13 $\mu g/m^3$ will result in lowering risks associated

with both long- and short-term $PM_{2.5}$ exposures. However, the Administrator recognizes that such an annual standard intended to serve as the primary means for providing protection from effects associated with both long- and short-term $PM_{2.5}$ exposures would not by itself be expected to offer requisite protection with an adequate margin of safety against the effects of all short-term $PM_{2.5}$ exposures. As a result, in conjunction with proposing an annual standard level in the range of 12 to 13 $\mu g/m^3$, the Administrator provisionally concludes that it is appropriate to continue to provide supplemental protection by means of a 24-hour standard set at the appropriate level, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources, or for $PM_{2.5}$-related effects that may be associated with shorter-than-daily exposure periods.

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

In considering the information provided by the short-term exposure studies, the Administrator recognizes that to the extent these studies were conducted in areas that likely did not meet one or both of the current standards, such studies do not help inform the characterization of the potential public health improvements of alternative standards set at lower levels. By reducing the $PM_{2.5}$ concentrations in such areas to just meet the current standards, the Administrator anticipates that additional public health protection will occur. Therefore, the Administrator has focused on studies that reported positive and statistically significant associations in areas that would likely have met both the current 24-hour and annual standards. She has also considered whether or not these studies were conducted in areas that would likely have met an annual standard level of 12 to 13 $\mu g/m^3$ to inform her decision regarding an appropriate 24-hour standard level. As discussed in section III.E.4.a, the Administrator concludes that

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

With regard to multi-city studies that evaluated effects associated with short-term $PM_{2.5}$ exposures, the Administrator observes an overall pattern of positive and statistically significant associations in studies with 98th percentile values averaged across study areas in the range of 45.8 to 34.2 μg/m^3 (Burnett et al., 2004; Zanobetti and Schwartz, 2009; Bell et al., 2008; Dominici et al., 2006a, Burnett and Goldberg, 2003; Franklin et al., 2008). The Administrator notes that, to the extent air quality distributions are reduced to reflect just meeting the current 24-hour standard, additional protection would be anticipated for the effects observed in the three multi-city studies with 98th percentile values greater than 35 μg/m^3 (Burnett et al., 2004; Burnett and Goldberg, 2003; Franklin et al., 2008). In the three additional studies with 98th percentile values below 35 μg/m^3, specifically 98th percentile concentrations of 34.2, 34.3, and 34.8 μg/m^3, the Administrator notes that these studies reported long-term mean $PM_{2.5}$ concentrations of 12.9, 13.2, and 13.4 μg/m^3, respectively (Bell et al., 2008; Zanobetti and Schwartz, 2009; Dominici et al., 2006a).

In proposing to revise the level of the annual standard to within the range of 12 to 13 μg/m^3, as discussed above, the Administrator recognizes that additional protection would be provided for the short-term effects observed in these multi-city studies in conjunction with an annual standard level of 12

$\mu g/m^3$, and in two of these three studies in conjunction with an annual standard level of 13 $\mu g/m^3$. She notes that the study-wide mean concentrations are based on averaging across monitors within study areas and that compliance with the standard would be based on concentrations measured at the monitor reporting the highest concentration within each area. The Administrator believes it would be reasonable to conclude that revision to the 24-hour standard would not be warranted in conjunction with an annual standard within this range. Based on the above considerations related to the epidemiological evidence, the Administrator provisionally concludes that it is appropriate to retain the level of the 24-hour standard at 35 $\mu g/m^3$, in conjunction with a revised annual standard level in the proposed range of 12 to 13 $\mu g/m^3$.

In addition to considering the epidemiological evidence, the Administrator also has taken into account air quality information based on county-level 24-hour and annual design values to understand the implications of retaining the 24-hour standard level at 35 $\mu g/m^3$ in conjunction with an annual standard level within the proposed range of 12 to 13 $\mu g/m^3$. She has considered whether this suite of standards would meet a public health policy goal which includes setting the annual standard to be the "generally controlling" standard in conjunction with setting the 24-hour standard to provide supplemental protection to the extent that additional protection is warranted. As discussed above, the Administrator provisionally concludes that this approach is the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures, resulting in more uniform protection across the U.S. than the alternative of setting the 24-hour standard to be the controlling standard.

In considering the air quality information, the Administrator first recognizes that there is no annual standard within the proposed range of levels, when combined with a 24-hour standard at the proposed level of 35 $\mu g/m^3$, for which the annual standard would be the generally controlling standard in all areas of the country. She further observes that such a suite of $PM_{2.5}$ standards with an annual standard level of 12 $\mu g/m^3$ would result in the annual standard as the generally controlling standard in most

regions across the country, except for certain areas in the Northwest, where the annual mean $PM_{2.5}$ concentrations have historically been low but where relatively high 24-hour concentrations occur, often related to seasonal wood smoke emissions (US EPA, 2011a, pp. 2-89 to 2-91, Figure 2-10). Although not explicitly delineated on Figure 2-10 in the Policy Assessment, an annual standard of 13 $\mu g/m^3$ would be somewhat less likely to be the generally controlling standard in some regions of the U.S. outside the Northwest in conjunction with a 24-hour standard level of 35 $\mu g/m^3$.

Taking the above considerations into account, the Administrator proposes to revise the level of the primary annual $PM_{2.5}$ standard from 15.0 $\mu g/m^3$ to within the range of 12.0 to 13.0 $\mu g/m^3$ and to retain the 24-hour standard level at 35 $\mu g/m^3$. In the Administrator's judgment, such a suite of primary $PM_{2.5}$ standards and the rationale supporting such levels could reasonably be judged to reflect alternative approaches to the appropriate consideration of the strength of the available evidence and other information and their associated uncertainties and the advice of CASAC.

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

Having reached her provisional judgment to propose revising the annual standard level from 15.0 to within a range of 12.0 to 13.0 $\mu g/m^3$ and to propose retaining the 24-hour standard level at 35 $\mu g/m^3$, the Administrator solicits public comment on this range of levels and on approaches to considering the

available evidence and information that would support the choice of levels within this range. The Administrator also solicits public comment on alternative annual standard levels down to 11 μg/m^3 and on the combination of annual and 24-hour standards that commenters may believe is appropriate, along with the approaches and rationales used to support such levels. In addition, given the importance the evidence from epidemiologic studies plays in considering the appropriate annual and 24-hour levels, the Administrator solicits public comment on issues related to translating epidemiological evidence into standards, including approaches for addressing the uncertainties and limitations associated with this evidence.

F. Administrator's Proposed Decisions on Primary $PM_{2.5}$ Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Integrated Science Assessment, Risk Assessment, and Policy Assessment, the advice and recommendations of CASAC, and public comments to date, the Administrator proposes to revise the current primary $PM_{2.5}$ standards. Specifically, the Administrator proposes to revise: (1) the level of the primary annual $PM_{2.5}$ standard to a level within the range of 12.0 to 13.0 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 allowance for spatial averaging. In conjunction with revising the primary annual $PM_{2.5}$ standard to provide protection from effects associated with long- and short-term $PM_{2.5}$ exposures, the Administrator proposes to retain the level and form of the primary 24-hour $PM_{2.5}$ standard to provide supplemental protection for areas with high peak $PM_{2.5}$ concentrations. The Administrator provisionally concludes that such a revised suite of standards, including a revised annual standard together with the current 24-hour standard, could provide requisite protection against health effects potentially associated with long- and short-term $PM_{2.5}$ exposures. The Administrator is not proposing any revisions to the current $PM_{2.5}$ indicator and the annual and 24-hour averaging times for the primary $PM_{2.5}$ standards. Data handling conventions are specified in proposed revisions to appendix N, as discussed in section VII below. The Administrator solicits comment on all aspects of this proposed decision.

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

This section presents the rationale for the Administrator's proposed decision to retain the current 24-hour PM_{10} standard to continue to provide public health protection against short-term exposures to thoracic coarse particles, that is inhalable particles which can penetrate into the trachea, bronchi, and deep lungs and which are in the size range of 2.5 to 10 µm ($PM_{10-2.5}$). As discussed more fully below, this rationale is based on a thorough review, in the Integrated Science Assessment, of the latest scientific information, published through mid-2009, on human health effects associated with long- and short-term exposures to thoracic coarse particles in the ambient air. This proposal also takes into account: (1) staff assessments of the most policy-relevant information presented and assessed in the Integrated Science Assessment and staff analyses of air quality and health evidence presented in the Policy Assessment, upon which staff conclusions regarding appropriate considerations in this review are based; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the Integrated Science Assessment and Policy Assessment at public meetings, in separate written comments, and in CASAC's letters to the Administrator; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately. The EPA notes that the final decision for retaining or revising the current primary PM_{10} standard is a public health policy judgment made by the Administrator. The Administrator's final decision will draw upon scientific information and analyses related to health effects; judgments about uncertainties that are inherent in the scientific evidence and analyses; CASAC advice; and comments received in response to this proposal.

In presenting the rationale for the proposed decision to retain the current primary PM_{10} standard, this section begins with background information on EPA's past reviews of the PM NAAQS and the general approach taken to review the current PM_{10} standard (section IV.A), the health effects associated with exposures to ambient $PM_{10-2.5}$ (section IV.B), the consideration of the current and potential alternative standards in the Policy Assessment (section IV.C), CASAC recommendations regarding the current and potential alternative standards (section IV.D), and the Administrator's proposed conclusions

regarding the adequacy of the current primary PM_{10} standard (section IV.E). Section IV.F summarizes the Administrator's proposed decision with regard to the primary PM_{10} NAAQS.

A. Background

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

1. Previous Reviews of the PM NAAQS

a. Reviews Completed in 1987 and 1997

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

In the 1997 review, in conjunction with establishing new fine particle (i.e., $PM_{2.5}$) standards (discussed above in sections II.B.1 and III.A.1), the EPA concluded that continued protection was warranted against potential effects associated with thoracic coarse particles in the size range of 2.5 to 10 µm. This conclusion was based on particle dosimetry, toxicological information, and on limited epidemiological evidence from studies that measured PM_{10} in areas where the coarse fraction was likely to dominate PM_{10} mass (62 FR 38677, July 18, 1997). Thus, the EPA concluded that a PM_{10} standard could provide requisite protection against effects associated with particles in the size range of 2.5 to 10 µm.[87] Although the EPA considered a more narrowly defined indicator for thoracic coarse particles in

[87]With regard to the 24-hour PM_{10} standard, the EPA retained the indicator, averaging time, and level (150 µg/m^3), but revised the form (i.e., from one-expected-exceedance to the 99th percentile).

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

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

b. Review Completed in 2006

In the review of the PM NAAQS that concluded in 2006, the EPA considered the growing, but

still limited, body of evidence supporting associations between health effects and thoracic coarse particles measured as $PM_{10-2.5}$.[88] The new studies available in the 2006 review included epidemiological studies that reported associations with health effects using direct measurements of $PM_{10-2.5}$, as well as dosimetric and toxicological studies. In considering this growing body of $PM_{10-2.5}$ evidence, as well as evidence from studies that measured PM_{10} in locations where the majority of PM_{10} was in the $PM_{10-2.5}$ fraction (US EPA, 2005, section 5.4.1), staff concluded that the level of protection afforded by the existing 1987 PM_{10} standard remained appropriate (US 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 (US 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,

[88]The PM Staff Paper (US 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 (US EPA, 2005, p. 5-69).

the Administrator decided it would not be appropriate to adopt the proposed qualified $PM_{10-2.5}$ indicator, or any qualified indicator. Underlying this determination was the decision that it was requisite to provide protection from exposure to all thoracic coarse PM, regardless of its origin, rejecting arguments that there are no health effects from community-level exposures to coarse PM in non-urban areas (71 FR 61189). The EPA concluded that dosimetric, toxicological, occupational and epidemiological evidence supported retention of a primary standard for short-term exposures that included all thoracic coarse particles (i.e., particles of both urban and non-urban origin), consistent with the Act's requirement that primary NAAQS provide an adequate margin of safety. At the same time, the Agency concluded that the standard should target protection toward urban areas, where the evidence of health effects from exposure to $PM_{10-2.5}$ was strongest (71 FR at 61193, 61197). The proposed indicator was not suitable for that purpose. Not only did it inappropriately provide no protection at all to many areas, but it failed to identify many areas where the ambient mix was dominated by coarse particles contaminated with urban/industrial types of coarse particles for which evidence of health effects was strongest (71 FR 61193).

The Agency ultimately concluded that the existing indicator, PM_{10}, was most consistent with the evidence. Although PM_{10} includes both coarse and fine PM, the Agency concluded that it remained an appropriate indicator for thoracic coarse particles because, as discussed in the PM Staff Paper (US EPA, 2005, p. 2–54, Figures 2–23 and 2– 24), fine particle levels are generally higher in urban areas and, therefore, a PM_{10} standard set at a single unvarying level will generally result in lower allowable concentrations of thoracic coarse particles in urban areas than in non-urban areas (71 FR 61195 to 96, October 17, 2006). The EPA considered this to be an appropriate targeting of protection given that the strongest evidence for effects associated with thoracic coarse particles came from epidemiological studies conducted in urban areas and that elevated fine particle concentrations in urban areas could result in increased contamination of coarse fraction particles by $PM_{2.5}$, potentially increasing the toxicity of thoracic coarse particles in urban areas (Id.). Given the evidence that the existing PM_{10} standard

afforded requisite protection with an adequate margin of safety, the Agency retained the level and form of the 24-hour PM_{10} standard.[89]

The Agency also revoked the annual PM_{10} standard, in light of the conclusion in the PM Criteria Document (US 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 (US EPA, 2005, p. 5-61) that there is no quantitative evidence that directly supports retention of an annual standard.

In the same rulemaking, the EPA also included a new FRM for the measurement of $PM_{10-2.5}$ in the ambient air (71 FR 61212 to 61213, October 17, 2006). Although the standard for thoracic coarse particles does not use a $PM_{10-2.5}$ indicator, the new FRM for $PM_{10-2.5}$ was established to provide a basis for approving FEMs and to promote the gathering of scientific data to support future reviews of the PM NAAQS (71 FR 61202/3, October 17, 2006).

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

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

First, the court upheld EPA's decision for a standard to encompass all thoracic coarse PM, both of urban and non-urban origin. The court rejected arguments that the evidence showed there are no risks from exposure to non-urban coarse PM. The court further found that the EPA had a reasonable basis not to set separate standards for urban and non-urban coarse PM, namely the inability to reasonably define what ambient mixes would be included under either 'urban' or 'non-urban;' and the evidence in the

[89]Thus, the standard is met when a 24-hour average PM_{10} concentration of 150 $\mu g/m^3$ is not exceeded more than one day per year, on average over a three-year period.

record that supported EPA's appropriately cautious decision to provide "some protection from exposure to thoracic coarse particles… in all areas." 559 F. 3d at 532-33. Specifically, the court stated,

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

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

With regard to the challenge from environmental and public health groups, the court upheld

EPA's decision to revoke the annual PM_{10} standard. Specifically, the court stated the following:

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

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

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

In contrast to previous reviews, where PM_{10} studies conducted in locations where PM_{10} is comprised predominantly of $PM_{10\text{-}2.5}$ were considered (US EPA, 2005, pp. 5-49 to 5-50), the focus in the current review is on $PM_{10\text{-}2.5}$ studies. It is difficult to interpret PM_{10} studies within the context of a standard meant to protect against exposures to $PM_{10\text{-}2.5}$ because PM_{10} is comprised of both fine and coarse particles, even in locations with the highest concentrations of $PM_{10\text{-}2.5}$ (US EPA, 2011a, Figure 3-4). In light of the considerable uncertainty in the extent to which PM_{10} effect estimates reflect associations with $PM_{10\text{-}2.5}$ versus $PM_{2.5}$, together with the availability in this review of a number of studies that evaluated associations with $PM_{10\text{-}2.5}$ and the fact that the Integrated Science Assessment weight of evidence conclusions for thoracic coarse particles were based on studies of $PM_{10\text{-}2.5}$, the EPA focuses in this review on studies that have specifically evaluated $PM_{10\text{-}2.5}$.

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

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

As discussed in more detail in the Risk Assessment (US 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 (US EPA, 2010a, p. 2-6).

B. Health Effects Related to Exposure to Thoracic Coarse Particles

The following sections discuss available information on the health effects associated with exposures to $PM_{10-2.5}$, including the nature of such health effects (section IV.B.1), the impacts of sources and composition on particle toxicity (section IV.B.2), ambient PM_{10} concentrations in $PM_{10-2.5}$ study locations (section IV.B.3), at-risk populations (section IV.B.4), and limitations and uncertainties (section IV.B.5).

1. Nature of Effects

Since the conclusion of the last review, the Agency has developed a more formal framework for reaching causal inferences from the body of scientific evidence. As discussed above in section III.B.1,

this framework uses a five-level hierarchy that classifies the overall weight of evidence using the following categorizations: causal relationship, likely to be a causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (US EPA, 2009a, section 1.5). Applying this framework to thoracic coarse particles, the Integrated Science Assessment concludes that the existing evidence is "suggestive" of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects (US EPA, 2009a, section 2.3.3).[90] In contrast, the Integrated Science Assessment concludes that available evidence is "inadequate" to infer a causal relationship between long-term $PM_{10-2.5}$ exposures and various health effects (US EPA, 2009a, sections 7.2 to 7.6). Similar to the judgment made in the 2004 AQCD regarding long-term exposures (US EPA, 2004, p. 9-79), the Integrated Science Assessment states, "To date, a sufficient amount of evidence does not exist in order to draw conclusions regarding the health effects and outcomes associated with long-term exposure to $PM_{10-2.5}$" (US EPA, 2009a, section 2.3.4). Given these weight of evidence conclusions in the Integrated Science Assessment, EPA's consideration of the scientific evidence for $PM_{10-2.5}$ focuses on effects that have been linked with short-term exposures. The evidence supporting a link between short-term thoracic coarse particle exposures and adverse health effects is discussed in detail in the Integrated Science Assessment (US EPA, 2009a, Chapter 6) and is summarized briefly below for mortality (section IV.B.1.a), cardiovascular effects (section IV.B.1.b), and respiratory effects (section IV.B.1.c).

a. Short-Term $PM_{10-2.5}$ Exposure and Mortality

The Integrated Science Assessment assesses a number of multi-city and single-city epidemiological studies that have evaluated associations between mortality and short-term $PM_{10-2.5}$

[90]The Integrated Science Assessment discusses the framework for causality determinations (US EPA, 2009a, section 1.5). In the case of a "suggestive" determination, "the evidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out. For example, at least one high-quality epidemiologic study shows an association with a given health outcome but the results of other studies are inconsistent" (US EPA, 2009a, Table 1-3).

concentrations (US EPA, 2009a, Figure 6-30 presents $PM_{10-2.5}$ mortality studies assessed in the last review and the current review). Different studies have used different approaches to estimate ambient $PM_{10-2.5}$. Some studies have used the difference between PM_{10} and $PM_{2.5}$ mass, either measured at co-located monitors (e.g., Lipfert et al., 2000; Mar et al., 2003; Ostro et al., 2003; Sheppard et al., 2003; Wilson et al., 2007) or as the difference in county-wide average concentrations (Zanobetti and Schwartz, 2009), while other studies have measured $PM_{10-2.5}$ directly with dichotomous samplers (e.g., Burnett and Goldberg, 2003; Fairley et al., 2003; Burnett et al., 2004; Klemm et al., 2004). Despite differences in the approaches used to estimate ambient $PM_{10-2.5}$ concentrations, the majority of multi- and single-city studies have reported positive associations between $PM_{10-2.5}$ and mortality, though most of these associations were not statistically significant (US EPA, 2009a, Figure 6-30).

One important $PM_{10-2.5}$ study conducted since the last review of the PM NAAQS is the U.S. multi-city study by Zanobetti and Schwartz (2009), which reported positive and statistically significant associations with $PM_{10-2.5}$ for all-cause, cardiovascular-related, and respiratory-related mortality (US EPA, 2009a, section 6.5.2.3). In this study, effect estimates for all-cause and respiratory-related mortality remained statistically significant in co-pollutant models that included $PM_{2.5}$, while the effect estimate for cardiovascular-related mortality remained positive but not statistically significant. Several other multi-city studies have reported positive, but not statistically significant, $PM_{10-2.5}$ effect estimates for mortality (US EPA, 2009a, Figure 6-30).

When risk estimates in the study by Zanobetti and Schwartz (2009) were evaluated by climatic region (US EPA, 2009a, Figure 6-28), a mix of positive and negative $PM_{10-2.5}$ effect estimates were reported in the regions that typically have the highest ambient $PM_{10-2.5}$ concentrations (i.e., regions corresponding to the western and southwestern U.S.). Regional effect estimates from western regions of the United States were generally not statistically significant. Positive and statistically significant effect estimates were more often reported in regions that typically have lower $PM_{10-2.5}$ concentrations (i.e., regions generally corresponding to the eastern half of the U.S.) (Schmidt and Jenkins, 2010 for $PM_{10-2.5}$

concentrations). In addition, single-city empirical Bayes-adjusted effect estimates (calculated using the methods discussed in Le Tertre et al., 2005) for the 47 cities evaluated by Zanobetti and Schwartz (2009) were generally positive, though typically not statistically significant (US EPA, 2009a, Figure 6-29).

Of the available single-city $PM_{10-2.5}$ mortality studies, most reported positive, but not statistically significant, $PM_{10-2.5}$ effect estimates (US EPA, 2009a, Figure 6-30). Of the three studies that did report statistically significant effect estimates (Mar et al., 2003; Ostro et al., 2003; Wilson et al., 2007), Ostro et al. (2003) reported that $PM_{10-2.5}$ effect estimates remained statistically significant in co-pollutant models that included either ozone or NO_2. The single-city studies by Mar et al. (2003) and Wilson et al. (2007) did not utilize co-pollutant models.

b. Short-Term $PM_{10-2.5}$ Exposure and Cardiovascular Effects

The Integrated Science Assessment assesses a number of studies that have evaluated the link between short-term ambient concentrations of thoracic coarse particles and cardiovascular effects. Single- and multi-city epidemiological studies generally report positive associations between short-term $PM_{10-2.5}$ concentrations and hospital admissions or emergency department visits for cardiovascular causes (US EPA, 2009a, sections 2.3.3 and 6.2.12.2). However, as is the case for the mortality studies, most of these positive associations are not statistically significant. In addition, most $PM_{10-2.5}$ effect estimates remained positive, but not statistically significant, in co-pollutant models that included either gaseous or particulate co-pollutants (US EPA, 2009a, Figure 6-5).

An important cardiovascular morbidity study published since the last review of the PM NAAQS is the U.S. multi-city study by Peng et al. (2008). This study evaluates hospital admissions and emergency department visits for cardiovascular disease in Medicare patients (MCAPS, Peng et al., 2008). The authors report a positive and statistically significant association between 24-hour $PM_{10-2.5}$ concentrations and cardiovascular disease hospitalizations in a single pollutant model using air quality data for 108 U.S. counties with co-located PM_{10} and $PM_{2.5}$ monitors. The magnitude of this effect

estimate was larger in counties with higher degrees of urbanization and larger in the eastern U.S. than the western U.S., though this regional difference was not statistically significant (Peng et al., 2008). The $PM_{10-2.5}$ effect estimate was reduced only slightly in a co-pollutant model that included $PM_{2.5}$, but it was no longer statistically significant (US EPA, 2009a, sections 2.3.3, 6.2.10.9).

In addition to this U.S. multi-city study, positive associations reported for short-term $PM_{10-2.5}$ exposures and cardiovascular-related morbidity reached statistical significance in a multi-city study in France (Host et al., 2007) and single-city studies in Detroit (Ito, 2003) and Toronto (Burnett et al., 1999) (US EPA, 2009a, Figures 6-2 and 6-3). In contrast, associations were positive but not statistically significant in single-city studies conducted in Atlanta (Metzger et al., 2004; Tolbert et al., 2007) and Boston (Peters et al., 2001) (and for some endpoints in Detroit (Ito, 2003)) (US EPA, 2009a, Figures 6-1 to 6-3, and 6-5).

The plausibility of the positive associations reported for $PM_{10-2.5}$ and cardiovascular-related hospital admissions and emergency department visits receives some measure of support from a small number of controlled human exposure studies that have reported alterations in heart rate variability following short-term exposure to $PM_{10-2.5}$ (Gong et al., 2004; Graff et al., 2009); by short-term $PM_{10-2.5}$ epidemiological studies reporting positive associations with cardiovascular-related mortality; by a small number of recent epidemiological studies that have examined dust storm events and reported increases in cardiovascular-related emergency department visits and hospital admissions (see below); and by associations with other cardiovascular effects including heart rhythm disturbances and changes in heart rate variability (US EPA, 2009a, sections 2.3.3 and 6.2.12.2). The few toxicological studies that examined the effect of $PM_{10-2.5}$ on cardiovascular health effects used intratracheal instillation and, as a result, provide only limited evidence on the biological plausibility of $PM_{10-2.5}$ induced cardiovascular effects (US EPA, 2009a, sections 2.3.3 and 6.2.12.2).

c. Short-Term $PM_{10-2.5}$ Exposure and Respiratory Effects

The Integrated Science Assessment also assesses a number of studies that have evaluated the link

between short-term ambient concentrations of thoracic coarse particles and respiratory effects. This includes recent studies conducted in the U.S., Canada, and France (US EPA, 2009a, section 6.3.8), including the U.S. multi-city study of Medicare patients by Peng et al. (2008). As discussed above, Peng estimated $PM_{10-2.5}$ concentrations as the difference between PM_{10} and $PM_{2.5}$ concentrations measured by co-located monitors. The authors reported a positive, but not statistically significant, $PM_{10-2.5}$ effect estimate for respiratory-related hospital admissions. Single-city studies have reported positive, and in some cases statistically significant, $PM_{10-2.5}$ effect estimates for respiratory-related hospital admissions and emergency department visits (US EPA, 2009a, Figures 6-10 to 6-15). Some of these $PM_{10-2.5}$ respiratory morbidity studies have reported positive and statistically significant $PM_{10-2.5}$ effect estimates in co-pollutant models that included gaseous pollutants while others reported that $PM_{10-2.5}$ effect estimates remain positive, but not statistically significant, in such co-pollutant models (US EPA, 2009a, Figure 6-15).

A limited number of epidemiological studies have focused on specific respiratory morbidity outcomes and reported both positive and negative, but generally not statistically significant, associations between $PM_{10-2.5}$ and lower respiratory symptoms, wheeze, and medication use (US EPA, 2009a, sections 2.3.3.1 and 6.3.1.1; Figures 6-7 to 6-9). Although controlled human exposure studies have not observed an effect on lung function or respiratory symptoms in healthy or asthmatic adults in response to short-term exposure to $PM_{10-2.5}$, healthy volunteers have exhibited increases in markers of pulmonary inflammation.[91] Toxicological studies using inhalation exposures are still lacking, but pulmonary injury and inflammation has been reported in animals after intratracheal instillation exposure (US EPA, 2009a, section 6.3.5.3) and, in some cases, $PM_{10-2.5}$ was found to be more potent than $PM_{2.5}$.

2. Potential Impacts of Sources and Composition on $PM_{10-2.5}$ Toxicity

In the absence of a systematic national effort to characterize $PM_{10-2.5}$ components, relatively little information (e.g., compared to fine particles) is available in the current review to inform consideration

[91] $PM_{10-2.5}$ controlled human exposure studies have not been conducted in children.

of the potential for composition to impact $PM_{10-2.5}$ toxicity. Given this, the Integrated Science Assessment concludes that currently available evidence is insufficient to draw distinctions in toxicity based on composition and notes that recent studies have reported that PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from a variety of sources is associated with adverse health effects (US EPA, 2009a, section 2.4.4).

As discussed above, positive associations between short-term $PM_{10-2.5}$ concentrations and mortality and morbidity have been reported in a number of urban locations in the U.S., Canada, and Europe. While little is known about how $PM_{10-2.5}$ composition varies across these locations or about how that variation could affect particle toxicity (US EPA, 2009a, sections 2.3.3, 2.3.4, 2.4.4), a number of trace elements (e.g., chromium, cobalt, nickel, copper, zinc, arsenic, selenium, and lead) have been detected in $PM_{10-2.5}$ from urban locations (US EPA, 2004, section 3.2.4).

An indication of the sources of some of these trace elements (e.g., metals such as lead, copper, and zinc) in ambient $PM_{10-2.5}$ samples has been obtained by examining urban runoff (US EPA, 2004, section 3.2.4). Wind-abrasion on building siding and roofs (coatings such as lead paint and building material such as brick, metal, and wood siding); brake wear (brake pads contain significant quantities of copper and zinc); tire wear (zinc is used as a filler in tire production); and burning engine oil could all produce particles containing metals (US EPA, 2004, section 3.2.4). Once deposited on the ground, these elements can be resuspended with other material as $PM_{10-2.5}$. In addition, resuspended crustal particles may become contaminated with trace elements and other components from previously deposited fine PM (e.g., metals from smelters or steel mills, PAHs from automobile exhaust, pesticides from agricultural lands) (US EPA, 2004, section 8.5, p. 8-344).

In considering the potential for $PM_{10-2.5}$ composition to impact toxicity, it is useful to consider studies conducted in locations where $PM_{10-2.5}$ composition is expected to be very different from that in typical urban locations. Specifically, a small number of studies have examined the health impacts of dust storm events (US EPA, 2009a, sections 6.2.10.1 and 6.5.2.3). Although these studies do not link specific particle constituents to health effects, they do provide some information on the toxicity of particles of

non-urban crustal origin. Several of these studies have reported positive and statistically significant associations between dust storm events and morbidity or mortality, including the following:

1) Middleton et al. (2008) reported that dust storms in Cyprus were associated with a statistically significant increase in risk of hospitalization for all causes and a non-significant increase in hospitalizations for cardiovascular disease.

2) Chan et al. (2008) studied the effects of Asian dust storms on cardiovascular-related hospital admissions in Taipei, Taiwan and reported a statistically significant increase associated with 39 Asian dust events. Evaluating the same data, Bell et al. (2008) also reported positive and statistically significant associations between hospitalization for ischemic heart disease and $PM_{10-2.5}$.

3) Perez et al. (2008) tested the hypothesis that outbreaks of Saharan dust exacerbate the effects of $PM_{10-2.5}$ on daily mortality in Spain. During Saharan dust days, the $PM_{10-2.5}$ effect estimate was larger than on non-dust days and it became statistically significant, whereas it was not statistically significant on non-dust days.

In addition, a study in Coachella Valley by Ostro et al. (2003) reported statistically significant associations in a location where thoracic coarse particles are expected to be largely due to windblown dust.

In contrast to the studies noted above, some dust storm studies have reported associations that were not statistically significant. Specifically, Bennett et al. (2006) reported on a dust storm in the Gobi desert that transported PM across the Pacific Ocean, reaching western North America in the spring of 1998. The authors reported no excess risk of cardiovascular-related or respiratory-related hospital admissions associated with the dust storm in the population of British Columbia's Lower Fraser Valley (Bennett et al., 2006). In addition, Yang et al. (2009) reported that hospitalizations for congestive heart failure were elevated during or immediately following 54 Asian dust storm events, though effect estimates were not statistically significant.

3. Ambient PM_{10} Concentrations in $PM_{10-2.5}$ Study Locations

As discussed above, a 24-hour PM_{10} standard is in place to protect public health against exposures to $PM_{10-2.5}$. Given this, the EPA considers ambient PM_{10} concentrations in locations where $PM_{10-2.5}$ health studies have been conducted (US EPA, 2011a, section 3.2.1). Specifically, the Agency

considers study locations for which ambient PM_{10} data are available for comparison to the current standard,[92] including study locations evaluated in single-city U.S. studies, in Bayes-adjusted single-city analyses of the U.S. locations assessed by Zanobetti and Schwartz (2009), in single-city studies conducted outside the U.S., and in recent U.S. multi-city studies (Peng et al., 2008; Zanobetti and Schwartz, 2009).

In considering 24-hour PM_{10} concentrations in locations of specific $PM_{10\text{-}2.5}$ epidemiological studies, the EPA has focused primarily on U.S. study locations where single-city analyses have been conducted (US EPA, 2011a, sections 3.2.1 and 3.3.4). While multi-city studies are particularly important when drawing conclusions about health effect associations,[93] it can be difficult to use these studies to link air quality in a given location to health effects in that same location. Multi-city studies often present overall effect estimates rather than single-city effect estimates, while short-term air quality can vary considerably across cities. Therefore, the extent to which effects reported in multi-city studies are associated with the short-term air quality in any particular location is uncertain, especially when considering short-term concentrations at the upper end of the distribution of daily concentrations for pollutants with relatively heterogeneous spatial distributions such as $PM_{10\text{-}2.5}$ and PM_{10} (US EPA, 2009a, section 2.1.1.2). In contrast, single-city studies are more limited in terms of power and geographic coverage but the link between reported health effects and the short-term air quality in a given city is more straightforward to establish. As a result, in considering 24-hour PM_{10} concentrations in locations

[92]As discussed in more detail in the Policy Assessment (US EPA, 2011a), these analyses are based on comparison of the one-expected-exceedance concentration-equivalent design values in study locations to the level of the current standard. The one-expected-exceedance concentration-equivalent design value is used as a surrogate concentration for comparison to the standard level in order to gain insight into whether a particular area would likely have met or violated the current PM_{10} standard. Therefore, locations with one-expected-exceedance concentration-equivalent design values below the level of the current PM_{10} standard (i.e., 150 $\mu g/m^3$) would likely meet that standard (US EPA, 2011a, section 3.2.1).

[93] Multi-city studies assess $PM_{10\text{-}2.5}$-associated health effects among large study populations and provide enhanced power to detect $PM_{10\text{-}2.5}$-associated health effects. In addition, multi-city studies often provide spatial coverage for different regions across the country, reflecting differences in $PM_{10\text{-}2.5}$ sources, composition, and potentially other factors that could impact $PM_{10\text{-}2.5}$-related effects. These factors make multi-city studies particularly important when drawing conclusions about health effect associations.

of epidemiological studies, the EPA has focused primarily on single-city studies and single-city analyses of the locations evaluated in the multi-city study by Zanobetti and Schwartz (2009) (US EPA, 2011a, sections 3.2.1 and 3.3.4).

Of the single-city mortality studies conducted in the United States where ambient PM_{10} concentration data were available for comparison to the current standard, positive and statistically significant $PM_{10-2.5}$ effect estimates were only reported in study locations that would likely have violated the current PM_{10} standard during the study period (US EPA, 2011a, Figure 3-2).[94] In U.S. study locations that would likely have met the current standard, $PM_{10-2.5}$ effect estimates for mortality were positive, but not statistically significant (US EPA, 2011a, Figure 3-2). Amongst U.S. study locations where single-city morbidity studies were conducted, and which would likely have met the current PM_{10} standard during the study period, $PM_{10-2.5}$ effect estimates were both positive and negative, with most not statistically significant (US EPA, 2011a, Figure 3-3).

As discussed above, $PM_{10-2.5}$ effect estimates for mortality were generally positive but not statistically significant in Bayes-adjusted single-city analyses in the locations evaluated by Zanobetti and Schwartz (US EPA, 2009a, Figure 6-30). These effect estimates were generally similar in magnitude and precision, particularly for cardiovascular-related mortality, across a wide range of estimated $PM_{10-2.5}$ concentrations (US EPA, 2009a, Figure 6-29). In most of the cities evaluated (37 of the 45 for which appropriate PM_{10} air quality data were available for comparison to the current standard, as described in Schmidt and Jenkins (2010) and Jenkins (2011), PM_{10} concentrations were below those that would have been allowed by the current PM_{10} standard (US EPA, 2011a, section 3.2.1). Of these 37 cities that would likely have met the current PM_{10} standard during the study period, positive and statistically significant $PM_{10-2.5}$ effect estimates were reported in three locations (Chicago, Pittsburgh, Birmingham). Of the eight cities likely to have violated the current PM_{10} standard during the study period, $PM_{10-2.5}$ effect

[94]See a previous footnote above and the Policy Assessment (US EPA, 2011a, section 3.2.1) for an explanation of how PM_{10} air quality in study locations was compared to the current PM_{10} standard.

estimates were positive and statistically significant in three (Detroit, St. Louis, Salt Lake City).

In considering $PM_{10-2.5}$ epidemiological studies conducted in Canada and elsewhere outside the U.S., the EPA notes that PM_{10} air quality information beyond that published by the study authors is generally not available. The available PM_{10} concentration data for these study areas is typically not appropriate for comparison to the current PM_{10} standard (i.e., concentrations are averaged across monitors, rather than from the highest monitor in the study area, and/or concentrations are reported as means or medians). However, in a small number of cases it is possible to draw conclusions based on available air quality information about whether a study area would likely have met or violated the current PM_{10} standard.

For example, Lin et al. (2002) reported positive and statistically significant associations between $PM_{10-2.5}$ and asthma hospital admissions in children in Toronto (US EPA, 2009a; Figures 6-12 and 6-15). The authors reported a maximum PM_{10} concentration measured at a single monitor in the study area of 116 $\mu g/m^3$, indicating that the PM_{10} air quality in Toronto during this study would have been allowed by the current 24-hour PM_{10} standard.[95]

In contrast Middleton et al. (2008), who reported that dust storms in Cyprus were associated with a statistically significant increase in risk of hospitalization for all causes and a non-significant increase in hospitalizations for cardiovascular diseases, reported a maximum 24-hour PM_{10} concentration of 1,371 $\mu g/m^3$. Thus, the dust storm-associated increases in hospitalizations reported in this study occurred in an area with PM_{10} concentrations that were likely well above those allowed by the current standard. Other dust storm studies did not report maximum 24-hour PM_{10} concentrations from individual monitors, though the studies by Chan et al. (2008) and Bell et al. (2008), which reported positive and statistically significant associations between dust storm metrics and cardiovascular-related hospital admissions, reported that 24-hour PM_{10} concentrations, averaged across monitors, exceeded 200 $\mu g/m^3$.

[95]This is the case because the maximum monitored 24-hour PM_{10} concentration (116 $\mu g/m^3$) was below the level of the current PM_{10} standard (150 $\mu g/m^3$).

It is likely that peak concentrations measured at individual monitors in these studies were much higher and, therefore, 24-hour PM_{10} concentrations in these study areas were likely above those allowed by the current standard.

In addition to the single-city studies discussed above, multi-city averages of PM_{10} one-expected-exceedance concentration-equivalent design values[96] for recent U.S. multi-city studies were 110 μg/m^3, for the locations evaluated by Zanobetti and Schwartz (2009), and 100 μg/m^3, for the locations evaluated by Peng et al. (2008) (US EPA, 2011a, section 3.2.1). As discussed above, the extent to which multi-city $PM_{10-2.5}$ effect estimates are associated with the air quality in any particular location is uncertain.

4. At-Risk Populations

Specific groups within the general population are likely at increased risk for suffering adverse effects following $PM_{10-2.5}$ exposures. As discussed in section III.B.3 above, in this proposal, the term "at-risk" is the all encompassing term used for groups with specific factors that increase the risk of PM-related health effects in a population.

Although studies have primarily used exposures to PM_{10} or $PM_{2.5}$ to investigate potential at-risk populations, the available evidence suggests that the identified factors also increase risk from $PM_{10-2.5}$[97] (US EPA, 2009a, section 8.1.8). As discussed in section III.B.3 above, at-risk populations include those with preexisting heart and lung diseases (e.g., asthma), specific genetic differences, and lower socioeconomic status as well as the lifestages of childhood and older adulthood. Evidence for PM-

[96]The one-expected-exceedance concentration-equivalent design value is used as a surrogate concentration for comparison to the standard level in order to gain insight into whether a particular area would likely have met or violated the current PM_{10} standard. Therefore, locations with one-expected-exceedance concentration-equivalent design values below the level of the current PM_{10} standard (i.e., 150 μg/m^3) would likely meet that standard (US EPA, 2011a, section 3.2.1).

[97]Although the Integrated Science Assessment notes that in $PM_{10-2.5}$ studies of respiratory-related hospital admissions and emergency department visits, "the strongest relationships were observed among children" (US EPA, 2009a, section 2.3.3.1). As discussed above (section III.B.3), children may be more at increased risk for effects associated with ambient PM exposures because, compared to adults, children typically spend more time outdoors and at higher activity levels; they have exposures that result in higher doses per body weight and lung surface area; and there is the potential for irreversible effects on the developing lung (US EPA, 2009a, section 8.1.1.2).

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 (US EPA, 2009a, section 2.4.1 and Table 8-2)..

Given the range of at-risk groups, the population potentially affected by $PM_{10-2.5}$ is large. In the United States, approximately 7 percent of adults (approximately 16 million adults) and 9 percent of children (approximately 7 million children) have asthma (US EPA, 2009a, Table 8-3; CDC, 2008[98]). In addition, approximately 4 percent of adults have been diagnosed with chronic bronchitis and approximately 2 percent with emphysema (US EPA, 2009a, Table 8-3). Approximately 11 percent of adults have been diagnosed with heart disease, 6 percent with coronary heart disease, 23 percent with hypertension, and 8 percent with diabetes (US EPA, 2009a, Table 8-3). In addition, approximately 3 percent of the U.S. adult population has suffered a stroke (US EPA, 2009a, Table 8-3). Therefore, although exposures to ambient $PM_{10-2.5}$ have not been well characterized on a national scale, the size of the potentially at-risk population suggests that ambient $PM_{10-2.5}$ could have a significant impact on public health in the United States.

5. Limitations and Uncertainties Associated with the Currently Available Evidence

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

The Integrated Science Assessment concludes that an important uncertainty in interpreting $PM_{10-2.5}$ epidemiological studies is the potential for confounding by co-occurring pollutants, particularly $PM_{2.5}$. This issue has been addressed with co-pollutant models in only a relatively small number of

[98]For percentages, see http://www.cdc.gov/ASTHMA/nhis/06/table4-1.htm. For population estimates, see http://www.cdc.gov/ASTHMA/nhis/06/table3-1.htm.

$PM_{10-2.5}$ epidemiological studies (US 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 toxicology studies) available to support the plausibility of associations between $PM_{10-2.5}$ and adverse health effects. The net impact of such limitations is to increase uncertainty in characterizations of the extent to which $PM_{10-2.5}$ itself, rather than one or more co-occurring pollutants, is responsible for the mortality and morbidity effects reported in epidemiological studies.

Another important uncertainty is related to exposure error. The Integrated Science Assessment concludes that "there is greater spatial variability in $PM_{10-2.5}$ concentrations than $PM_{2.5}$ concentrations, resulting in increased exposure error for the larger size fraction" (US EPA, 2009a, p. 2-8) and that available measurements do not provide sufficient information to adequately characterize the spatial distribution of $PM_{10-2.5}$ concentrations (US 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" (US EPA, 2009a, p. 2-21).

In addition, there is uncertainty in the air quality estimates used in $PM_{10-2.5}$ epidemiological studies (US EPA, 2009a, sections 2.3.3, 2.3.4) and, therefore, in the ambient $PM_{10-2.5}$ concentrations that are associated with mortality and morbidity. Only a relatively small number of $PM_{10-2.5}$ monitoring sites are currently operating and such sites have been in operation for a relatively short period of time, limiting the spatial and temporal coverage for routine measurement of $PM_{10-2.5}$ concentrations.[99] Given

[99]The EPA has required $PM_{10-2.5}$ mass monitoring, as part of the NCore network, beginning January 1, 2011 at approximately 80 stations. The NCore network is a multi-pollutant network that includes measurements of particles, gases, and meteorology (71 FR 61236, October 17, 2006). NCore monitoring stations are located away from direct emissions sources that could substantially impact the detection of area-wide concentrations. The network is comprised of stations in both urban and rural areas. Urban NCore stations are generally to be located at an urban or neighborhood scale to provide exposure concentrations that are expected to be representative of the metropolitan area. Rural NCore stations are to be located, to the maximum extent practicable, at a regional or larger scale away from any large local

these limitations in routine monitoring, epidemiological studies have employed different approaches for estimating $PM_{10-2.5}$ concentrations. For example, several of the studies discussed above, including the multi-city study by Peng et al. (2008), estimated $PM_{10-2.5}$ by taking the difference between mass measured at co-located PM_{10} and $PM_{2.5}$ monitors while the study by Zanobetti and Schwartz (2009) used the difference between county-wide average PM_{10} and $PM_{2.5}$ concentrations. In addition, a small number of studies have directly measured $PM_{10-2.5}$ concentrations with dichotomous samplers (e.g., Burnett et al., 2004; Villeneuve et al., 2003; Klemm et al., 2004). It is not clear how computed $PM_{10-2.5}$ measurements, such as those used by Zanobetti and Schwartz (2009), compare with the $PM_{10-2.5}$ concentrations obtained in other studies either by direct measurement with a dichotomous sampler or by calculating the difference using co-located samplers (US EPA, 2009a, section 6.5.2.3).[100] Given the relatively small number of $PM_{10-2.5}$ monitoring sites, the relatively large spatial variability in ambient $PM_{10-2.5}$ concentrations (see above), the use of different approaches to estimating ambient $PM_{10-2.5}$ concentrations across studies, and the limitations inherent in such estimates, the distributions of thoracic coarse particle concentrations over which reported health outcomes occur remain highly uncertain (US EPA, 2009a, sections 2.2.3, 2.3.3, 2.3.4, and 3.5.1.1).

Another uncertainty results from the relative lack of information on the chemical and biological composition of $PM_{10-2.5}$ and the effects associated with the various components (US EPA, 2009a, section 2.3.4). As discussed above, a few recent studies have evaluated associations between health effects and

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emission source, so that they represent ambient concentrations over an extensive area (US EPA, 2011a, Appendix B, section B.4).

[100]In addition, several sources of uncertainty can be specifically associated with $PM_{10-2.5}$ concentrations that are estimated based on co-located monitors. For example, the potential for differences among operational flow rates and temperatures for PM_{10} and $PM_{2.5}$ monitors add to the potential for exposure misclassification. As discussed in Appendix B of the Policy Assessment (US EPA, 2011a, sections B.2 and B.3), PM_{10} data are often reported at standard temperature and pressure (STP) while $PM_{2.5}$ is reported at local conditions (LC). In these cases, the PM_{10} data should be adjusted to LC when estimating $PM_{10-2.5}$ concentrations. In many of the epidemiological studies that estimated $PM_{10-2.5}$ concentrations based on co-located monitors, it is not made explicitly clear whether this adjustment was made, adding to the overall uncertainty in the $PM_{10-2.5}$ concentrations that are associated with health effects.

particles of non-urban, crustal origin by evaluating the health impacts of dust storm events. Though these studies provide some information on the health effects of ambient particles that likely differ in composition from the particles of urban origin that are typically studied, without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations with health effects across locations is difficult to characterize (US EPA, 2009a, section 6.5.2.3).

One of the implications of the uncertainties and limitations discussed above is that the Risk Assessment concluded it would not be appropriate to conduct a quantitative assessment of health risks associated with $PM_{10-2.5}$ (US EPA, 2009b, Appendix H). The decision not to conduct a $PM_{10-2.5}$ risk assessment for the current review was based on consideration of several key uncertainties, including the following:

1) Concerns that monitoring data that would be used in a $PM_{10-2.5}$ risk assessment (i.e., for the period 2005 to 2007) would not match ambient monitoring data used in the underlying epidemiological studies providing concentration-response functions.

2) Uncertainty in the prediction of ambient levels under current and alternative standard levels.

3) Concerns that locations used in the risk assessment may not be representative of areas experiencing the most significant 24-hour peak $PM_{10-2.5}$ concentrations (and consequently, may not capture locations with the highest risk).

4) Concerns about the relatively small (i.e., compared to $PM_{2.5}$) health effects database that supplies the concentration-response relationships.

When considered together, the limitations outlined above resulted in the conclusion that a quantitative $PM_{10-2.5}$ risk assessment would not significantly enhance the review of the NAAQS for coarse-fraction PM. Specifically, these limitations would likely result in sufficient uncertainty in the resulting risk estimates to significantly limit their utility to inform policy-related questions, including the assessment of whether the current standard is protective of public health and characterization of the degree of additional public health protection potentially afforded by alternative standards. The lack of a quantitative $PM_{10-2.5}$ risk assessment in the current review adds to the uncertainty in any conclusions about the extent to which revision of the current PM_{10} standard would be expected to improve the

protection of public health, beyond the protection provided by the current standard.

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

The following sections discuss EPA's consideration of whether to revise the current PM_{10} standard, as well as our consideration of potential alternative standards, drawing from such considerations in the Policy Assessment (US EPA, 2011a, chapter 3). Section IV.C.1 discusses the consideration of the current standard while section IV.C.2 discusses the consideration of potential alternative standards in terms of the basic elements of a standard: indicator (section IV.C.2.a), averaging time (section IV.C.2.b), form (section IV.C.2.c), and level (section IV.C.2.d).

1. Consideration of the Current Standard in the Policy Assessment

As discussed above, a 24-hour PM_{10} standard is in place to protect the public health against exposures to thoracic coarse particles (i.e., $PM_{10-2.5}$). In considering the adequacy of the current PM_{10} standard, the EPA considers the health effects evidence linking short-term $PM_{10-2.5}$ exposures with mortality and morbidity (US EPA, 2009a, chapters 2 and 6), the ambient PM_{10} concentrations in $PM_{10-2.5}$ study locations (US EPA, 2011a, section 3.2.1), the uncertainties and limitations associated with this health evidence (US 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 (US EPA, 2009a).

In considering the health evidence, air quality information, and associated uncertainties as they relate to the current PM_{10} standard, the EPA notes that a decision on the adequacy of the public health protection provided by that standard is a public health policy judgment in which the Administrator weighs the evidence and information, as well as its uncertainties. Therefore, depending on the emphasis placed on different aspects of the evidence, information, and uncertainties, consideration of different conclusions on the adequacy of the current standard could be supported. For example, the Policy Assessment notes that one approach to considering the evidence, information, and its associated uncertainties would be to place emphasis on the following (US EPA, 2011a, section 3.2.1):

1) While most of $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were positive, many were not statistically significant, even in single-pollutant models. This includes effect estimates reported in study locations with PM_{10} concentrations above those allowed by the current 24-hour PM_{10} standard.
2) The number of epidemiological studies that have employed co-pollutant models to address the potential for confounding, particularly by $PM_{2.5}$, remains limited. Therefore, the extent to which $PM_{10-2.5}$ itself, rather than one or more co-pollutants, contributes to reported health effects remains uncertain.
3) Only a limited number of experimental studies provide support for the associations reported in epidemiological studies, resulting in further uncertainty regarding the plausibility of a causal link between $PM_{10-2.5}$ and mortality and morbidity.
4) Limitations in $PM_{10-2.5}$ monitoring and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiological studies result in uncertainty in the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur.
5) The chemical and biological composition of $PM_{10-2.5}$, and the effects associated with the various components, remains uncertain. Without more information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across locations is difficult to characterize.
6) In considering the available evidence and its associated uncertainties, the Integrated Science Assessment concluded that the evidence is "suggestive" of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. These weight-of-evidence conclusions contrast with those for the relationships between $PM_{2.5}$ exposures and adverse health effects, which were judged in the Integrated Science Assessment to be either "causal" or "likely causal" for mortality, cardiovascular effects, and respiratory effects.

The Policy Assessment concludes that, to the extent a decision on the adequacy of the current 24-hour PM_{10} standard were to place emphasis on the considerations noted above, it could be judged that, although it remains appropriate to maintain a standard to protect against short-term exposures to thoracic coarse particles, the available evidence suggests that the current 24-hour PM_{10} standard appropriately protects public health and provides an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. Although such an approach to considering the adequacy of the current standard would recognize the positive, and in some cases statistically significant, associations between $PM_{10-2.5}$ and mortality and morbidity, it would place relatively greater emphasis on the limitations and uncertainties noted above, which tend to complicate the interpretation of that evidence.

In addition, the Policy Assessment notes that, when considering the uncertainties and limitations in the $PM_{10-2.5}$ health evidence and air quality information, the EPA judged that it would not be

appropriate to conduct a quantitative assessment of health risks associated with $PM_{10-2.5}$ (US EPA, 2011a, p. 3-6; US EPA, 2010a, pp. 2-6 to 2-7, Appendix H). As discussed above, the lack of a quantitative $PM_{10-2.5}$ risk assessment adds to the uncertainty associated with any characterization of potential public health improvements that would be realized with a revised standard.

The Policy Assessment also notes an alternative approach to considering the evidence and its uncertainties would place emphasis on the following:

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

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

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

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

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

conclusions that the evidence is only suggestive of a causal relationship.

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

2. Consideration of Potential Alternative Standards in the Policy Assessment

Given the conclusion that it would be appropriate to consider either retaining or revising the current PM_{10} standard, the Policy Assessment also considered what potential alternative standards, if any, could be supported by the available scientific evidence in order to increase public health protection against exposures to $PM_{10-2.5}$. These considerations are discussed below in terms of indicator, averaging time, form, and level.

a. Indicator

As noted above, PM_{10} includes both $PM_{10-2.5}$ and $PM_{2.5}$, with the relative contribution of each to PM_{10} mass varying across locations and over time. In the most recent review completed in 2006, the EPA concluded that the PM_{10} indicator remained appropriate in large part because a PM_{10} standard would provide some measure of protection against exposures to all $PM_{10-2.5}$ regardless of source or location, while also targeting protection to urban areas, where the evidence of effects from exposure to coarse PM is the strongest (71 FR at 61196, October 17, 2006). As noted above, the court explicitly endorsed this reasoning. 559 F. 3d at 535-36.

In considering the indicator in the current review, the Policy Assessment evaluated the extent to which PM_{10} is comprised of $PM_{10-2.5}$ across locations and over time. Based on the air quality analyses in the Integrated Science Assessment (US EPA, 2009a, section 3.5.1.1) and Schmidt and Jenkins (2010), and based on the concentration estimates of Zanobetti and Schwartz (2009), the Policy Assessment notes that $PM_{10-2.5}$ typically makes up a larger portion of PM_{10} mass in the western United States, with the southwest region having the highest ratios of $PM_{10-2.5}$ to PM_{10}. In addition, the ratios of $PM_{10-2.5}$ to PM_{10}

across the U.S. tended to be higher on days with relatively high PM_{10} concentrations than on days with more typical PM_{10} concentrations (i.e., comparing days with concentrations at or above the 95th percentile to all days) (US EPA, 2011a, section 3.3.1, Figure 3-4). Given this, the Policy Assessment concludes that high daily PM_{10} concentrations are driven, at least in part, by elevated $PM_{10-2.5}$ mass and that a PM_{10} standard focusing on the upper end of the distribution of daily PM_{10} concentrations could effectively control ambient $PM_{10-2.5}$ concentrations (US EPA, 2011a, p. 3-28).

The Policy Assessment also considered the appropriateness of a PM_{10} standard, given that such a standard allows lower $PM_{10-2.5}$ concentrations in areas with higher fine particle concentrations (urban areas) than areas with lower fine particle concentrations (rural areas) (US EPA, 2011a, section 3.3.1). In considering this issue, the Policy Assessment notes that most of the evidence for positive associations between $PM_{10-2.5}$ and morbidity and mortality, particularly evidence for these associations at relatively low concentrations of $PM_{10-2.5}$, comes from a number of studies conducted in locations where the $PM_{10-2.5}$ is expected to be largely of urban origin (US EPA, 2009a, Chapter 6). Although some studies have reported positive associations between relatively high concentrations of particles of non-urban origin (i.e., crustal material from windblown dust in non-urban areas, see above) and mortality and morbidity, the Policy Assessment notes that the extent to which these associations would remain at the lower particle concentrations more typical of U.S. and Canadian urban study locations remains uncertain.[101]

Given these considerations, and given the increased potential for coarse particles in urban areas to become contaminated by toxic components of fine particles from urban/industrial sources (US EPA, 2004 at 8-344; 71 FR 61196, October 17, 2006), the Policy Assessment concludes that it is reasonable to

[101]Other than the dust storm studies, we note that the study in Coachella Valley by Ostro et al. (2003) reported statistically significant associations in a location where thoracic coarse particles are expected to be largely due to windblown dust. Specifically, we note the CASAC conclusion in the last review that "studies from Ostro et al. showed significant adverse health effects, primarily involving exposures to coarse-mode particles arising from crustal sources" (Henderson, 2005b). In considering this study, we also note the relatively high PM_{10} concentrations in the study area (US EPA, 2011a, Figure 3-2), which would not have met the current PM_{10} standard.

consider an indicator that targets control to areas with the types of ambient mixes generally present in urban areas. The Policy Assessment notes that such an indicator would focus control on areas with ambient mixes known with greater certainty to be associated with adverse health effects and, therefore, would provide public health benefits with the greatest degree of certainty. Therefore, as in the last review, the Policy Assessment reaches the conclusion that a PM_{10} indicator would appropriately target protection to those locations where the evidence is strongest for associations between adverse health effects and exposures to thoracic coarse particles (US EPA, 2011a, p. 3-29).

In contrast, the Policy Assessment notes that a $PM_{10\text{-}2.5}$ indicator, for a standard set at a single unvarying level, would not achieve this targeting, given that allowable thoracic coarse particle concentrations would be the same regardless of the location or the likely sources of PM. Therefore, given the currently available evidence, one possible result of using a $PM_{10\text{-}2.5}$ indicator would be a standard that is overprotective in rural areas and/or underprotective in urban areas (Id.).

Given all of the above considerations, the Policy Assessment concludes that the available evidence supports consideration in the current review of a PM_{10} indicator for a standard that protects against exposures to thoracic coarse particles. The Policy Assessment further concludes that consideration of alternative indicators (e.g., $PM_{10\text{-}2.5}$) in future reviews is desirable and could be informed by additional research (US EPA, 2011a, section 3.5).

b. Averaging Time

Based primarily on epidemiological studies that reported positive associations between short-term (24-hour) $PM_{10\text{–}2.5}$ concentrations and mortality and morbidity, the Administrator concluded in the last review that the available evidence supported a 24-hour averaging time for a standard intended to protect against exposures to thoracic coarse particles. In contrast, given the relative lack of studies supporting a link between long-term exposures to thoracic coarse particles and morbidity or mortality (US EPA, 2004, Chapter 9), the Administrator further concluded that an annual coarse particle standard was not warranted at that time (71 FR 61198-61199, October 17, 2006).

In the current review, the Policy Assessment notes the conclusions from the Integrated Science Assessment regarding the weight of evidence for short-term and long-term $PM_{10-2.5}$ exposures as well as the studies on which those conclusions are based. Specifically, as discussed above, the Integrated Science Assessment concludes that the existing evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects (US EPA, 2009a, section 2.3.3). This conclusion is based largely on epidemiological studies which have primarily evaluated associations between 24-hour $PM_{10-2.5}$ concentrations and morbidity and mortality (e.g., US EPA, 2009a, Figure 2-3), though a small number of controlled human exposure studies have reported effects following shorter exposures (i.e., 2-hours) to $PM_{10-2.5}$ (US EPA, 2009a, sections 6.2.1.2 and 6.3.3.2). In contrast, with respect to long-term exposures, the Integrated Science Assessment concludes that available evidence is inadequate to infer a causal relationship with all health outcomes evaluated (US EPA, 2009a, section 2.3). Specifically, the Integrated Science Assessment states, "To date, a sufficient amount of evidence does not exist in order to draw conclusions regarding the health effects and outcomes associated with long-term exposure to $PM_{10-2.5}$" (US EPA, 2009a, section 2.3.4).

In considering these weight-of-evidence determinations, the Policy Assessment concludes that, at a minimum, they suggest the importance of maintaining a standard that protects against short-term exposures to thoracic coarse particles. Given that the majority of the evidence supporting the link between short-term $PM_{10-2.5}$ and morbidity and mortality is based on 24-hour average thoracic coarse particle concentrations, the Policy Assessment concludes that the evidence available in this review continues to support consideration of a 24-hour averaging time for a PM_{10} standard meant to protect against effects associated with short-term exposures to $PM_{10-2.5}$ (US EPA, 2011a, p. 3-31).

The Policy Assessment further concludes that the available evidence does not support consideration of an annual thoracic coarse particle standard at this time. In reaching this conclusion, the Policy Assessment also notes that, to the extent a short-term standard requires areas to reduce their 24-hour ambient particle concentrations, long-term concentrations would also be expected to decrease (Id.).

Therefore, a 24-hour standard meant to protect against short-term exposures to thoracic coarse particles would also be expected to provide some protection against potential effects associated with long-term exposures to ambient concentrations.

c. Form

The "form" of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains that standard. As discussed above, in the last review the Administrator retained the one-expected exceedance form of the primary 24-hour PM_{10} standard. This decision was linked to the overall conclusion that "the level of protection from coarse particles provided by the current 24-hour PM_{10} standard remains requisite to protect public health with an adequate margin of safety" (71 FR 61202, October 17, 2006). Because revising either the level or the form of the standard would have altered the protection provided, the Administrator concluded that such changes "would not be appropriate based on the scientific evidence available at this time" (71 FR 61202). Therefore, the decision in the last review to retain the one-expected-exceedance form was part of the broader decision that the existing 24-hour standard provided requisite public health protection.

In the current review, the Policy Assessment considers the form of the standard within the context of the overall decision on whether, and if so how, to revise the current 24-hour PM_{10} standard. Given the conclusions above regarding the appropriate indicator and averaging time for consideration for potential alternative standards, the Policy Assessment considers potential alternative forms for a 24-hour PM_{10} standard.

Although the selection of a specific form must be made within the context of decisions on the other elements of the standard, the Policy Assessment notes that the EPA generally favors concentration-based forms for short-term standards. In 1997, the EPA established a 98th percentile form for the 24-hour $PM_{2.5}$ standard and, in 2010, the EPA established a 98th percentile form for the primary 1-hour NO_2 standard (62 FR 38671, July 18, 1997; 75 FR 6474, February 9, 2010) and a 99th percentile

form for the primary 1-hour SO_2 standard (75 FR 35541, June 22, 2010).[102] In making these decisions, the EPA noted that, compared to an exceedance-based form, a concentration-based form is more reflective of the health risks posed by elevated pollutant concentrations because such a form gives proportionally greater weight to days when concentrations are well above the level of the standard than to days when the concentrations are just above the level of the standard. In addition, when averaged over three years, these concentration-based forms were judged to provide an appropriate balance between limiting peak pollutant concentrations and providing a stable regulatory target, facilitating the development of stable implementation programs.

These considerations are also relevant in the current review of the 24-hour PM_{10} standard. Specifically, the Policy Assessment concludes that it is appropriate to consider concentration-based forms that would provide a balance between limiting peak pollutant concentrations and providing a stable regulatory target. To accomplish this, it would be appropriate to consider forms from the upper end of the annual distribution of 24-hour PM_{10} concentrations.[103] However, given the potential for local sources to have important impacts on monitored PM_{10} concentrations (US EPA, 2009a, section 2.1.1.2), the Policy Assessment also notes that it would be appropriate to consider forms that, when averaged over three years, would be expected to promote the stability of local implementation programs.[104] In considering these issues in the most recent review of the primary NO_2 NAAQS, the Policy Assessment notes that a 98th percentile form was adopted, rather than a 99th percentile form, due to the potential for "instability in the higher percentile concentrations" near local sources (75 FR 6493, February 9,

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[102]As noted above (section IV.A.1.a), in the 1997 review the EPA revised the form of the 24-hour PM_{10} standard to the 99th percentile. However, the D.C. Circuit Court vacated the revised rule, based on EPA's retention of the PM_{10} indicator, and the 1987 standards remained in place (including the one-expected-exceedance form for the 24-hour standard).

[103]With regard to this conclusion, the Policy Assessment also notes that $PM_{10-2.5}$ is likely to make a larger contribution to PM_{10} mass on days with relatively high PM_{10} concentrations than on days with more typical PM_{10} concentrations (see above).

[104]As noted in section III.E.3.b above, stability of implementation programs has been held to be a legitimate consideration in determining a NAAQS (American Trucking Associations v. EPA, 283 F. 3d at 374 to 75).

2010).[105,106]

In considering the potential appropriateness of a 98th percentile form in the current review, the Policy Assessment notes that, compared to the current PM_{10} standard, attainment status for a PM_{10} standard with a 98th percentile form would be based on a more stable air quality statistic and would be expected to be less influenced by relatively rare events that can cause elevations in PM_{10} concentrations over short periods of time (Schmidt, 2011b). Specifically, the Policy Assessment notes that in areas that monitor PM_{10} every six days, every three days, or every day the PM_{10} concentrations that are comparable to the current standard level are, respectively, the highest, 2nd highest, or 4th highest 24-hour PM_{10} concentrations measured during a three year period. In contrast, for the same monitoring frequencies, the PM_{10} concentrations that would be comparable to the level of a standard with a 98th percentile form would be the three-year average of the 2nd highest, 3rd highest, or 7th/8th highest 24-hour PM_{10} concentrations measured during a single year (US EPA, 2011a, p. 3-33).

In further considering this issue the Policy Assessment notes that, compared to the current one-expected-exceedance form, a concentration-based form specified as a percentile of the annual distribution of PM_{10} concentrations (e.g., such as a 98th percentile form) would be expected to better compensate for missing data and less-than-daily monitoring. This is a particularly important consideration in the case of PM_{10} because, depending largely on ambient concentrations, the frequency of PM_{10} monitoring differs across locations (i.e., either daily, 1 in 2 days, 1 in 3 days, or 1 in 6 days) (US EPA, 2011a, section 1.3 and Appendix B). As discussed in earlier reviews of the PM NAAQS (e.g., 62 FR 38671, July 18, 1997), an area's attainment status for a standard with a 98th percentile form would

[105]See also, *ATA III*, 283 F. 3d at 374-75 (upholding 98th percentile form since "otherwise States would have to design their pollution control programs around single high exposure events that may be due to unusual meteorological conditions alone, rendering the programs less stable – and hence, we assume, less effective – than programs designed to address longer-term average conditions."). In contrast, in the recently completed review of the primary SO_2 NAAQS, a 99th percentile form was adopted. However, in the case of SO_2, the standard was intended to limit 5-minute exposures and a 99th percentile form was markedly more effective at doing so than a 98th percentile form (75 FR 35540 to 41, June 22, 2010).
[106]Similar considerations are noted in section III.E.3.b above, with regard to the form of the primary 24-hour $PM_{2.5}$ standard.

be based directly on monitoring data rather than on a calculated value adjusted for missing data or less-than-every-day monitoring, as is the case with the current one-expected-exceedance form.

In light of all of the above considerations, the Policy Assessment concludes that, to the extent it is judged appropriate to revise the current 24-hour PM_{10} standard, it would be appropriate to consider revising the form to the 3-year average of the 98th percentile of the annual distribution of 24-hour PM_{10} concentrations (US EPA, 2011a, p. 3-34).[107]

In their review of the second draft Policy Assessment, CASAC noted that such a change in form "will lead to changes in levels of stringency across the country" and recommended that this issue be explored further (Samet, 2010d). In considering this issue, the Policy Assessment acknowledges that, given differences in PM_{10} air quality distributions across locations (US EPA, 2009a, Table 3-10), a revised standard with a 98th percentile form would likely target public health protection to some different locations than does the current standard with its one-expected-exceedance form (US EPA, 2011a, p. 3-34). The final Policy Assessment notes that a further consideration with regard to the appropriateness of revising the form of the current PM_{10} standard is the extent to which, when compared with the current standard, a revised standard with a 98th percentile form would be expected to target public health protection to areas where we have more confidence that ambient $PM_{10-2.5}$ is associated with adverse health effects (Id., p. 3-34 to 3-35).

In giving initial consideration to this issue, the Policy Assessment used recent PM_{10} air quality concentrations (i.e., from 2007-2009) to identify counties that would meet, and counties that would violate, the current PM_{10} standard as well as potential alternative standards with 98th percentile forms

[107]As noted above, local sources can have important impacts on monitored PM_{10} concentrations. In the recent review of the NO_2 primary NAAQS, where this was also an important consideration, a 98th percentile form was adopted, rather than a 99th percentile form, due to the potential for "instability in the higher percentile concentrations" near local sources (75 FR 6493, February 9, 2010). A similar conclusion in the current review led the Policy Assessment to focus on the 98th percentile rather than the 99th percentile, in considering potential alternative forms for a PM_{10} standard.

(Schmidt, 2011b).[108,109] In some cases, counties that would violate the current standard do so because of a small number of "outlier" days (e.g., as few as one such day in three years) with PM_{10} concentrations well-above more typical concentrations (Schmidt, 2011b). Mean and 98th percentile PM_{10} and $PM_{10-2.5}$ concentrations were higher in counties that would have violated a revised standard with a 98th percentile form but met the current standard[110] than in counties that violated the current standard, but would have met a revised standard with a 98th percentile form (Schmidt, 2011b). This analysis suggests that, to the extent a revised PM_{10} standard with a 98th percentile form could target public health protection to different areas than the current standard, those areas preferentially targeted by a revised standard generally have higher ambient concentrations of thoracic coarse particles. The issue of targeting public health protection is considered further in section 3.3.4 of the Policy Assessment (US EPA, 2011a) and below, within the context of considering specific potential alternative standard levels for a 24-hour PM_{10} standard with a 98th percentile form.

d. Level

As noted above, the Policy Assessment concluded that, to the extent it is judged in the current review that the 24-hour PM_{10} standard does not provide adequate public health protection against exposures to thoracic coarse particles, potential alternative standards could be considered. The Policy Assessment considers potential alternative levels for a 24-hour PM_{10} standard with a 98th percentile form. To inform consideration of this issue, the Policy Assessment considers the available scientific evidence and air quality information (US EPA, 2011a, section 3.3.4).

i. Evidence-based Considerations in the Policy Assessment

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[108]Section 3.3.4 of the Policy Assessment (US EPA, 2011a) discusses potential alternative standard levels that would be appropriate to consider in conjunction with a revised standard with a 98th percentile form.

[109]The memo by Schmidt (2011b) identifies specific counties that are expected to meet, and counties that are not likely to meet the current standard and potential alternative standards with 98th percentile forms.

[110]This analysis considered a revised PM_{10} standard with a 98th percentile form and a level from the middle of the range discussed in section 3.3.4 of the Policy Assessment (i.e., 75 $\mu g/m^3$) (US EPA, 2011a).

As discussed above, in considering the evidence as it relates to potential alternative standard levels, the Policy Assessment first considers the relative weight to place on specific epidemiological studies, including the weight to place on the uncertainties associated with those studies. The Policy Assessment considers several factors in placing weight on specific epidemiological studies including the extent to which studies report statistically significant associations with $PM_{10-2.5}$ and the extent to which the reported associations are robust to co-pollutant confounding, in particular confounding by $PM_{2.5}$. In addition, the Policy Assessment considers the extent to which associations with $PM_{10-2.5}$ can be linked to the air quality in a specific location. With regard to this, as noted above, the Policy Assessment places the greatest weight on information from single-city analyses.

In considering PM air quality in study locations, the Policy Assessment also notes that the available evidence does not support the existence of thresholds, or lowest-observed-effects levels, in terms of 24-hour average concentrations (US EPA, 2009a, section 2.4.3).[111] In the absence of an apparent threshold, for purposes of identifying a range of standard levels potentially supported by the health evidence, the Policy Assessment focuses on the range of PM_{10} concentrations that have been measured in locations where U.S. epidemiological studies have reported associations with $PM_{10-2.5}$ (US EPA, 2009a, Figures 6-1 to 6-30 for studies).

In single-city mortality studies, as well as the single-city analyses of the locations evaluated by Zanobetti and Schwartz (2009), positive and statistically significant $PM_{10-2.5}$ effect estimates were reported in some locations with 98th percentile PM_{10} concentrations ranging from 200 $\mu g/m^3$ to 91 $\mu g/m^3$ (US EPA, 2011a, section 3.3.4). Lower PM_{10} concentrations were present in locations where positive, but not statistically significant, effect estimates were reported and when averaged across locations evaluated in the multi-city study by Zanobetti and Schwartz (2009) (US EPA, 2011a, section 3.3.4).

Among U.S. morbidity studies, Ito (2003) reported a positive and statistically significant $PM_{10-2.5}$

[111]Most studies that have evaluated the potential for thresholds have focused on PM_{10} or $PM_{2.5}$. However, there is no scientific basis for drawing different conclusions for $PM_{10-2.5}$.

effect estimate for hospital admissions for ischemic heart disease in Detroit, where the 98th percentile PM_{10} concentration (102 μg/m^3) was also within this range (US EPA, 2011a, section 3.3.4 and Figure 3-6). $PM_{10-2.5}$ effect estimates in this study remained positive, and in some cases statistically significant, in co-pollutant models with gaseous pollutants (US EPA, 2009a, Figures 6-5 and 6-15). Lower PM_{10} concentrations were present in locations where positive, but not statistically significant, effect estimates were reported and when averaged across locations evaluated in the multi-city study by Peng et al. (2008) (US EPA, 2011a, section 3.3.4).

ii. Air Quality-based Considerations in the Policy Assessment

In addition to the evidence-based considerations described above, the Policy Assessment estimated the level of a 24-hour PM_{10} standard with a 98th percentile form that would approximate the degree of protection, on average across the country, provided by the current 24-hour PM_{10} standard with its one-expected-exceedance form. The initial approach to estimating this "generally equivalent" 98th percentile PM_{10} concentration was to use EPA's Air Quality System (AQS)[112] as the basis for evaluating correlations between 98th percentile PM_{10} concentrations and one-expected-exceedance concentration equivalent design values (Schmidt and Jenkins, 2010).[113] Based on these correlations, using monitoring data from 1988 to 2008, a 98th percentile PM_{10} concentration of 87 μg/m^3 is, on average, generally equivalent to the current standard level (US EPA, 2011a, Figure 3-7). However, given the variability in the distributions of PM_{10} concentrations across locations (US EPA, 2009a, Table 3-10; Schmidt and Jenkins, 2010), the range of equivalent concentrations varies considerably (95 percent confidence interval ranges from 63 to 111 μg/m^3) (Schmidt and Jenkins, 2010). As a consequence, the Policy Assessment notes that in some locations a 98th percentile standard with a level of 87 μg/m^3 would likely

[112]See http://www.epa.gov/ttn/airs/airsaqs/.

[113]As discussed above, the one-expected-exceedance concentration-equivalent design value is used as a surrogate concentration for comparison to the standard level in order to gain insight into whether a particular area would likely have met or violated the current PM_{10} standard. Therefore, locations with one-expected-exceedance concentration-equivalent design values below the level of the current PM_{10} standard (i.e., 150 μg/m^3) would likely meet that standard (US EPA, 2011a, section 3.2.1).

be more protective than the current standard while in other locations it would likely be less protective than the current standard.[114]

The Policy Assessment also evaluates regional differences in the relationship between 98th percentile PM_{10} concentrations and one-expected-exceedance concentration equivalent design values (US EPA, 2011a, Figure 3-8), based on air quality data from 1988 to 2008. The 98th percentile PM_{10} concentrations that are, on average, generally equivalent to the current standard level ranged from just below 87 μg/m^3 in the Southeast, Southwest, upper Midwest, and outlying areas (i.e., generally equivalent 98th percentile PM_{10} concentrations ranged from 82 to 85 μg/m^3 in these regions) to just above 87 μg/m^3 in the Northeast, industrial Midwest, and southern California (i.e., generally equivalent 98th percentile PM_{10} concentrations ranged from 88 to 93 μg/m^3 in these regions) (Schmidt, 2011b). However, within each of these regions there is considerable variability in the "generally equivalent" 98th percentile PM_{10} concentration across monitoring sites (US EPA, 2011a, Figure 3-8).

To provide a broader perspective on the relationship between the current standard and potential alternative standards with 98th percentile forms, the Policy Assessment also compares the size of the populations living in counties with PM_{10} one-expected-exceedance concentration-equivalent design values greater than the current standard level to the size of the populations living in counties with 98th percentile PM_{10} concentrations above different potential alternative standard levels (based on air quality data from 2007 to 2009[115]). Such comparisons can be considered as surrogates for comparisons of the breadth of public health protection provided by the current and potential alternative standards. Based on

[114]The "generally equivalent" concentration also differs depending on the years of monitoring data used. For example, when this analysis was restricted to only the most recent years available (i.e., 2007 to 2009), the "generally equivalent" 98th percentile PM_{10} concentration was 78 μg/m^3. Given the temporal variability in the relationship between the current standard level and 98th percentile PM_{10} concentrations, and the potential for the "generally equivalent" 98th percentile concentration to vary year-to-year, staff concluded that it remains appropriate to consider the correlation analyses that use the broader range of available monitoring years (i.e., 1998-2008), as these analyses are likely to be more robust than analyses based on a shorter period of time.

[115]These analyses are based on three years of air quality data in order to simulate the requirements for determining whether areas attain or violate the current PM_{10} standard, which requires consideration of 3 years of air quality data.

these comparisons, a 98th percentile PM_{10} standard with a level between 75 and 80 μg/m^3 would be most closely equivalent to the current standard. That is, compared to the number of people living in counties that would violate the current PM_{10} standard, a similar number live in counties that would violate a revised 24-hour PM_{10} standard with a 98th percentile form and a level between 75 and 80 μg/m^3 (US EPA, 2011a, Table 3-2). However, there is considerably more variability across regions in the potential alternative standard that, based on this analysis, would be generally equivalent to the current PM_{10} standard (US EPA, 2011a, section 3.3.4).

Given the variability in the relationship between the current standard and potential alternative standards with 98th percentile forms, the Policy Assessment concludes that no single potential alternative standard level, for a revised standard with a 98th percentile form, would provide public health protection equivalent to that provided by the current standard, consistently over time and across locations.

One consequence of this variability, as noted above in the discussion of the form of the standard, would be that a 24-hour PM_{10} standard with a 98th percentile form and a revised level would likely target public health protection to some different locations than does the current standard. Therefore, in further considering the appropriateness of revising the form and level of the current PM_{10} standard, the Policy Assessment considered the extent to which, when compared with the current standard, a revised PM_{10} standard would be expected to target public health protection to areas where we have more confidence that $PM_{10\text{-}2.5}$ is associated with adverse health effects. To address this question, the Policy Assessment considered the potential impact of revising the form and level of the PM_{10} standard in locations where health studies have reported associations with $PM_{10\text{-}2.5}$.

The Policy Assessment initially considers U.S. study locations that would likely have met the current PM_{10} standard during the study period and where positive and statistically significant

associations with $PM_{10-2.5}$ were reported. Only Birmingham, Chicago, Pittsburgh, and Detroit[116] met these criteria. During study periods, none of these areas would likely have met a 98th percentile 24-hour PM_{10} standard with a level at or below 87 μg/m^3 (US EPA, 2011a, section 3.3.4 and Table 3-3).

The Policy Assessment also considered U.S. locations where health studies have reported positive associations (both statistically significant and non-significant) between $PM_{10-2.5}$ and mortality or morbidity. Such positive associations were reported in 47 locations that would likely have met the current PM_{10} standard during the study period.[117] Of these 47 locations, 13 would likely not have met a 98th percentile 24-hour PM_{10} standard with a level at 87 μg/m^3, 20 would likely not have met a 98th percentile 24-hour PM_{10} standard with a level of 75 μg/m^3, and 31 would likely not have met a 98th percentile 24-hour PM_{10} standard with a level of 65 μg/m^3 (US EPA, 2011a, section 3.3.4).

In addition to the above analyses, the Policy Assessment also considered locations where health studies reported positive associations with $PM_{10-2.5}$ and where ambient PM_{10} concentrations were likely to have exceeded those allowed under the current PM_{10} standard during the study period. Nine locations met these criteria.[118] Of these locations, all would also likely have exceeded a 98th percentile PM_{10} standard with a level at or below 87 μg/m^3 (US EPA, 2011a, section 3.3.4).

Therefore, among U.S. study locations where $PM_{10-2.5}$-associated health effects have been reported, some areas met the current standard but would likely have violated a 98th percentile PM_{10} standard with a level at or below 87 μg/m^3. In contrast, the locations that violated the current standard would also likely have violated a 98th percentile PM_{10} standard with a level at or below 87 μg/m^3. Given

[116]Positive and statistically significant $PM_{10-2.5}$ effect estimates for Birmingham, Chicago, and Pittsburgh are reported in the Integrated Science Assessment (US EPA, 2009a, Figure 6-29; from cities evaluated by Zanobetti and Schwartz, 2009). Effect estimates for Detroit are reported by Ito et al. (2003).
[117]Philadelphia (Lipfert et al., 2000), Detroit (Ito et al., 2003), Santa Clara (CA) (Fairley et al., 2003), Seattle (Sheppard et al., 2003), Atlanta (Klemm et al., 2004), Spokane (Slaughter et al., 2005), Bronx and Manhattan (NYS DOH, 2006), and 39 of the cities evaluated by Zanobetti and Schwartz (2009) (US EPA, 2009a, Figure 6-29).
[118]Pittsburgh (Chock et al., 2000), Coachella Valley (CA) (Ostro et al., 2003), Phoenix (Mar et al., 2003; Wilson et al., 2007), and 6 of the cities evaluated by Zanobetti and Schwartz (2009) (US EPA, 2009a, Figure 6-29).

this, the Policy Assessment concludes that, compared to the current PM_{10} standard, a 24-hour PM_{10} standard with a 98th percentile form could potentially better target public health protection to locations where we have more confidence that ambient $PM_{10-2.5}$ concentrations are associated with mortality and/or morbidity (US EPA, 2011a, pp. 3-45 to 3-46).

iii. Integration of Evidence-based and Air Quality-based Considerations in the Policy Assessment

In considering the integration of the evidence and air quality information within the context of identifying potential alternative standard levels for consideration, the Policy Assessment first notes the following:

1) Analyses of air quality correlations suggest that a 98th percentile 24-hour PM_{10} concentration as high as 87 μg/m^3 could be considered generally equivalent to the current PM_{10} standard, over time and across the country.

2) A 98th percentile 24-hour PM_{10} standard with a level at or below 87 μg/m^3 would be expected to maintain PM_{10} and $PM_{10-2.5}$ concentrations below those present in U.S. locations where single-city studies have reported $PM_{10-2.5}$ effect estimates that are positive and statistically significant (lowest concentration in such a location was 91 μg/m^3). Although some single-city studies have reported positive $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations below 87 μg/m^3, these effect estimates were not statistically significant.

3) Multi-city average 98th percentile PM_{10} concentrations were below 87 μg/m^3 for recent U.S. multi-city studies, which have reported positive and statistically significant $PM_{10-2.5}$ effect estimates. However, the extent to which effects reported in multi-city studies are associated with the short-term air quality in any particular location is highly uncertain.

4) Epidemiological studies have reported positive, and in a few instances statistically significant, associations with $PM_{10-2.5}$ in some locations likely to have met the current PM_{10} standard but not a PM_{10} standard with a 98th percentile form and a level at or below 87 μg/m^3.

To the extent the above considerations are emphasized, the Policy Assessment notes that a standard level as high as about 85 μg/m^3, for a 24-hour PM_{10} standard with a 98th percentile form, could be supported. Such a standard level would be expected to maintain PM_{10} and $PM_{10-2.5}$ concentrations below those present in U.S. locations of single-city studies where $PM_{10-2.5}$ effect estimates have been reported to be positive and statistically significant and below those present in some locations where single-city studies reported $PM_{10-2.5}$ effect estimates that were positive, but not statistically significant. These include some locations likely to have met the current PM_{10} standard during the study periods.

Given this, when compared to the current standard, a 24-hour PM_{10} standard with a 98th percentile form and a level at or below 85 μg/m^3 could have the effect of focusing public health protection on locations where there is more confidence that $PM_{10-2.5}$ is associated with mortality and/or morbidity.

Given the above, the Policy Assessment concludes that a 98th percentile standard with a level as high as 85 μg/m^3 could be considered to the extent that more weight is placed on the appropriateness of focusing public health protection in areas where positive and statistically significant associations with $PM_{10-2.5}$ have been reported, and to the extent less weight is placed on $PM_{10-2.5}$ effect estimates that are not statistically significant and/or that reflect estimates across multiple cities. The Policy Assessment notes that it could be judged appropriate to place less weight on $PM_{10-2.5}$ effect estimates that are not statistically significant given the relatively large amount of uncertainty that is associated with the broader body of $PM_{10-2.5}$ health evidence, including uncertainty in the extent to which health effects evaluated in epidemiological studies result from exposures to $PM_{10-2.5}$ itself, rather than one or more co-occurring pollutants. This uncertainty, as well as other uncertainties discussed above, are reflected in the Integrated Science Assessment conclusions that the evidence is "suggestive" of a causal relationship (i.e., rather than "causal" or "likely causal") between short-term $PM_{10-2.5}$ and mortality, respiratory effects, and cardiovascular effects. In addition, the Policy Assessment concludes that it could be appropriate to place less weight on 98th percentile PM_{10} concentrations averaged across multiple cities, given the uncertainty in linking multi-city effect estimates with the air quality in any particular location.

However, the Policy Assessment also notes that, overall across the U.S. based on recent air quality information (i.e., 2007-2009), fewer people live in counties with 98th percentile 24-hour PM_{10} concentrations above 85 μg/m^3 than in counties likely to exceed the current PM_{10} standard (US EPA, 2011a, Table 3-2 and p. 3-48). These results could be interpreted to suggest that a 98th percentile standard with a level of 85 μg/m^3 would decrease overall public health protection compared to the current standard. Based on this analysis of the number of people living in counties that could violate the current and potential alternative PM_{10} standards, a 24-hour PM_{10} standard with a 98th percentile form

and a level between 75 and 80 μg/m^3 would provide a level of public health protection that is generally equivalent, across the U.S., to that provided by the current standard. To the extent these population counts are emphasized in comparing the public health protection provided by the current and potential alternative standards, and to the extent it is judged appropriate to set a revised standard that provides at least the level of public health protection that is provided by the current standard based on such population counts, the Policy Assessment concludes that it would be appropriate to consider standard levels in the range of approximately 75 to 80 μg/m^3 (Id.).

The Policy Assessment concludes that alternative approaches to considering the evidence could also lead to consideration of standard levels below 75 μg/m^3. For example, a number of single-city epidemiological studies have reported positive, though not statistically significant, $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations below 75 μg/m^3. Given that exposure error is particularly important for $PM_{10-2.5}$ epidemiological studies and can bias the results of these studies toward the null hypothesis (see section IV.B.5 above), it could be judged appropriate to place more weight on positive associations reported in these epidemiological studies, even when those associations are not statistically significant. In addition, the multi-city averages of 98th percentile PM_{10} concentrations in the locations evaluated by Zanobetti and Schwartz (2009) and Peng et al. (2008) were 77 and 68 μg/m^3, respectively. Both of these multi-city studies reported positive and statistically significant $PM_{10-2.5}$ effect estimates that remained positive in co-pollutant models that included $PM_{2.5}$, though only Zanobetti and Schwartz (2009) reported $PM_{10-2.5}$ effect estimates that remained statistically significant in such co-pollutant models. Despite uncertainties in the extent to which effects reported in these multi-city studies are associated with the short-term air quality in any particular location, emphasis could be placed on these multi-city associations. The Policy Assessment concludes that, to the extent more weight is placed on single-city studies reporting positive, but not statistically significant, $PM_{10-2.5}$ effect estimates and on multi-city studies, it could be appropriate to consider standard levels as low as 65 μg/m^3 (US EPA, 2011a, p. 3-48). A standard level of 65 μg/m^3 would be expected to provide a

substantial margin of safety against health effects that have been associated with $PM_{10-2.5}$ and, as discussed above, could better focus (compared to the current standard) public health protection on areas where health studies have reported associations with $PM_{10-2.5}$.

In considering potential alternative standard levels below 65 μg/m^3, the Policy Assessment notes that, as discussed above, the overall body of $PM_{10-2.5}$ health evidence is relatively uncertain, with somewhat stronger support in U.S. studies for associations with $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations above 85 μg/m^3 than in locations with 98th percentile PM_{10} concentrations below 65 μg/m^3. Specifically, the Policy Assessment notes the following (Id., p. 3-49):

1) Epidemiological studies, either single-city or multi-city, have not reported positive and statistically significant $PM_{10-2.5}$ effect estimates in locations with 98th percentile PM_{10} concentrations (multi-city average 98th percentile concentrations in the case of multi-city studies) at or below 65 μg/m^3.

2) Although some single-city morbidity studies have reported positive, but not statistically significant, associations with $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations below 65 μg/m^3, the results of U.S. morbidity studies were generally less consistent than those of mortality studies, with some $PM_{10-2.5}$ effect estimates being positive while others were negative (i.e., negative effect estimates were reported in several studies conducted in Atlanta, where the 98th percentile PM_{10} concentrations ranged from 67 μg/m^3 to 71 μg/m^3).

3) Although Bayes-adjusted single-city $PM_{10-2.5}$ effect estimates were positive, but not statistically significant, in some locations with PM_{10} concentrations below 65 μg/m^3, these effect estimates were based on the difference between community-wide PM_{10} and $PM_{2.5}$ concentrations. As discussed above, it is not clear how these estimates of $PM_{10-2.5}$ concentrations compare to those more typically used in other studies to calculate $PM_{10-2.5}$ effect estimates. At present, few corroborating studies are available that use other approaches (i.e., co-located monitors, dichotomous samplers) to estimate/measure $PM_{10-2.5}$ in locations with 98th percentile PM_{10} concentrations below 65 μg/m^3.

In light of these limitations in the evidence for a relationship between $PM_{10-2.5}$ and adverse health effects in locations with relatively low PM_{10} concentrations, along with the overall uncertainties in the body of $PM_{10-2.5}$ health evidence as described above and in the Integrated Science Assessment, the Policy Assessment concludes that while it could be judged appropriate to consider standard levels as low as 65 μg/m^3, it is not appropriate, based on the currently available body of evidence, to consider standard levels below 65 μg/m^3.

D. CASAC Advice

Following their review of the first and second draft Policy Assessments, CASAC provided advice and recommendations regarding the current and potential alternative standards for thoracic coarse particles (Samet, 2010c,d). With regard to the existing PM_{10} standard, CASAC concluded that "the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard" (Samet, 2010d, p. 7).[119] In drawing this conclusion, CASAC noted the positive associations in multi-city and single-city studies, including in locations with PM_{10} concentrations below those allowed by the current standard. In addition, CASAC gave "significant weight to studies that have generally reported that $PM_{10-2.5}$ effect estimates remain positive when evaluated in co-pollutant models" and concluded that "controlled human exposure $PM_{10-2.5}$ studies showing decreases in heart rate variability and increases in markers of pulmonary inflammation are deemed adequate to support the plausibility of the associations reported in epidemiologic studies" (Samet, 2010d, p. 7). Given all of the above conclusions CASAC recommended that "the primary standard for PM_{10} should be revised" (Samet, 2010d, p. ii and p. 7). In discussing potential revisions, while CASAC noted that the scientific evidence supports adoption of a standard at least as stringent as current standard, they recommended revising the current standard in order to increase public health protection. In considering potential alternative standards, CASAC drew conclusions and made recommendations in terms of the major elements of a standard: indicator, averaging time, form, and level.

The CASAC agreed with staff's conclusions that the available evidence supports consideration in the current review of retaining the current PM_{10} indicator and the current 24-hour averaging time (Samet, 2010c, Samet, 2010d). Specifically, with regard to indicator, CASAC concluded that "[w]hile it

[119]With regard to limitations and uncertainties in the evidence, CASAC endorsed the ISA weight of evidence conclusions for $PM_{10-2.5}$ (i.e., that the evidence is only "suggestive" of a causal relationship between short-term exposures and mortality, respiratory effects, and cardiovascular effects) (Samet, 2009e; Samet, 2009f).

would be preferable to use an indicator that reflects the coarse PM directly linked to health risks ($PM_{10-2.5}$), CASAC recognizes that there is not yet sufficient data to permit a change in the indicator from PM_{10} to one that directly measures thoracic coarse particles" (Samet, 2010d, p. ii). In addition, CASAC "vigorously recommends the implementation of plans for the deployment of a network of $PM_{10-2.5}$ sampling systems so that future epidemiological studies will be able to more thoroughly explore the use of $PM_{10-2.5}$ as a more appropriate indicator for thoracic coarse particles" (Samet, 2010d, p. 7).

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

With regard to standard level, in conjunction with a 98th percentile form, CASAC concluded that "alternative standard levels of 85 and 65 $\mu g/m^3$ (based on consideration of 98th percentile PM_{10} concentration) could be justified" (Samet, 2010d, p.8). However, in considering the evidence and uncertainties, CASAC recommended a standard level from the lower part of the range discussed in the Policy Assessment, recommending a level "somewhere in the range of 75 to 65 $\mu g/m^3$" (Samet, 2010d, p. ii).

In making this recommendation, CASAC noted that the number of people living in counties with air quality not meeting the current standard is approximately equal to the number living in counties that would not meet a 98th percentile standard with a level between 75 and 80 $\mu g/m^3$. CASAC used this information as the basis for their conclusion that a 98th percentile standard between 75 and 80 $\mu g/m^3$ would be "comparable to the degree of protection afforded to the current PM_{10} standard" (Samet, 2010d, p. ii). Given this conclusion regarding the comparability of the current and potential alternative standards, as well as their conclusion on the public health protection provided by the current standard

(i.e., that available evidence is sufficient to call it into question), CASAC recommended a level within a range of 75 to 65 $\mu g/m^3$ in order to increase public health protection, relative to that provided by the current standard (Samet 2010d, p. ii).

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

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

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

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

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

With regard to the first point, in the last review the EPA concluded that dosimetric, toxicological, occupational, and epidemiological evidence supported retention of a primary standard to provide some

measure of protection against short-term exposures to all thoracic coarse particles, regardless of their source of origin or location, consistent with the Act's requirement that primary NAAQS provide an adequate margin of safety (71 FR 61197, October 17, 2006). In that review, the EPA concluded that a number of source types, including motor vehicle emissions, coal combustion, oil burning, and vegetative burning, are associated with health effects (US EPA, 2004). In litigation of the decisions from the last review, the D.C. Circuit affirmed the conclusion that it was appropriate to provide "some protection from exposure to thoracic coarse particles…in all areas" (American Farm Bureau Federation v. EPA, 559 F. 3d at 532-33).

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

In light of this body of available evidence reporting $PM_{10-2.5}$-associated health effects across different locations with a variety of sources, as well as the Integrated Science Assessment's conclusions regarding the links between adverse health effects and PM sources and composition, the Administrator provisionally concludes in the current review that it is appropriate to maintain a standard that provides

some measure of protection against exposures to all thoracic coarse particles, regardless of their location, source of origin, or composition.

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

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

The Administrator also notes that chemical constituents present at higher levels in urban or industrial areas, including byproducts of incomplete combustion (e.g. polycyclic aromatic hydrocarbons) emitted as $PM_{2.5}$ from motor vehicles as well as metals and other contaminants emitted from

anthropogenic sources, can contaminate $PM_{10-2.5}$ (US EPA, 2004, p. 8–344; 71 FR 2665, January 17, 2006). While the Administrator acknowledges the uncertainty expressed in the Integrated Science Assessment regarding the extent to which particle composition can be linked to health outcomes based on available evidence, she also considers the possibility that $PM_{10-2.5}$ contaminants typical of urban or industrial areas could increase the toxicity of thoracic coarse particles in urban locations.

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

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

in urban and non-urban areas.[120, 121]

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

With regard to the third point, in evaluating the degree of public health protection provided by the current PM_{10} standard, the Administrator notes that the Policy Assessment discusses two different approaches to considering the scientific evidence and air quality information (US EPA, 2011a, section 3.2.3). These different approaches, which are described above in detail (section IV.C.1), lead to different

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[120]The Administrator recognizes that this relationship is qualitative. That is, the varying coarse particle concentrations allowed under the PM_{10} standard do not precisely correspond to the variable toxicity of thoracic coarse particles in different areas (insofar as that variability is understood). Although currently available information does not allow any more precise adjustment for relative toxicity, the Administrator believes the standard will generally ensure that the coarse particle levels allowed will be lower in urban areas and higher in non-urban areas. Addressing this qualitative relationship, the D.C. Circuit held that "[i]t is true that the EPA relies on a qualitative analysis to describe the protection the coarse PM NAAQS will provide. But the fact that the EPA's analysis is qualitative rather than quantitative does not undermine its validity as an acceptable rationale for the EPA's decision." 559 F. 3d at 535.

[121]The D.C. Circuit agreed with similar conclusions in the last review and held that this rationale reasonably supported use of an unqualified PM_{10} indicator for thoracic coarse particles. *American Farm Bureau Federation v. EPA*, 559 F. 3d at 535-36.

conclusions regarding the appropriateness of the degree of public health protection provided by the current PM_{10} standard. The Administrator further notes that the primary difference between the two approaches lies in the extent to which weight is placed on the following (US EPA, 2011a, section 3.2.3):

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

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

3) The limited number of $PM_{10-2.5}$ epidemiological studies that have evaluated co-pollutant models;

4) The limited number of $PM_{10-2.5}$ controlled human exposure studies;

5) Uncertainties in the $PM_{10-2.5}$ air quality concentrations used in epidemiological studies, given limitations in $PM_{10-2.5}$ monitoring data and the different approaches used across studies to estimate ambient $PM_{10-2.5}$ concentrations; and

6) Uncertainties and limitations in the evidence that tend to call into question the presence of a causal relationship between $PM_{10-2.5}$ exposures and mortality/morbidity.

In evaluating the different possible approaches to considering the public health protection provided by the current PM_{10} standard, the Administrator first notes that when the available $PM_{10-2.5}$ scientific evidence and its associated uncertainties are considered, the Integrated Science Assessment concludes that the evidence is suggestive of a causal relationship between short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects. As discussed in section IV.B.1 above and in more detail in the Integrated Science Assessment (US EPA, 2009a, section 1.5), a suggestive determination is made when the "[e]vidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited because chance, bias and confounding cannot be ruled out." In contrast, the Administrator notes that she is proposing to strengthen the annual fine particle standard based on a body of scientific evidence judged sufficient to conclude that a causal relationship exists (i.e., mortality, cardiovascular effects) or is likely to exist (i.e., respiratory effects) (section III.B). The suggestive judgment for $PM_{10-2.5}$ reflects the greater degree of uncertainty associated with this body of evidence, as discussed above in detail (sections IV.B.5 and IV.C.1) and as summarized below.

The Administrator notes that the important uncertainties and limitations associated with the scientific evidence and air quality information raise questions as to whether public health benefits would be achieved by revising the existing PM_{10} standard. Such uncertainties and limitations include the following:

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

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

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

4) Limitations in $PM_{10-2.5}$ monitoring data and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiological studies result in uncertainty in the ambient $PM_{10-2.5}$ concentrations at which the reported effects occur, increasing uncertainty in estimates of the extent to which changes in ambient $PM_{10-2.5}$ concentrations would likely impact public health.

5) The lack of a quantitative $PM_{10-2.5}$ risk assessment further contributes to uncertainty regarding the extent to which any revisions to the current PM_{10} standard would be expected to improve the protection of public health, beyond the protection provided by the current standard (see section III.B.5 above).

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

In considering these uncertainties and limitations, the Administrator notes in particular the considerable degree of uncertainty in the extent to which health effects reported in epidemiological studies are due to $PM_{10-2.5}$ itself, as opposed to one or more co-occurring pollutants. As discussed above, this uncertainty reflects the fact that there are a relatively small number of $PM_{10-2.5}$ studies that have evaluated co-pollutant models, particularly co-pollutant models that have included $PM_{2.5}$, and a very limited body of controlled human exposure evidence supporting the plausibility of a causal relationship between $PM_{10-2.5}$ and mortality and morbidity at ambient concentrations. The Administrator notes that

these important limitations in the overall body of health evidence introduce uncertainty into the interpretation of individual epidemiological studies, particularly those studies reporting associations with $PM_{10-2.5}$ that are not statistically significant. Given this, the Administrator reaches the provisional conclusion that it is appropriate to place relatively little weight on epidemiological studies reporting associations with $PM_{10-2.5}$ that are not statistically significant in single-pollutant and/or co-pollutant models.

With regard to this provisional conclusion, the Administrator notes that, for single-city mortality studies conducted in the United States where ambient PM_{10} concentration data were available for comparison to the current standard, positive and statistically significant $PM_{10-2.5}$ effect estimates were only reported in study locations that would likely have violated the current PM_{10} standard during the study period (US 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 (US 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 (US EPA, 2011a, Figure 3-3).

In addition, in considering the single-city analyses for the locations evaluated in the multi-city study by Zanobetti and Schwartz (2009), the Administrator notes that associations in most of these locations were not statistically significant and that this was the only study to estimate ambient $PM_{10-2.5}$ concentrations as the difference between county-wide PM_{10} and $PM_{2.5}$ mass. As discussed above, it is not clear how computed $PM_{10-2.5}$ measurements, such as those used by Zanobetti and Schwartz (2009), compare with the $PM_{10-2.5}$ concentrations obtained in other studies either by direct measurement with a dichotomous sampler or by calculating the difference using co-located samplers (US EPA, 2009a,

section 6.5.2.3).[122] For these reasons, the Administrator notes that there is considerable uncertainty in interpreting the associations in these single-city analyses.

The Administrator acknowledges that an approach to considering the available scientific evidence and air quality information that emphasizes the above considerations differs from the approach taken by CASAC. Specifically, CASAC placed a substantial amount of weight on individual studies, particularly those reporting positive health effects associations in locations that met the current PM_{10} standard during the study period. In emphasizing these studies, as well as the limited number of supporting studies that have evaluated co-pollutant models and the small number of supporting experimental studies, CASAC concluded that "the current data, while limited, is sufficient to call into question the level of protection afforded the American people by the current standard" (Samet, 2010d, p. 7) and recommended revising the current PM_{10} standard (Samet, 2010d).

The Administrator has carefully considered CASAC's advice and recommendations. She notes that in making its recommendation on the current PM_{10} standard, CASAC did not discuss its approach to considering the important uncertainties and limitations in the health evidence, and did not discuss how these uncertainties and limitations are reflected in its recommendation. As discussed above, such uncertainties and limitations contributed to the conclusions in the Integrated Science Assessment that the $PM_{10\text{-}2.5}$ 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 $PM_{10\text{-}2.5}$ health studies for the current standard.

In light of the above approach to considering the scientific evidence, air quality information, and

[122]As noted in section IV.B.5 above and in the Policy Assessment (US EPA, 2011a, p. 3-16), there are also important uncertainties in estimates of ambient $PM_{10\text{-}2.5}$ concentrations based on the difference between PM_{10} mass and $PM_{2.5}$ mass, as measured at co-located monitors.

associated uncertainties, the Administrator reaches the following provisional conclusions:

1) Given the important uncertainties and limitations associated with the overall body of health evidence and air quality information for $PM_{10-2.5}$, as discussed above and as reflected in the Integrated Science Assessment weight-of-evidence conclusions; given that $PM_{10-2.5}$ effect estimates for the most serious health effect, mortality, were not statistically significant in U.S. locations that met the current PM_{10} standard and where coarse particle concentrations were either directly measured or estimated based on co-located samplers; and given that $PM_{10-2.5}$ effect estimates for morbidity endpoints were both positive and negative in locations that met the current standard, with most not statistically significant; when viewed as a whole the available evidence and information suggests that the degree of public health protection provided against short-term exposures to $PM_{10-2.5}$ does not need to be increased beyond that provided by the current PM_{10} standard.[123]

2) Given that positive and statistically significant associations with mortality were reported in single-city U.S. study locations likely to have violated the current PM_{10} standard, the degree of public health protection provided by the current standard is not greater than warranted.[124]

In reaching these provisional conclusions, the Administrator notes that the Policy Assessment also discusses the potential for a revised PM_{10} standard (i.e., with a revised form and level) to be "generally equivalent" to the current standard, but to better target public health protection to locations where there is greater concern regarding $PM_{10-2.5}$-associated health effects (US EPA, 2011a, sections

[123] This is not to say that the EPA could not adopt or revise a standard for a pollutant for which the evidence is suggestive of a causal relationship. Indeed, with respect to thoracic coarse particles itself, the D.C. Circuit noted that "[a]lthough the evidence of danger from coarse PM is, as the EPA recognizes, 'inconclusive', the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health." *American Farm Bureau Federation v EPA* 559 F. 3d at 533. As explained in the text above, it is the Administrator's provisional judgment that significant uncertainties presented by the evidence and information before her in this review, both as to causality and as to concentrations at which effects may be occurring, best support a decision to retain rather than revise the current primary 24-hour PM_{10} standard.

[124] There are similarities with the conclusions drawn by the Administrator in the last review. There, the Administrator concluded that there was no basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current 24-hour standard, but have not been associated with air quality levels that would generally meet that standard, and morbidity effects have been associated with air quality levels that exceeded the current 24-hour standard only a few times. 71 FR at 61202. In addition, the Administrator concluded that there was a high degree of uncertainty in the relevant population exposures implied by the morbidity studies suggesting that there is little basis for concluding that a greater degree of protection is warranted. *Id.* The D.C. Circuit in *American Farm Bureau Federation v EPA* explicitly endorsed this reasoning. 559 F. 3d at 534.

3.3.3 and 3.3.4).[125] In considering such a potential revised standard, the Policy Assessment discusses the large amount of variability in PM_{10} air quality correlations across monitoring locations and over time (US 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 (US 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 (US 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 $PM_{10\text{-}2.5}$ 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 $PM_{10\text{-}2.5}$, 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

[125]As discussed in detail above (section IV.C.2.d) and in the Policy Assessment (US 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.

uncertainty in the extent to which public health would be improved by changing the locations to which the PM_{10} standard targets protection. Therefore, she reaches the provisional conclusion that the current PM_{10} standard should not be revised in order to change that targeting of protection.

In considering all of the above, including the scientific evidence, the air quality information, the associated uncertainties, and CASAC's advice, the Administrator reaches the provisional conclusion that the current 24-hour PM_{10} standard is requisite (i.e., neither more protective nor less protective than necessary) to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10\text{-}2.5}$. In light of this provisional conclusion, the Administrator proposes to retain the current PM_{10} standard in order to protect against health effects associated with short-term exposures to $PM_{10\text{-}2.5}$.

The Administrator recognizes that her proposed conclusions and decision to retain the current PM_{10} standard differ from CASAC's recommendations, stemming from the differences in how the Administrator and CASAC considered and accounted for the evidence and its limitations and uncertainties. In light of CASAC's views and recommendation to revise the current PM_{10} standard, the Administrator welcomes the public's views on these different approaches to considering and accounting for the evidence and its limitations and uncertainties, as well as on the appropriateness of revising the primary PM_{10} standard, including revising the form and level of the standard.

F. Administrator's Proposed Decision on the Primary PM_{10} Standard

For the reasons discussed above, and taking into account the information and assessments presented in the Integrated Science Assessment and the Policy Assessment and the advice and recommendations of CASAC, the Administrator proposes to retain the current primary PM_{10} standard. The Administrator solicits comment on all aspects of this proposed decision, including her rationale for reaching the provisional conclusion that the current PM_{10} standard is requisite to protect public health with an adequate margin of safety and the provisional conclusion that it is not appropriate to revise the current PM_{10} standard by setting a "generally equivalent" standard with the goal of better targeting

public health protection.

V. Communication of Public Health Information

Sections 319(a)(1) and (3) of the CAA require the EPA to establish a uniform air quality index for reporting of air quality. These sections specifically direct the Administrator to ‘‘promulgate regulations establishing an air quality monitoring system throughout the United States which utilizes uniform air quality monitoring criteria and methodology and measures such air quality according to a uniform air quality index’’ and ‘‘provides for daily analysis and reporting of air quality based upon such uniform air quality index…’’ In 1979, the EPA established requirements for index reporting (44 FR 27598, May 10, 1979). The requirement for State and local agencies to report the AQI appears in 40 CFR 58.50 and the specific requirements (e.g., what to report, how to report, reporting frequency, calculations) are in appendix G to 40 CFR part 58.

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily by AQI reporting through EPA’s AIRNow website.[126] The current AQI has been in use since its inception in 1999.[127] It provides accurate, timely, and easily understandable information about daily levels of pollution (40 CFR 58.50). The AQI establishes a nationally uniform system of indexing pollution levels for ozone, carbon monoxide, nitrogen dioxide, PM and sulfur dioxide. The AQI is also recognized internationally as a proven tool to effectively communicate air quality information to the public. In fact, many countries have created similar indices based on the AQI.

The AQI converts pollutant concentrations in a community’s air to a number on a scale from 0 to 500. Reported AQI values enable the public to know whether air pollution levels in a particular location

[126] See http://www.airnow.gov/ .

[127] In 1976, the EPA established a nationally uniform air quality index, then called the Pollutant Standard Index (PSI), for use by State and local agencies on a voluntary basis (41 FR 37660, September 7, 1976). In August 1999, the EPA adopted revisions to this air quality index (64 FR 42530, August 4, 1999) and renamed the index the AQI.

are characterized as good (0–50), moderate (51–100), unhealthy for sensitive groups (101– 150), unhealthy (151–200), very unhealthy (201–300), or hazardous (301–500). The AQI index value of 100 typically corresponds to the level of the short-term (e.g., daily or hourly standard) NAAQS for each pollutant. Below an index value of 100, an intermediate value of 50 was defined either as the level of the annual standard if an annual standard has been established (e.g., $PM_{2.5}$, nitrogen dioxide), or as a concentration equal to one-half the value of the short-term standard used to define an index value of 100 (e.g., carbon monoxide). An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (i.e., unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous) on a given day. An AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (i.e., moderate or good). Decisions about the pollutant concentrations at which to set the various AQI breakpoints that delineate the various AQI categories for each pollutant specific sub-index within the AQI draw directly from the underlying health information that supports the NAAQS review.

Historically, state and local agencies have primarily used the AQI to provide general information to the public about air quality and its relationship to public health. For more than a decade, many states and local agencies, as well as the EPA and other Federal agencies, have been developing new and innovative programs and initiatives to provide more information to the public, in a more timely way. These initiatives, including air quality forecasting, real-time data reporting through the AIRNow website, and air quality action day programs, can serve to provide useful, up-to-date, and timely information to the public about air pollution and its effects. Such information will help individuals take actions to avoid or to reduce exposures to ambient pollution at levels of concern to them and can encourage the public to take actions that will reduce air pollution on days when levels are projected to be at levels of concern to local communities. Thus, these programs have significantly broadened the ways in which state and local agencies can meet the nationally uniform AQI reporting requirements, and are contributing to state and local efforts to provide community health protection and to attain or maintain

compliance with the NAAQS. The EPA and state and local agencies recognize that these programs are interrelated with AQI reporting and with the information on the effects of air pollution on public health that is generated through the periodic review, and revision when appropriate, of the NAAQS.

In recognition of the proposed change to the primary annual $PM_{2.5}$ standard summarized in section III.F above, the EPA proposes a conforming change to the PM2.5 sub-index of the AQI to be consistent with the proposed change to the annual standard. The health effects information that supports the proposed decisions on the $PM_{2.5}$ standards, as discussed in section III.B above, is also the basis for the proposed decisions on the AQI discussed below in this section. The EPA intends to finalize conforming changes to the AQI in conjunction with the Agency's final decisions on the primary annual and 24-hour $PM_{2.5}$ standards, if revisions to such standards are promulgated.

With respect to an AQI value of 50, as discussed above, the historical approach is to set it at the same level of the annual standard, if there is one. This is consistent with the current AQI sub-index for $PM_{2.5}$, in which the current AQI value of 50 is set at 15 $\mu g/m^3$, consistent with the level of the current primary annual $PM_{2.5}$ standard. The EPA sees no basis for deviating from this approach in this review. Thus, the EPA proposes to set an AQI value of 50 within a range of 12 to 13 $\mu g/m^3$, 24-hour average, consistent with the proposed annual $PM_{2.5}$ standard level (section III.F). The final AQI value of 50 will be set at the level of the annual $PM_{2.5}$ standard that is promulgated.

With respect to an AQI value of 100, which is the basis for advisories to individuals in sensitive groups, there are two general approaches that could be used to select the associated $PM_{2.5}$ level. By far the most common approach, which has been used with the other sub-indices as noted above, is to set an AQI value of 100 at the same level as the short-term standard. The EPA recognizes that some state and local air quality agencies have expressed a strong preference that the Agency set an AQI value of 100 equal to any short-term standard. These agencies typically express the view that this linkage is useful for the purpose of communicating with the public about the standard, as well as providing consistent messages about the health impacts associated with daily air quality. The EPA proposes to use this

approach to set the AQI value of 100 at 35 μg/m^3, 24-hour average, consistent with the proposal to retain the current 24-hour $PM_{2.5}$ standard (section III.F). If the 24-hour standard is set at a different level, the EPA proposes to set an AQI value of 100 at the level of the 24-hour $PM_{2.5}$ standard that is promulgated.

An alternative approach is to directly evaluate the health effects evidence to select the level for an AQI value of 100. This was the approach used in the 1999 rulemaking to set the AQI value of 100 at a level of 40 μg/m^3, 24-hour average,[128] when the 24-hour standard level was 65 μg/m^3. This alternative approach was used in the case of the $PM_{2.5}$ sub-index because the annual and 24-hour $PM_{2.5}$ standards set in 1997 were designed to work together, and the intended degree of health protection against short-term risks was not defined by the 24-hour standard alone, but by the combination of the two standards working in concert. Indeed, at that time, the 24-hour standard was set to provide supplemental protection relative to the principal protection provided by the annual standard. The EPA is soliciting comment on this alternative approach in recognition that, as proposed, the 24-hour $PM_{2.5}$ standard is intended to continue to provide supplemental protection against effects associated with short-term exposures of $PM_{2.5}$ by working in conjunction with the annual standard to reduce 24-hour exposures to $PM_{2.5}$. The EPA recognizes that some state and local air quality agencies have expressed support for this alternative approach. Using this alternative approach could result in consideration of a lower level for an AQI value of 100, based on the discussion of the health information pertaining to the level of the 24-hour standard in section III.E.4 above. The EPA encourages state and local air quality agencies that use the AQI to comment on both the approach and the level at which to set an AQI value of 100 together with any supporting rationale.

With respect to an AQI value of 150, this level is based upon the same health effects information that informs the selection of the level of the 24-hour standard and the AQI value of 100. The AQI value

[128] Currently, we are cautioning members of sensitive groups at the AQI value of 100 at 35 μg/m^3, 24-hour average, consistent with more recent guidance from EPA with regard to the development of State emergency episode contingency plans (Harnett, 2009, Attachment B).

of 150 was set in the 1999 rulemaking at a level of 65 μg/m^3, 24-hour average. In considering what level to propose for an AQI value of 150, we believe that the health effects evidence indicates that the level of 55 μg/m^3, 24-hour average, is appropriate to use[129] in conjunction with an AQI value of 100 set at the proposed level of 35 μg/m^3. Thus, if the EPA sets an AQI value of 100 at the $PM_{2.5}$ level of 35 μg/m^3, 24-hour average, the Agency proposes to set an AQI value of 150 at the $PM_{2.5}$ level of 55 μg/m^3, 24-hour average. If, however, the EPA decides to set an AQI value of 100 at a lower level, then the EPA would adjust an AQI value of 150 proportionally. The Agency's approach to selecting the levels at which to set the AQI values of 100 and 150 inherently recognizes that the epidemiological evidence upon which these decisions are based provides no evidence of discernible thresholds, below which effects do not occur in either sensitive groups or in the general population, at which to set these two breakpoints. Therefore, EPA concludes the use of a proportional adjustment would be appropriate.

With respect to an AQI value of 500, a review of the history of the AQI value of 500 for PM_{10} and of the AQI value of 500 for $PM_{2.5}$ is useful background. The current AQI value of 500 for PM_{10} was set in 1987 at the level of 600 μg/m^3, 24-hour average, on the basis of increased mortality associated with historical wintertime pollution episodes in London (52 FR 24687 to 24688, July 1, 1987). Particle concentrations during these episodes, measured by the British Smoke method, were in the range of 500 to 1000 μg/m^3. In the 1987 rulemaking that established the upper bound index value for PM_{10}, the EPA cited a generally held opinion that the British Smoke method measures PM with a cutpoint of approximately 4.5 microns (52 FR 24688, July 1, 1987). In establishing this value for PM_{10}, the EPA assumed that concentrations of PM_{10}, which includes both coarse and fine particles, during episodes of concern, would be about 100 μg/m^3 higher than the PM concentration measured in terms of British Smoke (52 FR 24688, July 1, 1987). The upper bound index value of 600 μg/m^3 was developed by selecting the lower end of the range of harmful concentrations during the historical wintertime pollution

[129] We note that this level is consistent with the level recommended in the more recent EPA guidance (Harnett, 2009, Attachment B), which is in use by many State and local agencies.

episodes in London (500 μg/m^3) and adding a margin of 100 μg/m^3 to account for this measurement difference. The current $PM_{2.5}$ concentration corresponding to an AQI value of 500 set in the 1999 rulemaking is 500 μg/m^3, 24-hour average. [130] Because there were few $PM_{2.5}$ monitoring data available at that time, the decision was based on the stated assumption that PM concentrations measured by the British Smoke method were approximately equivalent to $PM_{2.5}$ concentrations. In considering whether it is appropriate to retain or revise the AQI value of 500 for $PM_{2.5}$, the EPA notes that the 1999 rulemaking was based on an assumption of approximate equivalence between the British Smoke method and the current $PM_{2.5}$ method. This assumption is not entirely consistent with the view cited in 1987 that the British Smoke method has a size cutpoint of 4.5 microns (52 FR 24688, July 1, 1987), such that it would be reasonable to expect based on considering size cutpoint alone that a level of 500 μg/m^3 based on the British Smoke method would generally be equivalent to a somewhat lower level based on the current $PM_{2.5}$ method. Nonetheless, ;more recent comparisons between British Smoke and $PM_{2.5}$ measurement methods (Heal, et al., 2005; Chaloulakou, et al., 2005) suggest that on average British Smoke can be less than or more than $PM_{2.5}$, but generally represents a larger fraction in the seasons and locations when $PM_{2.5}$ predominantly results from directly emitted carbonaceous particles such as from combustion sources. More generally, the EPA recognizes that extremely high PM concentrations that would most likely be associated with combustion sources (e.g., coal burning in historic the London event, wildfires in contemporary U.S. environments) are typically dominated by fine particles, such that there may be very little difference between these measurement methods at such high levels.

Further, in considering the body of more recent health effects evidence available in this review, the EPA concludes that there is little information about more recent air pollution episodes similar to the wintertime pollution episodes in London and associated impacts on community health upon which to base a decision. Thus, the EPA concludes that it remains appropriate to use the historical wintertime

[130] We note that a level of 350 μg/m^3 is recommended for an AQI value of 500 in the more recent EPA guidance (Harnett, 2009, Attachment B),

pollution episodes in London as the basis for setting an AQI value of 500 for $PM_{2.5}$ as described above because it is still the best available directly relevant information. Nonetheless, the EPA takes note of a limited number of more recent studies cited in the Integrated Science Assessment that evaluated wood smoke health impacts which found effects such as cardiovascular morbidity and mortality as well as respiratory effects, albeit at much lower levels (US EPA, 2009a, sections 6.2 and 6.6). These more recent health studies may provide some support for considering a lower $PM_{2.5}$ level for an AQI value of 500.

Based on the above considerations, the EPA concludes that it is appropriate to propose to retain the current level of 500 $\mu g/m^3$, 24-hour average, for the AQI value of 500. The EPA solicits comment on alternative approaches to setting a level for the AQI value of 500 and on alternative levels that commenters believe may be appropriate as well as supporting information and rationales for such alternative levels. The EPA also solicits any additional information, data, research or analyses that may be useful to inform a final decision on the appropriate level to set the AQI value of 500.

For the intermediate breakpoints in the AQI between the values of 150 and 500, the EPA proposes $PM_{2.5}$ concentrations that generally reflect a linear relationship between increasing index values and increasing $PM_{2.5}$ values. The available scientific evidence of health effects related to population exposures to $PM_{2.5}$ concentrations between the level of the 24-hour standard and an AQI value of 500 suggest a continuum of effects in this range, with increasing $PM_{2.5}$ concentrations being associated with increasingly larger numbers of people likely to experience such effects. The generally linear relationship between AQI values and $PM_{2.5}$ concentrations in this range is consistent with the health evidence. This also is consistent with the Agency's practice of setting breakpoints in symmetrical fashion where health effects information does not suggest particular levels.

Table 2 below summarizes the proposed breakpoints for the $PM_{2.5}$ sub-index. [131]Table 2 shows the intermediate breakpoints for AQI values of 200, 300 and 400 based on a linear interpolation between the proposed levels for AQI values of 150 and 500. If a different level were to be set for an AQI value of 150 or 500, intermediate levels would be calculated based on a linear relationship between the selected levels for AQI values of 150 and 500.

Table 2. Proposed Breakpoints for $PM_{2.5}$ Sub-Index

AQI Category	Index Values	Proposed Breakpoints ($\mu g/m^3$, 24-hour average)
Good	0 - 50	0.0 – (12.0 -13.0)
Moderate	51 - 100	(12.1 – 13.1) – 35.4
Unhealthy for Sensitive Groups	101 - 150	35.5 – 55.4
Unhealthy	151 - 200	55.5 - 150.4
Very Unhealthy	201 - 300	150.5 - 250.4
Hazardous	301 - 400	250.5 - 350.4
	401 - 500	350.5 - 500.4

In proposing to retain the 500 level for the AQI as described above, we note that the EPA is not proposing to establish a Significant Harm Level (SHL) for $PM_{2.5}$. The SHL is an important part of air pollution Emergency Episode Plans, which are required for certain areas by CAA section 110(a)(2)(G) and associated regulations at 40 CFR 51.150, under the Prevention of Air Pollution Emergency Episodes program. The Agency believes that air quality responses established through an Emergency Episode Plan should be developed through a collaborative process working with State and Tribal air quality, forestry and agricultural agencies, Federal land management agencies, private land managers and the public. Therefore, if in future rulemaking EPA proposes revisions to the Prevention of Air Pollution

[131] As discussed in section VII.C below, the EPA is also proposing to update the data handling procedures for reporting the AQI and corresponding updates for other AQI-sub-indices presented in Table 2 of appendix G of 40 CFR part 58.

Emergency Episodes program, the proposal will include a SHL for $PM_{2.5}$ that is developed in collaboration with these organizations. As discussed in the 1999 Air Quality Index Reporting Rule (64 FR 42530), if a future rulemaking results in a SHL that is different from the 500 value of the AQI for $PM_{2.5}$, the AQI will be revised accordingly.

VI. Rationale for Proposed Decisions on the Secondary PM Standards

This section presents the rationale for the Administrator's proposed decisions to revise the current suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment while retaining the current secondary $PM_{2.5}$ and PM_{10} standards to address the other welfare effects considered in this review. In particular, this section presents background information on EPA's previous and current reviews of the secondary PM standards (section VI.A), information on visibility impairment (section VI.B), conclusions on the adequacy of the current secondary $PM_{2.5}$ standards to protect against PM-related visibility impairment (section VI.C), conclusions on alternative standards to protect against PM-related visibility impairment (section VI.D), conclusions on secondary PM standards to address other PM-related welfare effects (section VI.E), and a summary of the Administrator's proposed decisions on the secondary PM standards (section VI.F).

A. Background

The current suite of secondary PM standards is identical to the current suite of primary PM standards, including 24-hour and annual $PM_{2.5}$ standards and a 24-hour PM_{10} standard. The current secondary $PM_{2.5}$ standards are intended to provide protection from PM-related visibility impairment, whereas the entire suite of secondary PM standards is intended to provide protection from other PM-related effects on public welfare, including effects on sensitive ecosystems, materials damage and soiling, and climatic and radiative processes.

The approach used for reviewing the current suite of secondary PM standards builds upon and broadens the approaches used in previous PM NAAQS reviews. The following discussion focuses particularly on the current $PM_{2.5}$ standards related to visibility impairment and provides a summary of

the approaches used to review and establish secondary $PM_{2.5}$ standards in the last two reviews (section VI.A.1); judicial review of the 2006 standards that resulted in the remand of the secondary annual and 24-hour $PM_{2.5}$ NAAQS to the EPA (section VI.A.2); and the current approach for evaluating the secondary $PM_{2.5}$ standards (section VI.A.3).

1. Approaches Used in Previous Reviews

The original secondary $PM_{2.5}$ standards were established in 1997 and a revision to the 24-hour standard was made in 2006. The approaches used in making final decisions on secondary standards in those reviews, as well as the current review, utilize different ways to consider the underlying body of scientific evidence. They also reflect an evolution in EPA's understanding of the nature of the effect on public welfare from visibility impairment, from an approach focusing only on Federal Class I area visibility impacts to a more multifaceted approach that also considers PM-related impacts on non-Federal Class I area visibility, such as in urban areas. This evolution has occurred in conjunction with the expansion of available PM data and information from associated studies of public perception, valuation, and personal comfort and well-being.

In 1997, the EPA revised the identical primary and secondary PM NAAQS in part by establishing new identical primary and secondary $PM_{2.5}$ standards. In revising the secondary standards, the EPA recognized that PM produces adverse effects on visibility and that impairment of visibility was being experienced throughout the U.S., in multi-state regions, urban areas, and remote mandatory Federal Class I areas alike. However, in considering an appropriate level for a secondary standard to address adverse effects of $PM_{2.5}$ on visibility, the EPA concluded that the determination of a single national level was complicated by regional differences. These differences included several factors that influence visibility such as background and current levels of $PM_{2.5}$, composition of $PM_{2.5}$, and average relative humidity. Variations in these factors across regions could thus result in situations where attaining an appropriately protective concentration of fine particles in one region might or might not provide adequate protection in a different region. The EPA also determined that there was insufficient

information at that time to establish a level for a national secondary standard that would represent a threshold above which visibility conditions would always be adverse and below which visibility conditions would always be acceptable.

Based on these considerations, the EPA assessed potential visibility improvements in urban areas and on a regional scale that would result from attainment of the new primary standards for $PM_{2.5}$. The agency concluded that the spatially averaged form of the annual $PM_{2.5}$ standard was well suited to the protection of visibility, which involves effects of $PM_{2.5}$ throughout an extended viewing distance across an urban area. Based on air quality data available at that time, many urban areas in the Northeast, Midwest, and Southeast, as well as Los Angeles, were expected to see perceptible improvement in visibility if the annual $PM_{2.5}$ primary standard were attained. The EPA also concluded that attainment of the 24-hour $PM_{2.5}$ standard in some areas would be expected to reduce, to some degree, the number and intensity of ''bad visibility'' days, resulting in improvement in the 20 percent of days having the greatest impairment over the course of a year.

Having concluded that attainment of the annual and 24-hour $PM_{2.5}$ primary standards would lead to visibility improvements in many eastern and some western urban areas, the EPA also considered whether these standards could provide potential improvements to visibility on a regional scale. Based on information available at the time, the EPA concluded that attainment of secondary $PM_{2.5}$ standards set identical to the primary $PM_{2.5}$ standards would be expected to result in visibility improvements in the eastern U.S. at both urban and regional scales, but little or no change in the western U.S., except in and near certain urban areas.

The EPA then considered the potential effectiveness of a regional haze program, required by sections 169A and 169B of the CAA[132] to address those effects of PM on visibility that would not be

[132] In 1977, Congress established as a national goal ''the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Federal Class I areas which impairment results from manmade air pollution'', section 169A(a)(1) of the CAA. The EPA is required by section 169A(a)(4) of the CAA to promulgate regulations to ensure that ''reasonable progress'' is achieved toward meeting the

addressed through attainment of the primary $PM_{2.5}$ standards. The regional haze program would be designed to address the widespread, regionally uniform type of haze caused by a multitude of sources. The structure and requirements of sections 169A and 169B of the CAA provide for visibility protection programs that can be more responsive to the factors contributing to regional differences in visibility than can programs addressing a nationally applicable secondary NAAQS. The regional haze visibility goal is more protective than a secondary NAAQS since the goal addresses any anthropogenic impairment rather than just impairment at levels determined to be adverse to public welfare. Thus, an important factor considered in the 1997 review was whether a regional haze program, in conjunction with secondary standards set identical to the suite of $PM_{2.5}$ primary standards, would provide appropriate protection for visibility in non-Federal Class I areas. The EPA concluded that the two programs and associated control strategies should provide such protection due to the regional approaches needed to manage emissions of pollutants that impair visibility in many of these areas.

For these reasons, the EPA concluded that a national regional haze program, combined with a nationally applicable level of protection achieved through secondary $PM_{2.5}$ standards set identical to the primary $PM_{2.5}$ standards, would be more effective for addressing regional variations in the adverse effects of $PM_{2.5}$ on visibility than would be national secondary standards for PM with levels lower than the primary $PM_{2.5}$ standards. The EPA further recognized that people living in certain urban areas may place a high value on unique scenic resources in or near these areas, and as a result might experience visibility problems attributable to sources that would not necessarily be addressed by the combined effects of a regional haze program and $PM_{2.5}$ secondary standards. The EPA concluded that in such cases, state or local regulatory approaches, such as past action in Colorado to establish a local visibility standard for the City of Denver, would be more appropriate and effective in addressing these special situations because of the localized and unique characteristics of the problems involved. Visibility in an urban area located near a mandatory Federal Class I area could also be improved through state

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national goal.

implementation of the then-current visibility regulations, by which emission limitations can be imposed on a source or group of sources found to be contributing to ‘‘reasonably attributable’’ impairment in the mandatory Federal Class I area.

Based on these considerations, in 1997 the EPA set secondary $PM_{2.5}$ standards identical to the primary $PM_{2.5}$ standards, in conjunction with a regional haze program under sections 169A and 169B of the CAA, as the most appropriate and effective means of addressing the public welfare effects associated with visibility impairment. Together, the two programs and associated control strategies were expected to provide appropriate protection against PM-related visibility impairment and enable all regions of the country to make reasonable progress toward the national visibility goal.

In 2006, EPA revised the suite of secondary $PM_{2.5}$ standards to address visibility impairment by making the suite of secondary standards identical to the revised suite of primary $PM_{2.5}$ standards. The EPA’s decision regarding the need to revise the suite of secondary $PM_{2.5}$ standards reflected a number of new developments that had occurred and sources of information that had become available following the 1997 review. First, the EPA promulgated a Regional Haze Program in 1999 (65 FR 35713, July 1, 1999) which required states to establish goals for improving visibility in Federal Class I areas and to adopt control strategies to achieve these goals. Second, extensive new information from visibility and fine particle monitoring networks had become available, allowing for updated characterizations of visibility trends and PM concentrations in urban areas, as well as Federal Class I areas. These new data allowed the EPA to better characterize visibility impairment in urban areas and the relationship between visibility and $PM_{2.5}$ concentrations. Finally, additional studies in the U.S. and abroad provided the basis for the establishment of standards and programs to address specific visibility concerns in a number of local areas. These studies (Denver, Phoenix, and British Columbia) utilized photographic representations of visibility impairment and produced reasonably consistent results in terms of the visual ranges found to be generally acceptable by study participants. The EPA considered the information generated by these studies useful in characterizing the nature of particle-induced haze and for informing judgments about

the acceptability of various levels of visual air quality in urban areas across the U.S. Based largely on this information, the Administrator concluded that it was appropriate to revise the secondary $PM_{2.5}$ standards to provide increased protection from visibility impairment principally in urban areas, in conjunction with the regional haze program for protection of visual air quality in Federal Class I areas.

In so doing, the Administrator recognized that PM-related visibility impairment is principally related to fine particle concentrations and that perception of visibility impairment is most directly related to short-term, nearly instantaneous levels of visual air quality. Thus, in considering whether the then-current suite of secondary standards would provide the appropriate degree of protection, he concluded that it was appropriate to focus on just the 24-hour secondary $PM_{2.5}$ standard to provide requisite protection.

The Administrator then considered whether $PM_{2.5}$ mass remained the appropriate indicator for a secondary standard to protect visibility, primarily in urban areas. The Administrator noted that PM-related visibility impairment is principally related to fine particle levels. Hygroscopic components of fine particles, in particular sulfates and nitrates, contribute disproportionately to visibility impairment under high humidity conditions. Particles in the coarse mode generally contribute only marginally to visibility impairment in urban areas. With the substantial addition to the air quality and visibility data made possible by the national urban $PM_{2.5}$ monitoring networks, an analysis conducted for the 2006 review found that, in urban areas, visibility levels showed far less difference between eastern and western regions on a 24-hour or shorter time basis than implied by the largely non-urban data available in the 1997 review. In analyzing how well $PM_{2.5}$ concentrations correlated with visibility in urban locations across the U.S., the 2005 Staff Paper concluded that clear correlations existed between 24-hour average $PM_{2.5}$ concentrations and calculated (i.e., reconstructed) light extinction, which is directly related to visual range (US 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 (US EPA, 2005, p. 7-6). Based on their review of the Staff Paper, most CASAC Panel members also endorsed such a $PM_{2.5}$ indicator for a secondary standard to address visibility impairment (Henderson, 2005a. p. 9). Based on the above considerations, the Administrator concluded that $PM_{2.5}$ should be retained as the indicator for fine particles as part of a secondary standard to address visibility protection, in conjunction with averaging times from 4 to 24 hours.

In considering what level of protection against PM-related visibility impairment would be appropriate, the Administrator took into account the results of the public perception and attitude surveys regarding the acceptability of various degrees of visibility impairment in the U.S. and Canada, state and local visibility standards within the U.S., and visual inspection of photographic representations of several urban areas across the U.S. In the Administrator's judgment, these sources provided useful but still quite limited information on the range of levels appropriate for consideration in setting a national visibility standard primarily for urban areas, given the generally subjective nature of the public welfare effect involved. Based on photographic representations of varying levels of visual air quality, public perception studies, and local and state visibility standards, the 2005 Staff Paper had concluded that 30 to 20 $\mu g/m^3$ $PM_{2.5}$ represented a reasonable range for a national visibility standard primarily for urban areas, based on a sub-daily averaging time (US 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 (US EPA, 2005 pp. 7-11 to 7-13). While recognizing that it was difficult to select any specific level and form based on then-currently available information (Henderson, 2005a, p. 9), the CASAC Panel was generally in agreement with the ranges of levels and forms presented in the 2005 Staff Paper.

The Administrator also considered the level of protection that would be afforded by the proposed suite of primary $PM_{2.5}$ standards (71 FR 2681, January 17, 2006), on the basis that although significantly more information was available than in the 1997 review concerning the relationship between fine PM levels and visibility across the country, there was still little available information for use in making the relatively subjective value judgment needed in selecting the appropriate degree of protection to be afforded by such a standard. In so doing, the Administrator compared the extent to which the proposed suite of primary standards would require areas across the country to improve visual air quality with the extent of increased protection likely to be afforded by a standard based on a sub-daily averaging time. Based on such an analysis, the Administrator observed that the predicted percent of counties with monitors not likely to meet the proposed suite of primary $PM_{2.5}$ standards was actually somewhat greater than the predicted percent of counties with monitors not likely to meet a sub-daily secondary standard with an averaging time of 4 daylight hours, a level toward the upper end of the range recommended in the 2005 Staff Paper, and a form within the recommended range. Based on this comparison, the

Administrator tentatively concluded that revising the secondary 24-hour $PM_{2.5}$ standard to be identical to the proposed revised primary $PM_{2.5}$ standard (and retaining the then-current annual secondary $PM_{2.5}$ standard) was a reasonable policy approach to addressing visibility protection primarily in urban areas. In proposing this approach, the Administrator also solicited comment on a sub-daily (4- to 8-hour averaging time) secondary $PM_{2.5}$ standard (71 FR 2675 to 2781, January 17, 2006).

In commenting on the proposed decision, the CASAC requested that a sub-daily standard to protect visibility "be favorably reconsidered" (Henderson, 2006a, p.6). The CASAC noted three cautions regarding the proposed reliance on a secondary $PM_{2.5}$ standard identical to the proposed 24-hour primary $PM_{2.5}$ standard: (1) $PM_{2.5}$ mass measurement is a better indicator of visibility impairment during daylight hours, when relative humidity is generally low; the sub-daily standard more clearly matches the nature of visibility impairment, whose adverse effects are most evident during the daylight hours; using a 24- hour $PM_{2.5}$ standard as a proxy introduces error and uncertainty in protecting visibility; and sub-daily standards are used for other NAAQS and should be the focus for visibility; (2) CASAC and its monitoring subcommittees had repeatedly commended EPA's initiatives promoting the introduction of continuous and near-continuous PM monitoring, and recognized that an expanded deployment of continuous $PM_{2.5}$ monitors would be consistent with setting a sub-daily standard to protect visibility; and (3) the analysis showing a similarity between percentages of counties not likely to meet what the CASAC Panel considered to be a lenient 4- to 8-hour secondary standard and a secondary standard identical to the proposed 24-hour primary standard was a numerical coincidence that was not indicative of any fundamental relationship between visibility and health. The CASAC Panel further stated that "visual air quality is substantially impaired at $PM_{2.5}$ concentrations of 35 $\mu g/m^3$" and that "[i]t is not reasonable to have the visibility standard tied to the health standard, which may change in ways that make it even less appropriate for visibility concerns" (Henderson, 2006a, pp. 5 to 6).

In reaching a final decision, the Administrator focused on the relative protection provided by the proposed primary standards based on the above-mentioned similarities in percentages of counties

meeting alternative standards, and on the limitations in the information available concerning studies of public perception and attitudes regarding the acceptability of various degrees of visibility impairment in urban areas, as well as on the subjective nature of the judgment required. In so doing, the Administrator concluded that caution was warranted in establishing a distinct secondary standard for visibility impairment and that the available information did not warrant adopting a secondary standard that would provide either more or less protection against visibility impairment in urban areas than would be provided by secondary standards set equal to the proposed primary $PM_{2.5}$ standards.

2. Remand of 2006 Secondary $PM_{2.5}$ Standards

As noted above in section II.B.2 above, several parties filed petitions for review challenging EPA's decision to set the secondary NAAQS for fine PM identical to the primary NAAQS. On judicial review, the D.C. Circuit remanded to EPA for reconsideration the secondary NAAQS for fine PM because the Agency's decision was unreasonable and contrary to the requirements of section 109(b)(2). *American Farm Bureau Federation v. EPA*, 559 F. 3d 512 (D.C. Cir., 2009).

The petitioners argued that EPA's decision lacked a reasoned basis. First, they asserted that EPA never determined what level of visibility was "requisite to protect the public welfare." They argued that EPA unreasonably rejected the target level of protection recommended by its staff, while failing to provide a target level of its own. The court agreed, stating that "the EPA's failure to identify such a level when deciding where to set the level of air quality required by the revised secondary fine PM NAAQS is contrary to the statute and therefore unlawful. Furthermore, the failure to set any target level of visibility protection deprived the EPA's decision-making of a reasoned basis." 559 F. 3d at 530.

Second, the petitioners challenged EPA's method of comparing the protection expected from potential standards. They contended that EPA relied on a meaningless numerical comparison, ignored the effect of humidity on the usefulness of a standard using a daily averaging time, and unreasonably concluded that the primary standards would achieve a level of visibility roughly equivalent to the level the EPA staff and CASAC deemed "requisite to protect the public welfare." The court found that EPA's

equivalency analysis based on the percentages of counties exceeding alternative standards "failed on its own terms." The same table showing the percentages of counties exceeding alternative secondary standards, used for comparison to the percentages of counties exceeding alternative primary standards to show equivalency, also included six other alternative secondary standards within the recommended CASAC range that would be more "protective" under EPA's definition than the adopted primary standards. Two-thirds of the potential secondary standards within the CASAC's recommended range would be substantially more protective than the adopted primary standards. The court found that EPA failed to explain why it looked only at one of the few potential secondary standards that would be less protective, and only slightly less so, than the primary standards. More fundamentally, however, the court found that EPA's equivalency analysis based on percentages of counties demonstrated nothing about the relative protection offered by the different standards, and that the tables offered no valid information about the relative visibility protection provided by the standards. 559 F. 3d at 530-31.

Finally, the Staff Paper had made clear that a visibility standard using $PM_{2.5}$ mass as the indicator in conjunction with a daily averaging time would be confounded by regional differences in humidity. The court noted that EPA acknowledged this problem, yet did not address this issue in concluding that the primary standards would be sufficiently protective of visibility. 559 F. 3d at 530. Therefore, the court granted the petition for review and remanded for reconsideration the secondary $PM_{2.5}$ NAAQS.

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

The approach used in this review broadens the general approaches used in the last two PM NAAQS reviews by utilizing, to the extent available, enhanced tools, methods, and data to more comprehensively characterize visibility impacts. As such, the EPA is taking into account considerations based on both the scientific evidence ("evidence-based") and a quantitative analysis of PM-related impacts on visibility ("impact-based") to inform conclusions related to the adequacy of the current secondary $PM_{2.5}$ standards and alternative standards that are appropriate for consideration in this review.

As in past reviews, the EPA is also considering that the secondary NAAQS should address PM-related visibility impairment in conjunction with the Regional Haze Program, such that the secondary NAAQS would focus on protection from visibility impairment principally in urban areas in conjunction with the Regional Haze Program that is focused on improving visibility in Federal Class I areas. The EPA again recognizes that such an approach is the most appropriate and effective means of addressing the public welfare effects associated with visibility impairment in areas across the country.

The Policy Assessment draws from the qualitative evaluation of all studies discussed in the Integrated Science Assessment (US EPA, 2009a). Specifically, the Policy Assessment considers the extensive new air quality and source apportionment information available from the regional planning organizations, long-standing evidence of PM effects on visibility, and public preference studies from four urban areas (US EPA, 2009a, chapter 9), as well as the integration of evidence across disciplines (US EPA, 2009a, chapter 2). In addition, limited information that has become available regarding the characterization of public preferences in urban areas has provided some new perspectives on the usefulness of this information in informing the selection of target levels of urban visibility protection. On these bases, the Policy Assessment again focuses assessments on visibility conditions in urban areas.

The conclusions in the Policy Assessment reflect EPA staff's understanding of both evidence-based and impact-based considerations to inform two overarching questions related to: (1) the adequacy of the current suite of $PM_{2.5}$ standards and (2) what potential alternative standards, if any, should be considered in this review to provide appropriate protection from PM-related visibility impairment. In addressing these broad questions, the discussions in the Policy Assessment were organized around a series of more specific questions reflecting different aspects of each overarching question (US EPA, 2011a, Figure 4-1). When evaluating the visibility protection afforded by the current or any alternative standards considered, the Policy Assessment takes into account the four basic elements of the NAAQS: indicator, averaging time, level, and form.

B. PM-Related Visibility Impairment

As discussed below, the rationale for the Administrator's proposed decision regarding secondary PM standards to protect against visibility impairment focuses on those considerations most influential in the Administrator's proposed decisions, including consideration of: (1) the latest scientific information on visibility effects associated with PM as described in the Integrated Science Assessment (US 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 (US EPA, 2010b); and (3) specific conclusions regarding the need for revisions to the current standards (i.e., indicator, averaging time, form, and level) that, taken together, would be requisite to protect the public welfare from adverse effects on visual air quality.

This section outlines key information contained in the Integrated Science Assessment, the Visibility Assessment and the Policy Assessment on: (1) the nature of visibility impairment, including the relationship between ambient PM and visibility, temporal variations in light extinction, periods during the day of interest for assessing visibility conditions, and exposure durations of interest and (2) public perceptions and attitudes about visibility impairment and the impacts of visibility impairment on public welfare.

1. Nature of PM-related Visibility Impairment

New research conducted by regional planning organizations in support of the Regional Haze Rule, as discussed in chapter 9 of the Integrated Science Assessment, continues to support and refine EPA's understanding of the effect of PM on visibility and the source contributions to that effect in rural and remote locations. Additional by-products of this research include new insights regarding the regional source contributions to urban visibility impairment and better characterization of the increment in PM concentrations and visibility impairment that occur in many cities (i.e., the urban excess) relative to conditions in the surrounding rural areas (i.e., regional background). Ongoing urban $PM_{2.5}$ speciated and aggregated mass monitoring has produced new information that has allowed for updated characterization of current visibility levels in urban areas. Information from both of these sources of PM

data, while useful, has not however changed the fundamental and long understood science characterizing the contribution of PM, especially fine particles, to visibility impairment. This science, briefly summarized below, provides the basis for the Integrated Science Assessment designation of the relationship between PM and visibility impairment as causal.

a. Relationship Between Ambient PM and Visibility

Visibility impairment is caused by the scattering and absorption of light by suspended particles and gases in the atmosphere. The combined effect of light scattering and absorption by both particles and gases is characterized as light extinction, i.e., the fraction of light that is scattered or absorbed in the atmosphere. Light extinction is quantified by a light extinction coefficient with units of 1/distance, which is often expressed in the technical literature as 1/(1 million meters) or inverse megameters (abbreviated Mm^{-1}). When PM is present in the air, its contribution to light extinction typically greatly exceeds that of gases.

The amount of light extinction contributed by PM depends on the particle size distribution and composition, as well as its particle concentration. If details of the ambient particle size distribution and composition (including the mixing of components) are known, Mie theory can be used to accurately calculate PM light extinction (US EPA, 2009a, chapter 9). However, routine monitoring rarely includes measurements of particle size and composition information with sufficient detail for such calculations. To make estimation of light extinction more practical, visibility scientists have developed a much simpler algorithm, known as the IMPROVE algorithm,[133] to estimate light extinction using routinely monitored fine particle ($PM_{2.5}$) speciation and coarse particle mass ($PM_{10–2.5}$) data. In addition, relative humidity information is needed to estimate the contribution by liquid water that is in solution with hygroscopic PM components (US EPA, 2009a, section 9.2.2.2; US EPA, 2010b, chapter 3). There is

[133] The algorithm is referred to as the IMPROVE algorithm because it was developed specifically to use the aerosol monitoring data generated at network sites and with equipment specifically designed to support the IMPROVE program and was evaluated using IMPROVE optical measurements at the subset of sites that make those measurements (Malm et al., 1994).

both an original and a revised version of the IMPROVE algorithm (Pitchford et al., 2007). The revised version was developed to address observed biases in the predictions using the original algorithm under very low and very high light extinction conditions.[134] These IMPROVE algorithms are routinely used to calculate light extinction levels on a 24-hour basis in Federal Class I areas under the Regional Haze Program.

In either version of the IMPROVE algorithm, the concentration of each of the major aerosol components is multiplied by a dry extinction efficiency value and, for the hygroscopic components (i.e., ammoniated sulfate and ammonium nitrate), also multiplied by an additional factor to account for the water growth to estimate these components' contribution to light extinction. Both the dry extinction efficiency and water growth terms have been developed by a combination of empirical assessment and theoretical calculation using typical particle size distributions associated with each of the major aerosol components. They have been evaluated by comparing the algorithm estimates of light extinction with coincident optical measurements. Summing the contribution of each component gives the estimate of total light extinction per unit distance denoted as the light extinction coefficient (b_{ext}), as shown below for the original IMPROVE algorithm.

$$
\begin{aligned}
b_{ext} \approx\ & 3 \times f(\mathrm{RH}) \times [\mathrm{Sulfate}] \\
& + 3 \times f(\mathrm{RH}) \times [\mathrm{Nitrate}] \\
& + 4 \times [\mathrm{Organic\ Mass}] \\
& + 10 \times [\mathrm{Elemental\ Carbon}] \\
& + 1 \times [\mathrm{Fine\ Soil}] \\
& + 0.6 \times [\mathrm{Coarse\ Mass}] \\
& + 10
\end{aligned}
$$

Light extinction (b_{ext}) is in units of Mm^{-1}, the mass concentrations of the components indicated in brackets are in units of $\mu\mathrm{g/m}^3$, and $f(\mathrm{RH})$ is the unitless water growth term that depends on relative humidity. The final term of 10 Mm^{-1} is known as the Rayleigh scattering term and accounts for light scattering by the natural gases in unpolluted air. The dry extinction efficiency for particulate organic

[134] These biases were detected by comparing light extinction estimates generated from the IMPROVE algorithm to direct optical measurements in a number of rural Federal Class I areas.

mass is larger than those for particulate sulfate and nitrate principally because the density of the dry inorganic compounds is higher than that assumed for the PM organic mass components.

For the first two terms, "sulfate" is defined in terms of ammonium sulfate and "nitrate" is defined in terms of ammonium nitrate. Since IMPROVE does not include ammonium ion monitoring, the assumption is made that all sulfate is fully neutralized ammonium sulfate and all nitrate is assumed to be ammonium nitrate.[135] Though often reasonable, neither assumption is always true (see US EPA, 2009a, section 9.2.3.1). In the eastern U.S. during the summer there is insufficient ammonia in the atmosphere to neutralize the sulfate fully. Fine particle nitrates can include sodium or calcium nitrate, which are the fine particle fraction of generally much coarser particles due to nitric acid interactions with sea salt at near-coastal areas (sodium nitrate) or nitric acid interactions with calcium carbonate in crustal aerosol (calcium nitrate). Despite the simplicity of the algorithm, it performs reasonably well and permits the contributions to light extinction from each of the major components (including the water associated with the sulfate and nitrate compounds) to be separately approximated.

The $f(\mathrm{RH})$ term reflects the increase in light scattering caused by particulate sulfate and nitrate under conditions of high relative humidity. Particles with hygroscopic components (e.g., particulate sulfate and nitrate) contribute more light extinction at higher relative humidity than at lower relative humidity because they change size in the atmosphere in response to ambient relative humidity conditions. For relative humidity below 40 percent the $f(\mathrm{RH})$ 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

[135] To calculate ammonium sulfate, multiply the CSN measurement of the sulfate ion by 1.375. To calculate ammonium nitrate, multiply the CSN measurement of the nitrate ion by 1.29 (Lowenthal and Kumar, 2006).

efficiency exceeds the 10 m^2/g associated with elemental carbon (EC). Based on this algorithm, particulate sulfate and nitrate are estimated to have comparable light extinction efficiencies (i.e., the same dry extinction efficiency and *f*(RH*)* water growth terms), so on a per unit mass concentration basis at any specific relative humidity they are treated as equally effective contributors to visibility effects.

As noted above, particles with hygroscopic components (e.g., particulate sulfate and nitrate) contribute more light extinction at higher relative humidity than at lower relative humidity because they change size in the atmosphere in response to ambient relative humidity conditions. PM containing elemental or black carbon (BC) absorbs light as well as scattering it, making it the component with the greatest light extinction contributions per unit of mass concentration, except for the hygroscopic components under high relative humidity conditions.[136]

With regard to the fifth and sixth terms, the fine soil component is based on measurement of five elements: aluminum (Al), silicon (Si), calcium (Ca), iron (Fe), and titanium (Ti).[137] Inspection of the PM component-specific terms in the simple original IMPROVE algorithm shows that most of the $PM_{2.5}$ components contribute 5 times or more light extinction than a similar concentration of $PM_{10-2.5}$.

Subsequent to the development of the original IMPROVE algorithm, an alternative algorithm (variously referred to as the "revised algorithm" or the "new algorithm" in the literature) has been developed. It employs a more complex split-component mass extinction efficiency to correct biases believed to be related to particle size distributions, a sea salt term that can be important for remote coastal areas, a different multiplier for organic carbon for purposes of estimating organic carbonaceous material[138], and site-specific Rayleigh light scattering terms in place of a universal Rayleigh light scattering value. These features of the revised IMPROVE algorithm are described in section 9.2.3.1 of

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[136] The IMPROVE algorithm does not explicitly separate the light-scattering and light-absorbing effects of elemental carbon.

[137] Consistent with calculations used in the IMPROVE network and the Regional Haze Program, the fine soil component is calculated using the following formula:

$$\text{Fine Soil} = 2.20 \times [Al] + 2.49 \times [Si] + 1.63 \times [Ca] + 2.42 \times [Fe] + 1.94 \times [Ti].$$

[138] The revised IMPROVE algorithm uses a multiplier of 1.8 instead of 1.4 as used in the original algorithm for the mean ratio of organic mass to organic carbon.

the Integrated Science Assessment, which also presents a comparison of the estimates produced by the two algorithms for rural areas. Compared to the original algorithm, the revised IMPROVE algorithm can yield higher estimates of current light extinction levels in urban areas on days with relatively poor visibility (Pitchford, 2010). This difference is primarily attributable to the split-component mass extinction efficiency treatment in the revised algorithm rather than to the inclusion of a sea salt term or the use of site-specific Rayleigh scattering values.

As mentioned above, particles are not the only contributor to ambient visibility conditions. Light scattering by gases also occurs in ambient air. Under pristine atmospheric conditions, naturally occurring gases such as elemental nitrogen and oxygen cause what is known as Rayleigh scattering. Rayleigh scattering depends on the density of air, which is a function primarily of the elevation above sea level, and can be treated as a site-dependent constant. The Rayleigh scattering contribution to light extinction is only significant under pristine conditions. The only other commonly occurring atmospheric gas to appreciably absorb light in the visible spectrum is nitrogen dioxide. Nitrogen dioxide forms in the atmosphere from nitrogen oxide emissions associated with combustion processes. These combustion processes also emit PM at levels that generally contribute much higher light extinction than the nitrogen dioxide (i.e., nitrogen dioxide absorption is generally less than approximately 5 percent of the light extinction, except where emission controls remove most of the PM prior to releasing the remaining gases to the atmosphere). The final term in the IMPROVE algorithm of 10 Mm^{-1} is known as the Rayleigh scattering term and accounts for light scattering by the natural gases in unpolluted air. The remainder of this section focuses on the contribution of PM, which is typically much greater than that of gases, to ambient light extinction, unless otherwise specified.

In the following discussions, visual air quality is characterized in terms of both light extinction, as discussed above, and an alternative scale for characterizing visibility – the deciview scale - that is

defined directly in terms of light extinction (expressed in units of Mm^{-1}) by the following equation:[139]

$$\text{Deciview (dv)} = 10 \ln (b_{ext} / 10\ Mm^{-1})$$

The deciview scale is frequently used in the scientific and regulatory literature on visibility, as well as in the Regional Haze Program. In particular, the deciview scale is used in the public perception studies that were considered in the past and current reviews to inform judgments about an appropriate degree of protection to be provided by a secondary NAAQS.

b. Temporal Variations of Light Extinction

Particulate matter concentrations and light extinction in urban environments vary from hour-to-hour throughout the 24-hour day due to a combination of diurnal changes in meteorological conditions and systematic changes in emissions activity (e.g., rush hour traffic). Generally, low mixing heights at night and during the early morning hours tend to trap locally produced emissions, which are diluted as the mixing height increases due to heating during the day. Low temperatures and high relative humidity at night are conducive to the presence of ammonium nitrate particles and water growth by hygroscopic particles compared with the generally higher temperatures and lower relative humidity later in the day. These combine to make early morning the most likely time for peak urban light extinction. Superimposed on such systematic time-of-day variations are the effects of synoptic meteorology (i.e., those associated with changing weather) and regional-scale air quality that can generate peak light extinction impacts any time of day. The net effects of the systematic urban- and larger-scale variations are that peak daytime PM light extinction levels can occur any time of day, although in many areas they most often occur in early morning hours (US 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

[139] As used in the Regional Haze Program, the term b_{ext} refers to light extinction due to $PM_{2.5}$, $PM_{10-2.5}$, and "clean" atmospheric gases. In the Policy Assessment, in focusing on light extinction due to $PM_{2.5}$, the deciview values include only the effects of $PM_{2.5}$ and the gases. The "Rayleigh" term associated with clean atmospheric gases is represented by the constant value of 10 Mm^{-1}. Omission of the Rayleigh term would create the possibility of a negative deciview values when the $PM_{2.5}$ concentration is very low.

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.

c. Periods During the Day of Interest for Assessment of Visibility

Visibility is typically associated with daytime periods because people are outside more during the day than at night and there are more viewable scenes at a distance during the day than at night. The Policy Assessment recognizes, however, that physically PM light extinction behaves the same at night as during the day, enhancing the scattering of anthropogenic light, contributing to the "skyglow" within and over populated areas, adding to the total sky brightness, and contributing to the reduction in contrast of stars against the background. These effects produce the visual result of a reduction in the number of visible stars and the disappearance of diffuse or subtle phenomena such as the Milky Way. The extinction of starlight is a secondary and minor effect also caused by increased PM scattering and absorption.

However, there are significant and important differences between daytime and nighttime visual environments with regard to how light extinction per se relates to visual air quality (or visibility) and public welfare. First, daytime visibility has dominated the attention of those who have studied the visibility effects of air pollution, particularly in urban areas. As a result, little research has been conducted on nighttime visibility and the state of the science is not comparable to that associated with daytime visibility impairment. As noted in the Policy Assessment, no urban-focused preference or valuation studies providing information on public preferences for nighttime visual air quality have been identified (US EPA, 2011a, p. 4-17). Second, in addition to air pollution, nighttime visibility is affected by the addition of light into the sight path from numerous sources, including anthropogenic light sources in urban environments such as artificial outdoor lighting, which varies dramatically across space, and natural sources including the moon, planets, and stars. Light sources and ambient light conditions are

typically five to seven orders of magnitude dimmer at night than in sunlight. Moonlight, like sunlight, introduces light throughout an observer's sight path at a constant angle. On the other hand, dim starlight emanates from all over the celestial hemisphere while artificial lights are concentrated in cities and illuminate the atmosphere from below. These different light sources will yield variable changes in visibility as compared to what has been established for the daytime scenario, in which a single source, the sun, is by far the brightest source of light. Third, the human psychophysical response (e.g., how the human eye sees and processes visual stimuli) at night is expected to differ (US EPA, 2009a, section 9.2.2).

Given the above, the Policy Assessment notes that the science is not available at this time to support adequate characterization specifically of nighttime PM light extinction conditions and the related effects on public welfare (US EPA, 2011a, p. 4-18). Thus, the Policy Assessment focuses its assessments of PM visibility impacts in urban areas on daylight hours. For simplicity, and because perceptions and welfare effects from light extinction-related visual effects during the minutes of actual sunrise and sunset have not been explored, daylight hours are defined as those hours entirely after the local sunrise time and before the local sunset time.

In so doing, the Policy Assessment notes that the 24-hour averaging time used in the Regional Haze Program includes nighttime conditions (US EPA, 2011a, p. 4-18). It also notes, however, that the goal of the Regional Haze Program is to address any manmade impairment of visibility without regard to distinctions between daylight and nighttime conditions. Moreover, because of the lack of strong diurnal patterns in most Federal Class I areas, both nighttime and daylight visibility are strongly correlated with 24-hour average visibility conditions, so a 24-hour averaging period is suitable for driving both daylight and nighttime visibility towards their natural conditions. Also, the focus on 24-hour average visibility allows the Regional Haze Program to make use of more practically obtained ambient speciated PM measurements of adequate accuracy than if a shorter averaging period were used, which is an important consideration especially given the remoteness of many Federal Class I area

monitoring sites and given the low PM concentrations that must be measured accurately in such areas.

In addition, when natural conditions such as fog and rain cause poor visibility, it can be reasonably assumed that the light extinction properties of the air that are attributable to air pollution are not important from a public welfare perspective. Thus, it is appropriate to give special treatment to such periods when considering whether current $PM_{2.5}$ standards adequately protect public welfare from PM-related visibility impairment. In evaluating alternative sub-daily standards, the Policy Assessment addresses this issue by screening out hours with particularly high relative humidity. As discussed further below, the Policy Assessment uses a relative humidity screen of 90 percent on the basis that it serves as a reasonable surrogate for excluding hours affected by fog and rain (US EPA, 2011a, p. 4-18).

d. Exposure Durations of Interest

The roles that exposure duration and variations in visual air quality within any given exposure period play in determining the acceptability or unacceptability of a given level of visual air quality has not been investigated via preference studies. In the preference studies available for this review, subjects were simply asked to rate the acceptability or unacceptability of each image of a haze-obscured scene, without being provided any suggestion of assumed duration or of assumed conditions before or after the occurrence of the scene presented. Preference and/or valuation studies show that atmospheric visibility conditions can be quickly assessed and preferences determined. A momentary glance at an image of a scene (i.e., less than a minute) is enough for study participants to judge the acceptability or unacceptability of the viewed visual air quality conditions. Moreover, individual participants in general consistently judge the acceptability of same-scene images that differed only with respect to light extinction levels when these images were presented repeatedly for such short periods. That is, individuals generally did not say that a higher-light extinction image was acceptable while saying a lower-light extinction, same-scene image was unacceptable, even though they could not compare images side-to-side. However, the Policy Assessment does not have information about what assumptions, if any, the participants may have made about the duration of exposure in determining the acceptability of the

images and EPA staff is unaware of any studies that characterize the extent to which different frequencies and durations of exposure to visibility conditions contribute to the degree of public welfare impact that occurs.

In the absence of such studies, the Policy Assessment considers a variety of circumstances that are commonly expected to occur in evaluating the potential impact of visibility impairment on the public welfare based on available information (US EPA, 2011a, pp. 4-19 to 4-20). In some circumstances, such as infrequent visits to scenic vistas in natural or urban environments, people are motivated specifically to take the opportunity to view a valued scene and are likely to do so for many minutes to hours to appreciate various aspects of the vista they choose to view. In such circumstances, the viewer may consciously evaluate how the visual air quality at that time either enhances or diminishes the experience or view. However, the public also has many more opportunities to notice visibility conditions on a daily basis in settings associated with performing daily routines (e.g., during commutes and while working, exercising, or recreating outdoors). These scenes, whether iconic or generic, may not be consciously viewed for their scenic value and may not even be noticed for periods comparable to what would be the case during purposeful visits to scenic visits, but their visual air quality may still affect a person's sense of wellbeing. Research has demonstrated that people are emotionally affected by low visual air quality, that perception of pollution is correlated with stress, annoyance, and symptoms of depression, and that visual air quality is deeply intertwined with a "sense of place," affecting people's sense of the desirability of a neighborhood (US EPA, 2009a, section 9.2.4). Though it is not known to what extent these emotional effects are linked to different periods of exposure to poor visual air quality, providing additional protection against short-term exposures to levels of visual air quality considered unacceptable by subjects in the context of the preference studies would be expected to provide some degree of protection against the risk of loss in the public's "sense of wellbeing."

Some people have mostly intermittent opportunities on a daily basis (e.g., during morning and/or afternoon commutes) to experience ambient visibility conditions because they spend much of their time

indoors without access to windows. For such people a view of poor visual air quality during their morning commute may provide their perception of the day's visibility conditions until the next time they venture outside during daylight hours later or perhaps the next day. Other people have exposure to visibility conditions throughout the day, conditions that may differ from hour to hour. A day with multiple hours of visibility impairment would likely be judged as having a greater impact on their wellbeing than a day with just one such hour followed by clearer conditions.

As noted in the Policy Assessment, information regarding the fraction of the public that has only one or a few opportunities to experience visibility during the day, or on the role the duration of the observed visibility conditions has on wellbeing effects associated with those visibility conditions is not available (US EPA, 2011a, p. 4-20). However, it is logical to conclude that people with limited opportunities to experience visibility conditions on a daily basis would receive the entire impact of the day's visual air quality based on the visibility conditions that occur during the short time period when they can see it. Since this group could be affected on the basis of observing visual air quality conditions for periods as short as one hour or less, and because during each daylight hour there are some people outdoors, commuting, or near windows, the Policy Assessment judges that it would be appropriate to use the maximum hourly value of PM light extinction during daylight hours for each day for purposes of evaluating the adequacy of the current suite of secondary standards. This approach would recognize that at least some but not all of the population of an area will actually be exposed to this worst hour and that some of the people who are exposed to this worst hour may not have an opportunity to observe clearer conditions in other hours if they were to occur. Moreover, because visibility conditions and people's daily activities on work/school days both tend to follow the same diurnal pattern day after day, those who are exposed only to the worst hour will tend to have this experience day after day.

For another group of observers, those who have access to visibility conditions often or continuously throughout the day, the impact of the day's visibility conditions on their welfare may be based on the varying visibility conditions they observe throughout the day. For this group, it might be

that an hour with poor or "unacceptable" visibility can be offset by one or more other hours with clearer conditions. Based on these considerations, the Policy Assessment judges that it would also be appropriate to use a maximum multi-hour daylight period for evaluating the adequacy of the current suite of secondary standards (US EPA, 2011a, p. 4-20).

The above discussion is based on what people see, which is determined by the extinction of light along the paths between observers and the various objects they view. A related but separate issue is what measurement period is relevant, if what will be measured is the light extinction property or the PM concentration of the local air at a fixed site. Light extinction conditions at a fixed site can change quickly (i.e., in less than a minute). Sub-hourly variations in light extinction determined at any point in the atmosphere are likely the result of small-scale spatial pollution features (i.e., high concentration plumes that have just been generated in the immediate vicinity due to local sources or that have been transported by the wind across that point). These small-scale pockets of air causing short periods of higher light extinction at the fixed site likely do not determine the visual effect for scenes with longer sight paths. In contrast, atmospheric sight path-averaged light extinction which is pertinent to visibility impacts generally changes more slowly (i.e., tens of minutes generally), because a larger air mass must be affected by a broader set of emission sources or the larger air mass must be replaced by a cleaner or dirtier air mass due to the wind operating over time. At typical wind speeds found in U.S. cities, an hour corresponds to a few tens of kilometers of air flowing past a point, which is similar to sight path lengths of interest in urban areas. Based on the above considerations, the Policy Assessment concludes hourly average light extinction would generally be reasonably representative of the net visibility effect of the spatial pattern of light extinction levels, especially along site paths that generally align with the wind direction (US EPA, 2011a, p. 4-21).

2. Public Perception of Visibility Impairment

As noted in the Integrated Science Assessment, there are two main types of studies that evaluate the public perception of urban visibility impairment: urban visibility preference studies and urban

visibility valuation studies. As noted in the Integrated Science Assessment, "[b]oth types of studies are designed to evaluate individuals' desire (or demand) for good VAQ where they live, using different metrics to evaluate demand. Urban visibility preference studies examine individuals' demand by investigating what amount of visibility degradation is unacceptable while economic studies examine demand by investigating how much one would be willing to pay to improve visibility." Because of the limited number of new studies on urban visibility valuation, the Integrated Science Assessment cites to the discussion in the 2004 Criteria Document of the various methods one can use to determine the economic valuation of changes in visibility, which include hedonic valuation, contingent valuation and contingent choice, and travel cost.

Contingent valuation studies are a type of stated preference study that measures the strength of preferences and expresses that preference in dollar values. Contingent valuation studies often include payment vehicles that require respondents to consider implementation costs and their ability to pay for visibility improvements in their responses. This study design aspect is critical because the EPA cannot consider implementations costs in setting either primary or secondary NAAQS. Therefore in considering the information available to help inform the standard-setting process, the EPA has focused on the public perception studies that do not embed consideration of implementation costs. Nonetheless, the EPA recognizes that valuation studies do provide additional evidence that the public is experiencing losses in welfare due to visibility impairment.[140] The public perception studies are described in detail below.

In order to identify levels of visibility impairment appropriate for consideration in setting secondary PM NAAQS to protect the public welfare, the Visibility Assessment comprehensively

[140] In the regulatory impact analysis (RIA) accompanying this rulemaking, the EPA describes a revised approach to estimate urban residential visibility benefits that applies the results of several contingent valuation studies. The EPA is unable to apply the public perception studies to estimate benefits because they do not provide sufficient information on which to develop monetized benefits estimates. Specifically, the public perception studies do not provide preferences expressed in dollar values, even though they do provide additional evidence that the benefits associated with improving residential visibility are not zero. As previously noted in this preamble, the RIA is done for informational purposes only, and the proposed decisions on the NAAQS in this rulemaking are not in any way based on consideration of the information or analyses in the RIA.

examined information that was available in this review regarding people's stated preferences regarding acceptable and unacceptable visual air quality.

Light extinction is an atmospheric property that by itself does not directly translate into a public welfare effect. Instead, light extinction becomes meaningful in the context of the impact of differences in visibility on the human observer. This has been studied in terms of the acceptability or unacceptability expressed for the visibility impact of a given level of light extinction by a human observer. The perception of the visibility impact of a given level of light extinction occurs in conjunction with the associated characteristics and lighting conditions of the viewed scene.[141] Thus, a given level of light extinction may be perceived differently by observers looking at different scenes or the same scene with different lighting characteristics. Likewise, different observers looking at the same scene with the same lighting may have different preferences regarding the associated visual air quality. When scene and lighting characteristics are held constant, the perceived appearance of a scene (i.e., how well the scenic features can be seen and the amount of visible haze) depends only on changes in light extinction. This has been demonstrated using the WinHaze model (Molenar et al., 1994) that uses image processing technology to apply user-specified changes in light extinction values to the same base photograph with set scene and lighting characteristics.

Much of what is known about the acceptability of levels of visibility comes from survey studies in which participants were asked questions about their preference or the value they place on various visibility levels as displayed to them in scenic photographs and/or WinHaze images with a range of known light extinction levels. Urban visibility preference studies for four urban areas were reviewed in the Visibility Assessment (US EPA, 2010b, chapter 2) to assess the light extinction levels judged by the

[141] By "characteristics of the scene" the EPA means the distance(s) between the viewer and the object(s) of interest, the shapes and colors of the objects, the contrast between objects and the sky or other background, and the inherent interest of the objects to the viewer. Distance is particularly important because at a given value of light extinction, which is a property of air at a given point(s) in space, more light is actually absorbed and scattered when light passes through more air between the object and the viewer.

participant to have acceptable visibility for those particular scenes.

The reanalysis of urban preference studies conducted in the Visibility Assessment for this review includes three completed western urban visibility preference survey studies plus a pair of smaller focus studies designed to explore and further develop urban visibility survey instruments. The three western studies included one in Denver, Colorado (Ely et al., 1991), one in the lower Fraser River valley near Vancouver, British Columbia (BC), Canada (Pryor, 1996), and one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group study was also conducted for Washington, DC (Abt Associates Inc., 2001). In response to an EPA request for public comment on the Scope and Methods Plan (74 FR 11580, March 18, 2009), comments were received (Smith, 2009) about the results of a new focus group study of scenes from Washington, DC that had been conducted on subjects from both Houston, Texas and Washington, DC using scenes, methods and approaches similar to the method and approach employed in the EPA pilot study (Smith and Howell, 2009). When taken together, these studies from the four different urban areas included a total of 852 individuals, with each individual responding to a series of questions answered while viewing a set of images of various urban visual air quality conditions.

The approaches used in the four studies are similar and are all derived from the method first developed for the Denver urban visibility study. In particular, the studies all used a similar group interview type of survey to investigate the level of visibility impairment that participants described as "acceptable." In each preference study, participants were initially given a set of "warm up" exercises to familiarize them with how the scene in the photograph or image appears under different VAQ conditions. The participants next were shown 25 randomly ordered photographs (images), and asked to rate each one based on a scale of 1 (poor) to 7 (excellent). They were then shown the same photographs or images again, in the same order, and asked to judge whether each of the photographs (images) would violate what they would consider to be an appropriate urban visibility standard (i.e. whether the level of impairment was "acceptable" or "unacceptable". The term "acceptable" was not defined, so that each person's response was based on his/her own values and preferences for VAQ. However, when

answering this question, participants were instructed to consider the following three factors: (1) The standard would be for their own urban area, not a pristine national park area where the standards might be stricter; (2) The level of an urban visibility standard violation should be set at a VAQ level considered to be unreasonable, objectionable, and unacceptable visually; and (3) Judgments of standards violations should be based on visibility only, not on health effects. While the results differed among the four urban areas, results from a rating exercise show that within each preference study, individual survey participants consistently distinguish between photos or images representing different levels of light extinction, and that more participants rate as acceptable images representing lower levels of light extinction than do images representing higher levels.

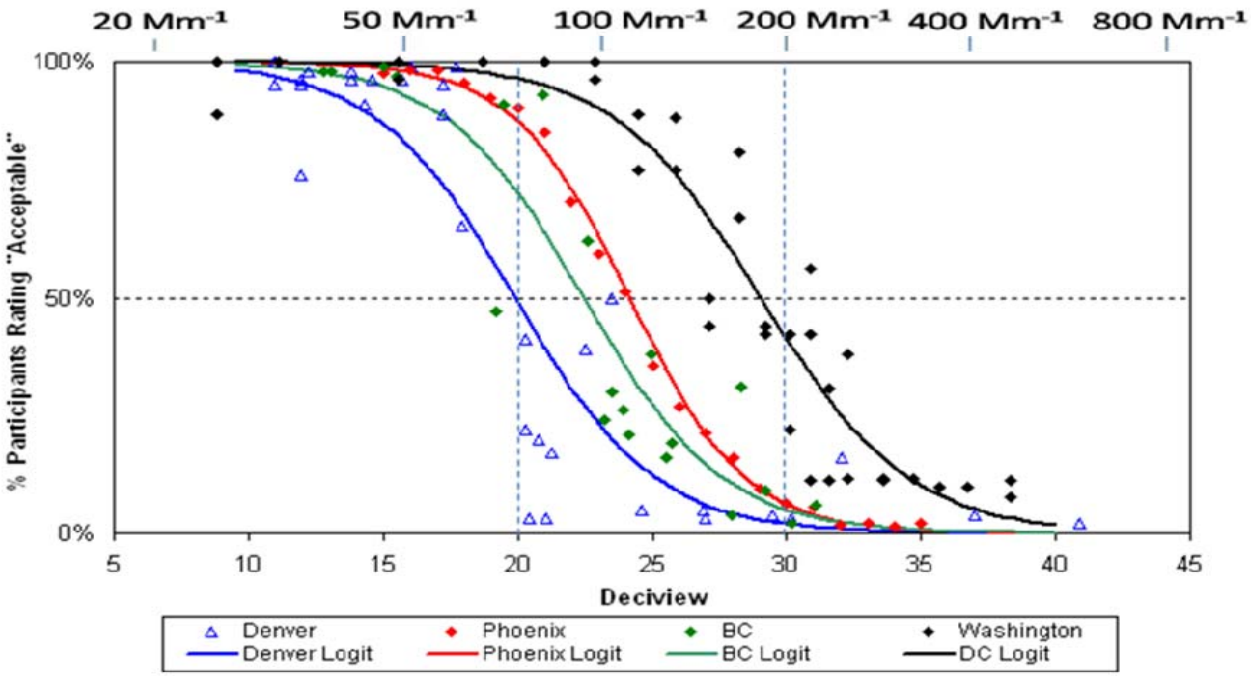
Given the similarities in the approaches used, it is reasonable to compare the results to identify overall trends in the study findings and to conclude that this comparison can usefully inform the selection of a range of levels for use in further analyses. However, variations in the specific materials and methods used in each study introduce uncertainties that should also be considered when interpreting the results of these comparisons. Key differences between the studies include: 1) scene characteristics; 2) image presentation methods (e.g., projected slides of actual photos, projected images generated using WinHaze (a significant technical advance in the method of presenting visual air quality conditions), or use of a computer monitor screen; 3) number of participants in each study; 4) participant representativeness of the general population of the relevant metropolitan area; and 5) specific wording used to frame the questions used in the group interview process.

In the Visibility Assessment, each study was evaluated separately and figures developed to display the percentage of participants that rated the visual air quality depicted in each photograph as "acceptable." Ely et al. (1991) introduced a "50% acceptability" criterion analysis of the Denver preference study results. The 50 percent acceptability criterion is designed to identify the visual air quality level (defined in terms of deciviews or light extinction) that best divides the photographs into two groups: those with a visual air quality rated as acceptable by the majority of the participants, and

those rated not acceptable by the majority of participants. The Visibility Assessment adopted the criterion as a useful index for comparison between studies. The results of each individual analysis were then combined graphically to allow for visual comparison. This information was then carried forward into the Policy Assessment. Figure 5 presents the graphical summary of the results of the studies in the four cities and draws on results previously presented in Figures 2-3, 2-5, 2-7, and 2-11 of chapter 2 in the Visibility Assessment. Figure 5 also contains lines at 20 dv and 30 dv that generally identify a range where the 50 percent acceptance criteria occur across all four of the urban preference studies (US EPA, 2011a, p. 4-24). Out of the 114 data points shown in Figure 5, only one photograph (or image) with a visual air quality below 20 dv was rated as acceptable by less than 50 percent of the participants who rated that photograph.[142] Similarly, only one image with a visual air quality above 30 dv was rated acceptable by more than 50 percent of the participants who viewed it.[143]

[142] Only 47 percent of the British Columbia participants rated a 19.2 dv photograph as acceptable.
[143] In the 2001 Washington, DC study, a 30.9 dv image was used as a repeated slide. The first time it was shown 56 percent of the participants rated it as acceptable, but only 11 percent rated it as acceptable the second time it was shown. The same visual air quality level was rated as acceptable by 4 percent of the participants in the 2009 study (Test 1). All three points are shown in Figure 5.

Figure 5. Summary of Results of Urban Visibility Studies in Four Cities, Showing the Identified Range of the 50% Acceptance Criteria[144]



Source: US EPA, 2011a, Figure 4-2; US EPA 2010b, Figure 2-16

As Figure 5 above shows, each urban area has a separate and unique response curve that appears to indicate that it is distinct from the others. These curves are the result of a logistical regression analysis using a logit model of the greater than 19,000 ratings of haze images as acceptable or unacceptable. The model results can be used to estimate the visual air quality in terms of dv values where the estimated response functions cross the 50 percent acceptability level, as well as any alternative criteria levels. Selected examples of these are shown in Table 4-1 of the Policy Assessment (US EPA, 2011a; US 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

[144] Top scale shows light extinction in inverse megameter units; bottom scale in deciviews. Logit analysis estimated response functions are shown as the color-coded curved lines for each of the four urban areas.

four urban preference studies shown in Figure 5 and Table 4-1 of the Policy Assessment, benchmark levels of (total) light extinction were selected by the Policy Assessment in a range from 20 dv to 30 dv (75 to 200 Mm^{-1})[145] for the purpose of provisionally assessing whether visibility conditions would be considered acceptable (i.e., less than the low end of the range), unacceptable (i.e., greater than the high end of the range), or potentially acceptable (within the range). A midpoint of 25 dv (120 Mm^{-1}) was also selected for use in the assessment. This level is also very near to the 50th percentile criterion value from the Phoenix study (i.e., 24.2 dv), which is by far the best of the four studies in terms of least noisy preference results and the most representative selection of participants. Based on the currently available information, the Policy Assessment concludes that the use of 25 dv to represent the middle of the distribution of results seemed well supported (US EPA, 2011a, p. 4-25).

These three benchmark values provide a low, middle, and high set of light extinction conditions that are used to provisionally define daylight hours with urban haze conditions that have been judged unacceptable by at least 50% of the participants in one or more of these preference studies. As discussed above, PM light extinction is taken to be (total) light extinction minus the Rayleigh scatter,[146] such that the low, middle, and high levels correspond to PM light extinction levels of about 65 Mm^{-1}, 110 Mm^{-1}, and 190 Mm^{-1}. In the Visibility Assessment, these three light extinction levels were called Candidate Protection Levels (CPLs). This term was also used in the Policy Assessment and continues to be used in this proposal notice. It is important to note, however, that the degree of protection provided by a secondary NAAQS is not determined solely by any one component of the standard but by all the components (i.e., indicator, averaging time, form, and level) being applied together. Therefore, the

[145] These values were rounded from 74 Mm^{-1} and 201 Mm^{-1} to avoid an implication of greater precision than is warranted. Note that the middle value of 25 dv when converted to light extinction is 122 Mm^{-1} is rounded to 120 Mm^{-1} for the same reason. Assessments conducted for the Visibility Assessment and the first and second drafts of the Policy Assessment used the unrounded values. The Policy Assessment considers the results of assessment using unrounded values to be sufficiently representative of what would result if the rounded values were used that it was unnecessary to redo the assessments. That is why some tables and figures in the Policy Assessment reflect the unrounded values.

[146] Rayleigh scatter is light scattering by atmospheric gases which is on average about 10 Mm^{-1}.

Policy Assessment notes that the term CPL is meant only to indicate target levels of visibility within a range that EPA staff feels is appropriate for consideration that could, in conjunction with other elements of the standard, including indicator, averaging time, and form, provide an appropriate degree of visibility protection.

In characterizing the Policy Assessment's confidence in each CPL and across the range, a number of issues were considered (US EPA, 2011a, p. 4-26). Looking first at the two studies that define the upper and lower bounds of the range, the Policy Assessment considers whether they represent a true regional distinction in preferences for urban visibility conditions between western and eastern U.S. There is little information available to help evaluate the possibility of a regional distinction especially given that there have been preference studies in only one eastern urban area. Smith and Howell (2009) found little difference in preference response to Washington, DC haze photographs between the study participants from Washington, DC and those from Houston, Texas.[147] This provides some limited evidence that the value judgment of the public in different areas of the country may not be an important factor in explaining the differences in these study results.

In further considering what factors could explain the observed differences in preferences across the four urban areas, the Policy Assessment notes that the urban scenes used in each study had different characteristics (US 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

[147] The first preference study using WinHaze images of a scenic vista from Washington, DC was conducted in 2001 using subjects who were residents of Washington, DC. More recently, Smith and Howell (2009) interviewed additional subjects using the same images and interview procedure. The additional subjects included some residents of the Washington, DC area and some residents of the Houston, Texas area.

study and those from the western urban studies. Having scenes with the object of greatest intrinsic value nearer and hence less sensitive in the eastern urban area compared with more distant objects of greatest intrinsic value in the western urban areas could further explain the difference in preference results.

Another question considered was whether the high CPL value that is based on the eastern preference results is likely to be generally representative of urban areas that do not have associated mountains or other valued objects visible in the distant background. Such areas would include the middle of the country and many areas in the eastern U.S., and possibly some areas in the western U.S. as well. In order to examine this issue, an effort would have to be made to see if scenes in such areas could be found that would be generally comparable to the western scenes (e.g., scenes that contain valued scenic elements at more sensitive distances than that used in the eastern study). This is only one of a family of issues concerning how exposure to urban scenes of varying sensitivity affects public perception for which no preference study information is currently available. Based on the currently available information, the Policy Assessment concludes that the high end of the CPL range (30 dv) is an appropriate level to consider (US EPA, 2011a, p. 4-27).

With respect to the low end of the range, the Policy Assessment considered factors that might further refine its understanding of the robustness of this level. The Policy Assessment concludes that additional urban preference studies, especially with a greater variety in types of scenes, could help evaluate whether the lower CPL value of 20 dv is generally supportable (US 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 represent sight path-averaged light extinction values. Reducing these

sources of noisiness and uncertainty in the results of future studies of sensitive urban scenes could provide more confidence in the selection of a low CPL value.

Based on the above considerations, and recognizing the limitations in the currently available information, the Policy Assessment concludes that it is reasonable to consider a range of CPL values including a high value of 30 dv, a mid-range value of 25 dv, and a low value of 20 dv (US EPA, 2011a, p. 4-27). Based on its review of the second draft Policy Assessment, CASAC also supports this set of CPLs for consideration by the EPA in this review. CASAC notes that these CPL values were based on all available visibility preference data and that they bound the study results as represented by the 50 percent acceptability criteria. CASAC concludes that this range of levels is "adequately supported by the evidence presented" (Samet, 2010d, p. iii).

C. Adequacy of the Current Standards for PM-Related Visibility Impairment

As noted above, visibility impairment occurs during periods with fog or precipitation irrespective of the presence or absence of PM. While it is a popular notion that areas with many foggy or rainy days are "dreary" places to live compared to areas with more sunny days per year, the Policy Assessment has no basis for taking into account how the occurrence of such days might modify the effect of pollution-induced hazy days on public welfare. It is logical that periods with naturally impaired visibility due to fog or precipitation should not be treated as having PM-impaired visibility. Moreover, depending on the specific indicator, averaging time, and measurement approach used for the NAAQS, foggy conditions might result in measured or calculated indicator values that are higher than the light extinction actually caused by PM.[148] Therefore, in order to avoid precipitation and fog confounding estimates of PM

[148] One example of an indicator and measurement approach for which indicator values could be higher than true PM light extinction as a result of fog would be a light extinction indicator measured in part by an unheated nephelometer, which is an optical instrument for measuring PM light scattering from an air sample as it flows through a measurement chamber. Raindrops would be removed by the initial size-selective inlet device, although some particles associated with fog may be small enough that they might pass through the inlet and enter the measurement chamber of the instrument. This would result in a reported scattering coefficient that does not correspond to true PM light extinction. Direct measurement

visibility impairment, and as advised by CASAC as part of its comments on the first draft Visibility Assessment, the assessment of visibility conditions was restricted to daylight hours with relative humidity less than or equal to 90 percent when evaluating sub-daily alternative standards (US EPA, 2010b, section 3.3.5, Appendix G).

The EPA recognizes that not all periods with relative humidity above 90 percent have fog or precipitation. Removing those hours from consideration for a secondary PM standard would involve a tradeoff between the benefits of not including many of the hours with meteorological causes of visibility impacts and the loss of public welfare protection of not including some hours with high relative humidity without fog or precipitation, where the growth of hygroscopic PM into large solution droplets results in enhanced PM visibility impacts. For the 15 urban areas included in the assessment for which meteorological data were obtained to allow an examination of the co-occurrence of high relative humidity and fog or precipitation, a 90 percent relative humidity cutoff criterion is effective in that on average less than 6 percent of the daylight hours are removed from consideration, yet those hours have on average ten times the likelihood of rain, six times the likelihood of snow/sleet, and 34 times the likelihood of fog compared with hours with 90 percent or lower relative humidity. Based on these findings, the Policy Assessment concludes that it is appropriate that a sub-daily standard intended to protect against PM-related visibility impairment would be defined in such a way as to exclude hours with relative humidity greater than approximately 90 percent, regardless of measured values of light extinction or PM (US EPA, 2011a, p. 4-29).

1. Visibility Under Current Conditions

Recent visibility conditions have been characterized in the Policy Assessment in terms of PM-related light extinction[149] levels for the 15 urban areas[150] that were selected for analysis in the Visibility

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of light extinction using an open-path instrument would be even more affected by both fog and precipitation.

[149] PM-related light extinction is used here to refer to the light extinction caused by PM regardless of particle size; PM_{10} light extinction refers to the contribution by particles sampled through an inlet with a

Assessment. Hourly average PM-related light extinction was analyzed in terms of both PM_{10} and $PM_{2.5}$ light extinction. These recent visibility conditions were then compared to the CPLs identified above. From Figure 4-3 and Table 4-2 in the Policy Assessment (US EPA, 2010b, Figure 3-8 and Table 3-7, respectively) it can be seen that among these 14 urban areas, those in the East and in California tend to have a higher frequency of visibility conditions estimated to be above the high CPL compared with those in the western U.S. Both the figure and table are based on data from the 2005 to 2007 time period and exclude hours with relative humidity greater than 90 percent. These displays indicate that all 14 urban areas have daily maximum hourly PM_{10} light extinction values that are estimated to exceed even the highest CPL some of the days. Except for the two Texas areas and the non-California western urban areas, all of the other urban areas are estimated to exceed the high CPL from about 20 percent to over 60 percent of the days. It is also noted that all 14 of the urban areas are estimated to exceed the low CPL from about 40 percent to over 90 percent of the days.

The Policy Assessment repeats the Visibility Assessment-type modeling based on $PM_{2.5}$ light extinction and data from the more recent 2007 to 2009 time period for the same 15 study areas (including St. Louis), as described in Policy Assessment Appendix F. Figure 4-4 and Table 4-3 in the Policy Assessment present the same type of information as do Figure 4-3 and Table 4-2, respectively. While the estimates of the percentage of daily maximum hourly $PM_{2.5}$ light extinction values exceeding the CPLs are somewhat lower than for PM_{10} light extinction, the patterns of these estimates across the

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particle size 50% cutpoint of 10 µm diameter; and $PM_{2.5}$ light extinction refers to the contribution by particles sampled through an inlet with a particle size 50% cutpoint of 2.5 µm diameter.

[150] The 15 urban areas are Tacoma, Fresno, Los Angeles, Phoenix, Salt Lake City, Dallas, Houston, St. Louis, Birmingham, Atlanta, Detroit, Pittsburgh, Baltimore, Philadelphia, and New York. Comments on the second draft Visibility Assessment from those familiar with the monitoring sites in St. Louis indicated that the site selected to provide continuous PM_{10} monitoring, although less than a mile from the site of the $PM_{2.5}$ data, is not representative of the urban area and resulted in unrealistically large $PM_{10-2.5}$ values. The EPA staff considers these comments credible and has set aside the St. Louis assessment results for PM_{10} light extinction. Thus, results and statements in this Policy Assessment regarding PM_{10} light extinction apply to only the other 14 areas. However, results regarding $PM_{2.5}$ light extinction in most cases apply to all 15 study areas because the St. Louis estimates for $PM_{2.5}$ light extinction were not affected by the PM_{10} monitoring issue.

study areas are similar. More specifically, except for the two Texas and the non-California western urban areas, all of the other urban areas are estimated to exceed the high CPL from about 10 percent up to about 50 percent of the days based on $PM_{2.5}$ light extinction, while all 15 areas are estimated to exceed the low CPL from over 10 percent to over 90 percent of the days.

2. Protection Afforded by the Current Standards

The Policy Assessment also conducted analyses to assess the likelihood that PM-related visibility impairment would exceed the various CPLs for a scenario based on simulating just meeting the current suite of $PM_{2.5}$ secondary standards: 15 $\mu g/m^3$ annual average $PM_{2.5}$ concentration and 35 $\mu g/m^3$ 24-hour average $PM_{2.5}$ concentration with a 98th percentile form, averaged over three years. As described in the Visibility Assessment, the steps needed to model meeting the current NAAQS involve explicit consideration of changes in $PM_{2.5}$ components. First, the Policy Assessment applied proportional rollback to all the $PM_{2.5}$ monitoring sites in each study area, taking into account policy-relevant background $PM_{2.5}$ mass, to "just meet" the current NAAQS scenario for the area as a whole, not just at the visibility assessment study site. The quantitative health risk assessment document (US EPA, 2010a) describes this air quality roll-back procedure in detail. The degree of rollback (i.e., the percentage reduction in non-policy-relevant background $PM_{2.5}$ mass) is controlled by the highest annual or 24-hour design value, which in most study areas is from a site other than the site used in this visibility assessment.[151] The relevant result from this analysis is the percentage reduction in non-policy-relevant background $PM_{2.5}$ mass needed to "just meet" the current NAAQS, for each study area. These percentage reductions are shown in Table 4-4 of the Visibility Assessment. It was noted that Phoenix and Salt Lake City meet the current $PM_{2.5}$ NAAQS under current conditions and require no reduction. $PM_{2.5}$ levels in these two cities were not "rolled up." Second, for each day and hour for each $PM_{2.5}$ component, the Policy Assessment subtracted the policy-relevant background concentration from the

[151] The selection of the site used to assess visibility was driven by the need for several types of PM data, and for most study areas the site with the highest annual or 24-hour design value did not have the needed types of data.

current conditions concentration to determine the non- policy-relevant background portion of the current conditions concentration. Third, the Policy Assessment applied the same percentage reduction from the first step to the non- policy-relevant background portion of each of the five $PM_{2.5}$ components and added back the policy-relevant background portion of the component. Finally, the Policy Assessment applied the original IMPROVE algorithm, using the reduced $PM_{2.5}$ component concentrations, the current conditions $PM_{10-2.5}$ concentration for the day and hour, and relative humidity for the day and hour to calculate the PM_{10} light extinction.

In these analyses, the Policy Assessment has estimated both $PM_{2.5}$ and PM_{10} light extinction in terms of both daily maximum 1-hour average values and multi-hour (i.e., 4-hour) average values for daylight hours. Figure 4-7 and Table 4-6 of the Policy Assessment display the results of the rollback procedures as a box and whisker plot of daily maximum daylight 1-hour $PM_{2.5}$ light extinction and the percentage of daily maximum hourly $PM_{2.5}$ light extinction values estimated to exceed the CPLs when just meeting the current suite of $PM_{2.5}$ secondary standards for all 15 areas considered in the Visibility Assessment (including St. Louis) (excluding hours with relative humidity greater than 90 percent). These displays show that the daily maximum 1-hour average $PM_{2.5}$ light extinction values in all of the study areas other than the three western non-California areas are estimated to exceed the high CPL from about 8 percent up to over 30 percent of the days and the middle CPL from about 30 percent up to about 70 percent of the days, while all areas except Phoenix are estimated to exceed the low CPL from over 15 percent to about 90 percent of the days. Figure 4-8 and Table 4-7 of the Policy Assessment present results based on daily maximum 4-hour average values. These displays show that the daily maximum 4-hour average $PM_{2.5}$ light extinction values in all of the study areas other than the three western non-California areas and the two areas in Texas are estimated to exceed the high CPL from about 4 percent up to over 15 percent of the days and the middle CPL from about 15 percent up to about 45 percent of the days, while all areas except Phoenix are estimated to exceed the low CPL from over 10 percent to about 75 percent of the days. A similar set of figures and tables have been developed in terms of PM_{10}

light extinction (US EPA, 2011a, Figures 4-5 and 4-6, Tables 4-4 and 4-5).

Taking into account the above considerations, the Policy Assessment concludes that the available information in this review, as described above and in the Visibility Assessment and Integrated Science Assessment, clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards in the context of public welfare protection from visibility impairment, primarily in urban areas, and supports consideration of alternative standards to provide appropriate protection (US EPA, 2011a, p. 4-39).

This conclusion is based in part on the large percentage of days, in many urban areas, that exceed the range of CPLs identified for consideration under simulations of conditions that would just meet the current suite of $PM_{2.5}$ secondary standards. In particular, for air quality that is simulated to just meet the current $PM_{2.5}$ standards, greater than 10 percent of the days are estimated to exceed the highest, least protective CPL of 30 dv in terms of $PM_{2.5}$ light extinction for 9 of the 15 urban areas, based on 1-hour average values, and would thus likely fail to meet a 90th percentile-based standard at that level. For these areas, the percent of days estimated to exceed the highest CPL ranges from over 10 percent to over 30 percent. Similarly, when the middle CPL of 25 dv is considered, greater than 30 percent up to approximately 70 percent of the days are estimated to exceed that CPL in terms of $PM_{2.5}$ light extinction, for 11 of the 15 urban areas, based on 1-hour average values. Based on a 4-hour averaging time, 5 of the areas were estimated to have at least 10 percent of the days exceeding the highest CPL in terms of $PM_{2.5}$ light extinction, and 8 of the areas were estimated to have at least 30 percent of the days exceeding the middle CPL in terms of $PM_{2.5}$ light extinction. For the lowest CPL of 20 dv, the percentages of days estimated to exceed that CPL are even higher for all cases considered. Based on all of the above, the Policy Assessment concludes that PM light extinction estimated to be associated with just meeting the current suite of $PM_{2.5}$ secondary standards in many areas across the country exceeds levels and percentages of days that could reasonably be considered to be important from a public welfare perspective (US EPA, 2011a, p. 4-40).

Further, the Policy Assessment concludes 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 (US EPA, 2011a, p. 4-40). This is because such a standard is inherently confounded by regional differences in relative humidity and species composition of $PM_{2.5}$, which are critical factors in the relationship between the mix of fine particles in the ambient air and the associated impairment of visibility. The Policy Assessment notes that this concern was one of the important elements in the court's decision to remand the $PM_{2.5}$ secondary standards set in 2006 to the Agency, as discussed above in section 4.1.2.

Thus, in addition to concluding that the available information clearly calls into question the adequacy of the protection against PM-related visibility impairment afforded by the current suite of $PM_{2.5}$ standards, the Policy Assessment also concludes that it clearly calls into question the appropriateness of each of the current standard elements: indicator, averaging time, form, and level (US EPA, 2011a, p. 4-40).

3. CASAC Advice

Based on its review of the second draft Policy Assessment, CASAC concludes that the "currently available information clearly calls into question the adequacy of the current standards and that consideration should be given to revising the suite of standards to provide increased public welfare protection" (Samet, 2010d, p. iii). CASAC notes that the detailed estimates of hourly PM light extinction associated with just meeting the current standards "clearly demonstrate that current standards do not protect against levels of visual air quality which have been judged to be unacceptable in all of the available urban visibility preference studies." Further, CASAC states, with respect to the current suite of secondary $PM_{2.5}$ standards, that "[T]he levels are too high, the averaging times are too long, and the $PM_{2.5}$ mass indicator could be improved to correspond more closely to the light scattering and absorption properties of suspended particles in the ambient air" (Samet, 2010d, p. 9).

4. Administrator's Proposed Conclusions on the Adequacy of Current Standards for PM-related Visibility Impairment

In considering whether the current suite of secondary $PM_{2.5}$ standards is requisite to protect the public welfare against PM-related visibility impairment primarily in urban areas, the Administrator has taken into account the information discussed above with regard to the nature of PM-related visibility impairment, the results of public perception surveys on the acceptability of varying degrees of visibility impairment in urban areas, analyses of the number of days that are estimated to exceed a range of candidate protection levels under conditions simulated to just meet the current standards, and the advice of CASAC. As an initial matter, the Administrator recognizes the clear causal relationship between PM in the ambient air and impairment of visibility. She takes note of the evidence from the visibility preference studies, and the rationale for determining a range of candidate protection levels based on those studies. She notes the relatively large number of days estimated to exceed the three candidate protection levels, including the highest level of 30 dv, under the current standards. While recognizing the limitations in the available information on public perceptions of the acceptability of varying degree of visibility impairment and the information on the number of days estimated to exceed the CPLs, the Administrator concludes that such information provides an appropriate basis to inform a conclusion as to whether the current standards provide adequate protection against PM-related visibility impairment in urban areas. Based on these considerations, and placing great importance on the advice of CASAC, the Administrator provisionally concludes that the current standards are not sufficiently protective of visual air quality, and that consideration should be given to an alternative secondary standard that would provide additional protection against PM-related visibility impairment, with a focus primarily in urban areas.

Having reached this conclusion, the Administrator also recognizes that the current indicator of $PM_{2.5}$ mass, in conjunction with the current 24-hour and annual averaging times, is not well suited for a national standard intended to protect public welfare from PM-related visibility impairment. She recognizes that the current standards do not incorporate information on the concentrations of various species within the mix of ambient particles, nor do they incorporate information on relative humidity,

both of which plays a central role in determining the relationship between the mix of PM in the ambient air and impairment of visibility. The Administrator notes that such considerations were reflected in CASAC's advice to set a distinct secondary standard that would more directly reflect the relationship between ambient PM and visibility impairment. The Administrator also notes that such considerations were reflected in the court's remand of the current secondary $PM_{2.5}$ standards. Based on the above considerations, the Administrator provisionally concludes that the current secondary $PM_{2.5}$ standards, taken together, are neither sufficiently protective nor are they suitably structured to provide an appropriate degree of public welfare protection from PM-related visibility impairment, primarily in urban areas. Thus, the Administrator has considered alternative standards by looking at each of the elements of the standards -- indicator, averaging time, form, and level – as discussed below.

D. Consideration of Alternative Standards for Visibility Impairment

1. Indicator

a. Alternative Indicators Considered in the Policy Assessment

As described below, the Policy Assessment considers three indicators: the current $PM_{2.5}$ mass indicator and two alternative indicators, including directly measured $PM_{2.5}$ light extinction and calculated $PM_{2.5}$ light extinction (US EPA, 2011a, section 4.3.1.1).[152] Directly measured $PM_{2.5}$ light extinction is a measurement (or combination of measurements) of the light absorption and scattering caused by $PM_{2.5}$ under ambient conditions. Calculated $PM_{2.5}$ light extinction uses the IMPROVE algorithm to calculate $PM_{2.5}$ light extinction using measured speciated $PM_{2.5}$ mass and measured relative humidity.[153]

[152] In the second draft Policy Assessment, the calculated $PM_{2.5}$ light extinction indicator was referred to as speciated $PM_{2.5}$ mass calculated light extinction.

[153] In 2009, the D.C. Circuit remanded the secondary $PM_{2.5}$ standards to the Agency in part because the EPA did not address the problem that a $PM_{2.5}$ mass-based standard using a daily averaging time would be confounded by regional differences in relative humidity, although EPA had acknowledged this problem. The EPA notes that the light extinction indicators considered in the Policy Assessment explicitly took into account differences in relative humidity in areas across the country (US EPA, 2011a, section 4.3.1).

The Policy Assessment concludes that consideration of the use of either directly measured $PM_{2.5}$ light extinction or calculated $PM_{2.5}$ light extinction as an indicator is justified because light extinction is a physically meaningful measure of the characteristic of ambient $PM_{2.5}$ characteristic that is most relevant and directly related to PM-related visibility effects (US 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, although at some locations (US EPA, 2010b, Figure 3-13 for Phoenix) $PM_{10–2.5}$ can be a major contributor to urban visibility effects. Few urban areas conduct continuous $PM_{10-2.5}$ monitoring. For example, among the 15 urban areas assessed in this review, only four areas had collocated continuous PM_{10} data allowing calculation of hourly $PM_{10-2.5}$ data for 2005 to 2007. In the absence of $PM_{10-2.5}$ air quality information from a much larger number of urban areas across the country, it is not possible at this time to know in how many urban areas $PM_{10–2.5}$ is a major contributor to urban visibility effects, though it is reasonable to assume that other urban areas in the desert southwestern region of the country may have conditions similar to the conditions shown for Phoenix. $PM_{10-2.5}$ is generally less homogenous in urban areas than $PM_{2.5}$, making it more challenging to select sites that would adequately represent urban visibility conditions. While it would be possible to include a $PM_{10–2.5}$ light extinction term in a calculated light extinction indicator, as was done in the Visibility Assessment, there is insufficient information available at this time to assess the impact and effectiveness of such a refinement in providing public welfare protection in areas across the country (US EPA, 2011a, pp. 4-41 to 4-42).

The basis for considering each of these three indicators is discussed below. The discussion also addresses monitoring data requirements for directly measured $PM_{2.5}$ light extinction and for calculated $PM_{2.5}$ light extinction. The following discussion also takes into consideration different averaging times since the combination of indicator and averaging time is relevant to understanding the monitoring data requirements. Consideration of alternative averaging times is addressed more specifically in section VI.D.2 on averaging time.

i. $PM_{2.5}$ Mass

$PM_{2.5}$ mass monitoring methods are in widespread use, including the FRM involving the collection of periodic (usually 1-day-in-6 or 1-day-in-3) 24-hour filter samples. Blank and loaded filters are weighed to determine 24-hour $PM_{2.5}$ mass. Continuous $PM_{2.5}$ monitoring produces hourly average mass concentrations and is conducted at about 900 locations. About 180 of these locations employ newer model continuous instruments that have been approved by EPA as FEMs, although the Policy Assessment notes that FEM approval has been based only on 24-hour average, not hourly, $PM_{2.5}$ mass. These routine monitoring activities do not include measurement of the full water content of the ambient $PM_{2.5}$ that contributes, often significantly, to visibility impacts.[154] Further, the $PM_{2.5}$ mass concentration monitors do not provide information on the composition of the ambient $PM_{2.5}$, which plays a central role in the relationship between PM-related visibility impairment and ambient $PM_{2.5}$ mass concentrations.[155]

The overall performance of 1-hour average $PM_{2.5}$ mass as a predictor of PM-related visibility impairment as indicated by PM_{10} calculated light extinction can be seen in scatter plots shown in Figure 4-9 of the Policy Assessment for two illustrative urban areas, Pittsburgh and Philadelphia (Similar plots for all 14 urban areas that have estimates of PM_{10} light extinction are in Appendix D, Figure D-2 of US EPA, 2010b). These illustrative examples demonstrate the large variations in hourly PM_{10} light extinction corresponding to any specific level of hourly $PM_{2.5}$ mass concentration as well as differences in the statistical average relationships (depicted as the best fit lines) between cities. This poor correlation between hourly PM_{10} light extinction and hourly $PM_{2.5}$ mass is not due to any great extent to the contribution of $PM_{10-2.5}$ to light extinction, but rather is principally due to the impact of the water content of the particles on light extinction, which depends on both the composition of the $PM_{2.5}$ and the ambient

[154] FRM filters are stabilized in a laboratory at fixed temperature and relative humidity levels, which alters whatever water content was present on the filter when removed from the sampler. FEM instruments are designed to meet performance criteria compared to FRM measurements, and accordingly typically manage temperature and/or humidity at the point of measurement to levels that are not the same as ambient conditions.

[155] As discussed below, 24-hour average $PM_{2.5}$ chemical component mass is measured at about 200 CSN sites.

relative humidity. Both composition and especially relative humidity vary during a single day, as well as from day-to-day, at any site and time of year. This contributes to the noisiness of the data on the relationship at any site and time of year. Also, there are systematic regional and seasonal differences in the distribution of ambient humidity and $PM_{2.5}$ composition conditions that make it impossible to select a $PM_{2.5}$ concentration that generally would correspond to the same PM-related light extinction levels across all areas of the nation.

As part of the Visibility Assessment, an assessment was conducted that estimated PM_{10} light extinction levels that may prevail if areas were simulated to just meet a range of alternative secondary standards based on hourly $PM_{2.5}$ mass as the indicator. Appendix E of the Policy Assessment contains the results of this rollback-based assessment. This assessment quantifies the projected uneven protection, noted qualitatively above, that would result from the use of 1-hour average $PM_{2.5}$ mass as the indicator.

ii. Directly Measured $PM_{2.5}$ Light Extinction

PM light extinction is the major contributor to light extinction, which is the property of the atmosphere that is most directly related to visibility effects. It differs from light extinction by the nearly constant contributions for Rayleigh (or clean air) light scattering and the minor contributions by NO_2 light absorption. The net result is that PM light extinction has a nearly one-to-one relationship to light extinction, unlike $PM_{2.5}$ mass concentration. As explained above, $PM_{2.5}$ is the component responsible for the large majority of PM light extinction in most places and times. $PM_{2.5}$ light extinction can be directly measured. Direct measurement of $PM_{2.5}$ light extinction can be accomplished using several instrumental methods, some of which have been used for decades to routinely monitor the two components of $PM_{2.5}$ light extinction (light scattering and absorption) or to jointly measure both as total light extinction (from which Rayleigh scattering is subtracted to get $PM_{2.5}$ light extinction). There are a number of advantages to direct measurements of light extinction for use in a secondary standard relative to estimates of $PM_{2.5}$ light extinction calculated using $PM_{2.5}$ mass and speciation data. These include greater accuracy of direct measurements with shorter averaging times and overall greater simplicity when compared to the

need for measurements of multiple parameters to calculate PM light extinction.

As part of the Visibility Assessment, an assessment was conducted that estimated PM_{10} light extinction levels that may prevail in 14 urban study areas if the areas were simulated to just meet a secondary standard based on directly measured hourly PM_{10} light extinction as the indicator (US EPA, 2010b, section 4.3).[156] As would be expected, this assessment indicated that a secondary standard based on a directly measured PM_{10} light extinction indicator would provide the same percentage of days having values above the level of the standard in each of the areas, with the percentage being dependent on the statistical form of the standard. The Policy Assessment considers this assessment reasonably informative for a directly measured $PM_{2.5}$ light extinction indicator as well, because in most of the assessment study areas PM_{10} light extinction is dominated by $PM_{2.5}$ light extinction.

In evaluating whether direct measurement of $PM_{2.5}$ or PM_{10} light extinction is appropriate to consider in the context of this PM NAAQS review, the EPA produced a White Paper on Particulate Matter (PM) Light Extinction Measurements (US EPA, 2010g), and solicited comment on the White Paper from the Ambient Air Monitoring and Methods Subcommittee (AAMMS) of CASAC. In its review of the White Paper (Russell and Samet, 2010a), the CASAC AAMMS made the recommendation that consideration of direct measurement should be limited to $PM_{2.5}$ light extinction as this can be accomplished by a number of commercially available instruments and because $PM_{2.5}$ is generally responsible for most of the PM visibility impairment in urban areas. The CASAC AAMMS indicated that it is technically more challenging at this time to accurately measure the $PM_{10–2.5}$ component of light extinction.

The CASAC AAMMS also commented on the capabilities of currently available instruments, and expressed optimism regarding the near-term development of even better instruments for such measurement than are now commercially available. The CASAC AAMMS advised against choosing any

[156] This assessment was conducted prior to staff's decision to focus on $PM_{2.5}$ light extinction indicators in the Policy Assessment.

currently available commercial instrument, or even a general measurement approach, as an FRM because to do so could discourage development of other potentially superior approaches. Instead, the CASAC AAMMS recommended that EPA develop performance-based approval criteria for direct measurement methods in order to put all approaches on a level playing field. Such criteria would necessarily include procedures and pass/fail requirements for demonstrating that the performance criteria have been met. For example, instruments might be required to demonstrate their performance in a wind tunnel, where the concentration of $PM_{2.5}$ components, and thus of $PM_{2.5}$ light extinction, could be controlled to known values. It might also be possible to devise approval testing procedures based on operation in ambient air, although knowing the true light extinction level (without in effect treating some particular instrument as if it were the FRM) would be more challenging. At the present time, the EPA has not undertaken to develop and test such performance-base approval criteria. The EPA anticipates that if an effort were begun it would take at least several years before such criteria would be ready for regulatory use.

iii. Calculated $PM_{2.5}$ Light Extinction

As discussed above in section VI.B.1 above, $PM_{2.5}$ light extinction can be calculated from speciated $PM_{2.5}$ mass concentration data plus relative humidity data, as is presently routinely done on a 24-hour average basis under the Regional Haze Program using data from the rural IMPROVE monitoring network. This same calculation procedure, using a 24-hour average basis, could also be used for a NAAQS focused on protecting against PM-related visibility impairment primarily in urban areas. This could use the type of data that is routinely collected from the urban CSN[157] in combination with climatological relative humidity data as used in the Regional Haze Program (US EPA, 2011a, Appendix G, section G.2). This calculation procedure, using the original IMPROVE light extinction equation presented above in section VI.B.1 on a 24-hour basis (or the revised IMPROVE equation), does not

[157] About 200 sites in the CSN routinely measure 24-hour average $PM_{2.5}$ chemical components using filter-based samplers and chemical analysis in a laboratory, on either a 1-day-in-3 or 1-day-in-6 schedule (US EPA, 2011a, Appendix B, section B.1.3).

require $PM_{2.5}$ mass concentration measurements.

Alternatively, a conceptually similar approach could be applied in urban areas on an hourly or multi-hour basis. Applying this conceptual approach on a sub-daily basis would involve translating 24-hour speciation data into hourly estimates of species concentrations, and using 24-hour average species concentrations in conjunction with hourly $PM_{2.5}$ mass concentrations. This translation can be made using more or less complex alternative approaches, as discussed below.

The approach used to generate hourly PM_{10} light extinction for the Visibility Assessment was a relatively more complex method for implementing such a conceptual approach. It involved the use of the original IMPROVE algorithm[158] with estimates of hourly $PM_{2.5}$ components derived from day-specific 24-hour and hourly measurements of $PM_{2.5}$ mass, 24-hour measurements of $PM_{2.5}$ composition, hourly measurements of $PM_{2.5}$ mass and (for some but not all study sites) hourly $PM_{10-2.5}$ mass, along with hourly relative humidity information (US EPA, 2010b, section 3.3). The Visibility Assessment approach also involved the use of output from a chemical transport modeling run to provide initial estimates of diurnal profiles for $PM_{2.5}$ components at particular sites. The Visibility Assessment approach entailed numerous and complex data processing steps to generate hourly $PM_{2.5}$ composition information from these less time-resolved data, including application of a mass-closure approach, referred to as the SANDWICH approach[159] (Frank, 2006), to adjust for nitrate retention differences between FRM and CSN filters, which is a required step for consistency with the IMPROVE algorithm and for estimating organic carbonaceous material via mass balance.[160] The EPA staff employed complex custom software to do these data processing steps.

While the complexity of the approach used in the Visibility Assessment was reasonable for assessment purposes at 15 urban areas, the Policy Assessment recognizes that a relatively more simple

[158] The original IMPROVE algorithm was selected for the described analysis in the Visibility Assessment because of its simplicity relative to the revised algorithm.
[159] Sulfate, adjusted nitrate, derived water, inferred carbonaceous mass (SANDWICH) approach.
[160] Daily temperature data were also used as part of the SANDWICH method.

approach would be more straightforward and have greater transparency, and thus should be considered for purposes of a national standard.[161] Therefore, the Policy Assessment evaluated the degree to which simpler approaches would correlate with the results of the highly complex method used in the Visibility Assessment. This evaluation of two specific simpler approaches (described briefly below and in more detail in US EPA, 2011a, Appendix F, especially Table F-1) demonstrated that the $PM_{2.5}$ portions of the PM_{10} light extinction values developed for the Visibility Assessment can be well approximated using the same IMPROVE algorithm applied to hourly $PM_{2.5}$ composition values that were much more simply generated than with the method used in the Visibility Assessment.

The simplified approaches examined were aimed at calculating hourly $PM_{2.5}$ light extinction using the original IMPROVE algorithm (see section VI.B.1.a. above) excluding the Rayleigh term for light scattering by atmospheric gases and the term for $PM_{10-2.5}$.[162] These approaches, including a description of the sources of the data and steps required to determine calculated $PM_{2.5}$ light extinction for these simplified approaches, are described in more detail in the Policy Assessment (US EPA, 2011a, pp. 4-46 to 48, Appendix F, Table F-2). Also, Table F-1 of Appendix F of the Policy Assessment compares and contrasts each of these approaches with the Visibility Assessment approach and with each other.

The hourly $PM_{2.5}$ light extinction values generated by using either simplified approach are comparable to those developed for use in the Visibility Assessment as indicated by the regression statistics for scatter plots of the paired data (i.e., the slopes of the regression equation and the R^2 values are near 1 as shown in US EPA, 2011a, Appendix F, Tables F-3 and F-4). Appendix F notes that both

[161] The sheer size of the ambient air quality, meteorological, and chemical transport modeling data files involved with the Visibility Assessment approach would make it very difficult for state agencies or any interested party to consistently apply such an approach on a routine basis for the purpose of implementing a national standard defined in terms of the Visibility Assessment approach.

[162] The original IMPROVE algorithm was the basis for the approaches considered in the Policy Assessment to maintain comparability to the estimates developed in the Visibility Assessment. This allowed the effects of other simplifications relative to the Visibility Assessment approach to be better discerned.

approaches underestimate $PM_{2.5}$ light extinction on some days in a few study areas, which the Policy Assessment attributes to the occurrence of very high nitrate concentrations and the failure of the FRM-correlated/adjusted FEM instrument to report the entire nitrate mass. Nevertheless, the Policy Assessment concludes that each of these simplified approaches provides reasonably good estimates of $PM_{2.5}$ light extinction and each is appropriate to consider as the indicator for a distinct hourly or multi-hour secondary standard (US EPA, 2011a, p. 4-48).

In addition, the Policy Assessment notes that there are variations of these simplified approaches that may also be appropriate to consider. For example, some variations that may improve the correlation with actual ambient light extinction in certain areas of the country include the use of the split-component mass extinction efficiency approach from the revised IMPROVE algorithm,[163] the use of more refined value(s) for the organic carbon multiplier (see US EPA, 2011a, Appendix F)[164], and the use of the reconstructed 24-hour $PM_{2.5}$ mass (i.e., the sum of the five $PM_{2.5}$ components from speciated monitoring) as a normalization value for the hourly measurements from the $PM_{2.5}$ instrument as a way of better reflecting ambient nitrate concentrations. Other variations may serve to simplify the calculation of $PM_{2.5}$ light extinction values, such as those suggested by CASAC for consideration, including the use of historical monthly or seasonal speciation averages as well as speciation estimates on a regional basis (Samet, 2010d, p. 11). Some of these variations would also be appropriate to consider in conjunction with a 24-hour average calculated $PM_{2.5}$ light extinction indicator, including the use of the revised IMPROVE algorithm, the use of an alternative value for the organic carbon multiplier (e.g., 1.6), and the use of historical monthly or seasonal, or regional, speciation averages.

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[163] If the revised IMPROVE algorithm were used to define the calculated $PM_{2.5}$ mass-based indicator, it would not be possible to algebraically reduce the revised algorithm to a two-factor version as described above and in Appendix F of the Policy Assessment for the simplified approaches. Instead, five component fractions would be determined from each day of speciated sampling, and then either applied to hourly measurements of $PM_{2.5}$ mass on the same day or averaged across a month and then applied to measurements of $PM_{2.5}$ mass on each day of the month.

[164] An organic carbon (OC)-to-organic mass (OM) multiplier of 1.6 was used for the assessment, which was found to produce a value of OM comparable to the one derived with the original, albeit more complex Visibility Assessment method.

As mentioned above, as part of the Visibility Assessment, an assessment was conducted of PM_{10} light extinction levels that would prevail if areas met a standard based on directly measured hourly PM_{10} light extinction as the indicator. This assessment indicated that a standard based on a directly measured PM_{10} light extinction indicator would provide the same percentage of days having indicator values above the level of the standard across areas, with the percentage being dependent on the statistical form of the standard. This assessment was based on the more complex Visibility Assessment approach to estimating PM_{10} light extinction, rather than the simpler approaches for estimating $PM_{2.5}$ light extinction. Nevertheless, the generally close correspondence between design values for $PM_{2.5}$ light extinction developed consistent with the Visibility Assessment approach and design values based on the simplified approaches (US EPA, 2011a, Appendix F, Figure F-5) suggest that the findings regarding the protection offered by alternative PM_{10} light extinction standards using directly measured light extinction would also hold quite well for standards based on the simplified indicators.[165] Thus, the Policy Assessment concludes that the use of a calculated $PM_{2.5}$ light extinction indicator would provide a much higher degree of uniformity in terms of the visibility levels across the country than is possible using $PM_{2.5}$ mass as the indicator (US EPA, 2011a, p. 4-49). This is due to the fact that the $PM_{2.5}$ mass indicator does not account for the effects of humidity and $PM_{2.5}$ composition differences between various regions, while a calculated $PM_{2.5}$ light extinction indicator directly incorporates those effects.

The inputs that would be necessary to use either simplified approach to calculate a sub-daily $PM_{2.5}$ light extinction indicator (e.g., 1- or 4-hour averaging time) include $PM_{2.5}$ chemical speciation, relative humidity, and hourly $PM_{2.5}$ mass measurements. In defining a standard in terms of calculated light extinction, the criteria for allowable protocols for these calculations would need to be specified. It would be appropriate to base these criteria on the protocols utilized in the IMPROVE[166] and CSN

[165] The degree of emission reduction needed to meet a standard is tightly tied to the degree to which the design value exceeds the level of the standard.
[166] Several monitoring agencies utilize IMPROVE in urban areas to meet their chemical speciation monitoring needs. These sites are known as IMPROVE-protocol stations.

networks, as well as sampling and analysis protocols for ambient relative humidity sensors, and approved FEM mass monitors for $PM_{2.5}$. Any approach to approving methods for use in calculating a light extinction indicator should take advantage of the existing inventory of monitoring and analysis methods.

The CSN measurements have a strong history of being reviewed by CASAC technical committees, both during their initial deployment about ten years ago (Mauderly 1999a,b) and during the more recent transition to carbon sampling that is consistent with the IMPROVE protocols (Henderson, 2005c). Because the methods for the CSN are well documented in a nationally implemented Quality Assurance Project Plan (QAPP) and accompanying standard operating procedures (SOPs), are validated through independent performance testing, and are used to meet multiple data objectives (e.g., source apportionment, trends, and as an input to health studies), consideration should be given to an approach that utilizes the existing methods as the basis for criteria for allowable sampling and analysis protocols for purposes of a calculated light extinction indicator. Such an approach of basing criteria on the current CSN and IMPROVE methods provides a nationally consistent way to provide the chemical species data used in the light extinction calculation, while preserving the opportunity for improved methods for measuring the chemical species. For relative humidity, in conjunction with either hourly, multi-hour, or 24-hour average calculated $PM_{2.5}$ light extinction, consideration should be given to simply using criteria based on available relative humidity sensors such as already utilized by the National Oceanic and Atmospheric Administration (NOAA) at routine weather stations. These relative humidity sensors are already widely used by a number of monitoring agencies and can be easily compared to other relative humidity measurements.[167] Finally, the simplified approaches for a sub-daily averaging period depend on having values of hourly $PM_{2.5}$ mass, as discussed below.

[167] For the purposes of using relative humidity measurements to derive multi-hour or 24-hour average $PM_{2.5}$ calculated light extinction, the non-linear f(RH) enhancement factor should be developed separately for each hour and then averaged over the desired multi-hour period. This averaging approach is consistent with derivation of climatological f(RH) factors used by the IMPROVE program and for the Regional Haze rule.

Since 2008, EPA has approved several $PM_{2.5}$ continuous mass monitoring methods as FEMs.[168] These methods have several advantages over filter-based FRMs, such as producing hourly data and the ability to report air quality information in near real-time. However, initial assessments of the data quality as operated by state and local monitoring agencies have had mixed results. A recent assessment of continuous FEMs and collocated FRMs conducted by EPA staff (Hanley and Reff, 2011) found some sites and continuous FEM instruments to have an acceptable degree of comparability of 24-hour average $PM_{2.5}$ mass values derived from continuous FEMs and filter-based FRMs, while others had poor data quality that would not meet current data quality objectives. The EPA is working closely with the monitoring committee of the National Association of Clean Air Agencies (NACAA), instrument manufacturers, and monitoring agencies to document and communicate best practices on these methods to improve quality and consistency of resulting data. It should be noted that performance testing submitted to EPA for purposes of designating the $PM_{2.5}$ continuous methods as FEMs, and the recent assessment of collocated FRMs and continuous FEMs, are both based on 24-hour sample periods. Therefore, the EPA does not have similar performance data for continuous $PM_{2.5}$ FEMs for 1-hour or 4-hour averaging periods, nor is there an accepted practice to generate performance standards for these time periods.[169] Until issues regarding the comparability of 24-hour $PM_{2.5}$ mass values derived from continuous FEMs and filter-based FRMs are resolved, there is reason to be cautious about relying on a calculation procedure that uses hourly $PM_{2.5}$ mass values reported by continuous FEMs and speciated $PM_{2.5}$ mass values from 24-hour filter-based samplers. Section 4.3.2.1 of the Policy Assessment discusses another reason for such caution, based on a preliminary assessment of hourly data from continuous FEMs (US EPA, 2011a, pp. 4-52 to 4-54).

This section has addressed the types of measurements that would be necessary to support a

[168] The EPA maintains a list of designated Reference and Equivalent Methods on its website at: http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-list.pdf.

[169] Filter-based FRMs are designed to adequately quantify the amount of $PM_{2.5}$ collected over 24-hours. They cannot be presumed to be appropriate for quantifying average concentrations over 1-hour or 4-hour periods.

calculated $PM_{2.5}$ light extinction indicator for either 24-hour or sub-daily (e.g., 1-hour and 4-hour) averaging periods. Considerations related specifically to each of these alternative averaging times, in conjunction with a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, are discussed further in section 4.3.2 of the Policy Assessment.

iv. Conclusions in the Policy Assessment

Taking the above considerations and CASAC's advice into account, the Policy Assessment concludes that consideration should be given to establishing a new calculated $PM_{2.5}$ light extinction indicator (US EPA, 2011a, p. 4-51). This conclusion takes into consideration the available evidence that demonstrates a strong correspondence between calculated $PM_{2.5}$ light extinction and PM-related visibility impairment, as well as the significant degree of variability in visibility protection across the U.S. allowed by a $PM_{2.5}$ mass indicator. While a secondary standard that uses a $PM_{2.5}$ mass indicator could be set to provide additional protection from $PM_{2.5}$-related visibility impairment, the Policy Assessment concludes that the advantages of using a calculated $PM_{2.5}$ light extinction indicator make it the preferred choice (US EPA, 2011a, p. 4-51). In addition, the Policy Assessment recognizes that while in the future it would be appropriate to consider a direct measurement of $PM_{2.5}$ light extinction, or the sum of separate measurements of light scattering and light absorption, as the indicator for the secondary $PM_{2.5}$ standard, it concludes that this is not an appropriate option in this review because a suitable specification of the equipment or appropriate performance-based verification procedures cannot be developed in the time frame for this review (US EPA, 2011a, p. 4-51, -52).

Further, the Policy Assessment concludes that consideration could be given to defining a calculated $PM_{2.5}$ light extinction indicator on either a 24-hour or a sub-daily basis (US EPA, 2011a, p. 4-52). In either case, it would be appropriate to base criteria for allowable monitoring and analysis protocols to obtain $PM_{2.5}$ speciation measurements on the protocols utilized in the IMPROVE and CSN networks. Further, in the case of a calculated $PM_{2.5}$ light extinction indicator defined on a sub-daily basis, it would be appropriate to consider using the simplified approaches described, or some variations

on these approaches. In reaching this conclusion, as discussed above, the Policy Assessment notes that while it is possible to utilize data from $PM_{2.5}$ continuous FEMs on a 1-hour or multi-hour (e.g., 4-hour) basis, the mixed results of data quality assessments on a 24-hour basis, as well as the near absence of performance data for sub-daily averaging periods, increases the uncertainty of utilizing continuous methods to support 1-hour or 4-hour $PM_{2.5}$ mass measurements as an input to the light extinction calculation.

b. CASAC Advice

Based on its review of the second draft Policy Assessment, CASAC stated that it "overwhelmingly . . . would prefer the direct measurement of light extinction," recognizing it as the property of the atmosphere that most directly relates to visibility effects (Samet, 2010d, p. iii). CASAC noted that "[I]t has the advantage of relating directly to the demonstrated harmful welfare effect of ambient PM on human visual perception." However, CASAC also concludes that the calculated $PM_{2.5}$ light extinction indicator "appears to be a reasonable approach for estimating hourly light extinction" (Samet, 2010d, p. 11). Further, based on CASAC's understanding of the time that would be required to develop an FRM for this indicator, CASAC agreed with the staff preference presented in the second draft Policy Assessment for a calculated $PM_{2.5}$ light extinction indicator. CASAC noted that "[I]ts reliance on procedures that have already been implemented in the CSN and routinely collected continuous $PM_{2.5}$ data suggest that it could be implemented much sooner than a directly measured indicator" (Samet, 2010d, p. iii).[170]

c. Administrator's Proposed Conclusions on Indicator

In reaching a proposed conclusion on the appropriate indicator for a standard intended to protect against PM-related visibility impairment, as an initial matter, the Administrator concurs with CASAC that a directly measured PM light extinction indicator would provide the most direct link between PM in

[170] In commenting on the second draft Policy Assessment, CASAC did not have an opportunity to review the assessment of continuous $PM_{2.5}$ FEMs compared to collocated FRMs (Hanley and Reff, 2011) as presented and discussed in the final Policy Assessment (US EPA, 2011a, p. 4-50).

the ambient air and PM-related light extinction. However, she also recognizes that while instruments currently exist that can directly measure $PM_{2.5}$ light extinction, they are not an appropriate option in this review because a suitable specification of the equipment or performance-based verification procedures cannot be developed in the time frame of this review.

Taking the above considerations and CASAC advice into account, the Administrator provisionally concludes a new calculated $PM_{2.5}$ light extinction indicator, similar to that used in the Regional Haze Program (i.e., using an IMPROVE algorithm as translated into the deciview scale), is an appropriate indicator to replace the current $PM_{2.5}$ mass indicator. Such an indicator, referred to as a $PM_{2.5}$ visibility index, appropriately reflects the relationship between ambient PM and PM-related light extinction, based on the analyses discussed above and incorporation of factors based on measured $PM_{2.5}$ speciation concentrations and relative humidity data. In addition, this addresses, in part, the issues raised in the court's remand of the 2006 $PM_{2.5}$ standards. The Administrator also notes that such a $PM_{2.5}$ visibility index would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by virtue of directly incorporating the effects of differences in $PM_{2.5}$ composition and relative humidity across the country.

Based on the above considerations, the Administrator proposes to set a distinct secondary standard for $PM_{2.5}$ defined in terms of a $PM_{2.5}$ visibility index (i.e., a calculated $PM_{2.5}$ light extinction indicator, translated into the deciview scale) to protect against PM-related visibility impairment primarily in urban areas. The Administrator proposes that such an index be based on the original IMPROVE algorithm in conjunction with climatological relative humidity data as used in the Regional Haze Program. A more detailed discussion of the steps involved in the calculation of $PM_{2.5}$ visibility index values is presented in section VII.A.5 below.

The Administrator solicits comment on all aspects of the proposed indicator. In particular, the Administrator solicits comment on the proposed use of a $PM_{2.5}$ visibility index rather than a PM_{10} visibility index which would include an additional term for coarse particles. The Administrator also

solicits comment on alternatively using the revised IMPROVE algorithm rather than the original IMPROVE algorithm the use of alternative values for the organic carbon multiplier in conjunction with either the original or revised IMPROVE algorithm; the use of historical monthly, seasonal, or regional speciation averages; and on alternative approaches to determining relative humidity, as discussed above. Further, in conjunction with an hourly or multi-hour indicator, comment is solicited on variations on the simplified approaches discussed above and on other approaches that may be appropriate to consider for such an indicator.

2. Averaging Times

a. Alternative Averaging Times

Consideration of appropriate averaging times for use in conjunction with a $PM_{2.5}$ visibility index was informed by information related to the nature of PM visibility effects, as discussed above in section VI.B.1 and in section 4.2.1 of the Policy Assessment, and the nature of inputs to the calculation of $PM_{2.5}$ light extinction, as discussed above in section VI.D.1 and in section 4.3.1 of the Policy Assessment. Based on this information, the Policy Assessment considered both sub-daily (1- and 4-hour averaging times) and 24-hour averaging times, as discussed below. In considering sub-daily averaging times, the Policy Assessment also addressed what diurnal periods and ambient relative humidity conditions would be appropriate to consider in conjunction with such an averaging time.

i. Sub-daily

As an initial matter, in considering sub-daily averaging times, the Policy Assessment took into account what is known from available studies concerning how quickly people experience and judge visibility conditions, the possibility that some fraction of the public experiences infrequent or short periods of exposure to ambient visibility conditions, and the typical rate of change of the path-averaged PM light extinction over urban areas. While perception of change in visibility can occur in less than a minute, meaningful changes to path-averaged light extinction occur more slowly. As discussed above and in section 4.2.1 of the Policy Assessment, one hour is a short enough averaging period to result in

indicator values that are close to the maximum one- or few-minute visibility impact that an observer could be exposed to within the hour. Further, a 1-hour averaging time could reasonably characterize the visibility effects experienced by the segment of the population that experiences infrequent short-term exposures during peak visibility impairment periods in each area/site. Based on the above considerations, the initial analyses conducted in the Policy Assessment as part of the Visibility Assessment to support consideration of alternative standards focused on a 1-hour averaging time.

In its review of the first draft Policy Assessment, CASAC agreed that a 1-hour averaging time would be appropriate to consider, noting that PM effects on visibility can vary widely and rapidly over the course of a day and such changes are almost instantaneously perceptible to human observers (Samet, 2010c, p. 19). The Policy Assessment notes that this view related specifically to a standard defined in terms of a directly measured PM light extinction indicator, in that CASAC also noted that a 1-hour averaging time is well within the instrument response times of the various currently available and developing optical monitoring methods. However, CASAC also advised that if a $PM_{2.5}$ mass indicator were to be used, it would be appropriate to consider "somewhat longer averaging times – 2 to 4 hours – to assure a more stable instrumental response" (Samet, 2010c, p. 19). In considering this advice, the Policy Assessment concludes that since a calculated $PM_{2.5}$ light extinction indicator relies in part on measured $PM_{2.5}$ mass, as discussed above and in section 4.3.1 of the Policy Assessment, it is also appropriate to consider a multi-hour averaging time in conjunction with such an indicator (US EPA, 2011a, p. 4-53).

Thus, the Policy Assessment has considered multi-hour averaging times, on the order of a few hours as illustrated by a 4-hour averaging time. Such averaging times might reasonably characterize the visibility effects experienced by the segment of the population who have access to visibility conditions often or continuously throughout the day. For this segment of the population, it may be that their perception of visual air quality reflects some degree of offsetting an hour with poor visual air quality with one or more hours of clearer visual conditions. Further, the Policy Assessment recognizes that a

multi-hour averaging time would have the effect of averaging away peak hourly visibility impairment, which can change significantly from one hour to the next (US EPA, 2011a, p. 4-53; US EPA, 2010b, Figure 3-12). In considering either 1-hour or multi-hour averaging times, the Policy Assessment recognizes that no data are available with regard to how the duration and variation of time a person spends outdoors during the daytime impacts his or her judgment of the acceptability of different degrees of visibility impairment. As a consequence, it is not clear to what degree, if at all, the protection levels found to be acceptable in the public preference studies would change for a multi-hour averaging time as compared to a 1-hour averaging time. Thus, the Policy Assessment concludes that it is appropriate to consider a 1-hour or multi-hour (e.g., 4-hour) averaging time as the basis for a sub-daily standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator (US EPA, 2011a, p. 4-53).

Additionally, as part of the review of data from all continuous FEM $PM_{2.5}$ instruments operating at state/local monitoring sites, as discussed above, the Policy Assessment notes that the occurrence of questionable outliers in 1-hour data submitted to AQS from continuous FEM $PM_{2.5}$ instruments has been observed at some of these sites (Evangelista, 2011). Some of these outliers are questionable simply by virtue of their extreme magnitude, as high as 985 $\mu g/m^3$, whereas other values are questionable because they are isolated to single hours with much lower values before and after, a pattern that is much less plausible than if the high concentrations were more sustained.[171] The nature and frequency of questionable 1-hour FEM data collected in the past two years are being investigated. At this time, the Policy Assessment notes that any current data quality problems might be resolved in the normal course of monitoring program evolution as operators become more adept at instrument operation and maintenance and data validation or by improving the approval criteria and testing requirements for

[171] Similarly questionable hourly data were not observed in the 2005 to 2007 continuous $PM_{2.5}$ data used in the Visibility Assessment, all of which came from early-generation continuous instruments that had not been approved as FEMs. However, only 15 sites and instruments were involved in the Visibility Assessment analyses, versus about 180 currently operating FEM instruments submitting data to AQS. Therefore, there were more opportunities for very infrequent measurement errors to be observed in the larger FEM data set.

continuous instruments. Regardless, the Policy Assessment notes that multi-hour averaging of FEM data could serve to reduce the effects of such outliers relative to the use of a 1-hour averaging time.

In considering an appropriate diurnal period for use in conjunction with a sub-daily averaging time, the Policy Assessment recognizes that nighttime visibility impacts, described in the Integrated Science Assessment (US EPA, 2009a, section 9.2.2) are significantly different from daytime impacts and are not sufficiently well understood to be included at this time. As a result, consistent with CASAC advice (Samet, 2010c, p. 4), the Policy Assessment concludes that it would be appropriate to define a sub-daily standard in terms of only daylight hours at this time (US EPA, 2011a, p. 4-54). In the Visibility Assessment, daylight hours were defined to be those morning hours having no minutes prior to local sunrise and afternoon hours having no minutes after local sunset. This definition ensures the exclusion of periods of time where the sun is not the primary outdoor source of light to illuminate scenic features.

In considering the well-known interaction of PM with ambient relative humidity conditions, the Policy Assessment recognizes that PM is not generally the primary source of visibility impairment during periods with fog or precipitation. In order to reduce the probability that hours with a high degree of visibility impairment caused by fog or precipitation are unintentionally used for purposes of determining compliance with a standard, the Policy Assessment determined that a relative humidity screen that excludes daylight hours with average relative humidity above approximately 90 percent is appropriate (US EPA, 2001, pp. 4-54 to 4-55; see also US EPA, 2010b, section 3.3.5, Appendix G). For example, for the 15 urban areas[172] included in the Visibility Assessment, a 90 percent relative humidity cutoff criterion proved effective in that on average less than 6 percent of the daylight hours were removed from consideration, yet those same hours had on average 10 times the likelihood of rain, 6 times the likelihood of snow/sleet, and 34 times the likelihood of fog compared with hours with 90

[172] The 90 percent relative humidity cap assessment was conducted as part of the Visibility Assessment on all 15 of the urban areas, including St. Louis.

percent or lower relative humidity. However, not all periods with relative humidity above 90 percent have fog or precipitation. The Policy Assessment recognizes that removing those hours from consideration involves a tradeoff between the benefits of avoiding many of the hours with meteorological causes of visibility impacts and not counting some hours without fog or precipitation in which high humidity levels (e.g., greater than 90 percent) lead to the growth of hygroscopic PM to large solution droplets resulting in larger PM visibility impacts.

ii. 24-Hour

As discussed in section 4.3.1 of the Policy Assessment and below, there are significant reasons to consider using $PM_{2.5}$ light extinction calculated on a 24-hour basis to reduce the various data quality concerns over relying on continuous $PM_{2.5}$ monitoring data. However, the Policy Assessment recognizes that 24 hours is far longer than the hourly or multi-hour time periods that might reasonably characterize the visibility effects experienced by various segments of the population, including both those who do and do not have access to visibility conditions often or continuously throughout the day, as discussed above and in section 4.3.2.1 of the Policy Assessment. Thus, consideration of a 24-hour averaging time depends upon the extent to which PM-related light extinction calculated on a 24-hour average basis would be a reasonable and appropriate *surrogate* for PM-related light extinction calculated on a sub-daily basis, as discussed below in this section. Further, since a 24-hour averaging time combines daytime and nighttime periods, the Policy Assessment recognizes that the public preference studies do not directly provide a basis for identifying an appropriate level of protection, in terms of 24-hour average light extinction, based on judgments of acceptable daytime visual air quality obtained in those studies. Thus, consideration of a 24-hour averaging time also depends upon developing an approach to translate the candidate levels of protection derived from the public preference studies, which the Policy Assessment has interpreted on an hourly or multi-hour basis, to a candidate level of protection defined in terms of a 24-hour average calculated light extinction, as discussed in section.VI.D.4 below.

To determine whether $PM_{2.5}$ light extinction calculated on a 24-hour basis is a reasonable and

appropriate surrogate to $PM_{2.5}$ light extinction calculated on a sub-daily basis, the Policy Assessment performed comparative analyses of 24-hour and 4-hour averaging times in conjunction with a calculated $PM_{2.5}$ indicator.[173] These analyses are presented and discussed in Appendix G, section G.4 of the Policy Assessment. For these analyses, 4-hour average $PM_{2.5}$ light extinction was calculated based on using the Visibility Assessment approach. The 24-hour average $PM_{2.5}$ light extinction calculations used the original IMPROVE algorithm and long-term (1988 to 1997) average relative humidity conditions, to calculate monthly average values of the relative humidity term in the IMPROVE algorithm, consistent with the approach used for the Regional Haze Program. Similar to the approach used to assess a sub-daily visibility index discussed in section VI.2.a.i above, these 1988-1997 humidity data are similarly screened to remove the effect of high hourly relative humidity. In this case, any relative humidity value great than 95 percent was treated as 95 percent. Because 10-years of hourly data were used to produce a single humidity term for each month, the EPA believes that the resulting monthly average of the humidity term is sufficient and appropriate to reduce the effects of fog or precipitation. Based on these analyses, scatter plots comparing 24-hour and 4-hour calculated $PM_{2.5}$ light extinction are shown for each of the 15 cities included in the Visibility Assessment and for all 15 cities pooled together (US EPA, 2011a, Figures G-4 and G-5). It can be seen, as expected, that there is some scatter around the regression line for each city, because the calculated 4-hour light extinction includes day-specific and hour-specific influences that are not captured by the simpler 24-hour approach. The Policy Assessment notes that this scatter could be reduced by the use of same-day hourly relative humidity data to calculate a 24-hour average value of the relative humidity term in the IMPROVE algorithm. In the Policy Assessment, scatter plots are also shown for the annual 90th percentile values, based on data from 2007 to 2009, for 4-hour and 24-hour calculated $PM_{2.5}$ light extinction across all 15 cities (US EPA, 2011a, Figure G-7) and for the 3-year design values across all 15 cities (US EPA, 2011a, Figure G-8). These analyses showed

[173] These analyses are also based on the use of a 90th percentile form, averaged over 3 years, as discussed below in section VI.D.3 and in section 4.3.3 of the Policy Assessment (US EPA, 2011a).

good correlation between 24-hour and 4-hour average $PM_{2.5}$ light extinction, as evidenced by reasonably high city-specific and pooled R^2 values, generally in the range of over 0.6 to over 0.8.[174]

iii. Conclusions in the Policy Assessment

Taking the above considerations and CASAC's advice into account, the Policy Assessment concludes that it is appropriate to consider in this review a 24-hour averaging time, in conjunction with a calculated $PM_{2.5}$ light extinction indicator and an appropriately specified standard level (US EPA, 2011a, p. 4-57). This conclusion reflects the judgment that $PM_{2.5}$ light extinction calculated on a 24-hour basis is a reasonable and appropriate surrogate for sub-daily $PM_{2.5}$ light extinction calculated on a 4-hour average basis. This conclusion is also predicated on consideration of a 24-hour average standard level, as discussed below and in section 4.3.4 of the Policy Assessment, that is appropriately translated from the CPLs derived from the public preference studies, which the Policy Assessment has interpreted as providing information on the acceptability of daytime visual air quality over an hourly or multi-hour exposure period.

A 24-hour average calculated $PM_{2.5}$ light extinction indicator would avoid data quality uncertainties that have recently been associated with currently available instruments for measurement of hourly $PM_{2.5}$ mass. The particular 24-hour indicator considered by the Policy Assessment uses the original IMPROVE algorithm and long-term relative humidity conditions to calculate $PM_{2.5}$ light extinction. By using site-specific daily data on $PM_{2.5}$ composition and site-specific long-term relative humidity conditions, this 24-hour average indicator would provide more consistent protection from $PM_{2.5}$-related visibility impairment than would a secondary $PM_{2.5}$ NAAQS based only on 24-hour or annual average $PM_{2.5}$ mass. In particular, this approach would account for the systematic difference in humidity conditions between most eastern states and most western states.

Further, the Policy Assessment concludes that it would also be appropriate to consider a multi-hour, sub-daily averaging time, for example a period of 4 hours, in conjunction with a calculated $PM_{2.5}$

[174] The EPA staff note that the R^2 value (0.44) for Houston was notably lower than for the other cities.

light extinction indicator and with further consideration of the data quality issues that have been raised by the recent EPA study of continuous FEMs (US EPA, 2011a, p. 4-58). Such an averaging time, to the extent that data quality issues can be appropriately addressed, would be more directly related to the short-term nature of the perception of visibility impairment, short-term variability in PM-related visual air quality, and the short-term nature (hourly to multiple hours) of relevant exposure periods for segments of the viewing public. Such an averaging time would still result in an indicator that is less sensitive than a 1-hour averaging time to short-term instrument variability with respect to $PM_{2.5}$ mass measurement. In conjunction with consideration of a multi-hour, sub-daily averaging time, the Policy Assessment concludes that consideration should be given to including daylight hours only and to applying a relative humidity screen of approximately 90 percent to remove hours in which fog or precipitation is much more likely to contribute to the observed visibility impairment (US EPA, 2011a, p. 4-58). Recognizing that a 1-hour averaging time would be even more sensitive to data quality issues, including short-term variability in hourly data from currently available continuous monitoring methods, the Policy Assessment concludes that it would not be appropriate to consider a 1-hour averaging time in conjunction with a calculated $PM_{2.5}$ light extinction indicator in this review (US EPA, 2011a, p. 4-58).

b. CASAC Advice

As noted above, in its review of the first draft Policy Assessment, CASAC concludes that PM effects on visibility can vary widely and rapidly over the course of a day and such changes are almost instantaneously perceptible to human observers (Samet, 2010c, p. 19). Based in part on this consideration, CASAC agreed that a 1-hour averaging time would be appropriate to consider in conjunction with a directly measured PM light extinction indicator, noting that a 1-hour averaging time is well within the instrument response times of the various currently available and developing optical monitoring methods. At that time, CASAC also advised that if a $PM_{2.5}$ mass indicator were to be used, it would be appropriate to consider "somewhat longer averaging times – 2- to 4-hours – to assure a more stable instrumental response" (Samet, 2010c, p. 19). Thus, CASAC's advice on averaging times that

would be appropriate for consideration was predicated in part on the capabilities of monitoring methods that were available for the alternative indicators discussed in the draft Policy Assessment. CASAC's views on a multi-hour averaging time would also apply to the calculated $PM_{2.5}$ light extinction indicator since hourly $PM_{2.5}$ mass measurements are also required for this indicator when calculated on a sub-daily basis.

In considering this advice, the Policy Assessment first notes that CASAC did not have the benefit of EPA's recent assessment of the data quality issues associated with the use of continuous FEMs as the basis for hourly $PM_{2.5}$ mass measurements. The Policy Assessment also notes that since earlier drafts of this Policy Assessment did not include discussion of a calculated $PM_{2.5}$ indicator based on a 24-hour averaging time, CASAC did not have a basis to offer advice regarding a 24-hour averaging time. In addition, the 24-hour averaging time is not based on consideration of 24-hours as a relevant exposure period, but rather as a surrogate for a sub-daily period of 4 hours, which is consistent with CASAC's advice concerning an averaging time associated with the use of a $PM_{2.5}$ mass indicator.

c. Administrator's Proposed Conclusions on Averaging Time

In reaching a proposed conclusion on the appropriate averaging time for a standard intended to protect against PM-related visibility impairment, the Administrator has taken into account the information discussed above with regard to analyses and conclusions presented in the final Policy Assessment as well as the views of CASAC based on its reviews of the first and second drafts of the Policy Assessment. As an initial matter, the Administrator recognizes that hourly or sub-daily, multi-hour averaging times, within daylight hours and excluding hours with relative humidity above approximately 90 percent, are more directly related than a 24-hour averaging time to the short-term nature of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. On the other hand, she recognizes that data quality uncertainties have recently been associated with currently available instruments that would be used to provide the hourly $PM_{2.5}$ mass measurements that would be needed in conjunction with an averaging time shorter than

24-hours. As a result, while the Administrator recognizes the desirability of a sub-daily averaging time, she has strong reservations about proposing to set a standard at this time in terms of a sub-daily averaging time.

In considering the information and analyses related to consideration of a 24-hour averaging time, the Administrator recognizes that the Policy Assessment concludes that $PM_{2.5}$ light extinction calculated on a 24-hour averaging basis is a reasonable and appropriate surrogate for sub-daily $PM_{2.5}$ light extinction calculated on a 4-hour average basis (US EPA, 2011a, p. 4-57). In light of this finding, the Administrator proposes to set a distinct secondary standard with a 24-hour averaging time in conjunction with a $PM_{2.5}$ visibility index.

Further, in light of the desirability of a sub-daily averaging time, the Administrator solicits comment on a sub-daily (e.g., 4-hour) averaging time and related data quality issues associated with currently available monitoring instrumentation. In so doing, the Administrator notes that CASAC's advice on averaging times was predicated in part on the capabilities of available monitoring instrumentation as CASAC understood them when it provided its advice.

3. Form

The "form" of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether the standard is achieved. The form of the current 24-hour $PM_{2.5}$ NAAQS is such that the level of the standard is compared to the 3-year average of the annual 98th percentile value of the measured indicator. The purpose in averaging for three years is to provide stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year. The use of a multi-year percentile form, among other things, makes the standard less subject to the possibility of transient violations caused by statistically unusual indicator values, thereby providing more stability to the air quality management process that may enhance the practical effectiveness of efforts to implement the NAAQS. Also, a percentile form can be used to take into account the number of times an exposure might occur as part of

the judgment on protectiveness in setting a NAAQS. For all of these reasons, the Policy Assessment concludes it is appropriate to consider defining the form of a distinct secondary standard in terms of a 3-year average of a specified percentile air quality statistic (US EPA, 2011a, p. 4-58).

The urban visibility preference studies that provided results leading to the range of CPLs being considered in this review offer no information that addresses the frequency of time that visibility levels should be below those values. Given this lack of information, and recognizing that the nature of the public welfare effect is one of aesthetics and/or feelings of well-being, the Policy Assessment concludes that it would not be appropriate to consider eliminating all exposures above the level of the standard and that allowing some number of hours/days with reduced visibility can reasonably be considered (US EPA, 2011a, p. 4-59). In the Visibility Assessment, 90th, 95th, and 98th percentile forms were assessed for alternative PM light extinction standards (US EPA, 2010b, section 4.3.3). In considering these alternative percentiles, the Policy Assessment notes that the Regional Haze Program targets the 20 percent most impaired days for improvements in visual air quality in Federal Class I areas. If improvement in the 20 percent most impaired days were similarly judged to be appropriate for protecting visual air quality in urban areas, a percentile well above the 80th percentile would be appropriate to increase the likelihood that all days in this range would be improved by control strategies intended to attain the standard. A focus on improving the 20 percent most impaired days suggests that the 90th percentile, which represents the median of the distribution of the 20 percent worst days, would be an appropriate form to consider. Strategies that are implemented so that 90 percent of days have visual air quality that is at or below the level of the standard would reasonably be expected to lead to improvements in visual air quality for the 20 percent most impaired days. Higher percentile values within the range assessed could have the effect of limiting the occurrence of days with peak PM-related light extinction in urban areas to a greater degree. In considering the limited information available from the public preference studies, the Policy Assessment finds no basis to conclude that it would be appropriate to consider limiting the occurrence of days with peak PM-related light extinction in urban

areas to a greater degree.

Another aspect of the form that was considered in the Visibility Assessment for a sub-daily (i.e., 1-hour) averaging time is whether to include all daylight hours or only the maximum daily daylight hour. This consideration would also be relevant for a multi-hour (e.g., 4-hour) averaging time, although such an analysis was not included in the Visibility Assessment. The maximum daily daylight 1-hour or multi-hour form is most directly protective of the welfare of people who have limited, infrequent or intermittent exposure to visibility during the day (e.g., during commutes), but spend most of their time without an outdoor view. For such people a view of poor visibility during their morning commute may represent their perception of the day's visibility conditions until the next time they venture outside during daylight, which may be hours later or perhaps the next day. Other people have exposure to visibility conditions throughout the day. For those people, it might be more appropriate to include every daylight hour in assessing compliance with a standard, since it is more likely that each daylight hour could affect their welfare.

The Policy Assessment does not have information regarding the fraction of the public that has only one or a few opportunities to experience visibility during the day, nor does it have information on the role the duration of the observed visibility conditions has on wellbeing effects associated with those visibility conditions. However, it is logical to conclude that people with limited opportunities to experience visibility conditions on a daily basis would experience the entire impact associated with visibility based on their short-term exposure. The impact of visibility for those who have access to visibility conditions often or continuously during the day may be based on varying conditions throughout the day.

In light of these considerations, the Visibility Assessment analyses included both the maximum daily hour and the all daylight hours forms. The Policy Assessment observed a close correspondence between the level of protection afforded for all 15 urban areas in the assessment by the maximum daily daylight 1-hour approach using the 90th percentile form and the all daylight hours approach combined

with the 98th percentile form (US EPA, 2010b, section 4.1.4). On this basis, the Policy Assessment notes that the reductions in visibility impairment required to meet either form of the standard would provide protection to both fractions of the public (i.e., those with limited opportunities and those with greater opportunities to view PM-related visibility conditions). The Policy Assessment also notes that CASAC generally supported consideration of both types of forms without expressing a preference based on its review of information presented in the second draft Policy Assessment (Samet, 2010d, p. 11).

In conjunction with a calculated $PM_{2.5}$ light extinction indicator and alternative 24-hour or sub-daily (e.g., 4-hour) averaging times, based on the above considerations, and given the lack of information on and the high degree of uncertainty over the impact on public welfare of the number of days with visibility impairment over a year, the Policy Assessment concludes that it is appropriate to give primary consideration to a 90th percentile form, averaged over three years (US EPA, 2011a, p. 4-60). Further, in the case of a multi-hour, sub-daily alternative standard, the Policy Assessment concludes that it is appropriate to give primary consideration to a form based on the maximum daily multi-hour period in conjunction with the 90th percentile form (US EPA, 2011a, p. 4-60). This sub-daily form would be expected to provide appropriate protection for various segments of the population, including those with limited opportunities during a day and those with more extended opportunities over the daylight hours to experience PM-related visual air quality.

Based on its review of the second draft Policy Assessment, CASAC did not provide advice as to a specific form that would be appropriate, but took note of the alternative forms considered in that document and encouraged further analyses in the final Policy Assessment that might help to clarify a basis for selecting from within the range of forms identified. In considering the available information and the conclusions in the final Policy Assessment in light of CASAC's comments, the Administrator provisionally concludes that a 90th percentile form, averaged over 3 years, is appropriate, and proposes such a form in conjunction with a $PM_{2.5}$ visibility index and a 24-hour averaging time.

4. Level

In considering alternative levels for a new standard that would provide requisite protection against PM-related visibility impairment primarily in urban areas, the Policy Assessment has taken into account the evidence- and impact-based considerations discussed above and in section 4.2.1 of the Policy Assessment, with a focus on the results of public perception and attitude surveys related to the acceptability of various levels of visual air quality and on the important limitations in the design and scope of such available studies. The Policy Assessment considered this information in the context of a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, discussed above and in the Policy Assessment section 4.3.1; with alternative averaging times of 24-hours or multi-hour, sub-daily periods (e.g., 4-hours), discussed above and in Policy Assessment section 4.3.2; and a 90th percentile-based form, discussed above and in section 4.3.3 of the Policy Assessment.

As part of the Policy Assessment's assessment of the adequacy of the current standards, summarized in section VI.B. above and in Policy Assessment section 4.2.1, it interpreted the results from the visibility preferences studies conducted in four urban areas to define a range of low, middle, and high CPLs for a sub-daily standard (e.g., 1- to 4-hour averaging time) of 20, 25, and 30 dv, which are approximately equivalent to $PM_{2.5}$ light extinction of values of 65, 110, and 190 Mm^{-1}. The Policy Assessment notes that CASAC agreed that this was an appropriate range of levels to consider for such a standard (Samet, 2010d, p. 11).[175] The Policy Assessment also recognizes that to define a range of alternative levels that would be appropriate to consider for a 24-hour calculated $PM_{2.5}$ light extinction standard, it is appropriate to consider whether some adjustment to these CPLs is warranted since these preference studies cannot be directly interpreted as applying to a 24-hour exposure period (as noted above and in Policy Assessment section 4.3.1). Considerations related to such adjustments are more

[175] In 2009, the D.C. Circuit remanded the secondary $PM_{2.5}$ standards to the EPA in part because the Agency failed to identify a target level of protection, even though EPA staff and CASAC had identified a range of target levels of protection that were appropriate for consideration. The court determined that the Agency's failure to identify a target level of protection as part of its final decision was contrary to the statute and therefore unlawful, and that it deprived EPA's decision-making of a reasoned basis. See 559F. 3d at 528-31; see also section VI.A.2 above and the Policy Assessment, section 4.1.2.

specifically discussed below.

As an initial matter, in considering alternative levels for a sub-daily standard based directly on the four preference study results, the Policy Assessment notes that the individual low and high CPLs are in fact generally reflective of the results from the Denver and Washington, DC studies respectively, and the middle CPL is very near to the 50th percentile criteria result from the Phoenix study. As discussed above and in section 4.2.1 of the Policy Assessment, the Phoenix study was by far the best of the studies, providing somewhat more support for the middle CPL. In considering the results from these studies, the Policy Assessment recognizes that the available studies are limited in that they were conducted in only four areas, three in the U.S. and one in Canada. Further, the Policy Assessment recognizes that available studies provide no information on how the duration and variation of time a person spends outdoors during the daytime may impact their judgment of the acceptability of different degrees of visibility impairment. As such, there is a relatively high degree of uncertainty associated with using the results of these studies to inform consideration of a national standard for any specific averaging time. Nonetheless, the Policy Assessment concludes, as did CASAC, that these studies are appropriate to use for this purpose (US EPA, 2011a, p. 4-61).

In considering potential alternative levels for a 24-hour standard, the Policy Assessment explores various approaches to adjusting the CPLs derived directly from the preference studies, as presented and discussed in Appendix G of the Policy Assessment, especially section G-5. These various approaches, based on analyses of 2007 – 2009 data from the 15 urban areas assessed in the Visibility Assessment, focused on estimating CPLs for a 24-hour standard that would provide generally equivalent protection as that provided by a 4-hour standard with CPLs of 20, 25, and 30 dv. In so doing, staff recognized that there are multiple approaches for estimating generally equivalent levels on a city-specific or national basis, and that the inherent spatial and temporal variability in relative humidity and fine particle composition across cities leads to a set of alternative estimates of levels that may be construed as being generally equivalent on a national basis.

In conducting these analyses, staff initially expected that the values of 24-hour average $PM_{2.5}$ light extinction and daily maximum daylight 4-hour average $PM_{2.5}$ light extinction would differ on any given day, with the shorter term peak value generally being larger. This would mean that, in concept, the level of a 24-hour standard should include a downward adjustment compared to the level of a 4-hour standard to provide generally equivalent protection. As discussed more fully in section G.5 of Appendix G and summarized below, this initial expectation was not found to be the case across the range of CPLs considered. In fact, as shown in Table G-6 of Appendix G,[176] in considering estimates aggregated or averaged over all 15 cities as well as the range of city-specific estimates for the various approaches considered, the generally equivalent 24-hour levels ranged from somewhat below the 4-hour level to just above the 4-hour level for each of the CPLs.[177]

Some of the approaches used in these analyses focused on comparing 24-hour and 4-hour light extinction values in each of the 15 urban areas, whereas other approaches focused on comparisons based on using aggregated data across the urban areas. Two of these approaches, which used regressions of city-specific annual 90th percentile light extinction values or 3-year light extinction design values, gave nearly identical results and were considered by staff to be most appropriate for further consideration. These approaches (shown in US EPA, 2011a, Appendix G, Figures G-7 and G-8, referred to as Approaches A and B) were preferred by staff based on the high R^2 values of the regressions and because

[176]Note that the city-specific ranges shown in Table G-6, Appendix G of the Policy Assessment are incorrectly stated for Approaches C and E. Drawing from the more detailed and correct results for Approaches C and E presented in Tables G-7 and G-8, respectively, the city-specific ranges in Table G-6 for Approach C should be 17 – 21 dv for the CPL of 20 dv; 21 – 25 dv for the CPL of 25 dv; and 24 – 30 dv for the CPL of 30 dv; the city-specific ranges in Table G-6 for Approach E should be 17 – 21 dv for the CPL of 20 dv; 21 – 26 dv for the CPL of 25 dv; and 25 – 31 dv for the CPL of 30 dv

[177]As discussed in more detail in Appendix G of the Policy Assessment, some days have higher values for 24-hour average light extinction than for daily maximum 4-hour daylight light extinction, and consequently an adjusted "equivalent" 24-hour CPL can be greater than the original 4-hour CPL. This can happen for two reasons. First, the use of monthly average historical RH data will lead to cases in which the *f*(RH) values used for the calculation of 24-hour average light extinction are higher than all or some of the four hourly values of *f*(RH) used to determine daily maximum 4-hour daylight light extinction on the same day. Second, $PM_{2.5}$ concentrations may be greater during non-daylight periods than during daylight hours.

the regressions were determined by data from days with $PM_{2.5}$ light extinction conditions in the range of 20 to 40 dv. This contrasted with the other approaches that were influenced by $PM_{2.5}$ light extinction conditions well below this range. Based on these analyses (presented in Appendix G of the Policy Assessment), the Policy Assessment notes that the single approach thought by staff to be more appropriate for further consideration (referred to as Approach B in Appendix G) yielded adjusted 24-hour CPLs of 21, 25, and 28 dv as being levels that are generally equivalent in an aggregate or central tendency sense to 4-hour CPLs of 20, 25, and 30 dv.[178]

Two of the approaches yielded not only estimates of generally equivalent levels on an aggregated basis but also city-specific estimates (referred to as Approaches C and E in Appendix G) that showed greater variability than the aggregated estimates. In all cases, the range of city-specific estimates of generally equivalent 24-hour levels included the 4-hour level for each of the CPLs of 20, 25, and 30 dv (as shown in Tables G-7 and G-8, Appendix G of the Policy Assessment, for Approaches C and E, respectively). Looking more broadly at these results could support consideration of using the same CPL for a 24-hour standard as for a 4-hour standard, recognizing that there is no one approach that can most closely identify a generally equivalent 24-hour standard level in each urban area for each CPL. The use of such an unadjusted CPL for a 24-hour standard would place more emphasis on the relatively high degree of spatial and temporal variability in relative humidity and fine particle composition observed in urban areas across the country, so as to reduce the potential of setting a 24-hour standard level that would require more than the intended degree of protection in some areas.

In more broadly considering alternative standard levels that would be appropriate for a nationally applicable secondary standard focused on protection from PM-related urban visibility impairment based on either a 24-hour or multi-hour, sub-daily (e.g., 4-hour) averaging time, the Policy Assessment was

[178] To provide some perspective in considering these results (US EPA, 2011a, Appendix G, Table G-6), the Policy Assessment notes that 1 dv is about the amount that persons can distinguish when viewing scenic vistas, and that a difference of 1 dv is equivalent to about a 10 percent difference in light extinction expressed in Mm^{-1}.

mindful of the important limitations in the available evidence from public preference studies. While the Policy Assessment concluded, consistent with CASAC advice, that it is appropriate to consider a distinct secondary $PM_{2.5}$ standard to address PM-related visibility impairment focused primarily in urban areas based on the evidence from public preference studies, it also recognized that there are a number of uncertainties and limitations associated with the preference studies that have served as a basis for selecting an appropriate range of levels to consider, as discussed above in section VI.B.2. These uncertainties and limitations are due in part to the small number of stated preference studies available for this review; the relatively small number of study participants and the extent to which the study participants may not be representative of the broader study area population in some of the studies; and the variations in the specific materials and methods used in each study such as scene characteristics, the range of VAQ levels presented to study participants, image presentation methods and specific wording used to frame the questions used in the group interviews. In addition the Policy Assessment was mindful that the scenic vistas available on a daily basis in many urban areas across the country generally do not have the inherent visual interest or the distance between viewer and object of greatest intrinsic value as in the Denver and Phoenix preference studies, and that there is the possibility that there could be regional differences in individual preferences for VAQ.

Given the uncertainties and limitations noted above, the EPA broadly solicits comment on the strengths and limitations associated with these preference studies and the use of these studies to inform the selection of a range of levels that could be used to provide an appropriate degree of public welfare protection when combined with the other elements of the standard (i.e. indicator, form and averaging time). In particular, the EPA solicits comment on the following specific aspects of the public preference studies and on how these studies should appropriately be considered in this review. Recognizing that all of these studies evaluated a 50 percent acceptability criterion as the basis for reaching judgments in the context of each study, the EPA requests comment on the extent to which this criterion is an appropriate basis for establishing target protection levels in the context of establishing a distinct secondary NAAQS

to address PM-related visibility impairment in urban areas. Recognizing that these studies vary in the extent to which the study participants may be representative of the broader study area population, the EPA requests comment on how this aspect of the study designs should appropriately be weighed in the context of considering these studies in reaching proposed conclusions on a distinct secondary NAAQS. The EPA also solicits comment on the extent to which the ranges of VAQ levels presented to participants in each of the studies may have influenced study results and on how this aspect of the study designs should appropriately be weighed in the context of considering these studies in the context of this review.

As in past reviews, the EPA is considering a national visibility standard in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in urban, non-urban, and Federal Class I areas across the country. The EPA recognizes that programs implemented to meet a national standard focused primarily on the visibility problems in urban areas can be expected to improve visual air quality in surrounding non-urban areas as well, as would programs now being developed to address the requirements of the Regional Haze Program established for protection of visual air quality in Federal Class I areas. The EPA also believes that the development of local programs, such as those in Denver and Phoenix, can continue to be an effective and appropriate approach to provide additional protection, beyond that afforded by a national standard, for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas.

Based on the above considerations, the Policy Assessment concludes that it is appropriate to give primary consideration to alternative standard levels toward the upper end of the ranges identified above for 24-hour and sub-daily standards, respectively (US EPA, 2011a, p. 4-63). Thus, the Policy Assessment concludes it is appropriate to consider the following alternative levels: a level of 28 dv or somewhat below, down to 25 dv, for a standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, a 90th percentile form, and a 24-hour averaging time; and a standard level of 30 dv or

somewhat below, down to 25 dv, for a similar standard but with a 4-hour averaging time (US EPA, 2011a, p. 4-63). The Policy Assessment judges that such standards would provide appropriate protection against PM-related visibility impairment primarily in urban areas. The Policy Assessment notes that CASAC generally supported consideration of the 20 – 30 dv range as CPLs and, more specifically, that support for consideration of the upper part of the range of the CPLs derived from the public preference studies was expressed by some CASAC Panel members during the public meeting on the second draft Policy Assessment. The Policy Assessment concludes that such a standard would be appropriate in conjunction with the Regional Haze Program to achieve appropriate levels of protection against PM-related visibility impairment in areas across the country (US EPA, 2011a, p. 4-63).

Based on the above considerations, taking into account the conclusions in the Policy Assessment and the extent to which those conclusions reflected consideration of CASAC advice during the development of the Policy Assessment, as an initial matter, the Administrator provisionally concludes that it is appropriate to establish a target level of protection – for a standard defined in terms of a $PM_{2.5}$ visibility index; a 90th percentile form averaged over 3 years; and a 24-hour averaging time -- equivalent to the protection afforded by such a sub-daily (i.e., 4-hour) standard at a level of 30 dv, which is the upper end of the range of CPLs identified in the Policy Assessment and generally supported by CASAC. More specifically, the Administrator provisionally concludes that a 24-hour level of either 30 dv or 28 dv could be construed as providing such a degree of protection, and that either level is supported by the available information and is generally consistent with the advice of CASAC. The option of setting such a 24-hour standard at a level of 30 dv would reflect recognition that there is considerable spatial and temporal variability in the key factors that determine the value of the $PM_{2.5}$ visibility index in any given urban area, such that there is a relatively high degree of uncertainty as to the most appropriate approach to use in selecting a 24-hour standard level that would be generally equivalent to a specific 4-hour standard level. Selecting a 24-hour standard level of 30 dv would reflect a judgment that such substantial degrees of variability and uncertainty should be reflected in a higher standard level than would be

appropriate if the underlying information were more consistent and certain. Alternatively, the option of setting such a 24-hour standard at a level of 28 dv would reflect placing more weight on statistical analyses of aggregated data from across the study cities and not placing as much emphasis on the city-to-city variability as a basis for determining an appropriate degree of protection on a national scale.

In light of these provisional conclusions, the Administrator proposes to set a new 24-hour standard (defined in terms of a $PM_{2.5}$ visibility index and a 90th percentile form, averaged over 3 years) to provide appropriate protection from PM-related visibility impairment based on one of two options. One option is to set the level of such a standard at 30 dv and the other option is to set the level at 28 dv. In so doing, the Administrator solicits comment on each of these levels and on the various approaches to identifying generally equivalent levels discussed above upon which the alternative proposed levels are based. Recognizing that there was some support for consideration of a broader range of levels, the Administrator also solicits comment on a range of levels down to 25 dv in conjunction with a 24-hour averaging time. Further, having solicited comment on a sub-daily (e.g., 4-hour) averaging time, the Administrator also solicits comment on a range of alternative levels from 30 to 25 dv in conjunction with such a sub-daily averaging time.

Finally, as we have indicated, the information available for the Administrator to consider when setting the secondary PM standard raises a number of uncertainties. While CASAC supported moving forward with a new standard on the basis of the available information, CASAC also recognized these uncertainties, referencing the discussion of key uncertainties and areas for future research in the second draft of the Policy Assessment. In discussing areas of future research, CASAC stated that: "The range of 50% acceptability values discussed as possible standards are based on just four studies (Figure 4-2), which, given the large spread in values, provide only limited confidence that the benchmark candidate protection levels cover the appropriate range of preference values. Studies using a range of urban scenes (including, but not limited to, iconic scenes – "valued scenic elements" such as those in the Washington DC study), should also be considered." (Samet, 2010d, p. 12). We invite comment on how the

Administrator should weigh those uncertainties as well as any additional comments and information to inform her consideration of these uncertainties.

E. Other PM-related Welfare Effects

In the 2006 review, the Administrator concluded that there was insufficient information to consider a distinct secondary standard based on PM-related impacts to ecosystems, materials damage and soiling, and climatic and radiative processes (71 FR 61144, October 17, 2006). Specifically, there was a lack of evidence linking various non-visibility welfare effects to specific levels of ambient PM. To provide a level of protection for welfare-related effects, the secondary standards were set equal to the revised primary standards to directionally improve the level of protection afforded vegetation, ecosystems, and materials (71 FR 61210, October 17, 2006).

In that review, the 2004 AQCD concluded that regardless of size fraction, particles containing nitrates and sulfates have the greatest potential for widespread environmental significance (US EPA, 2004, sections 4.2.2 and 4.2.3.1). Considerable supporting evidence was available that indicated a significant role of oxides of nitrogen and sulfur, and their transformation products in acidification and nutrient enrichment of terrestrial and aquatic ecosystems (71 FR 61209, October 17, 2006). The recognition of these ecological effects, coupled with other considerations detailed below, led EPA to initiate a joint review of the secondary NO_2 and SO_2 NAAQS that is considering the gaseous and particulate species of oxides of nitrogen and sulfur with respect to the ecosystem-related welfare effects that result from the deposition of these pollutants and transformation products.

This section presents the Policy Assessment's conclusions with regard to the current suite of secondary PM standards to protect against non-visibility PM-related welfare effects. Specifically, the Policy Assessment has assessed the relevant information related to effects of atmospheric PM on the environment, including effects on climate, ecological effects, and materials. Non-visibility welfare-based effects of oxides of nitrogen and sulfur are divided between two NAAQS reviews; (1) PM NAAQS review and, (2) the joint secondary NAAQS review for oxides of nitrogen (NO_x) and oxides of

sulfur (SO_x).[179] The scope of each document and the compounds of nitrogen and sulfur considered in each review are summarized in this section and in Table 5-1 of the Policy Assessment.

In reviewing the current suite of secondary PM standards, the Policy Assessment considers all PM-related effects that are not being covered in the ongoing NOx/SOx review, including visibility impairment (US EPA, 2011a, chapter 4), climate forcing effects (US EPA, 2011a, section 5.2), ecological effects (US EPA, 2011a, section 5.3), and materials damage (US EPA, 2011a, section 5.4). By excluding the effects associated with deposited particulate matter components of NO_x and SO_x and their transformation products which are addressed fully in the NO_x/SO_x secondary review, the discussion of ecological effects of PM has been narrowed to focus on effects associated with the deposition of metals and, to a lesser extent, organics (US EPA, 2011a, section 5.3). With regard to the materials section, because the NOx/SOx review is not considering materials, the discussion includes particles and gases that are associated with the presence of ambient NO_x and SO_x, as well as reduced forms of nitrogen such as ammonia and ammonium ions for completeness.

In contrast, the proposed rulemaking for the joint NO_x/SO_x secondary review (76 FR 46084, August 1, 2011) focuses on the welfare effects associated with exposures from deposited particulate and gaseous forms of oxides of nitrogen and sulfur and related nitrogen- and sulfur- containing compounds and transformation products on ecosystem receptors, including effects of acidifying deposition associated with particulate nitrogen and sulfur. In addition, the NO_x/SO_x secondary review includes evidence related to direct ecological effects of gas-phase NO_x and SO_x.

1. Climate

Information and conclusions about what is currently known about the role of PM in climate is summarized in Chapter 9 of the Integrated Science Assessment (US EPA, 2009a). The Integrated Science Assessment concludes "that a causal relationship exists between PM and effects on climate,

[179] For the purposes of this discussion, NO_x and SO_x refers to all oxides of nitrogen and all oxides of sulfur, respectively.

including both direct effects on radiative forcing and indirect effects that involve cloud feedbacks that influence precipitation formation and cloud lifetimes" (US EPA, 2009a, section 9.3.10). The Policy Assessment summarizes and synthesizes the policy-relevant science in the Integrated Science Assessment for the purpose of helping to inform consideration of climate aspects in the review of the secondary PM NAAQS (US EPA, 2011a, section 5.2). This discussion is summarized below.

Atmospheric PM (referred to as aerosols[180] in the remainder of this section to be consistent with the Integrated Science Assessment) affects multiple aspects of climate. These include absorbing and scattering of incoming solar radiation, alterations in terrestrial radiation, effects on the hydrological cycle, and changes in cloud properties (US EPA, 2009a, section 9.3.1). Major aerosol components that contribute to climate processes include black carbon (BC), organic carbon (OC), sulfates, nitrates, and mineral dusts. There is a considerable ongoing research effort focused on understanding aerosol contributions to changes in global mean temperature and precipitation patterns. The Climate Change Research Initiative identified research on atmospheric concentrations and effects of aerosols as a high research priority (National Research Council, 2001) and the IPCC 2007 Summary for Policymakers states that anthropogenic contributions to aerosols remain the dominant uncertainty in radiative forcing (IPCC, 2007). The current state of the science of climate alterations attributable to PM is in flux as a result of continually updated information.

Global climate change has increasingly been the focus of intense international research endeavors. As discussed in chapter 5 of the Policy Assessment, major efforts are underway to understand the complexities inherent in atmospheric aerosol interactions and to decrease uncertainties associated with climate estimations.

Aerosols have direct and indirect effects on climate processes. The direct effects of aerosols on climate result mainly from particles scattering light away from Earth into space, directly altering the

[180] In the sections of the Integrated Science Assessment included from IPCC AR4 and CCSP SAP2.3 (US EPA, 2009a, section 9.3), the term "aerosols" is more frequently used than "PM" and that word is retained in the Policy Assessment (US EPA, 2011a, section 5.2) and in this section of the preamble.

radiative balance of the Earth-atmosphere system. This reflection of solar radiation back to space decreases the transmission of visible radiation to the surface of the Earth and results in a decrease in the heating rate of the surface and the lower atmosphere. At the same time, absorption of either incoming solar radiation or outgoing terrestrial radiation by particles, primarily BC, results in an increased heating rate in the lower atmosphere. Global estimates of aerosol direct radiative forcing (RF) were recently summarized using a combined model-based estimate (Forster et al., 2007). The overall, model-derived aerosol direct RF was estimated in the IPCC AR4 as -0.5 (-0.9 to -0.1) watts per square meter (W/m^2), with an overall level of scientific understanding of this effect as "medium low" (Forster et al., 2007), indicating a net cooling effect in contrast to greenhouse gases (GHGs) which have a warming effect.

The contribution of individual aerosol components to total aerosol direct radiative forcing is more uncertain than the global average (US EPA, 2009a, section 9.3.6.6). The direct effect of radiative scattering by atmospheric particles exerts an overall net cooling of the atmosphere, while particle absorption of solar radiation leads to warming. For example, the presence of OC and sulfates decrease warming from sunlight by scattering shortwave radiation back into space. Such a perturbation of incoming radiation by anthropogenic aerosols is designated as aerosol climate forcing, which is distinguished from the aerosol radiative effect of the total aerosol (natural plus anthropogenic). The aerosol climate forcing and radiative effect are characterized by large spatial and temporal heterogeneities due to the wide variety of aerosol sources, the spatial non-uniformity and intermittency of these sources, the short atmospheric lifetime of aerosols (relative to that of the greenhouse gases), and processing (chemical and microphysical) that occurs in the atmosphere. For example, OC can be warming (positive forcer) when deposited on or suspended over a highly reflective surface such as snow or ice but, on a global average, is a negative forcer in the atmosphere.

More information has also become available on indirect effects of aerosols. Particles in the atmosphere indirectly affect both cloud albedo (reflectivity) and cloud lifetime by modifying the cloud amount, and microphysical and radiative properties (US EPA, 2009a, section 9.3.6.4). The RF due to

these indirect effects (cloud albedo effect) of aerosols is estimated in the IPCC AR4 to be -0.7 (-1.8 to -0.3) W/m^2 with the level of scientific understanding of this effect as "low" (Forster et al., 2007). Aerosols act as cloud condensation nuclei (CCN) for cloud formation. Increased particulates in the atmosphere available as CCN with no change in moisture content of the clouds have resulted in an increase in the number and decrease in the size of cloud droplets in certain clouds that can increase the albedo of the clouds (the Twomey effect). Smaller particles slow the onset of precipitation and prolong cloud lifetime. This effect, coupled with changes in cloud albedo, increases the reflection of solar radiation back into space. The altitude of the clouds also affects cloud radiative forcing. Low clouds reflect incoming sunlight back to space but do not effectively trap outgoing radiation, thus cooling the planet, while higher elevation clouds reflect some sunlight but more effectively can trap outgoing radiation and act to warm the planet (US EPA, 2009a, section 9.3.3.5).

The total negative RF due to direct and indirect effects of aerosols computed from the top of the atmosphere, on a global average, is estimated at -1.3 (-2.2 to -0.5) W/m^2 in contrast to the positive RF of +2.9 (+3.2 to +2.6) W/m^2 for anthropogenic GHGs (IPCC 2007, p. 200).

The understanding of the magnitude of aerosol effects on climate has increased substantially in the last decade. Data on the atmospheric transport and deposition of aerosols indicate a significant role for PM components in multiple aspects of climate. Aerosols can impact glaciers, snowpack, regional water supplies, precipitation, and climate patterns (US EPA, 2009a, section 9.3.9). Aerosols deposited on ice or snow can lead to melting and subsequent decrease of surface albedo (US EPA, 2009a, section 9.3.9.2). Aerosols are potentially important agents of climate warming in the Arctic and other locations (US EPA, 2009a, section 9.3.9). Carbonaceous aerosols emitted from intermittent fires can occur at large enough scales to affect hemispheric aerosol concentrations. In addition to incidental fires, routine biomass burning, usually associated with agriculture in eastern Europe, has also been shown to contribute to hemispheric concentrations of carbonaceous aerosols and is therefore recognized as having a significant impact on $PM_{2.5}$ concentrations and climate forcing (US EPA, 2009a, section 9.3.7).

A series of studies available since the last review examines the role of aerosols on local and regional scale climate processes (US EPA, 2009a, section 9.3.9.3). Studies on the South Coast Air Basin (SCAB) in California indicate aerosols may reduce near-surface wind speeds, which, in turn reduce evaporation rates and increase cloud lifetimes. The overall impact can be a reduction in local precipitation (Jacobson and Kaufmann, 2006). Conditions in the SCAB impact ecologically sensitive areas including the Sierra Nevadas. Precipitation suppression due to aerosols in California (Givati and Rosenfield, 2004) and other similar studies in Utah and Colorado found that mountain precipitation decreased by 15 to 30 percent downwind of pollution sources. Evidence of regional-scale impacts of aerosols on meteorological conditions in other regions of the U.S. is lacking.

Advances in the understanding of aerosol components and how they contribute to climate change have enabled refined global forcing estimates of individual PM constituents. The global mean radiative effect from individual components of aerosols was estimated for the first time in the IPCC AR4 where they were reported to be (all in W/m^2 units): -0.4 ($\pm$0.2) for sulfate, -0.05 ($\pm$0.05) for fossil fuel-derived OC, +0.2 (+0.15) for fossil fuel derived BC, +0.03 ($\pm$0.12) for biomass burning, -0.1 ($\pm$0.1) for nitrates, and -0.1 ($\pm$0.2) for mineral dust (US EPA, 2009a, section 9.3.10). Sulfate and fossil fuel-derived OC cause negative forcing whereas BC causes positive forcing because of its highly absorbing nature (US EPA, 2009a, 9.3.6.3). Although BC comprises only a small fraction of anthropogenic aerosol mass load and aerosol optical depth (AOD), its forcing efficiency (with respect to either AOD or mass) is an order of magnitude stronger than sulfate and particulate organic matter (POM), so its positive shortwave forcing largely offsets the negative direct forcing from sulfate and POM (IPCC, 2007; US EPA, 2009a, 9.3.6.3). Global loadings for nitrates and anthropogenic dust remain very difficult to estimate, making the radiative forcing estimates for these constituents particularly uncertain (US EPA, 2009a, section 9.3.7).

Improved estimates of anthropogenic emissions of some aerosols, especially BC and OC, have promoted the development of improved global emissions inventories and source-specific emissions

factors useful in climate modeling (Bond et al. 2004). Recent data suggests that BC is one of the largest individual warming agents after carbon dioxide (CO_2) and perhaps methane (CH_4) (Jacobson 2000; Sato et al., 2003; Bond and Sun 2005). There are several studies modeling BC effects on climate and/or considering emission reduction measures on anthropogenic warming detailed in section 9.3.9 of the Integrated Science Assessment. In the U.S., most of the warming aerosols are emitted by biomass burning and internal engine combustion and much of the cooling aerosols are formed in the atmosphere by oxidation of SO_2 or volatile organic compounds (VOCs) (US EPA, 2009a, section 3.3). Fires release large amounts of BC, CO_2, CH_4 and OC (US EPA, 2009a, section 9.3.7).

Based on the above newly available scientific information on climate-aerosol relationships, the Policy Assessment concludes that aerosols alter climate processes directly through radiative forcing and by indirect effects on cloud brightness, changes in precipitation, and possible changes in cloud lifetimes (US EPA, 2011a, p. 5-10). Further, the Policy Assessment notes that the major aerosol components that contribute to climate processes (i.e. BC, OC, sulfate, nitrate and mineral dusts) vary in their reflectivity, forcing efficiencies and even in the direction of climate forcing, though there is an overall net climate cooling associated with aerosols in the global atmosphere (US EPA, 2009a, section 9.2.10). In light of this information, the Policy Assessment considered the appropriateness of the current secondary standards defined in terms of $PM_{2.5}$ and PM_{10} indicators, for providing protection against potential climate effects of aerosols. The current standards that are defined in terms of aggregate size mass cannot be expected to appropriately target controls on components of fine and coarse particles that are related to climate forcing effects. Thus, the Policy Assessment concludes that the current mass-based $PM_{2.5}$ and PM_{10} secondary standards are not an appropriate or effective means of focusing protection against PM-associated climate effects due to these differences in components (US EPA, 2011a, p. 5-11).

Further, in light of the uncertainties associated with the spatial and temporal heterogeneity of PM components that contribute to climate forcing and the uncertainties associated with measurement of aerosol components, the inadequate consideration of aerosol impacts in climate modeling and the

insufficient data on local and regional microclimate variations and the heterogeneity of cloud formations, the Policy Assessment concludes it is not currently feasible to conduct a quantitative analysis for the purpose of informing revisions of the current secondary PM standards based on climate (US EPA, 2011a, p. 5-11). Based on these considerations, the Policy Assessment concludes that there is insufficient information at this time to base a national ambient standard on climate impacts associated with current ambient concentrations of PM or its constituents (US EPA, 2011a, p. 5-11, -12).[181]

2. Ecological Effects

Information on what is currently known about ecological effects of PM is summarized in Chapter 9 of the Integrated Science Assessment (US EPA, 2009a). Four main categories of ecological effects are identified in the Integrated Science Assessment: direct effects, effects of PM-altered radiative flux, indirect effects of trace metals, and indirect effects of organics. Exposure to PM for direct effects occurs via deposition (e.g., wet, dry or occult) to vegetation surfaces, while indirect effects occur via deposition to ecosystem soils or surface waters where the deposited constituents of PM then interact with biological organisms. Both fine and coarse-mode particles may affect plants and other organisms; however, PM size classes do not necessarily relate to ecological effects (U.S. EPA, 1996). More often, the chemical constituents drive the ecosystem response to PM (Grantz et al., 2003). The trace metal constituents of PM considered in the ecological effects section of the Integrated Science Assessment are cadmium (Cd), copper (Cu), chromium (Cr), mercury (Hg), nickel (Ni) and zinc (Zn). Ecological effects of lead (Pb) in particulate form are covered in the Air Quality Criteria Document for Lead (US EPA, 2006). The organics included in the ecological effects section of the PM Integrated Science Assessment are persistent organic pollutants (POPs), polyaromatic hydrocarbons (PAHs), and polybromiated diphenyl ethers (PBDEs).

Ecological effects of PM include direct effects to metabolic processes of plant foliage;

[181] This conclusion would apply for both the secondary (welfare-based) and the primary (health-based) standards.

contribution to total metal loading resulting in alteration of soil biogeochemistry and microbiology, and plant and animal growth and reproduction; and contribution to total organics loading resulting in bioaccumulation and biomagnification across trophic levels.

The Integrated Science Assessment states that overall, ecological evidence is sufficient to conclude that a causal relationship is likely to exist between deposition of PM and a variety of effects on individual organisms and ecosystems based on information from the previous review and limited new findings in this review (US EPA, 2009a, sections 2.5.3 and 9.4.7). However the Integrated Science Assessment also finds, in many cases, it is difficult to characterize the nature and magnitude of effects and to quantify relationships between ambient concentrations of PM and ecosystem response due to significant data gaps and uncertainties as well as considerable variability that exists in the components of PM and their various ecological effects.

Ecological effects of PM must then be evaluated to determine if they are known or anticipated to have an adverse impact on public welfare. Characterizing a known or anticipated adverse effect to public welfare is an important component of developing any secondary NAAQS. The most recent secondary NAAQS reviews have assessed changes in ecosystem structure or processes using a weight-of-evidence approach that uses both quantitative and qualitative data. A paradigm useful in evaluating ecological adversity is the concept of ecosystem services. Ecosystem services consist of the varied and numerous ways that ecosystems are important to human welfare. Ecosystems provide many goods and services that are of vital importance for the functioning of the biosphere and provide the basis for the delivery of tangible benefits to human society. An EPA initiative to consider how ecosystem structure and function can be interpreted through an ecosystem services approach has resulted in the inclusion of ecosystem services in the NOx/SOx Risk and Exposure Assessment (US EPA, 2009h). The Millennium Ecosystem Assessment (MEA) defines these to include supporting, provisioning, regulating, and cultural services (Hassan et al., 2005).

An important consideration in evaluating biologically adverse effects of PM and linkages to

ecosystem services is that many of the MEA categories overlap and any one pollutant may impact multiple services. For example, deposited PM may alter the composition of soil-associated microbial communities, which may affect supporting services such as nutrient cycling. Changes in available soil nutrients could result in alterations to provisioning services such as timber yield and regulating services such as climate regulation. If enough information is available, these alterations can be quantified based upon economic approaches for estimating the value of ecosystem services. Valuation may be important from a policy perspective because it can be used to compare the benefits of altering versus maintaining an ecosystem. Knowledge about the relationships linking ambient concentrations and ecosystem services can be used to inform a policy judgment on a known or anticipated adverse public welfare effect.

The Policy Assessment seeks to build upon and focus this body of science using the concept of ecosystem services to qualitatively evaluate linkages between biologically adverse effects and particulate deposition. This approach is similar to that taken in the NO_x/SO_x Risk and Exposure Assessment in which the relationship between air quality indicators, deposition of nitrogen and sulfur, ecologically relevant indicators, and effects on sensitive receptors are linked to changes in ecosystem structure and services (US EPA, 2009h). This approach considers the benefits received from the resources and processes that are supplied by ecosystems. Several ecosystem components (e.g., plants, soils, water, and wildlife) are impacted by PM air pollution, which may alter the services provided by the ecosystems in question. Key scientific evidence regarding PM effects on plants, soil and nutrient cycling, wildlife, and water available since the last review is summarized below to evaluate how this information has improved understanding of ecosystem responses to PM.

a. Plants

As primary producers, plants play a pivotal role in energy flow through ecosystems. Ecosystem services derived from plants include all of the categories (supporting, provisioning, regulating, and cultural) identified in the MEA (Hassan et al., 2005). Vegetation supports other ecosystem processes by cycling nutrients through food webs and serving as a source of organic material for soil formation and

enrichment. Trees and plants provide food, wood, fiber, and fuel for human consumption. Flora help to regulate climate by sequestering CO_2, and control flooding by stabilizing soils and cycling water via uptake and evapotranspiration. Plants are significant in aesthetic, spiritual, and recreational aspects of human interactions.

Particulate matter can adversely impact plants and ecosystem services provided by plants by deposition to vegetative surfaces (US EPA, 2009a, section 9.4.3). Particulates deposited on the surfaces of leaves and needles can block light, altering the radiation received by the plant. PM deposition can obstruct stomata limiting gas exchange, damage leaf cuticles, and increase plant temperatures. This level of PM accumulation is typically observed near sources of heavy deposition such as smelters and mining operations (US EPA, 2009a, section 9.4.3). Plants growing on roadsides exhibit impact damage from near-road PM deposition, having higher levels of organics and heavy metals, and accumulate salt from road de-icing during winter months (US EPA, 2009a, sections 9.4.3.1 and 9.4.5.7).

In addition to damage to plant surfaces, deposited PM can be taken up by plants from soil or foliage. The ability of vegetation to take up heavy metals and organics is dependent upon the amount, solubility, and chemical composition of the deposited PM. Uptake of PM by plants from soils and vegetative surfaces can disrupt photosynthesis, alter pigments and mineral content, reduce plant vigor, decrease frost hardiness, and impair root development. The Integrated Science Assessment indicates that there are little or no effects on foliar processes at ambient levels of PM (US EPA, 2009a, sections 9.4.3 and 9.4.7). However, damage due to atmospheric pollution can occur near individual point sources or under conditions where plants are subjected to multiple stressors.

Although all heavy metals can be directly toxic at sufficiently high concentrations, only Cu, Ni, and Zn have been documented as being frequently toxic to plants (U.S. EPA, 2004), while toxicity due to Cd, Co, and Pb has been observed less frequently (Smith, 1990; US EPA, 2009a, section 9.4.5.3). In general, plant growth is negatively correlated with trace metal and heavy metal concentration in soils and plant tissue (Audet and Charest, 2007). Trace metals, particularly heavy metals, can influence forest

growth. Growth suppression of foliar microflora has been shown to result from iron (Fe), aluminum (Al), and Zn. These three metals can also inhibit fungal spore formation, as can Cd, Cr, magnesium (Mg), and Ni (see Smith, 1990). Metals cause stress and decreased photosynthesis (Kucera et al., 2008) and disrupt numerous enzymes and metabolic pathways (Strydom et al., 2006). Excessive concentrations of metals result in phytotoxicity.

New information since the last review provides additional evidence of plant uptake of organics (US EPA, 2009a, section 9.4.6). An area of active study is the impact of PAHs on provisioning ecosystem services due to the potential for human and other animal exposure via food consumption (US EPA, 2009a, section 9.4.6 page 9-190). The uptake of PAHs depends on the plant species, site of deposition, physical and chemical properties of the organic compound, and prevailing environmental conditions. It has been established that most bioaccumulation of PAHs by plants occurs via leaf uptake, and to a lesser extent, through roots. Differences between species in uptake of PAHs confound attempts to quantify impacts to ecosystem provisioning services.

Plants as ecosystem regulators can serve as passive monitors of pollution (US EPA, 2009a, section 9.4.2.3). Lichens and mosses are sensitive to pollutants associated with PM and have been used with limited success to show spatial and temporal patterns of atmospheric deposition of metals (US EPA, 2009a, section 9.4.2.3). A limitation to employing mosses and lichens to detect for the presence of air pollutants is the difference in uptake efficiencies of metals between species. Thus, quantification of ecological effects is not possible due to the variability of species responses (US EPA, 2009a, section 9.4.2.3).

A potentially important regulating ecosystem service of plants is their capacity to sequester contaminants (US EPA, 2009a, section 9.4.5.3). Ongoing research on the application of plants to environmental remediation efforts are yielding some success in removing heavy metals and organics from contaminated sites (phytoremediation) with tolerant plants such as the willow tree (Salix spp.) and members of the family Brassicaceae (US EPA, 2009a, section 9.4.5.3). Tree canopies can be used in

urban locations to capture particulates and improve air quality (Freer-Smith et al., 2004). Plant foliage is a sink for Hg and other metals and this regulating ecosystem service may be impacted by atmospheric deposition of trace metals.

An ecological endpoint (phytochelatin concentration) associated with presence of metals in the environment has been correlated with the ecological effect of tree mortality (Grantz et al., 2003). Metal stress may be contributing to tree injury and forest decline in the Northeastern U.S. where red spruce populations are declining with increasing elevation. Quantitative assessment of PM damage to forests potentially could be conducted by overlaying PM sampling data and elevated phytochelatin levels. However, limited data on phytochelatin levels in other species currently hinders use of this peptide as a general biomarker for PM.

The presence of PM in the atmosphere affects ambient radiation as discussed in the Integrated Science Assessment which can impact the amount of sunlight received by plants (US EPA, 2009a, section 9.4.4). Atmospheric PM can change the radiation reaching leaf surfaces through attenuation and by converting direct radiation to diffuse radiation. Diffuse radiation is more uniformly distributed in a tree canopy, allowing radiation to reach lower leaves. The net effect of PM on photosynthesis depends on the reduction of photosynthetically active radiation (PAR) and the increase in the diffuse fraction of PAR. Decreases in crop yields (provisioning ecosystem service) have been attributed to regional scale air pollution, however, global models suggest that the diffuse light fraction of PAR can increase growth (US EPA, 2009a, section 9.4.4).

b. Soil and Nutrient Cycling

Many of the major indirect plant responses to PM deposition are chiefly soil-mediated and depend on the chemical composition of individual components of deposited PM. Major ecosystem services impacted by PM deposition to soils include support services such as nutrient cycling, products such as crops and regulating flooding and water quality. Upon entering the soil environment, PM pollutants can alter ecological processes of energy flow and nutrient cycling, inhibit nutrient uptake to

plants, change microbial community structure and, affect biodiversity. Accumulation of heavy metals in soils depends on factors such as local soil characteristics, geologic origin of parent soils, and metal bioavailability. It can be difficult to assess the extent to which observed heavy metal concentrations in soil are of anthropogenic origin (US EPA, 2009a, section 9.4.5.1). Trace element concentrations are higher in some soils that are remote from air pollution sources due to parent material and local geomorphology.

Heavy metals such as Zn, Cu, and Cd and some pesticides can interfere with microorganisms that are responsible for decomposition of soil litter, an important regulating ecosystem service that serves as a source of soil nutrients (US EPA, 2009a, sections 9.4.5.1 and 9.4.5.2). Surface litter decomposition is reduced in soils having high metal concentrations. Soil communities have associated bacteria, fungi, and invertebrates that are essential to soil nutrient cycling processes. Changes to the relative species abundance and community composition can be quantified to measure impacts of deposited PM to soil biota. A mutualistic relationship exists in the rhizophere (plant root zone) between plant roots, fungi, and microbes. Fungi in association with plant roots form mycorrhizae that are essential for nutrient uptake by plants. The role of mychorrizal fungi in plant uptake of metals from soils and effects of deposited PM on soil microbes is discussed in section 9.4.5.2 of the Integrated Science Assessment.

c. Wildlife

Animals play a significant role in ecosystem function including nutrient cycling and crop production (supporting ecosystem service), and as a source of food (provisioning ecosystem service). Cultural ecosystem services provided by wildlife include bird and animal watching, hunting, and fishing. Impacts on these services are dependent upon the bioavailability of deposited metals and organics and their respective toxicities to ecosystem receptors. Pathways of PM exposure to fauna include ingestion, absorption and trophic transfer. Bioindicator species (known as sentinel organisms) can provide evidence of contamination due to atmospheric pollutants. Use of sentinel species can be of particular

value because chemical constituents of deposited PM are difficult to characterize and have varying bioavailability (US EPA, 2009a, section 9.4.5.5). Snails readily bioaccumulate contaminants such as PAHs and trace metals. These organisms have been deployed as biomonitors for urban pollution and have quantifiable biomarkers of exposure including growth inhibition, impairment of reproduction, peroxidomal proliferation, and induction of metal detoxifying proteins (metallothioneins) (Gomet-de Vaufleury, 2002; Regoli, et. al, 2006). Earthworms have also been used as sensitive indicators of soil metal contamination.

Evidence of deposited PM effects on animals is limited (US EPA, 2009a, section 9.4.5.5). Trophic transfer of pollutants of atmospheric origin has been demonstrated in limited studies. PM may also be transferred between aquatic and terrestrial compartments. There is limited evidence for biomagnifications of heavy metals up the food chain except for Hg which is well known to move readily through environmental compartments (US EPA, 2009a, section 9.4.5.6). Bioconcentration of POPs and PBDEs in the Arctic and deep-water oceanic food webs indicates the global transport of particle-associated organics (US EPA, 2009a, section 9.4.6). Salmon migrations are contributing to metal accumulation in inland aquatic systems, potentially impacting the provisioning and cultural ecosystem service of fishing (US EPA, 2009a, section 9.4.6). Stable isotope analysis can be applied to establish linkages between PM exposure and impacts to food webs however, the use of this evaluation tool is limited for this ecological endpoint due to the complexity of most trophic interactions (US EPA, 2009a, section 9.4.5.6). Foraging cattle have been used to assess atmospheric deposition and subsequent bioaccumulation of Hg and trace metals and their impacts on provisioning services (US EPA, 2009a, section 9.4.2.3).

d. Water

New limited information on impacts of deposited PM on receiving water bodies indicate that the ecosystem services of primary production, provision of fresh water, regulation of climate and floods, recreational fishing and water purification are adversely impacted by atmospheric inputs of metals and

organics (US EPA, 2009a, sections 9.4.2.3 and 9.4.5.4). Deposition of PM to surfaces in urban settings increases the metal and organic component of storm water runoff (US EPA, 2009a, sections 9.4.2.3). This atmospherically-associated pollutant burden can then be toxic to aquatic biota.

Atmospheric deposition can be the primary source of some organics and metals to watersheds. The contribution of atmospherically deposited PAHs to aquatic food webs was demonstrated in high elevation mountain lakes with no other anthropogenic contaminant sources (US EPA, 2009a, section 9.4.6). Metals associated with PM deposition limit phytoplankton growth, impacting aquatic trophic structure. Long-range atmospheric transport of 47 pesticides and degradation products to the snowpack in seven national parks in the Western U.S. was recently quantified indicating PM-associated contaminant inputs to receiving waters during spring snowmelt (Hageman et al., 2006).

The recently completed Western Airborne Contaminants Assessment Project (WACAP) is the most comprehensive database on contaminant transport and PM depositional effects on sensitive ecosystems in the U.S. In this project, the transport, fate, and ecological impacts of anthropogenic contaminants from atmospheric sources were assessed from 2002 to 2007 in seven ecosystem components (air, snow, water, sediment, lichen, conifer needles and fish) in eight core national parks (Landers et al., 2008). The goals of the study were to identify where the pollutants were accumulating, identify ecological indicators for those pollutants causing ecological harm, and to determine the source of the air masses most likely to have transported the contaminants to the parks (US EPA, 2009a, section 9.4.6). The study concluded that bioaccumulation of semi-volatile organic compounds was observed throughout park ecosystems (Landers et al., 2008). Findings from this study included the observation of an elevational gradient in PM deposition with greater accumulation at higher altitude areas of the parks. Furthermore, specific ecological indicators were identified in the WACAP that can be useful in assessing contamination on larger spatial scales.

In the WACAP study, bioaccumulation and biomagnification of airborne contaminants were demonstrated on a regional scale in remote ecosystems in the Western United States. Contaminants were

shown to accumulate geographically based on proximity to individual sources or source areas, primarily agriculture and industry (Landers et al., 2008). Although this assessment focuses on chemical species that are components of PM, it does not specifically assess the effects of particulates versus gas-phase forms; therefore, in most cases it is difficult to apply the results to this assessment based on particulate concentration and size fraction (US EPA, 2009a, section 9.4.6). There is a need for ecological modeling of PM components in different environmental compartments to further elucidate links between PM and ecological indicators.

Europe and other countries are using the critical load approach to assess pollutant effects at the level of the ecosystem. This type of assessment requires site-specific data and information on individual species responses to PM. In respect to trace metals and organics, there are insufficient data for the vast majority of U.S. ecosystems to calculate critical loads. However, a methodology is being presented in the NOx/SOx Secondary Risk and Exposure Assessment (US EPA, 2010h) to calculate atmospheric concentrations from deposition that may be applicable to other environmental contaminants.

e. Effects Associated with Ambient PM Concentrations

As reviewed above, there is considerable data on impacts of PM on ecological receptors, but few studies that link ambient PM concentrations to observed effect. This is due, in part, to the nature, deposition, transport and fate of PM in ecosystems. PM is not a single pollutant, but a heterogeneous mixture of particles differing in size, origin and chemical composition (US EPA, 2009a, section 9.4.1). The heterogeneity of PM exists not only within individual particles or samples from individual sites, but to even a greater extent, between samples from different sites. Since vegetation and other ecosystem components are affected more by particulate chemistry than size fraction, exposure to a given mass concentration of airborne PM may lead to widely differing plant or ecosystem responses, depending on the particular mix of deposited particles. Many of the PM components bioaccumulate over time in organisms or plants making correlations to ambient concentrations of PM difficult.

Bioindicator organisms demonstrated biological effects including growth inhibition,

metallothionein induction and reproductive impairment when exposed to complex mixtures of ambient air pollutants (US EPA, 2009a, section 9.4.5.5). Other studies quantify uptake of metals and organics by plants or animals. However, due to the difficulty in correlating individual PM components to a specific physiological response, these studies are limited. Furthermore, there may be differences in uptake between species such as differing responses to metal uptake observed in mosses and lichens (US EPA, 2009a, section 9.4.2.3). PM may also biomagnify across trophic levels confounding efforts to link atmospheric concentrations to physiological endpoints (US EPA, 2009a, section 9.4.5.6).

Evidence of PM effects that are linked to a specific ecological endpoint can be observed when ambient levels are exceeded. Most direct ecosystem effects associated with particulate pollution occur in severely polluted areas near industrial point sources (quarries, cement kilns, metal smelting) (US EPA, 2009a, sections 9.4.3 and 9.4.5.7). Extensive research on biota near point sources provide some of the best evidence of ecosystem function impacts and demonstrates that deposited PM has the potential to alter species composition over long time scales. The Integrated Science Assessment indicates at 4 km distance, species composition of vegetation, insects, birds, and soil microbiota changed, and within 1 km only the most resistant organisms were surviving (US EPA, 2009a, section 9.4.5.7).

f. Conclusions in the Policy Assessment

Based on the above discussions, the Policy Assessment made the following observations:

1) A number of significant environmental effects that either have already occurred or are currently occurring are linked to deposition of chemical constituents found in ambient PM.

2) Ecosystem services can be adversely impacted by PM in the environment, including supporting, provisioning, regulating and cultural services.

3) The lack of sufficient information to relate specific ambient concentrations of particulate metals and organics to a degree of impairment of a specific ecological endpoint hinders the identification of a range of appropriate indicators, levels, forms and averaging times of a distinct secondary standard to protect against associated effects.

4) Data from regionally-based ecological studies can be used to establish probable local, regional and/or global sources of deposited PM components and their concurrent effects on ecological receptors.

Taking into consideration the responses to specific questions regarding the adequacy of the current secondary PM standards for ecological effects, the Policy Assessment concludes that the available information is insufficient to assess the adequacy of the protection for ecosystems afforded by the current suite of PM secondary standards (US EPA, 2011a, p. 5-24). Ecosystem effects linked to PM are difficult to determine because the changes may not be observed until pollutant deposition has occurred for many decades. Because the high levels necessary to cause injury occur only near a few limited point sources and/or on a very local scale, protection against these effects alone may not provide sufficient basis for considering a separate secondary NAAQS based on the ecological effects of particulate metals and organics. Data on ecological responses clearly linked with atmospheric PM is not abundant enough to perform a quantitative analysis although the WACAP study may represent an opportunity for quantification at a regional scale. The Policy Assessment further concludes that available evidence is not sufficient for establishing a distinct national standard for ambient PM based on ecosystem effects of particulates not addressed in the NO_x/SO_x secondary review (e.g., metals, organics) (US EPA, 2011a, p. 5-24).

The Policy Assessment considered the appropriateness of continuing to use the $PM_{2.5}$ and PM_{10} size fractions as the indicators for protection of ecological effects of PM. The chemical constitution of individual particles can be strongly correlated with size, and the relationship between particle size and particle composition can be quite complex, making it difficult in most cases to use particle size as a surrogate for chemistry. At this time it remains to be determined as to what extent PM secondary standards focused on a given size fraction would result in reductions of the ecologically relevant constituents of PM for any given area. Nonetheless, in the absence of information that provides a basis for specific standards in terms of particle composition, the Policy Assessment concludes that observations continue to support retaining an appropriate degree of control on both fine and coarse particles to help address effects to ecosystems and ecosystem components associated with PM (US EPA, 2011a, p. 5-24).

3. Materials Damage

Welfare effects on materials associated with deposition of PM include both physical damage (materials damage effects) and impaired aesthetic qualities (soiling effects). Because the effects of PM are exacerbated by the presence of acidic gases and can be additive or synergistic due to the complex mixture of pollutants in the air and surface characteristics of the material, this discussion will also include those particles and gases that are associated with the presence of ambient oxides of nitrogen and oxides of sulfur, as well as reduced forms of nitrogen (such as ammonia and ammonium ions) for completeness. Building upon the information presented in the last PM Staff Paper (US EPA, 2005), and including the limited new information presented in Chapter 9 of the PM Integrated Science Assessment (US EPA, 2009a) and *Annex E. Effects of NO_y, NH_x, and SO_x on Structures and Materials of the Integrated Science Assessment for Oxides of Nitrogen and Sulfur-Ecological Criteria* (US EPA, 2008c) the following sections consider the policy-relevant aspects of physical damage and aesthetic soiling effects of PM on materials including metal and stone.

The Integrated Science Assessment concludes that evidence is sufficient to support a causal relationship between PM and effects on materials (US 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 (US EPA, 2009a, section 9.5). Particles contribute to these physical effects because of their electrolytic, hygroscopic and acidic properties, and their ability to sorb corrosive gases (principally sulfur dioxide). In addition, the deposition of ambient PM can reduce the aesthetic appeal of buildings and objects through soiling. Particles consisting primarily of carbonaceous compounds cause soiling of commonly used building materials and culturally important items such as statues and works of art. Soiling is the deposition of particles on surfaces by impingement, and the accumulation of particles on the surface of an exposed material that results in degradation of its appearance (US EPA, 2009a, section 9.5). Soiling can be

remedied by cleaning or washing, and depending on the soiled material, repainting.

The majority of available new studies on materials effects of PM are from outside the U.S., however, they provide limited new data for consideration of the secondary standard.

Metal and stone are also susceptible to damage by ambient PM. Considerable research has been conducted on the effects of air pollutants on metal surfaces due to the economic importance of these materials, especially steel, Zn, Al, and Cu. Chapter 9 of the PM Integrated Science Assessment and Annex E of the NO_x/SO_x Integrated Science Assessment summarize the results of a number of studies on the corrosion of metals (US EPA, 2009a; US EPA, 2008c). Moisture is the single greatest factor promoting metal corrosion, however, deposited PM can have additive, antagonistic or synergistic effects. In general, sulfur dioxide is more corrosive than oxides of nitrogen although mixtures of oxides of nitrogen, sulfur dioxide and other particulate matter corrode some metals at a faster rate than either pollutant alone (US EPA, 2008c, Annex E.5.2). Information from both the PM Integrated Science Assessment and NO_x/SO_x Integrated Science Assessment suggest that the extent of damage to metals due to ambient PM is variable and dependent upon the type of metal, prevailing environmental conditions, rate of natural weathering and presence or absence of other pollutants.

The PM Integrated Science Assessment and NO_x/SO_x Integrated Science Assessment summarize the results of a number of studies on PM and stone surfaces. While it is clear from the available information that gaseous air pollutants, in particular sulfur dioxide, will promote the deterioration of some types of stones under specific conditions, carbonaceous particles (non-carbonate carbon) and particles containing metal oxides may help to promote the decay process. Studies on metal and stone summarized in the Integrated Science Assessment do not show an association between particle size, chemical composition and frequency of repair.

A limited number of new studies available on materials damage effects of PM since the last review consider the relationship between pollutants and biodeterioration of structures associated with microbial communities that colonize monuments and buildings (US EPA, 2009a, section 9.5). Presence

of air pollutants may synergistically enhance microbial deterioration processes. The role of heterotrophic bacteria, fungi and cyanobacteria in biodeterioration varied by local meterological conditions and pollutant components.

Particulate matter deposition onto surfaces such as metal, glass, stone and paint can lead to soiling. Soiling results when PM accumulates on an object and alters the optical characteristics (appearance). The reflectivity of a surface may be changed or presence of particulates may alter light transmission. These effects can impact the aesthetic value of a structure or result in reversible or irreversible damage to statues, artwork and architecturally or culturally significant buildings. Due to soiling of building surfaces by PM, the frequency and duration of cleaning may be increased. Soiling affects the aesthetic appeal of painted surfaces. In addition to natural factors, exposure to PM may give painted surfaces a dirty appearance. Pigments in works of art can be degraded or discolored by atmospheric pollutants, especially sulfates (US EPA, 2008c, Annex E-15).

Formation of black crusts due to carbonaceous compounds and buildup of microbial biofilms results in discoloration of surfaces. Black crust includes a carbonate component derived from building material and OC and EC. In limited new studies quantifying the organic carbon and elemental contribution to soiling by black crust, organic carbon predominated over elemental carbon at almost all locations (Bonazza et al., 2005). Limited new studies suggest that traffic is the major source of carbon associated with black crust formation (Putaud et al., 2004) and that soiling of structures in Oxford, UK showed a relationship with traffic and nitrogen dioxide concentrations (Viles and Gorbushina, 2003). These findings attempt to link atmospheric concentrations of PM to observed damage. However, no data on rates of damage are available and all studies were conducted outside of the U.S.

Based on the above discussion, the Policy Assessment makes the following observations:

1) Materials damage and soiling that occur through natural weathering processes are enhanced by exposure to atmospheric pollutants, most notably sulfur dioxide and particulate sulfates.
2) While ambient particles play a role in the corrosion of metals and in the weathering of materials, no quantitative relationships between ambient particle concentrations and rates of damage have

been established.

3) While soiling associated with fine and course particles can result in increased cleaning frequency and repainting of surfaces, no quantitative relationships between particle characteristics and the frequency of cleaning or repainting have been established.

4) Limited new data on the role of microbial colonizers in biodeterioration processes and contributions of black crust to soiling are not sufficient for quantitative analysis.

5) While several studies in the PM Integrated Science Assessment and NO_x/SO_x Integrated Science Assessment suggest that particles can promote corrosion of metals there remains insufficient evidence to relate corrosive effects to specific particulate levels or to establish a quantitative relationship between ambient PM and metal degradation. With respect to damage to calcareous stone, numerous studies suggest that wet or dry deposition of particles and dry deposition of gypsum particles can enhance natural weathering processes.

Revisiting the overarching policy question as to whether the available scientific evidence supports or calls into question the adequacy of the protection for materials afforded by the current suite of secondary PM standards, the Policy Assessment concludes that no new evidence in this review calls into question the adequacy of the protection for materials afforded by the current standard (US EPA, 2011a, p. 5-29). PM effects on materials can play no quantitative role in considering whether any revisions of the secondary PM NAAQS are appropriate at this time. Nonetheless, in the absence of information that provides a basis for establishing a different level of control, the Policy Assessment concludes that observations continue to support retaining an appropriate degree of control on both fine and coarse particles to help address materials damage and soiling associated with PM (US EPA, 2011a, p. 5-29).

4. CASAC Advice

Regarding the other non-visibility welfare effects, CASAC stated that it "concurs with the Policy Assessment's conclusions that while these effects are important, and should be the focus of future research efforts, there is not currently a strong technical basis to support revisions of the current standards to protect against these other welfare effects" (Samet, 2010c). More specifically, with regard to climate impacts, CASAC concludes that while there is insufficient information on which to base a national standard, the causal relationship is established and the risk of impacts is high, so further

research on a regional basis is urgently needed (Samet, 2010c, p. 5). CASAC also notes that reducing certain aerosol components could lead to increased radiative forcing and regional climate warming while having a beneficial effect on PM-related visibility. As a consequence, CASAC notes that a secondary standard directed toward reducing PM-related visibility impairment has the potential to be accompanied by regional warming if light scattering aerosols are preferentially targeted.

With regard to ecological effects, CASAC concludes that the published literature is insufficient to support a national standard for PM effects on ecosystem services (Samet, 2010c, p.23). CASAC notes that the best-established effects are related to particles containing nitrogen and sulfur, which are being considered in the EPA's ongoing review of the secondary NAAQS for NO_x/SO_x. With regard to PM-related effects on materials, CASAC concludes that the published literature, including literature published since the last review, is insufficient either to call into question the current level of the standard or to support any specific national standard for PM effects on materials (Samet, 2010c, p.23). Nonetheless, with regard to both types of effects, CASAC notes the importance of maintaining an appropriate degree of control of both fine and coarse particles to address such effects, even in the current absence of sufficient information to develop a standard.

5. Administrator's Proposed Conclusions on Secondary Standards for Other PM-related Welfare Effects

Based on the above considerations and the advice of CASAC, the Administrator provisionally concludes that it is not appropriate to establish any distinct secondary PM standards to address other non-visibility PM-related welfare effects. Nonetheless, the Administrator concurs with the conclusions of the Policy Assessment and CASAC advice that it is important to maintain an appropriate degree of control of both fine and coarse particles to address such effects, including ecological effects, effects on materials, and climate impacts. In the absence of information that would support any different standards,

the Administrator proposes generally to retain the current suite of secondary PM standards[182] to address non-visibility welfare effects. These secondary standards were set identical to the primary PM standards in the last review. More specifically, the Administrator proposes to retain all aspects of the current 24-hour $PM_{2.5}$ and PM_{10} standards. With regard to the secondary annual $PM_{2.5}$ standard, the Administrator proposes to retain the level of the current standard and to revise the form of the standard by removing the option for spatial averaging for the reasons discussed below in section VII.A. 2. In so doing, she notes that no areas in the country are currently using the option for spatial averaging to demonstrate attainment with the secondary annual $PM_{2.5}$ standard.

F. Administrator's Proposed Decisions on Secondary PM Standards

With regard to the secondary PM standards, the Administrator proposes to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment, focused primarily on visibility in urban areas. This distinct secondary standard is defined in terms of a calculated $PM_{2.5}$ light extinction indicator, translated into the deciview scale, which is referred to as a $PM_{2.5}$ visibility index; a 24-hour averaging time; a 90th percentile form, averaged over 3 years; and a level set at one of two options – either 30 dv or 28 dv. The Administrator solicits comment on a range of levels for such a standard down to 25 dv, as well as on alternative standards to address PM-related visibility impairment, including a sub-daily averaging time (e.g., 4 hours) and associated alternative levels in the range of 30 to 25 dv. To address other non-visibility welfare effects, the Administrator proposes to revise the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging and to retain all other elements of the current suite of secondary PM standards.

VII. Interpretation of the NAAQS for PM

With regard to the NAAQS for $PM_{2.5}$, this section discusses EPA's proposed revisions to the data handling procedures in 40 CFR part 50, appendix N, for the proposed primary and secondary annual and

[182] As summarized in section VI.A and Table 1 above, the current suite of secondary PM standards includes annual and 24-hour $PM_{2.5}$ standards and a 24-hour PM_{10} standard.

24-hour standards for $PM_{2.5}$ (referred to as $PM_{2.5}$ standards) and for the proposed distinct secondary standard for $PM_{2.5}$ to address PM-related visibility impairment (referred to as the $PM_{2.5}$ visibility index standard).[183] Appendix N describes the computations necessary for determining when these standards are met and also addresses which measurement data are appropriate for comparison to the proposed standards, as well as data reporting protocols, data completeness criteria, and rounding conventions.

As discussed in sections III and VI above, the EPA is proposing to: (1) revise the form and level of the primary annual $PM_{2.5}$ standard, and retain the current primary 24-hour $PM_{2.5}$ standard (section III.F); (2) retain the current secondary 24-hour $PM_{2.5}$ standard, and revise the form and retain the level of the secondary annual $PM_{2.5}$ standard for non-visibility-related welfare protection (section VI.F); and (3) establish a distinct secondary $PM_{2.5}$ visibility index standard (section VI.F). The EPA proposes to revise appendix N to conform to the proposed revisions to the standards. The Agency also proposes to make additional changes in the appendix N data handling provisions to codify existing practices currently included in guidance documents or implemented as EPA standard operating procedures as well as to provide greater clarity and consistency in the application of these provisions. The proposed revisions to appendix N are discussed in section VII.A below.

Section 1(b) of appendix N refers to special considerations that may be given to data resulting from exceptional events. An exceptional event is defined in 40 CFR 50.1 as an event that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. Air quality data that are determined to have been affected by an exceptional event under the procedural steps, substantive criteria, and schedule specified in section 50.14 may be excluded from consideration when EPA makes a determination that an area is meeting or violating the associated NAAQS. Proposed revisions to the schedule specified in

[183] With regard to the PM_{10} NAAQS, as summarized in sections IV.F and VI.F, the EPA is proposing to retain the current primary and secondary PM_{10} standards. Data handling procedures for these PM_{10} standards would remain as presented in 40 CFR part 50, appendix K.

section 50.14 for data flagging and submission of demonstrations for exceptional events data considered for initial area designations under the proposed revised primary and secondary PM standards are discussed in section VII.B below.

Several proposed updates and clarifications to the data handling provisions associated with AQI reporting in 40 CFR part 58, Appendix G are discussed in section VII.C below. These modifications reflect the proposed changes to the AQI sub-index for $PM_{2.5}$ as discussed in section V above and harmonize reporting procedures for AQI sub-indices for other criteria pollutants.

A. Proposed Amendments to Appendix N: Interpretation of the NAAQS for $PM_{2.5}$

As discussed below, the proposed revisions to appendix N corresponding to proposed changes in the standards addressed in sections III and VI above are: (1) modification of the level of the primary annual $PM_{2.5}$ standard (sections VII.A.1 and VII.A.4); (2) modification of the form of the primary and secondary annual $PM_{2.5}$ standards to remove the option for spatial averaging (sections VII.A.2 and VII.A.4); and (3) addition of data handling procedures that detail how to make comparisons to the proposed secondary standard for $PM_{2.5}$ that addresses PM-related visibility impairment (section VII.A.5), as well as to summarize associated changes proposed in other sections of appendix N to accommodate this proposed standard (sections VII.A.1, VII.A.2, and VII.A.3). In addition to these three proposed appendix modifications that are discussed in depth in sections III and VI above, the EPA also proposes additional revisions to appendix N in order to: (1) better align appendix N language and requirements with proposed changes in the $PM_{2.5}$ ambient monitoring and reporting requirements as discussed in section VIII below; (2) enhance consistency with recently codified changes in data handling procedures for other criteria pollutants; (3) codify existing practices currently included in guidance documents or implemented as EPA standard operating procedures; and (4) provide enhanced clarity and consistency in the articulation and application of appendix N provisions. Key elements of the proposed revisions to appendix N are summarized in sections VII.A.1 through VII.A.5 below, where each of these preamble sections corresponds to the similarly numbered section in appendix N.

1. General

The EPA proposes to modify section 1.0 of appendix N to provide additional clarity regarding the scope and interpretation of the NAAQS for $PM_{2.5}$. This section would reference the proposed revisions to the primary annual $PM_{2.5}$ standard and the proposed revision to the form of the secondary annual $PM_{2.5}$ standard (40 CFR 50.18) and the proposed addition of a distinct secondary $PM_{2.5}$ visibility index standard (40 CFR 50.19). As summarized in section VI.F, the proposed secondary standard is defined in terms of a calculated $PM_{2.5}$ light extinction indicator, which would use 24-hour average speciated $PM_{2.5}$ mass concentration data, along with associated relative humidity information, to calculate light extinction, which would then be translated to the deciview scale (referred to as a $PM_{2.5}$ visibility index); a 24-hour averaging time; a 90th percentile form averaged over 3 years; and a level of either 30 dv or 28 dv. The result (i.e., the $PM_{2.5}$ visibility index design value) would be compared to the level of the standard. As noted earlier, the NAAQS indicator and proposed data handling procedures are similar to those of the Regional Haze Program. The EPA proposes to add to section 1.0 of appendix N, a reference to section 2.9 of appendix C to 40 CFR part 58 which identifies the acceptable methods for the speciated $PM_{2.5}$ mass concentration data. With regard to the appendix N term definitions which are delineated in this initial section, the EPA proposes to add, modify, or eliminate term definitions, as appropriate, in accordance with the proposed data handling rule revisions such as the addition of terms associated with the proposed secondary $PM_{2.5}$ visibility index standard and the modification of terms that referenced spatial averaging. Additional term definitions are also being added to reference otherwise unchanged appendix N logic in an effort to streamline the appendix text, enhance clarity and thus improve readability and understanding.

2. Monitoring Considerations

The EPA proposes revisions to section 2.0 of appendix N consistent with the proposed modification of the form of the primary annual $PM_{2.5}$ standard to remove the option for spatial averaging. As described in more detail in section III.E.3.a above, the EPA is proposing to remove this

option as part of the form of the primary annual $PM_{2.5}$ standard. This proposed change is based on an analysis that indicates the existing constraints on spatial averaging, as modified in 2006, may be inadequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on susceptible populations (Schmidt 2011a, Analysis A).

With respect to the form of the secondary annual $PM_{2.5}$ standard, while, as discussed in section VI.E.5 above, the EPA is proposing to retain the current secondary annual $PM_{2.5}$ standard to provide protection for non-visibility welfare effects, the EPA believes it would be reasonable and appropriate to align the data handling procedures for the primary and secondary annual $PM_{2.5}$ standards. Therefore, the EPA proposes to remove the option for spatial averaging for the secondary annual $PM_{2.5}$ standard consistent with the proposed change in the form of the primary annual $PM_{2.5}$ standard. The EPA notes that no areas in the country are currently using the option for spatial averaging to demonstrate attainment with the secondary annual $PM_{2.5}$ standard.

Consistent with the proposed change to revise the forms of the primary and secondary annual $PM_{2.5}$ standards, the levels of the standards would be compared to measurements from each appropriate (i.e., "eligible") monitoring site in an area operated in accordance with the network technical requirements specified in 40 CFR 58.11, the operating schedule described in 40 CFR 58.12, and the special considerations for data comparisons to the NAAQS specified in 40 CFR 58.30, with no allowance for spatial averaging. Thus, for an area with multiple eligible monitoring sites, the site with the highest design value would determine the attainment status for that area. As a result of this proposed change, the EPA proposes to remove all references to the spatial averaging option throughout appendix N.

3. Requirements for Data Use and Reporting for Comparisons with the NAAQS for $PM_{2.5}$

The EPA proposes to make changes to section 3.0 of appendix N to correspond with the proposed secondary $PM_{2.5}$ visibility index standard, to improve consistency with procedures used for other NAAQS, and to improve consistency with current standard operating procedures. Specifically, the

EPA proposes revisions to this section regarding: (1) requirements for reporting monitored aggregated $PM_{2.5}$ and speciated $PM_{2.5}$ mass concentration data; (2) clarification of monitoring data appropriate to compare to the $PM_{2.5}$ and $PM_{2.5}$ visibility index NAAQS; (3) clarification of procedures for using hourly concentrations to calculate 24-hour concentrations; and (4) clarification of procedures for combining monitoring data from collocated instruments into a single "combined site" record. Further, the EPA proposes to codify, in this same section, modifications to the $PM_{2.5}$ data handling provisions to make them consistent with recent changes made for other criteria pollutants. For example, data for which the certification deadline has passed, and the monitoring agency has not requested certification of the data, can nevertheless be used to determine compliance with the $PM_{2.5}$ NAAQS and the $PM_{2.5}$ visibility index NAAQS when EPA judges the data to be complete and accurate.

With regard to the criteria for reporting $PM_{2.5}$ concentrations, section 3.0 of appendix N specifies that $PM_{2.5}$ mass concentrations used for NAAQS comparisons shall be reported in units of $\mu g/m^3$ with the values truncated (not rounded) to one digit to the right of the decimal point (i.e., truncated to one decimal place). Since, to date, appendix N has dealt only with $PM_{2.5}$ mass concentrations, intrinsically these requirements have dealt only with that particular set of data.

With regard to the proposed secondary $PM_{2.5}$ visibility index standard, the EPA already has a requirement in 40 CFR 58.16 to report speciated $PM_{2.5}$ mass concentration data. This includes the nine required speciated $PM_{2.5}$ mass concentration inputs (i.e., sulfate, nitrate, OC (and related $PM_{2.5}$ OC which is reported OC with an adjustment for the organic carbon artifact present on a filter), EC, Al, Si, Ca, Fe, and Ti) used to calculate $PM_{2.5}$ visibility index values as described in section VII.A.5 below. Specifically, the EPA proposes to require that all nine parameters be used in the appendix N procedures in units of $\mu g/m^3$ with the values rounded to four decimal places (or three significant digits if the value is 0.1 $\mu g/m^3$ or larger). These rounding conventions are consistent with the AQS reporting protocols used in the CSN program, discussed in section VIII.A.2 below, which is proposed to be a major source of ambient data used in calculating $PM_{2.5}$ visibility index design values to compare to the level of proposed

secondary NAAQS.

Monitoring sites eligible for comparison to the NAAQS for $PM_{2.5}$ include those following the network technical requirements specified in 40 CFR 58.11 as well as following the eligibility criteria specified in 40 CFR 58.30.[184] However, as discussed in section VIII.A.1 below, an analysis of the quality of data from two different methods used by FEMs has indicated that some sites with continuous $PM_{2.5}$ FEMs have an acceptable degree of comparability with collocated FRMs, while other FEMs have less acceptable data comparability that would not meet the performance criteria originally used to approve the FEMs (Hanley and Reff, 2011). Therefore, as explained in more detail in section VIII.B.3.b.ii below, the EPA is proposing to allow monitoring agencies to identify $PM_{2.5}$ FEMs that are not providing data of sufficient comparability to the FRM and, with EPA approval, to exclude the use of these data in making comparisons to the NAAQS for $PM_{2.5}$.[185]

With regard to data handling procedures for using hourly mass concentrations to calculate 24-hour average mass concentrations, current procedures are specific for handling aggregated $PM_{2.5}$ mass concentrations and are not currently relevant for handling the speciated $PM_{2.5}$ mass concentrations that would be used for calculating $PM_{2.5}$ visibility index design values for the proposed secondary standard. In considering data handling procedures for hourly speciated $PM_{2.5}$ mass concentrations, the EPA notes that the vast majority of speciation data collected across the country are from filter-based sampling

[184] As discussed in more detail in section VIII.B.2.b below, the EPA is proposing to change the current presumption in 40 CFR 58.30 that micro- and middle-scale monitoring sites are "unique" and are comparable only to the 24-hour $PM_{2.5}$ standards, unless approved by the Regional Administrator to collectively identify a larger region of localized high ambient $PM_{2.5}$ concentrations. Today's proposal, if finalized, would change this presumption, such that micro- and middle-scale monitoring sites would not be presumed to be unique and, therefore, would be comparable to the annual $PM_{2.5}$ standards as well as the 24-hour $PM_{2.5}$ standards, unless the Regional Administrator determines that the micro- or middle-scale site is unique.

[185] The EPA also allows use of alternative methods where explicitly stated in the monitoring methodology requirements (appendix C of 40 CFR part 58), such as $PM_{2.5}$ Approved Regional Methods (ARMs) which can be used to determine compliance with the NAAQS. Monitoring agencies identifying ARMs that are not providing data of sufficient quality would also be allowed to exclude these data in making comparisons to the $PM_{2.5}$ and $PM_{2.5}$ visibility index NAAQS. Currently, there are no designated ARMs for $PM_{2.5}$.

methods which typically operate on a 24-hour sampling period. There are several monitoring sites reporting hourly speciation data, but even in these cases the methods employed only provide for a small number of speciation parameters (e.g., EC, OC, sulfate) to be reported. However, in anticipation that such continuous methods might be more widely implemented for the speciated $PM_{2.5}$ mass components in the future, the EPA proposes to add clarifying language to section 3.0(a) to indicate that the data handling procedures for using hourly concentration data to calculate 24-hour average concentration data would be applicable to both aggregated $PM_{2.5}$ mass concentrations and speciated $PM_{2.5}$ mass concentrations.

With respect to the procedures for combining monitored data from collocated instruments into a single "combined site" data record, the EPA proposes to revise the current methodology in situations where an FRM monitor operating on a non-daily schedule is collocated with a continuous FEM monitor (that has acceptable comparability with an FRM). The EPA is not proposing to change the procedures for calculating a combined site record[186] but rather the subsequent evaluation of whether the specific measurements are considered "creditable" or "extra" samples. Samples in the combined site record are deemed "creditable" or "extra" according to the required sampling frequency for a specific monitoring site (i.e., "site-level sampling frequency") which, by default, is defined to be the same as the sampling frequency required of the primary monitor. Samples in the combined site data record that correspond to scheduled days according to the site-level sampling frequency are deemed "creditable" and, thus, are considered for determining whether or not a specific monitoring site meets data completeness requirements. These samples also determine which daily value in the ranked list of daily values for a year represents the annual 98th percentile concentration. Samples that are not deemed "creditable" are classified as "extra" samples. These samples do not count towards data completeness requirements and do not affect which daily values represent the annual 98th percentile concentration; "extra" samples,

[186] Data for a combined site record originates by default from the designated "primary" monitor at the site location and is then augmented with data from collocated FRM or FEM monitors whenever valid data are not generated by the primary monitor.

however, are candidates for selection as the 98th percentile

Before the introduction of continuous $PM_{2.5}$ FEMs, when two or more samplers were collocated at the same site, monitoring agencies typically identified the sampler that operated on the more frequent sampling schedule as the "primary" monitor for developing a single site record. However, due to concerns regarding the comparability of continuous $PM_{2.5}$ FEMs to FRMs operated in some monitoring agency networks, and as briefly discussed above and in more detail in section VIII.A.1 below, many monitoring agencies have kept the FRM as the "primary" monitor while continuing to evaluate the continuous FEM monitor. In cases where the FRM either does not have a scheduled measurement or has a measurement that is invalidated and the continuous FEM data are available for use, and the continuous FEM data are not identified as not to be used (i.e., a special purpose monitor (SPM) in its first 24 months of operation) the FEM data will be substituted into the site record. In cases where the continuous FEM measurements are reported on the FRM "off" days, these data are technically considered "extra" samples.

In light of this practice, the EPA modified standing operating procedures and now proposes a conforming revision to section 3.0(e) whereby collocated FEM samples reported on the FRM "off" days would be considered "scheduled" and "creditable." Thus, collocated FEM samples would count towards data capture rates (actually, increasing both the numerator and the denominator in the capture rate equation), and also would count towards identifying annual 98th percentile concentrations. Further, consistent with current practices, if data from a collocated FEM are missing on an FRM "off" day (and no unscheduled FRM data are reported that day), the EPA proposes not to identify these as "scheduled" samples. Thus, reported data generated from the collocated continuous FEMs can only help increase data capture rates. The EPA specifically solicits comment on whether "non-primary" (i.e., collocated) FEM data should be combined with the primary data as part of the comparison to the NAAQS for $PM_{2.5}$.

The EPA proposes to utilize the same general procedures for combining speciated $PM_{2.5}$ mass concentration data from collocated monitors into a single "combined site" record as those specified for

the $PM_{2.5}$ mass measurements.

4. Comparisons with the Annual and 24-Hour $PM_{2.5}$ NAAQS

Section 4.0 of appendix N specifies the procedures for comparing monitored data to the annual and 24-hour $PM_{2.5}$ standards. The EPA proposes revisions to section 4.0 of appendix N to: (1) provide consistency with the proposed primary and secondary annual $PM_{2.5}$ standards; (2) expand the data completeness assessments to be consistent with current guidance and standard operating procedures; and (3) simplify the procedure for calculating annual 98th percentile concentrations when using an approved seasonal sampling schedule.

Consistent with the proposed decisions to revise the level of the primary annual $PM_{2.5}$ standard (section III.F) and to retain the current level of the secondary annual $PM_{2.5}$ standard (section VI.F), the EPA proposes to modify section 4.1(a) of appendix N to separately list the levels of the primary and secondary annual $PM_{2.5}$ standards. Additionally, consistent with the proposed decision to remove the option for spatial averaging for the primary annual $PM_{2.5}$ standard (section III.F) as well as for the secondary annual $PM_{2.5}$ standard (section VII.A.2), the EPA proposes to amend section 4.4 of appendix N to remove equations and associated instructions that relate to spatial averaging.

With regard to assessments of data completeness, the EPA proposes to include two additional data substitution tests[187] (making a total of three data substitution tests) for validating annual and 24-hour $PM_{2.5}$ design values otherwise deemed incomplete (via the 75 percent and 11 creditable sample minimum quarterly data completeness checks). Data substitution tests are diagnostic in nature; that is; they are only used in an illustrative manner to show that the NAAQS status based on incomplete data is reasonable. If an "incomplete" design value using substituted data passes the diagnostic test, this "incomplete" design value (without the data substitutions) is then considered the true actual "complete" design value. If an incomplete design value does not pass any stipulated data substitution test, then the

[187] Data substitution tests are supplemental data completeness assessments that use estimates of 24-hour average concentrations to fill in for missing data (i.e., "data substitution").

original design value is still considered incomplete.

Currently, section 4.1(c) specifies one data substitution test for validating an otherwise incomplete design value. This diagnostic test is only applicable to the primary and secondary annual $PM_{2.5}$ standard and only applies in instances of a violation. The EPA proposes to modify the data completeness requirements by adding two additional data substitution tests for handling incomplete data sets in order to make the data handling procedures for $PM_{2.5}$ more consistent with the procedures used for other NAAQS pollutants and to codify existing practices currently included in guidance documents (US EPA, 1999) and implemented as EPA standard operating procedures. The proposed additional data substitution tests would be applicable for making comparisons to the primary and secondary annual and 24-hour $PM_{2.5}$ standards. One of these tests uses collocated PM_{10} data to fill in "slightly incomplete"[188] data records, and the other uses quarter-specific maximum values to fill in "slightly incomplete" data records.

With regard to identifying annual 98th percentile concentrations for comparison to the primary and secondary 24-hour $PM_{2.5}$ standards, the EPA proposes to simplify the procedures used with an approved seasonal sampling schedule. Specifically, the EPA proposes to eliminate the use of a special formula for calculating annual 98th percentile concentrations with a seasonal sampling schedule and proposes to use only one method for calculating annual 98th percentile concentrations at all sites.

Currently, with an approved seasonal sampling schedule, a site typically samples as required during periods of the year when the highest concentrations are expected to occur, but less frequently during periods of the year when lower concentrations are expected to occur. This type of sampling schedule generally leads to an "unbalanced" data record; that is, a data record with proportionally more ambient measurements (with respect to the total number of days in the sampling period) in the "high" season and proportionally fewer ambient measurements in the "low" season.

[188] "Slightly incomplete" is defined as less than 75 percent but greater than or equal to 50 percent data capture.

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[189] (or near-balanced) data record, the special formula yields the same result as the regular procedure for calculating annual 98th percentile concentrations.

To qualify for a seasonal sampling schedule, monitoring agencies are required to collocate a continuous $PM_{2.5}$ instrument with the seasonal sampling FRM. Since the last review, there has been considerable deployment of continuous $PM_{2.5}$ FEM monitors. In situations where a $PM_{2.5}$ FRM monitor operating on a non-daily periodic schedule (such as a 1-day-in-3 or a 1-day-in-6 schedule) is collocated with a continuous $PM_{2.5}$ FEM monitor, data are combined based on procedures stated in section 3.0 of appendix N as modified as discussed in section VII.A.3 above. The end result of combining collocated FRM and FEM data is effectively an "every day" site-based sampling frequency, resulting in a balanced data record. In such a case, if a site used a seasonal sampling schedule regime for the FRM monitor, these data would be balanced by the "every day" FEM data and there would be no need for the special formula for calculating annual 98th percentile concentrations on the combined site data.

The EPA notes that currently there are very few $PM_{2.5}$ FRM monitors that actually operate on an approved seasonal sampling schedule (only 15 sites out of approximately 1,000 total sites in 2010) and that almost half of these sites have a collocated $PM_{2.5}$ FEM monitor. For the most recent 3-year period (2008-2010), the annual 98th percentile concentrations calculated with the special formula at these 15 sites were approximately five percent lower than if the regular procedure was used. The EPA also notes that, in the last review, the Agency modified the monitoring requirements for areas with an FRM

[189] A balanced data record has the same proportion of ambient measurements (with respect to the total number of days in the sampling period) in the "high" season as in the "low" season.

operating on a non-daily schedule such that, if the design values were within five percent of the 24-hour $PM_{2.5}$ NAAQS, such areas are required to increase the frequency of sampling to every day (40 CFR 58.12(d)(1); 71 FR 61165, October 17, 2006; 71 FR 61249, October 17, 2006). Thus, the EPA proposes to simplify the data handling procedures for sites operating on a seasonal sampling schedule by eliminating the special formula and all references to it based on: (1) the small difference between 98th percentile concentrations calculated using the special formula versus the regular procedure and the small number of sites currently using the special formula; (2) the EPA requirements for every day sampling in areas with design values that are within five percent of the 24-hour $PM_{2.5}$ NAAQS; and (3) the EPA requirement that FRMs operating on an approved seasonal sampling schedule be collocated with a continuous $PM_{2.5}$ instrument (and if that instrument were an FEM, the resulting combined site record would tend to be balanced over the year and thus the special formula would be superfluous). Thus, the EPA proposes to use only one method for calculating annual 98th percentile concentrations for all sites, that being the "regular" table look-up method specified in section 4.5(a)(1) of appendix N. The EPA solicits comment on the proposal to eliminate the special formula for sites operating on a seasonal sampling schedule.

5. Data Handling Procedures for the Proposed Secondary $PM_{2.5}$ Visibility Index NAAQS

As summarized in section VI.F above, the EPA is proposing to establish a distinct secondary standard for $PM_{2.5}$ to address PM-related visibility impairment. The EPA is proposing to define this standard in terms of a $PM_{2.5}$ visibility index (section VI.D.1.c), which would use 24-hour average speciated $PM_{2.5}$ mass concentration and historic monthly average relative humidity data to calculate $PM_{2.5}$ light extinction, translated into the deciview scale, similar to the Regional Haze Program.

The EPA proposes to add a new section 5.0 to appendix N to detail the data handling procedures for calculating $PM_{2.5}$ visibility index design values and comparing these design values to the level of the proposed $PM_{2.5}$ visibility index NAAQS. These proposed procedures are drawn from and are generally consistent with the original approach used in the Regional Haze Program [US EPA, 2003] and discussed

in the Policy Assessment (US EPA, 2011a, chapter 4, Appendix G).

As discussed in section VI.B.1.a above, visibility impairment is caused by the scattering and absorption of light by suspended particles and gases in the atmosphere. The combined effect of light scattering and absorption by both particles and gases is characterized as light extinction. The amount of light extinction contributed by PM depends on the particle size distribution and composition, as well as the concentrations of speciated components of ambient PM. To make estimation of light extinction more practical, visibility scientists have developed simple algorithms, referred to as the IMPROVE algorithms to relate speciated $PM_{2.5}$ concentrations to light extinction. These IMPROVE algorithms are routinely used to calculate light extinction levels on a 24-hour basis in Federal Class I areas under the Regional Haze Program.

The EPA proposes to define the $PM_{2.5}$ visibility index using a $PM_{2.5}$ light extinction indicator calculated on a 24-hour basis using the original IMPROVE algorithm without the terms for coarse mass and Rayleigh scatter. As discussed in section VI.D.1.c above, using such an index appropriately reflects the relationship between ambient PM and PM-related light extinction. When converting $PM_{2.5}$ light extinction values in Mm^{-1} to the deciview scale, the Rayleigh scattering term must be included to avoid the possibility of negative values.

Consistent with the analyses and terminology used in the Policy Assessment (US EPA, 2011a, chapter 4, Appendix G), $PM_{2.5}$ light extinction ($PM_{2.5}\ b_{ext}$) is defined as

$$\begin{aligned} PM_{2.5}\ b_{ext} = {} & 3 \times f(RH) \times [\text{Sulfate}] \\ & + 3 \times f(RH) \times [\text{Nitrate}] \\ & + 4 \times [\text{Organic Mass}] \\ & + 10 \times [\text{Elemental Carbon}] \\ & + 1 \times [\text{Fine Soil}] \end{aligned} \qquad \text{(appendix N, equation 6)}$$

The above formula is implemented using 24-hr speciated $PM_{2.5}$ concentration data together with monthly climatological relative humidity factors as outlined below. The six steps involved in the calculation of the $PM_{2.5}$ visibility index values are as follows:

1) As discussed in Section VI.B.1.a above, "sulfate" is defined as ammonium sulfate and "nitrate"

is defined as ammonium nitrate. Multiply 24-hour average speciation measurements of sulfate and nitrate ions by factors 1.375 and 1.29, respectively, to convert the reported ion concentrations into sulfate and nitrate ammonium concentrations (appendix N, equations 5a and 5b).

2) Convert artifact adjusted measured OC, which is termed "$PM_{2.5}$ OC", into an estimate of organic mass (OM). The $PM_{2.5}$ OC is derived by subtracting the sampler-dependent OC measurement artifact from the measured OC. [190] The $PM_{2.5}$ OC is then multiplied by 1.4 to account for the additional mass of hydrogen, oxygen and other elements associated with the carbon in measured OC (appendix N, equation 5c).

3) Calculate fine soil/crustal $PM_{2.5}$ (FS) component based on measurements of five soil derived elements (i.e., Al, Si, Ca, Fe, and Ti) together with multipliers to account for their normal oxides[191] (appendix N, equation 5d).

4) Determine a representative long-term monthly average of hourly relative humidity hygroscopic growth factors, referred to as *f*(RH) values, at the speciation monitoring site, for each month of the year. There will be 12 such values for any monitoring site. The EPA proposes that the *f*(RH) values be selected using historical data. A spatial interpolation of historical relative humidity data is available which presents a gridded field of *f*(RH) values across the U.S. at a resolution of 0.25 degrees (SAIC, 2001). As discussed in section VI.D.2.a.ii above, these monthly average values were developed to support the Regional Haze Program and are based on considering any hour with relative humidity greater than 95 percent as 95 percent. Because 10 years of hourly data were used to produce a single humidity term for each month, the EPA believes that the resulting monthly average of the humidity term is sufficient and appropriate to reduce the effects of fog or precipitation. The EPA proposes that the 10-year climatological data base be used to specify the *f*(RH) value associated with the grid-point closest in distance to the speciation monitoring site.[192]

5) Apply the original IMPROVE algorithm without the terms for coarse mass and Rayleigh scatter (appendix N, equation 6) to calculate a daily average $PM_{2.5}$ light extinction ($PM_{2.5}$ b_{ext}, in units of Mm^{-1}).

6) To translate $PM_{2.5}$ light extinction to the deciview scale for making comparisons to the level of the proposed secondary $PM_{2.5}$ visibility index standard, the following equation, which includes the term for Rayleigh scattering term, is used:

$$PM_{2.5} \text{ visibility index (dv)} = 10 \ln [(PM_{2.5}\ b_{ext} \text{ in } Mm^{-1} + 10)/10] \qquad \text{(appendix N, equation 7)}$$

The EPA solicits comment on all aspects of the calculation of the $PM_{2.5}$ visibility index, $PM_{2.5}$ b_{ext}.

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[190] In the IMPROVE program, artifact adjusted OC (i.e., $PM_{2.5}$ OC) is simply reported as OC. That is the value used to produce OM for haze calculations. For the CSN measurements, the OC artifact needed to convert measured OC into $PM_{2.5}$ OC is estimated from sampler-specific network-wide field blanks (Frank, 2012).

[191] Fine Soil = 2.2[Al] + 2.49[Si] + 1.63[Ca] + 2.42[Fe] + 1.94[Ti]

[192] To facilitate the use of relative humidity data, the EPA would make this ten-year climatological data base publically available on its website.

As discussed in section VI.D.3 above, the EPA is proposing a 90th percentile form, averaged over 3 years, for the proposed secondary $PM_{2.5}$ visibility index standard. Thus, 3 years of valid 24-hr speciated $PM_{2.5}$ mass concentration data would be required to calculate $PM_{2.5}$ visibility index design values. The proposed new section 5.0 for appendix N addresses data completeness requirements for speciated $PM_{2.5}$ mass concentrations (section 5.0(b)), specifically that $PM_{2.5}$ visibility index values be present for at least 11 creditable days of each quarter, for each of the three consecutive years. The 11 sample minimum is consistent with criteria specified for the current and proposed primary and secondary annual $PM_{2.5}$ standards (i.e., 40 CFR part 50, appendix N 4.1(b)) and, furthermore, has been used extensively for various PM characterization exercises (e.g., US EPA, 2009a; US EPA, 2011a). In addition, the proposed new section 5.0 outlines procedures for identifying annual 90th percentile $PM_{2.5}$ visibility index values (section 5.0(d)(3)) similar to procedures used to identify annual 98th percentile values for the primary and secondary 24-hour $PM_{2.5}$ standards. In situations where a year does not contain the minimum 11 creditable samples in each quarter, the EPA proposes (in section 5.0) to still consider the identified 90th percentile index value to be valid if it, or a 3-year average of 90th percentile index values (i.e., a visibility impairment design value) including it, exceeds the level of the NAAQS. The EPA is not proposing any data substitution tests for $PM_{2.5}$ visibility index design values like those codified and proposed for the aggregated $PM_{2.5}$ mass standard design values; however, the EPA solicits comment on the inclusion of such data substitution tests.

With regard to rounding conventions, the EPA proposes that all decimal digits be retained in the intermediate steps of the calculation of the $PM_{2.5}$ light extinction indicator and that the $PM_{2.5}$ visibility index values be rounded to the nearest tenth deciview. Furthermore, the EPA proposes to round the 3-year average 90th percentile $PM_{2.5}$ visibility index design values to the nearest 1 dv for comparison to the level of the proposed secondary standard.

Consistent with current procedures for PM and the other criteria pollutants, the EPA plans to calculate design values for the proposed secondary $PM_{2.5}$ visibility index NAAQS using the procedures

described above. The EPA plans to post these design values on its website.[193]

B. Exceptional Events

States[194] are responsible for identifying air quality data that they believe warrant special consideration, including data affected by exceptional events. States identify such data by flagging (making a notation in a designated field in the electronic data record) specific values in the AQS database. States must flag the data and submit supporting documentation showing that the data have been affected by exceptional events if they wish the EPA to consider excluding the data in regulatory decisions, including determining whether or not an area is attaining the proposed revised PM NAAQS.

All states and areas of Indian country that include areas that could exceed the proposed PM NAAQS and could therefore be designated as nonattainment for the proposed PM NAAQS have the potential to be affected by this rulemaking. Therefore, this action would apply to all states; to local air quality agencies to which a state has delegated relevant responsibilities for air quality management including air quality monitoring and data analysis; and to tribal air quality agencies where appropriate.

The "Treatment of Data Influenced by Exceptional Events; Final Rule" (72 FR 13560, March 22, 2007), known as the Exceptional Events Rule and codified at 40 CFR 50.14, contains generic deadlines for a state to submit to EPA specified information about exceptional events and associated air pollutant concentration data. A state must initially notify the EPA that data have been affected by an event by July 1 of the calendar year following the year in which the event occurred. This is done by flagging the data in AQS and providing an initial event description. The state must also, after notice and opportunity for public comment, submit a demonstration to justify any claim within three years after the quarter in which the data were collected. However, if a regulatory decision based on the data (for example, a designation action) is anticipated, the schedule to flag data in AQS and submit complete documentation

[193] Design values calculated by the EPA are computed and published annually by EPA's OAQPS and reviewed in conjunction with the EPA Regional Offices. These values are available at: http://www.epa.gov/airtrends/values.html.

[194] References to "state" are meant to include state, local and tribal agencies responsible for implementing the Exceptional Events Rule.

to EPA for review may be shortened and all information must be submitted to the EPA no later than one year before the decision is to be made.

These generic deadlines in the Exceptional Events Rule are suitable after initial designations have been made under a NAAQS or when an area is to be redesignated, either from attainment to nonattainment or from nonattainment to attainment, and the redesignation status may depend on the excluded data. However, these same generic deadlines may need to be adjusted to accommodate the initial area designation process and schedule under a newly revised NAAQS. Until the level and form of the NAAQS have been promulgated, a state does not know whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met for a given event. In some cases, the generic deadlines, especially the deadlines for flagging some relevant data, may have already passed by the time the new or revised NAAQS is promulgated. In addition, it may not be feasible for information on some exceptional events that may affect final designations decisions to be collected and submitted to EPA at least one year in advance of the final designation decision. This scheduling constraint could have the unintended consequence of the EPA designating an area nonattainment because of uncontrollable natural or other qualified exceptional events.

The Exceptional Events Rule at section 50.14(c)(2)(vi) indicates "when EPA sets a NAAQS for a new pollutant or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging exceptional event data, providing initial data descriptions and providing detailed data documentation in AQS for the initial designations of areas for those NAAQS."

The EPA intends to promulgate the revised PM NAAQS in December 2012. State Governors (and tribes, if they choose) should submit designations recommendations by December 2013, based on air quality data from the years 2010 to 2012 or 2011 to 2013, if there are sufficient data for these years. Initial designations under the revised NAAQS would be made by December 2014 based on air quality data from the years 2011 to 2013. (See section IX.A for a more detailed discussion of the designation schedule.) Assuming this schedule, all events to be considered during the designations process would

need to be flagged and fully documented by states one year prior to designations, or by December 2013, under the existing generic deadline in the Exceptional Events Rule. Without revision to 40 CFR 50.14, a state would not be able to flag and submit documentation regarding events that occurred in December 2013 by one year before designations are made in December 2014. The EPA believes this is not an appropriate restriction, and therefore is proposing revisions to 40 CFR 50.14.

The EPA proposes revisions to 40 CFR 50.14 only to change submission dates for information supporting claimed exceptional events affecting PM data for initial area designations under the proposed new and revised PM NAAQS. The proposed rule language at the end of this notice shows the changes that would apply assuming promulgation of the new and revised PM NAAQS in December 2012 and initial area designations by December 2014. For air quality data collected in 2010 or 2011, the EPA proposes extending to July 1, 2013 the otherwise applicable generic deadlines of July 1, 2011 and July 1, 2012, respectively, for flagging data and providing an initial description of an event (40 CFR 50.14(c)(2)(iii)). The EPA proposes to retain the existing generic deadline in the Exceptional Events Rule of July 1, 2013 for flagging data and providing an initial description of events occurring in 2012. Similarly, the EPA proposes to revise to December 12, 2013 the deadline for submitting documentation to justify PM-related exceptional events occurring in 2010 through 2012. The EPA believes these revisions/extensions will provide adequate time for states to review the impact of exceptional events from 2010 through 2012 on any revised standards, to notify the EPA by flagging the relevant data and providing an initial description in AQS, and to submit documentation to support claims for exceptional events.

If a state intends the EPA to consider in the PM designations decisions whether PM data collected during 2013 have been affected by exceptional events, the EPA proposes that these data must be flagged by the generic Exceptional Event Rule deadline of July 1, 2014. The EPA proposes to revise to August 1, 2014 the deadline for submitting documentation to justify PM-related exceptional events

occurring in 2013. The EPA believes that these deadlines provide states with adequate time to review and identify potential exceptional events that occur in calendar year 2013.

Therefore, using the authority provided in CAA section 319(b)(2) and in the Exceptional Events Rule at 40 CFR 50.14 (c)(2)(vi), the EPA proposes to modify the schedule for data flagging and submission of demonstrations for exceptional events data considered for initial area designations under the proposed PM primary and secondary NAAQS as presented in Table 3. If the promulgation date for a revised PM NAAQS occurs on a different date than in December 2012, the EPA will revise the final PM exceptional event flagging and documentation submission deadlines accordingly, consistent with the logic of this proposal, to provide states with reasonably adequate opportunity to review, identify, and document exceptional events that may affect an area designation under a revised NAAQS. The EPA invites comment on these proposed changes, shown in Table 3, to the exceptional event data flagging and documentation submission deadlines for the proposed revised PM NAAQS.

Table 3. Revised Schedule for Exceptional Event Flagging and Documentation Submission for Data to be Used in Initial Area Designations for the 2012 PM NAAQS

NAAQS Pollutant/ Standard/(Level)/ Promulgation Date	Air Quality Data Collected for Calendar Year	Event Flagging & Initial Description Deadline	Detailed Documentation Submission Deadline
$PM_{2.5}$/ 24-Hour Standard (final level and promulgation date TBD)	2010 to 2011	July 1, 2013	December 12, 2013
	2012	July 1, 2013[a]	December 12, 2013
	2013	July 1, 2014[a]	August 1, 2014
$PM_{2.5}$/ Annual Standard (final level and promulgation date TBD)	2010 to 2011	July 1, 2013	December 12, 2013
	2012	July 1, 2013[a]	December 12, 2013
	2013	July 1, 2014[a]	August 1, 2014
Secondary PM (final level and promulgation date TBD)	2010 to 2011	July 1, 2013	December 12, 2013
	2012	July 1, 2013[a]	December 12, 2013
	2013	July 1, 2014[a]	August 1, 2014

[a]This date is the same as the general schedule in 40 CFR 50.14.
Note: The table of revised deadlines *only* applies to data the EPA will use to establish the final initial area designations for revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by the EPA for redesignations to attainment. TBD = to be determined.

C. Proposed Updates for Data Handling Procedures for Reporting the Air Quality Index

The EPA is proposing to update appendix G of 40 CFR part 58 to clarify units, breakpoint precision, and truncation methods for AQI sub-indices. These changes are intended to harmonize the AQI reporting requirements with data handling provisions expressed elsewhere in 40 CFR part 50. Currently, the breakpoints for NO_2 and SO_2 in Table 2 of appendix G of 40 CFR part 58 are expressed in parts per million (ppm). The EPA proposes to change the sub-indices for NO_2 and SO_2 to be based on parts per billion (ppb) rather than ppm to be consistent with the units used for defining the current levels of the primary NO_2 and SO_2 NAAQS (75 FR 6474, February 9, 2010; 75 FR 35520, June 22, 2010). In

addition, in modifying the sub-index for NO_2 to express the breakpoints in units of ppb, the EPA proposes to clarify the breakpoints for NO_2 in the Very Unhealthy and Hazardous ranges to include four rather than three significant digits to increase precision. Finally, the EPA proposes to modify appendix G to explicitly identify truncation methods for using ambient measured concentrations in AQI calculations.

VIII. Proposed Amendments to Ambient Monitoring and Reporting Requirements

The EPA proposes changes to the ambient air monitoring, reporting, and network design requirements associated with the PM NAAQS. Ambient PM monitoring data are used to meet a variety of monitoring objectives including determining whether an area is in violation of the PM NAAQS. Ambient PM monitoring data are collected by state, local, and tribal monitoring agencies ("monitoring agencies") in accordance with the monitoring requirements contained in 40 CFR parts 50, 53, and 58. This section discusses the monitoring changes that the EPA is proposing to support the proposed PM NAAQS summarized in sections III.F, IV.F, and VI.F above.

A. Issues Related to 40 CFR Part 53 (Reference and Equivalent Methods)

To be used in a determination of compliance with the PM NAAQS, PM data are typically collected using samplers or monitors employing an FRM or FEM. The EPA also allows use of alternative methods where explicitly stated in the monitoring methodology requirements (appendix C of 40 CFR part 58), such as $PM_{2.5}$ ARMs which can be used to determine compliance with the NAAQS. The EPA prescribes testing and approval criteria for FRM and FEM methods in 40 CFR part 53.

1. $PM_{2.5}$ and $PM_{10\text{-}2.5}$ Federal Equivalent Methods

In 2006, the EPA finalized new testing and performance criteria for Class II and Class III FEMs (71 FR 61281 to 61289, October 17, 2006). Class II methods are equivalent methods for $PM_{2.5}$ or $PM_{10\text{-}2.5}$ that utilize a $PM_{2.5}$ sampler or $PM_{10\text{-}2.5}$ sampler in which integrated $PM_{2.5}$ samples or $PM_{10\text{-}2.5}$ samples are obtained from the atmosphere by filtration and are then subjected to a filter conditioning

process followed by gravimetric mass determination. Class II equivalent methods are different from Class I equivalent methods because of substantial deviations from the design specifications of the sampler specified for reference methods in appendix L or appendix O (as applicable) of 40 CFR part 50. Class III refers to those methods for $PM_{2.5}$ or $PM_{10-2.5}$ that are employed to provide $PM_{2.5}$ or $PM_{10-2.5}$ ambient air measurements representative of one-hour or less integrated $PM_{2.5}$ or $PM_{10-2.5}$ concentrations, as well as 24-hour measurements determined as, or equivalent to, the mean of 24 one-hour consecutive measurements. These new testing and performance criteria were developed by the EPA and reviewed through consultation with the CASAC AAMMS[195] and then through proposal (71 FR 2710 to 2808, January 17, 2006) and final rulemaking in 2006 (71 FR 61236 to 61328, October 17, 2006). The performance criteria were designed to ensure enough stringency in testing that subsequently deployed monitors would provide data of expected quality (i.e., they would meet the data quality objectives), but not so stringent that instrument manufacturers would be discouraged from testing their instrument and seeking approval as a Class II or III equivalent method. At the time of this proposal, the EPA has approved two $PM_{10-2.5}$ Class II manual methods, one Class III $PM_{10-2.5}$ continuous method, and six Class III $PM_{2.5}$ continuous methods.[196]

While the EPA has approved these $PM_{2.5}$ Class III continuous FEMs, only two of those methods are deployed on a wide-enough basis across the country to support initial analyses of data quality and comparability to collocated FRM samplers. The Policy Assessment discusses an analysis of the quality of data from these two FEMs (US EPA, 2011a, p. 4-50). This initial analysis found that some sites with continuous $PM_{2.5}$ FEMs have an acceptable degree of comparability with collocated FRMs, while others had less acceptable data comparability that would not meet the performance criteria used to approve the FEMs.

[195] The EPA consulted with the CASAC AAMMS on several PM monitoring topics in a public meeting on September 21 and 22, 2005. Materials from this meeting can be found on EPA's website at: http://www.epa.gov/ttn/amtic/casacinf.html.

[196] A list of designated Reference and Equivalent methods is available on EPA's website at: http://www.epa.gov/ttn/amtic/criteria.html.

The EPA continues to believe that an effective $PM_{2.5}$ monitoring strategy includes the use of both filter-based FRM samplers and well-performing continuous $PM_{2.5}$ monitors. Well-performing continuous $PM_{2.5}$ monitors would include both non-approved continuous $PM_{2.5}$ monitors and approved Class III continuous FEMs that meet the performance criteria described in table C-4 of 40 CFR part 53 when comparing to a collocated FRM operated by the monitoring agency. The use of Class III continuous FEMs at SLAMS is described in more detail in section VIII.B.3.b.ii below. Monitoring agencies are encouraged to evaluate the quality of data being generated by FEMs and, where appropriate, reduce the use of manual, filter-based samplers to improve operational efficiency and lower overall operating costs. To encourage such a strategy, the EPA is working with numerous stakeholders including the monitoring committee of NACAA, instrument manufacturers, and monitoring agencies to support national data analyses of continuous $PM_{2.5}$ FEM performance, and where such performance does not meet data quality objectives, to develop and institute a program of best practices to improve the quality and consistency of resulting data.

The EPA believes that progress is being made to implement well performing $PM_{2.5}$ continuous FEMs across the nation. As noted earlier, the first few steps involved the EPA developing and approving the testing and performance criteria which were finalized in 2006, followed by instrument companies performing field testing and submitting applications to the EPA, and EPA review and approval, as appropriate, of Class III FEMs. In the current step, monitoring agencies are testing and assessing the data comparability from continuous $PM_{2.5}$ FEMs. While some agencies are achieving acceptable data comparability and others are not, the EPA wants to ensure that all monitoring agencies have the appropriate information to maximize data quality from their $PM_{2.5}$ continuous FEMs before considering any changes to regulatory testing requirements intended to demonstrate equivalency of candidate Class III FEMs. Since we are still early in the process of learning the data comparability between approved $PM_{2.5}$ continuous methods and collocated FRMs (assessments across the country are only available for two of the six methods), and some of the agencies operating those methods are achieving acceptable

data comparability, the EPA does not believe it is appropriate at this time to propose any modifications to either the performance or testing criteria in 40 CFR part 53 used to approve $PM_{2.5}$ continuous FEMs.

While EPA is not proposing any changes to the performance or testing criteria in 40 CFR part 53 used to approve $PM_{2.5}$ continuous FEMs, the EPA proposes an administrative change to part 53.9 – "Conditions of designations." This section describes a number of conditions that must be met by a manufacturer as a condition of maintaining designation of an FRM or FEM. Subsection (c) of this section reads, "Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as part of a FRM or FEM shall function within the limits of the performance specifications referred to in 40 CFR 53.20(a), 53.30(a), 53.50, or 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in 40 CFR 53.4(b)(3)." The EPA's intent in this requirement is to ensure that methods work within performance criteria, which includes methods for $PM_{2.5}$ and $PM_{10-2.5}$; however, there is no specific reference to performance criteria for Class II and III $PM_{2.5}$ and $PM_{10-2.5}$ methods. Therefore, the EPA proposes to link the performance criteria referred to in 40 CFR part 53.35 associated with Class II and III $PM_{2.5}$ and $PM_{10-2.5}$ methods with this requirement for maintaining designation of approved FEMs. The specific performance criteria identified in 40 CFR 53.35 for $PM_{2.5}$ and $PM_{10-2.5}$ methods are available in table C-4 to subpart C of 40 CFR part 53.

2. Use of CSN Methods to Support the Proposed New Secondary $PM_{2.5}$ Visibility Index NAAQS

The EPA, monitoring agencies, and external scientists and policy makers use $PM_{2.5}$ data from the CSN to support several important monitoring objectives such as: development of modeling tools and the application of source apportionment modeling for control strategy development to implement the NAAQS; health effects and exposure research studies; assessment of the effectiveness of emission reductions strategies through the characterization of air quality; and development of SIPs. The initial CSN began with a pilot of 13 sites in 2000 and grew rapidly over the next two years. Since 2006, the size of the CSN has remained relatively stable at approximately 200 stations.

The methods employed in the CSN are well documented and uniformly implemented across the country. However, between May 2007 and October 2009, the CSN transitioned to a new method of sampling and analyses for carbon that is consistent with the IMPROVE network methodology.[197] The CSN measurements have a strong history of being reviewed by CASAC technical committees, both during their initial deployment about ten years ago, and during the more recent transition to carbon sampling that is consistent with the IMPROVE protocols (Henderson, 2005c). The CSN network is described in the Policy Assessment (US EPA, 2011a, Appendix B, section B.1.3).

As noted in section VI.D.1.c above, the proposed new secondary standard for $PM_{2.5}$ to address PM-related visibility impairment is defined in terms of a $PM_{2.5}$ visibility index, which would use $PM_{2.5}$ speciation measurement data. The EPA proposes that measurements using either the CSN or IMPROVE methods[198] be eligible for use to calculate $PM_{2.5}$ visibility index values. The EPA believes this proposed approach is appropriate because the methods for CSN and IMPROVE are well documented[199] in nationally implemented Quality Assurance Project Plans (QAPPs) and accompanying Standard Operating Procedures (SOPs) are validated through independent performance testing, and because numerous state, local, and tribal agencies are already experienced in the use of these methods.

With reference to CSN methods, the EPA is specifically not proposing to include testing or performance criteria for approval of CSN measurements as FRMs. The EPA believes that the proposed framework of using the current, well-documented set of CSN and IMPROVE methods provides a nationally consistent way to provide the chemical species data used in calculating $PM_{2.5}$ visibility index values, while preserving the flexibility for timely improvements to methods for measuring chemical

[197] In the IMPROVE program, artifact adjusted OC (i.e., $PM_{2.5}$ OC) is simply reported as OC. That is the value used to produce OM for haze calculations. For the CSN measurements, the OC artifact needed to convert measured OC into $PM_{2.5}$ OC is estimated from sampler-specific network-wide field blanks (Frank, 2012).

[198] Appendix C to 40 CFR part 58 – Ambient Air Quality Monitoring Methodology is where EPA specifies the criteria pollutant monitoring methods which must be used at SLAMS and NCore, which are a subset of SLAMS.

[199] CSN documents are available at: http://www.epa.gov/ttn/amtic/speciepg.html; IMPROVE documents are available at: http://vista.cira.colostate.edu/improve/Data/QA_QC/qa_qc_Branch.htm).

species. Monitoring programs wishing to establish methods for chemical speciation in support of the proposed $PM_{2.5}$ visibility index would do so by following the methods and SOPs publically available on both the IMPROVE or the EPA (for CSN) websites.[200] The EPA solicits comment on this approach to include the CSN and IMPROVE measurements by reference and not require that such methods be approved as FRMs.

As discussed in section VII.A.5 above, the calculation of the $PM_{2.5}$ visibility index values would use historic monthly average relative humidity data based on a ten-year climatological data base. This data base would be based on measurements of relative humidity reported through NOAA at routine weather stations and not relative humidity measurements specific to the SLAMS stations.

B. Proposed Changes to 40 CFR Part 58 (Ambient Air Quality Surveillance)

1. Proposed Terminology Changes

The EPA proposes to revise several terms associated with $PM_{2.5}$ monitor placement to ensure consistency with other NAAQS and to conform with long-standing practices in siting of equipment by monitoring agencies.

The EPA proposes to revoke the term "community-oriented" and replace it with the term "area-wide." The term "community-oriented," while used within the description of the design criteria for $PM_{2.5}$, is not defined and has not been used in the design criteria for other NAAQS pollutants. Appendix D to 40 CFR part 58 presents a functional usage of the term where sites at the neighborhood and urban scale area are considered to be "community-oriented." In addition, population-oriented, micro-or middle-scale $PM_{2.5}$ monitoring may also be considered "community-oriented" when determined by the Regional Administrator to represent many such locations throughout a metropolitan area. The EPA proposes to replace this functional usage of "community-oriented" with the term "area-wide" in the text

[200] SOP's for the CSN program are available in Docket number EPA-HQ-OAR-2007-0492 and on EPA's website at: http://www.epa.gov/ttn/amtic/specsop.html. SOP's for the IMPROVE program are available in Docket number EPA-HQ-OAR-2007-0492 and on the IMPROVE website at: http://vista.cira.colostate.edu/improve/publications/IMPROVE_SOPs.htm.

of the $PM_{2.5}$ network design criteria and to define it in 40 CFR 58.1 to provide a more consistent usage of this concept throughout appendix D of 40 CFR part 58. The EPA proposes that the terminology would read – "Area-wide means all monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro-or middle-scale that are representative of many such locations in the same CBSA."

The EPA proposes to revoke the term "Community Monitoring Zone" (CMZ) and references to it in 40 CFR part 58. Community monitoring zone is currently defined as "an optional averaging area with established, well defined boundaries, such as county or census block, within an MPA that has relatively uniform concentrations of annual $PM_{2.5}$ as defined by appendix N of 40 CFR part 50 of this chapter. Two or more community oriented state and local air monitoring stations (SLAMS) monitors within a CMZ that meet certain requirements as set forth in appendix N of 40 CFR part 50 may be averaged for making comparisons to the annual $PM_{2.5}$ NAAQS." The EPA proposes to revoke this term and references to it since, as discussed in section VII.A.2 above, the EPA is proposing to eliminate all references to the spatial averaging option throughout appendix N.

2. Special Considerations for Comparability of $PM_{2.5}$ Ambient Air Monitoring Data to the NAAQS

In general, ambient monitors must meet a basic set of requirements before the resulting data can be used for comparison to the NAAQS; these requirements include the presence and implementation of an approved quality assurance project plan, the use of methods that are reference, equivalent, or other approved method as described in appendix C to 40 CFR part 58, and compliance with the probe and siting path criteria as described in appendix E to 40 CFR part 58. While these 40 CFR part 58 requirements apply to a monitor that provides data for comparison to the NAAQS, only in the $PM_{2.5}$ monitoring requirements are additional restrictions prescribed within the monitoring rules.[201] These additional restrictions provide that sites must be "population-oriented" for comparison to either the 24-hour or annual NAAQS, and specifically for comparison to the annual NAAQS, sites must

[201] These are referenced in 40 CFR 58.30 (Special considerations for data comparisons to the NAAQS).

additionally be sited to represent area-wide locations. There is a related provision that provides for comparing sites at smaller scales to the annual NAAQS when the (micro- or middle-scale) site collectively identifies a larger region of localized high ambient $PM_{2.5}$ concentration.

The inclusion of these provisions in the $PM_{2.5}$ monitoring requirements since the 1997 promulgation of the $PM_{2.5}$ NAAQS and associated monitoring requirements has resulted in substantial ambiguity when the EPA and state, local, and tribal agencies consider the design of $PM_{2.5}$ monitoring networks as NAAQS are revised as well as how unmonitored locations should be treated in modeling exercises.[202] Accordingly, the EPA proposes to revise these particular $PM_{2.5}$ requirements for consistency with long-standing practices in all other NAAQS pollutant monitoring networks, and to ensure interpretation of the monitoring rules does not cause ambiguity in considering treatment of unmonitored areas. Each of these topics and our proposal to revoke or modify the requirements is described below.

a. Revoking Use of Population-Oriented as a Condition for Comparability of $PM_{2.5}$ Monitoring Sites to the NAAQS

The EPA proposes to revoke the requirement that $PM_{2.5}$ monitoring sites be "population-oriented" for comparison to the NAAQS. This requirement is inconsistent with our definition of ambient air which the NAAQS employ. The EPA's definition of ambient air is specified in 40 CFR 50.1 – "Ambient air means that portion of the atmosphere, external to buildings, to which the general public has access." The EPA's definition of "population-oriented" is provided in 40 CFR 58.1 - "Population-oriented monitoring (or sites) means residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day." The EPA's intention in proposing to revoke the requirement that $PM_{2.5}$ monitoring sites be "population-oriented" for comparison to the

[202] Modeling can be associated with either PSD or transportation conformity as discussed in sections IX.F and IX.G, respectively, below.

NAAQS is to ensure that the monitoring rules do not create an ambiguity in the use of data by having a different definition from the definition of ambient air in 40 CFR 50.1 itself. Also, EPA's proposal to revoke this term in no way changes the requirements in the $PM_{2.5}$ network design criteria, which will continue to focus on sites representing "area-wide" locations; thus continuing to represent locations with population exposure. While the use of the term "population-oriented" has little effect on how data from existing sites are treated (as explained below there are no remaining sites designated as not being "population-oriented"), the inclusion of this requirement in the monitoring rules creates substantial ambiguity in how to treat potential locations of exposure such as in applying modeling across an area. By reverting to the long-standing definition of ambient air, the EPA will be able to more clearly define how to treat potential exposure receptors, regardless of whether monitoring exists or not.

In reviewing the impact that this proposed change might have on the nation's $PM_{2.5}$ monitoring network, the EPA notes that there are no remaining sites operating affirmatively as "non population-oriented." The last known non population-oriented site at Sun Metro in El Paso Texas (AQS ID: 48-141-0053), was shut down in October 2010 and is in the process of being moved to a nearby neighborhood. While a monitoring agency could still set up a new site in any area, including one in an area that does not meet the definition of population-oriented, which the EPA is proposing to revoke, there are other monitoring options that may provide more useful information and still result in data that are not comparable to the NAAQS; for instance, using a chemical speciation network sampler that provides chemical species information or continuous $PM_{2.5}$ monitor that provides high time-resolution data, but is not approved as an FEM. Even if a monitoring agency wanted to use an FRM, an agency could still operate a monitor for up to 24 months as an SPM without any risk of data being used for comparison to the NAAQS.

b. Applicability of Micro- and Middle-scale Monitoring Sites to the Annual $PM_{2.5}$ NAAQS

The EPA is clarifying language used to determine when $PM_{2.5}$ monitoring sites at micro- and middle-scale locations are comparable to the annual NAAQS. EPA's intent in clarifying this language is

to provide consistency and predictability in the interpretation of the monitoring regulations to minimize the burden on state monitoring programs as they plan and implement their monitoring programs. The EPA's current rules, as specified in 40 CFR 58.30, state that "$PM_{2.5}$ data that are representative, not of area-wide but rather, of relatively unique population-oriented micro-scale, or localized hot spot, or unique population-oriented middle-scale impact sites are only eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. For example, if the $PM_{2.5}$ monitoring site is adjacent to a unique dominating local $PM_{2.5}$ source or can be shown to have average 24-hour concentrations representative of a smaller than neighborhood spatial scale, then data from a monitor at the site would only be eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS." The EPA is clarifying language to explicitly state that measuring $PM_{2.5}$ in micro- and middle-scale environments near emissions of mobile sources, such as a highway, does not constitute being impacted by a "unique" source. Mobile sources are rather ubiquitous and, as such, there are many locations throughout an urban area where elevated exposures could occur. Therefore, any potential location for a $PM_{2.5}$ monitoring site, even micro- and middle-scale sites near roadways would be eligible for comparison to the annual NAAQS. The EPA's existing definition of middle-scale for $PM_{2.5,}$ as specified in appendix D to 40 CFR part 58, already states, "(2) Middle scale—People moving through downtown areas, or living near major roadways, encounter particle concentrations that would be adequately characterized by this spatial scale. Thus, measurements of this type would be appropriate for the evaluation of possible short-term exposure public health effects of particulate matter pollution. In many situations, monitoring sites that are representative of micro- or middle-scale impacts are not unique and are representative of many similar situations. This can occur along traffic corridors or other locations in a residential district. In this case, one location is representative of a number of small scale sites and is appropriate for evaluation of long-term or chronic effects. This scale also includes the characteristic concentrations for other areas with dimensions of a few hundred meters such as the parking lot and feeder streets associated with shopping centers, stadia, and office buildings." With the reference to "traffic corridors" and related text, the EPA emphasizes that this type of location, which is

referred to as near-road, should not be considered "unique."

EPA and monitoring agencies already have a process for approving $PM_{2.5}$ monitoring sites as described in the Annual Monitoring Network Plan due to the applicable EPA Regional Office by July 1 of each year (described in 40 CFR 58.10). This existing process provides for identification of sites that are suitable and sites that are not suitable for comparison against the annual $PM_{2.5}$ NAAQS (§58.10 (b)(7)). This clarifying language will provide consistency between the $PM_{2.5}$ design criteria described in appendix D to 40 CFR part 58 and the example provided in the special considerations for data comparisons to the NAAQS network design (§58.30). This clarifying language will help to ensure a more consistent identification and approval of sites, and therefore a reduction in burden to monitoring agencies and EPA as annual monitoring network plans are prepared, reviewed, public comments are considered, plans are approved and implemented, and data are ultimately used.

3. Proposed Changes to Monitoring for the National Ambient Air Monitoring System

a. Background

As described in appendix D to 40 CFR part 58, the ambient air monitoring networks must be designed to meet three basic monitoring objectives: (a) Provide air pollution data to the general public in a timely manner. Data can be presented to the public in a number of attractive ways including through air quality maps, newspapers, Internet sites, and as part of weather forecasts and public advisories. (b) Support compliance with ambient air quality standards and emissions strategy development. Data from FRM, FEM, and ARM monitors for NAAQS pollutants will be used for comparing an area's air pollution levels against the NAAQS. Data from monitors of various types can be used in the development of attainment and maintenance plans. SLAMS, and especially National Core Monitoring Network (NCore)[203] station data, will be used to evaluate the regional air quality models used in developing emission strategies and to track trends in air pollution abatement control measures' impact

[203] NCore is a multi-pollutant network that integrates several advanced measurements for particles, gases and meteorology (US 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.

on improving air quality. In monitoring locations near major air pollution sources, source-oriented monitoring data can provide insight into how well industrial sources are controlling their pollutant emissions. (c) Support for air pollution research studies. Air pollution data from the NCore network can be used to supplement data collected by researchers working on health effects assessments and atmospheric processes or for monitoring methods development work.

To support the air quality management work indicated in the three basic air monitoring objectives, a network must be designed with a variety of types of monitoring sites. Monitoring sites must be capable of informing managers about many things including the peak air pollution levels, typical levels in populated areas, air pollution transported into and outside of a city or region, and air pollution levels near specific sources. To summarize some of these sites, here is a listing of six general site types: (a) sites located to determine the highest concentrations expected to occur in the area covered by the network; (b) sites located to measure typical concentrations in areas of high population density; (c) sites located to determine the impact of significant sources or source categories on air quality; (d) sites located to determine general background concentration levels; and (e) sites located to determine the extent of regional pollutant transport among populated areas; and in support of secondary standards.

b. Primary $PM_{2.5}$ NAAQS

In this section, the EPA proposes to add a near-road component to the $PM_{2.5}$ network design criteria and to clarify the use of approved $PM_{2.5}$ continuous FEMs at SLAMS.

i. Proposed Addition of a Near-road Component to the $PM_{2.5}$ Monitoring Network

The EPA believes that there are gradients in near-roadway $PM_{2.5}$ that are most likely to be associated with heavily travelled roads, particularly those with significant heavy-duty diesel activity, with the largest numbers of impacted populations in the largest CBSAs in the country (Ntziachristos et al., 2007; Ross et al., 2007; Yanosky et al., 2008; Zwack et al., 2011). To better understand the potential health impacts of these exposures, the EPA proposes to add a near-road component to the compliance network design for $PM_{2.5}$ monitoring. The EPA believes that by adding a modest number of $PM_{2.5}$

monitoring sites that are leveraged with measurements of other pollutants in the near-road environment, a number of key monitoring objectives will be supported, including collection of NAAQS comparable data in the near-road environment, support for long-term health studies investigating adverse effects on people, providing a better understanding of pollutant gradients impacting neighborhoods that parallel major roads, availability of data to validate performance of models simulating near-road dispersion, characterization of areas with potentially elevated concentrations and/or poor air quality, implementation of a multi-pollutant paradigm as stated in the NO_2 NAAQS proposed rule (74 FR 34442, July 15, 2009), and monitoring goals consistent with existing objectives noted in the specific design criteria for $PM_{2.5}$ described in appendix D, 4.7.1(b) to 40 CFR part 58.

The monitoring methods that are appropriate for this purpose are an FRM, FEM, or ARM. The EPA recognizes that there are limitations in the ability of some of these PM methods to accurately measure $PM_{2.5}$ mass due to the incomplete retention of semi-volatile material on the sampling medium (US EPA, 2009a, section 3.4.1.1). This limitation is relevant to the near-road environment as well as to other environments where PM is expected to have semi-volatile components. The EPA also recognizes that continuous $PM_{2.5}$ FEMs, which provide mass concentration data on an hourly basis, are better suited to accomplish the goals of near-road monitoring as they will complement the time resolution of the other air quality measurements and traffic data collected at the same sites. In this regard, particular $PM_{2.5}$ FEMs are better suited for near-road monitoring than FRMs. However, filter-based FRMs do offer some advantages which may be highly desirable for near-road monitoring, such as readily available filters for later chemical analysis such as for elemental composition by x-ray fluorescence and BC by transmissometry. As a result of these tradeoffs, monitoring agencies are encouraged to select one or more $PM_{2.5}$ methods for deployment at near–road monitoring stations that best meet their agencies monitoring objectives while ensuring that at least one of those methods is appropriate for comparison to the NAAQS (i.e., a FRM, FEM, or ARM). EPA believes that by allowing State monitoring agencies to choose the FRM, FEM, or ARM method(s) that best fits their needs, whether filter-based or continuous,

that the data will still be able to meet the objectives cited above while ensuring maximum flexibility for the States in the operation of their network.

Additionally, the EPA recognizes that the near-road sites would provide a valuable platform for evaluating emerging monitoring technologies and for measuring other pollutants besides $PM_{2.5}$ mass to enhance knowledge of exposure in the near road environment and to support the characterization and comparison of specific method readings in an emission-rich environment. Further, in its response to the EPA on a "Review of the "Near-road Guidance Document – Outline" and "Near-road Monitoring Pilot Study Objectives and Approach" (US EPA, 2010i), the CASAC AAMMS cited several other measurements that may be useful or potentially linked to health and welfare effects such as BC, ultrafine particles, and particle size distribution (Russell and Samet, 2010b, pp. xi and xii). The EPA agrees with these recommendations and encourages monitoring agencies to include these measurements, and others cited in the Subcommittee letter, where possible, in addition to the $PM_{2.5}$ mass measurement. The EPA also encourages monitoring agencies to explore partnerships with instrument manufacturers and researchers to use the sites to evaluate the performance of emerging $PM_{2.5}$ methods in the near-road environment, especially potential or current FEMs able to provide temporally resolved data and capture the semi-volatile components of $PM_{2.5}$. Such emerging $PM_{2.5}$ methods could be operated as SPMs to provide comparisons to the EPA approved methods supporting compliance to advance the understanding of instrument performance in the near-road environment. Monitoring agencies are also encouraged to partner with instrument manufacturers and researchers to operate monitors able to measure other PM properties relevant for the near-road environment (e.g., ultrafine particles, BC) to provide additional information about exposure to PM in this environment. The EPA is interested in supporting monitoring agencies willing to operate and report the data from these supplemental monitors. EPA notes that the implementation of additional measurements, while encouraged, is completely voluntary to ensure maximum flexibility for state monitoring programs. The EPA solicits comment on the best way to support such research efforts.

The EPA believes that requiring a modest network of near-road compliance $PM_{2.5}$ monitors is necessary to provide characterization of concentrations in near-road environments. These long-term monitors will supplement shorter-term networks operated by researchers to support the tracking of long-term trends of near-road $PM_{2.5}$ mass concentrations and other pollutants in near-road environments. Therefore, the EPA proposes to require near-roadway monitoring of $PM_{2.5}$ at one location within each CBSA with a population of one million persons or greater. The EPA believes that this network will be adequate to support the NAAQS since the largest CBSAs are likely to have greater numbers of exposed populations, a higher likelihood of elevated near-road $PM_{2.5}$ concentrations, and a wide range of diverse situations with regard to traffic volumes, traffic patterns, roadway designs, terrain/topography, meteorology, climate, surrounding land use and population characteristics. Given the latest population data available, this proposed requirement would result in approximately 52 required near-road $PM_{2.5}$ monitors across the country. An indirect benefit of this network design is that monitoring agencies in these largest CBSAs are more likely to have redundant monitors that could be relocated to the near-road environment, reducing costs for equipment and ongoing operation.[204] While only a single $PM_{2.5}$ monitor is required within each of the CBSAs, agencies may elect to add additional $PM_{2.5}$ monitoring sites in near-road environments.

While the EPA recognizes that the location of maximum concentration of $PM_{2.5}$ from roadway sources might differ from the maximum location of NO_2 or other pollutants, the EPA proposes to require that near-road $PM_{2.5}$ monitors be collocated with the planned NO_2 monitors. The NO_2 network design considers multiple factors that are also relevant for $PM_{2.5}$ concentrations (e.g., average annual daily traffic and fleet mix by road segment) and significant thought and review has gone into its design, including pilot studies at two locations, and the development of a technical assistance document in conjunction with the affected monitoring agencies and the CASAC AAMMS (Russell and Samet,

[204] EPA Regional Administrator approval would be required prior to the discontinuation of SLAMS monitors, based on the criteria described in paragraph 58.14(c) to 40 CFR part 58.

2010b) to support deployment. Further, this collocation will allow multiple pollutants to be tracked in the near-road environment. Therefore, while there may be limitations to collocating the proposed 52 near –road $PM_{2.5}$ monitors with the NO_2 stations that will also host CO monitors, on balance, EPA believes this is the most efficient and beneficial approach for deployment of this component of the network. Thus EPA is seeking to maximize the utility of the network while also reducing the burden on monitoring agencies that have already put significant effort into designing their near-road stations for NO_2 and CO.

The EPA notes that the 52 proposed near-road monitors represent a small number of the total approximate 900 operating $PM_{2.5}$ monitoring stations across the country. The EPA could consider proposing more near-road sites; however, the addition of sites in lower population CBSAs is not expected to lead to much if any difference in characterization of air quality since the bump in $PM_{2.5}$ concentration associated with near-road environments in lower population CBSAs, which typically have corresponding less travelled roads, is expected to be very small. The EPA could also consider proposing multiple sites in larger CBSAs; however, State monitoring programs are already working towards representative near-road monitoring stations and there is a synergistic value in ensuring these measurements are collocated with multiple measurements to serve the monitoring objectives noted above. Since EPA has already finalized requirement of CO monitoring at near-road stations in CBSAs with a population of 1 million or more at sites that are collocated with NO_2, there would be less value in requiring any more than 52 $PM_{2.5}$ monitors as any more stations will not have CO for use in multi-pollutant monitoring objectives (e.g., health studies and model evaluation). Also, EPA wants to ensure there is minimal disruption to the existing network and moving more than the proposed 52 $PM_{2.5}$ monitors may lead to losing some valuable existing $PM_{2.5}$ stations. Therefore, EPA believes the 52 proposed near road monitoring stations represent the least burdensome, but most useful number of near-road monitoring stations to meet the monitoring objectives cited above for deployment across the country.

Ideally, near-road sites would be located at the elevation and distance from the road where maximum concentration of $PM_{2.5}$ occurs in this environment, and within reasonable proximity to an area-wide $PM_{2.5}$ compliance monitoring site at which a similar PM monitor is used (i.e., for comparison purposes). Although the EPA is not proposing that the near-road $PM_{2.5}$ monitors be located within a specific distance of area-wide sites, monitoring agencies are encouraged to consider that a near-road site selected in accordance with monitoring requirements and also located in proximity to a robust area-wide site, such as an NCore station, would provide useful information in characterizing the near-road contribution to multiple pollutants, including $PM_{2.5}$.

The timeline to implement the proposed near-road $PM_{2.5}$ monitors should be as minimally disruptive to on-going operations of monitoring agency programs as possible, while still meeting the need to collect for near-road $PM_{2.5}$ data in a timely fashion. Since the near-road $PM_{2.5}$ monitors are proposed to be collocated with the emerging near-road NO_2 network that is scheduled to be operational by January 1, 2013, the EPA believes it is appropriate to wait until after the near-road NO_2 network is established before implementing the near-road $PM_{2.5}$ monitors. Therefore, the EPA proposes that each $PM_{2.5}$ monitor planned for collocation with a near-road NO_2 monitoring site be implemented no later than January 1, 2015. The EPA believes this proposed deadline provides an appropriate amount of time for monitoring agencies to select existing $PM_{2.5}$ monitors suitable for relocation, receive EPA approval, and physically relocate the $PM_{2.5}$ monitor to the near-road NO_2 site. Based on this proposed timeline, complete data sets (i.e., 3-years representing 2015-2017), from $PM_{2.5}$ monitors in the near-road environment would be available to calculate site-level design values in 2018.

In summary, the EPA proposes to specifically include a near-road component in the $PM_{2.5}$ network design criteria for CBSA's of 1 million persons or greater, with at least one $PM_{2.5}$ monitor collocated with a near-road NO_2 and CO monitors by January 1, 2015. EPA believes that the 52 proposed $PM_{2.5}$ monitors to be collocated with NO_2 and CO monitors in the near-road environment represent the minimal number of sites needed to characterize $PM_{2.5}$ in representative near road

environments of large population CBSA's. EPA believes that a number of $PM_{2.5}$ monitors can be moved from single pollutant locations to multi-pollutant locations in the near-road environment, thus encouraging efficiencies in operation by monitoring agencies and reducing the burden of continuing to support some of the existing single pollutant $PM_{2.5}$ stations. The EPA solicits comment on this approach, especially the proposed network design requirements; any alternative strategies that would provide comparable long-term characterization of $PM_{2.5}$ in area-wide locations of maximum concentration in the absence of a specific near-road compliance requirement for monitoring of $PM_{2.5}$; priorities for the collection of supplemental data at a small subset of near-road monitoring sites to enhance knowledge of particle exposure (e.g., non-compliance SPMs); and the interest of monitoring agencies (or other parties) in the collection of supplemental (e.g., non-compliance) measurements relevant for the near-road environment.

ii. Use of $PM_{2.5}$ Continuous FEMs at SLAMS

The EPA proposes that each agency specify their intention to use or not use data from continuous $PM_{2.5}$ FEMs that are eligible for comparison to the NAAQS as part of their annual monitoring network plan due to the applicable EPA Region Office by July 1 each year. The proposal also provides that the EPA Regional Administrator would be responsible for approving annual monitoring network plans where agencies have provided a recommendation that certain $PM_{2.5}$ FEMs be considered ineligible for comparison to the NAAQS.

In 2006, the EPA finalized new performance criteria for approval of continuous $PM_{2.5}$ monitors as either Class III FEMs or ARMs. The EPA has already approved six $PM_{2.5}$ continuous FEMs and there are nearly 200 of these monitors already operating in State, local, and Tribal networks. Monitoring agencies have been deploying and field-testing these units over the last couple of years and the EPA recently compiled an assessment of the FEM data in relationship to collocated FRMs (Hanley and Reff, 2011; US EPA, 2011a, pp. 4-50 to 4-51). As described in section VI.D.1.a.iii above, the EPA found that some sites with continuous $PM_{2.5}$ FEMs have an acceptable degree of comparability with collocated

FRMs, while others had poor data comparability that would not meet the performance criteria used to approve the FEMs (71 FR 61285-61286, Table C-4, October 17, 2006). The EPA is encouraging use of the FEM data from those sites with acceptable data comparability including for purposes of comparison to the NAAQS. For sites with unacceptable data comparability, the EPA is working closely with the monitoring committee of the NACAA, instrument manufacturers, and monitoring agencies to document best practices on these methods to improve the comparability and consistency of resulting data wherever possible. The EPA believes that the performance of many of these continuous $PM_{2.5}$ FEMs at locations with poor data comparability can be improved to a point where the acceptance criteria noted above can be met.

Given the varying data comparability of continuous $PM_{2.5}$ FEMs noted above, we believe that a need exists for flexibility in the approaches for how such data are utilized, particularly for the objective of determining NAAQS compliance. Accordingly, we propose that monitoring agencies address the use of data from $PM_{2.5}$ continuous FEMs in their annual monitoring network plans due to the applicable EPA Regional Office by July 1 of each year for any cases where the agency believes that the data generated by $PM_{2.5}$ continuous FEMs in their network should not to be compared to the NAAQS. The annual network plans would include assessments such as comparisons of continuous FEMs to collocated FRMs, and analyses of whether the resulting statistical performance would meet the established approval criteria. Based on these quantitative analyses, monitoring agencies would have the option of requesting that data from continuous FEMs be excluded from NAAQS comparison; however, these data could still be utilized for other objectives such as AQI reporting.

The issue exists of whether such data use provisions should be prospective only (i.e., future NAAQS comparability excluded based on an analysis of recent past performance) or a combination of retrospective and prospective (i.e., the implications of unacceptable FEM performance impacting usage of previously collected data as well as future data). The EPA believes that in most cases, monitoring agencies should be restricted to addressing prospective data issues to provide stability and predictability

in the long-term $PM_{2.5}$ data sets used for supporting attainment decisions. However in the first year after this proposed option would become effective, we believe it is appropriate to provide monitoring agencies with a one-time opportunity to review already reported continuous $PM_{2.5}$ FEM data and request that data with unacceptable performance be restricted (retrospectively) from NAAQS comparability. Accordingly, in the first year after this rule becomes effective, we propose that monitoring agencies have the option of requesting in their annual monitoring network plans that a portion or all of the existing continuous $PM_{2.5}$ FEM data, as applicable, as well as future data, be restricted from NAAQS comparability for the period of time that the plan covers.[205] Annual monitoring network plans in subsequent years would only need to cover new data for the period of time that the plan covers.

As noted above, in cases where an agency is operating a $PM_{2.5}$ continuous FEM that is not meeting the expected performance criteria used to approve the FEMs (71 FR 61285 to 61286, Table C-4, October 17, 2006) when compared to their collocated FRMs, an agency can recommend that the data not be used for comparison to the NAAQS. However, all required SLAMS would still be required to have an operating FRM (or other well performing FEM, as evidenced by a prior collocation with an FRM) to ensure a data record is available for comparison to the NAAQS. In cases where a $PM_{2.5}$ continuous FEM was not meeting the expected performance criteria, and the Regional Administrator has approved that the FEM data will not be considered eligible for comparison to the NAAQS, the data would still be required to be loaded to AQS; however, these data would be stored separately from data used for comparison to the NAAQS.

The goal of proposing to allow monitoring agencies the opportunity to recommend not having data from $PM_{2.5}$ continuous FEMs as comparable to the NAAQS is to ensure that only high quality data (i.e., data from FRMs which are already well established and new continuous FEMs that meet the performance criteria used to approve FEMs when compared to collocated FRMs operated in each

[205] Data from any $PM_{2.5}$ monitor being used to meet minimum monitoring requirements could not be restricted from NAAQS comparability.

agencies network) are used when comparing data to the $PM_{2.5}$ NAAQS. Under the current monitoring regulations, a monitoring agency can identify a $PM_{2.5}$ continuous FEM as an SPM, which allows the method to be operated for up to 24 months without its data being used in comparison to the NAAQS. While 24 months should be sufficient time to operate the method across all seasons, assess the data quality, and in some cases resolve operational issues with the instrument, it may still leave some agencies with methods whose data are not sufficiently comparable to data from their FRMs. In these cases there may be a disincentive to continue operating the $PM_{2.5}$ continuous FEM, especially in networks where the monitoring data is near the level of the NAAQS. With the proposed provision where a monitoring agency can recommend not having data from $PM_{2.5}$ continuous FEMs as comparable to the NAAQS, a monitoring agency can continue to operate their $PM_{2.5}$ continuous FEM to support other monitoring objectives (e.g., diurnal characterization of $PM_{2.5}$, AQI forecasting and reporting), while working through options for improved data comparability.

The EPA believes that an assessment of FEM performance should include several elements based on the original performance criteria. The Agency also believes that certain modifications to the performance criteria are appropriate in recognition of the differences between how monitoring agencies operate routine monitors versus how instrument manufacturers conduct required FRM and FEM testing protocols. The details below summarize these issues. The EPA proposes to use the performance criteria used to approve the FEMs (71 FR 61285 to 61286, Table C-4, October 17, 2006) for those agencies that recommend not having data from $PM_{2.5}$ continuous FEMs as comparable to the NAAQS. To accommodate how routine monitoring networks operate, the EPA proposes that agencies seeking to demonstrate insufficient data comparability in an assessment base the analysis mainly on collocated data from FRMs and continuous FEMs at monitoring stations in their network. The EPA does not believe it is practical to utilize the requirement in table C-4 of 40 CFR part 53 for having multiple FRMs and FEMs at each site since such arrangements are not typically found in monitoring agency networks. Accordingly, the requirement for assessing intra-method replicate precision would be inapplicable.

Another consideration is the range of 24-hour data concentrations, for instance, the performance criteria in table C-4 of 40 CFR part 53, provides for an acceptable concentration range of 3 to 200 $\mu g/m^3$. However, the EPA notes that during an evaluation of data quality from two FEMs (US EPA, 2011a, p. 4-50), the Agency found that including low concentration data were helpful for understanding whether an intercept or slope was driving a potential bias in an instrument. Therefore, the EPA proposes that agencies may include low concentration data (i.e., below 3 $\mu g/m^3$) for purposes of evaluating the data comparability of continuous FEMs. With regard to the minimum number of samples needed for the assessment, the EPA notes that a minimum of 23 sample pairs are specified for each season in table C-4 of 40 CFR part 53. Having 23 sample pairs per season should be easily obtainable within one year for sites with a FRM operating on at least a 1 in 3 day sample frequency and we propose that this requirement be applicable to the assessments being discussed here. For sites on a one in 6 day sampling frequency, two years of data may be necessary to meet this requirement. The EPA recognizes that it would be best to assess the data based on the most recently available information; however, having data across all seasons in multiple years will provide a more robust data set for use in the data comparability assessment; therefore, the EPA proposes that data quality assessments be permitted to utilize up to the last three years of data for purposes of recommending not having data from $PM_{2.5}$ continuous FEMs as comparable to the NAAQS.

The EPA recognizes that only a portion of continuous $PM_{2.5}$ FEMs will be collocated with FRMs, and it would be impractical to restrict the applicability of data comparability assessments to only those sites that had collocated FRM and FEM monitors. In these cases, the monitoring agency will be permitted to group the sites that are not collocated with an FRM with another similar site that is collocated with an FRM for purposes of recommending that the data are not eligible for use in comparison to the NAAQS. Monitoring agencies may recommend having $PM_{2.5}$ continuous FEM data eligible for comparison to the NAAQS from locations where the method has been demonstrated to provide acceptable data comparability, while also recommending not having it eligible in other types of

areas where the method has not been demonstrated to meet data comparability criteria. For example, a rural site may be more closely associated with aged particles where volatilization issues are minimized resulting in acceptable data comparability between filter-based and continuous methods, while a highly populated urban site with fresh emissions may result in higher readings on the $PM_{2.5}$ continuous FEM that would not meet the expected performance criteria as compared to a collocated FRM. In all cases where a monitoring agency chose to group sites for purposes of identifying a subset of $PM_{2.5}$ continuous FEMs that would not be comparable to the NAAQS, the assessment submitted with the annual monitoring network plan would have to provide sufficient detail to support the identification of which combinations of method and sites would, and would not, be comparable to the NAAQS, as well as the rationale and quantitative basis for the grouping and recommendation.

The EPA solicits comment on all aspects of this proposed approach of allowing monitoring agencies to recommend that $PM_{2.5}$ continuous FEM data should not be compared to the NAAQS, when demonstrated to not meet the performance criteria used to approve FEMs based on data in their own network, and as appropriate, approved by the EPA Regional Administrators as ineligible for comparison to the NAAQS.

c. Revoking $PM_{10-2.5}$ Speciation Requirements at NCore Sites

The EPA issued revisions to the Ambient Air Monitoring Regulations (40 CFR parts 53 and 58) on October 17, 2006 (71 FR 61236). In the 2006 final rule, the EPA required that $PM_{10-2.5}$ speciation be conducted at NCore multi-pollutant monitoring stations by January 1, 2011. $PM_{10-2.5}$ speciation at NCore was intended to support further research in the understanding of the chemical composition and sources of PM_{10}, $PM_{10-2.5}$ and $PM_{2.5}$ at a variety of urban and non-urban NCore locations. Subsequent to the completion of the 2006 final monitoring rule, several technical issues were raised concerning the readiness of $PM_{10-2.5}$ speciation monitoring methodologies to support such a nation-wide deployment strategy. Based on these issues and as explained in detail below, the EPA proposes to revoke the requirement for $PM_{10-2.5}$ speciation monitoring as part of the current suite of NCore monitoring

requirements. The requirement to monitor for $PM_{10-2.5}$ mass (total) at all NCore multi-pollutant sites remains. Monitoring was commenced on January 1, 2011 as part of the nationwide startup of the NCore network (US EPA, 2011a, p. 1-15).

As part of the process to further define appropriate techniques for $PM_{10-2.5}$ speciation monitoring, a public consultation with the CASAC AAMMS on monitoring issues related to $PM_{10-2.5}$ speciation was held in February 2009 (74 FR 4196, January 23, 2009). At that time, the subcommittee noted the lack of consensus on appropriate sampling and analytical methods for $PM_{10-2.5}$ speciation and expressed concern that the Agency's 2006 commitment to launch the $PM_{10-2.5}$ monitoring network without sufficient time to analyze the data from a planned pilot project was premature (Russell, 2009). Based on the noted lack of consensus on $PM_{10-2.5}$ speciation monitoring techniques, the Agency did plan and implement a small pilot monitoring project to evaluate the available monitoring and analytical technologies and supplement the $PM_{10-2.5}$ speciation measurements that have mostly been done as part of other research efforts. The EPA expects that this field study will address the issues needed to develop a more robust, long-term $PM_{10-2.5}$ speciation monitoring plan.

The EPA pilot monitoring project will be completed in 2011, with plans to analyze the data and prepare a final report on findings and recommendations in 2012. At that time, the EPA will consider what $PM_{10-2.5}$ speciation sampling techniques, analytical methodologies, and network design strategies would be most appropriate as part of a potential nation-wide monitoring deployment. Such a deployment could be based on the NCore multi-pollutant framework, or some other strategy that targets such measurements in areas with higher levels of coarse particles. This latter type of strategy would be consistent with CASAC AAMMS members written comments that not all NCore sites would be adequate for $PM_{10-2.5}$ speciation and that more flexibility in $PM_{10-2.5}$ speciation network design would allow for a geographically diverse network to support health studies and research (Russell, 2009).

The EPA may consider reintroducing some $PM_{10-2.5}$ speciation monitoring requirements in a subsequent monitoring rulemaking or as part of a future review of the PM NAAQS. Until that time, the

EPA believes it is appropriate to propose to revoke the current set of $PM_{10-2.5}$ speciation monitoring requirements. The EPA solicits comment on this proposed revision to monitoring requirements.

d. Measurements for the Proposed New $PM_{2.5}$ Visibility Index NAAQS

The EPA proposes requirements for sampling of $PM_{2.5}$ chemical speciation in states with large CBSAs. The CSN has been operating for approximately 10 years and as described earlier in this proposal already supports a number of important monitoring objectives. Since the CSN network is already well established in states with large CBSAs, the EPA believes that using the data from these existing sites as an input for calculating $PM_{2.5}$ visibility index values will help ensure that the network can continue to support existing objectives, while also supporting the proposed new secondary standard.

To ensure the CSN network can support its existing network objectives while also supporting the proposed new secondary $PM_{2.5}$ visibility index standard (section VI.F), the EPA proposes that each state with a CBSA over 1 million have measurements based on the methods in CSN (or IMPROVE), as discussed in section VII.A.5 above, in at least one of its CBSAs. For states with urban or suburban NCore Stations, their existing CSN measurements at all NCore sites would be appropriate to meet this proposed requirement. For states with multiple high population CBSAs, the EPA proposes that each CBSA with a population over 2.5 million people be required to have CSN measurements. The EPA does not believe it would be appropriate to require multiple cities in the same state to have CSN measurements for purposes of supporting the proposed new secondary $PM_{2.5}$ visibility index standard when these cities have relatively smaller populations (i.e., less than 2.5 million people) as the chemical species data may be similar across cities in the same state. The exception to this will be the most highly populated states and cities, which are either already covered by requirements for multiple NCore stations or the proposed population threshold of 2.5 million people. For example, the following high population states are already required to have multiple NCore stations: California, Florida, Illinois, Michigan, New York, North Carolina, Ohio, Pennsylvania, and Texas. The EPA also proposes that states be allowed to request alternative CBSAs to locate their CSN measurements, when the alternative location is better

suited to support providing data for multiple monitoring objectives, including for the proposed new secondary $PM_{2.5}$ visibility index standard. For example, in some cases a large CBSA with a marine influence may have relatively cleaner air than a smaller inland CBSA in the same state with a lower population. In these cases, states may request an alternative location for their CSN measurements. The EPA solicits comment of these proposed requirements and on alternative requirements for CSN measurements to support the proposed new secondary $PM_{2.5}$ visibility index standard.

The EPA proposes that the network design criteria for CSN measurements focus on area-wide locations that are generally representative of long distances throughout a CBSA. For most CBSAs, this will mean that the existing inventory of CSN measurements can be used where the location of the sampling equipment is at an NCore station or other station(s) sited at the neighborhood or urban scale of representation. The EPA points out that while the existing $PM_{2.5}$ network design criteria established to support the primary $PM_{2.5}$ NAAQS focuses on the area-wide locations of expected maximum concentration, there would not necessarily be the same focus for the proposed new secondary $PM_{2.5}$ visibility index standard. One reason for this difference is that for urban visibility, we are interested in the impact of visibility degradation over as representative a location as possible as the impact of the aerosol is a function of an entire site path and not just one monitoring location within a CBSA. Also, the EPA is interested in leveraging as much of the existing inventory of CSN and IMPROVE measurements operating in CBSAs where they can support the proposed new secondary $PM_{2.5}$ visibility index standard.

The EPA considered the issue of siting measurements to support a new secondary standard to address PM-related visibility impairment during a consultation with the CASAC AAMMS (75 FR 4069, January 26, 2010). In its letter to the EPA, the CASAC AAMMS stated that "the Subcommittee strongly favored collocation of extinction measurements with PM mass, PM speciation, and precursor gas measurements, identifying continuous PM mass and speciation measurements as being of particular value. NCore multi-pollutant monitoring sites were identified as worth considering even though these would not necessarily capture maximum concentrations and visibility impairment in an urban area"

(Russell and Samet, 2010a, p. 18). The EPA notes that the Subcommittee also identified that "[t]here was general support for making public communication an important consideration in network design, for example by selecting a monitoring site that can be associated with a vista that is recognized by a significant fraction of the local population" (Russell and Samet, 2010a, p. 18). While the EPA agrees that siting associated with a recognizable vista would be a useful consideration for establishing new sites, the EPA does not believe it would be appropriate to include such a requirement for cities with existing sites as this may disrupt the use of data to meet other important monitoring objectives. The EPA also notes existing long-standing public communication tools such as the "Haze-Cam" network are already well suited for public communications of important vistas.[206] In addition to collocation with several important measurements at NCore as cited by the Subcommittee, the EPA is also encouraging monitoring agencies to add other important measurements such as commercially available technologies for light absorption and light scattering; however, the EPA does not believe these technologies should be specified by regulation.

Since EPA's proposal to require CSN (or IMPROVE) sampling is consistent with a network that is largely already in place, there is no expectation new sites will be needed. However, from time to time there is a disruption of sampling due to loss of a sites lease agreement or other circumstances. Therefore, for any state that does not have a minimally required CSN (or IMPROVE) set of measurements in place, the EPA proposes that these measurements be in place and sampling by January 1, 2015.

4. Proposed Revisions to the Quality Assurance Requirements for SLAMS, SPMs, and PSD

a. Quality Assurance Weight of Evidence

The EPA believes that the process by which monitoring organizations and the EPA use the appendix A of 40 CFR part 58 regarding quality assurance requirements in regulatory decision making needs to be articulated. Prior interpretations of appendix A have led to disqualification of data for noncompliance with a particular appendix A requirement. The proposed language described below,

[206] See http://www.hazecam.net/.

provides the interpretation the EPA would use moving forward.

The appendix A to 40 CFR part 58 requirements represent a portion of the quality control activities that are implemented by monitoring organizations to control data quality. The EPA believes that while it is essential to require a minimum set of checks and procedures in appendix A to support the successful implementation of a quality system, the success or failure of any one check or series of checks does not preclude the EPA from determining that data are of acceptable quality to be used for regulatory decision-making purposes. The EPA proposes to use a weight-of-evidence approach for determining whether the quality of data is appropriate for regulatory decision-making purposes. Furthermore, the suitability of data for any regulatory purpose also relies, in part, on several other quality-related requirements found elsewhere in 40 CFR part 58. These requirements include air monitoring methodology (appendix C), network design criteria (appendix D) and network design plans for SLAMS, probe siting criteria (appendix E), the reporting of data to AQS, data completeness, and data certification by the reporting organization. This weight of evidence approach recognizes that all measurement systems have uncertainty and there are numerous factors that can affect data quality at a particular monitoring site. The specific appendix A criteria are designed to provide a quantification of this uncertainty, support a framework for assessing such uncertainty against known data quality goals and to support corrective actions when necessary to control uncertainty back to acceptable levels. Accordingly, the EPA proposes additional wording in appendix A to clarify the role that appendix A generated data quality indicators have in the overall quality system that supports ambient air monitoring activities.

b. Quality Assurance Requirements for the Chemical Speciation Network

The EPA proposes to include requirements for flow rate verifications and flow rate audits for the $PM_{2.5}$ CSN. These audits are currently being performed so, although they will be considered a new requirement, they are not new implementation activities. In addition, the CSN already includes six collocated sites which the EPA proposes to include in the 40 CFR part 58 appendix A requirements. The

EPA proposes that PSD sites would not be required to collocate a second set of instruments for speciated $PM_{2.5}$ mass monitoring.

The EPA performed an assessment of measurement uncertainty from the collocated CSN and IMPROVE stations using the proposed visibility index (Papp, 2012) and concluded that the current data quality goals for the $PM_{2.5}$ mass can be achieved for the proposed calculated light extinction indicator.

c. Waivers for Maximum Allowable Separation of Collocated $PM_{2.5}$ Samplers and Monitors

The EPA proposes to allow waivers for the maximum allowable distance associated with collocated $PM_{2.5}$ samplers and monitors. As described in section VIII.A.1 of this proposal, the EPA has already approved six Class III $PM_{2.5}$ continuous FEMs. Several of these approved FEMs are required to be installed in a shelter with sufficient control of heating and air conditioning to ensure stable operation of the instrument. In many cases monitoring agencies are installing these approved continuous FEMs in shelters where they already have gas analyzers operating. Some agencies operate filter-based samplers (e.g., $PM_{2.5}$ FRMs) on top of their shelter, while others operate platforms next to their shelter. In either case, ensuring $PM_{2.5}$ continuous FEMs and $PM_{2.5}$ FRMs meet collocation requirements (i.e., 1 to 4 meters for $PM_{2.5}$ samplers with flow rates of less than 200 liters/minute) can be challenging, since in some cases multiple instruments, some installed in the shelter and some installed on a platform, are being sited at the same station.

The EPA believes that maintaining the current requirement of 1 to 4 meters for $PM_{2.5}$ samplers with flow rates of less than 200 liters/minute is useful since it ensures consistency with long-standing practices of collocation and ensures that any air drawn through collocated samplers is well within the operational precision of the instruments. However, the EPA also believes that instruments spaced farther apart could also be within the operational precision of the instruments, especially at sites located at larger scales of representation (e.g., neighborhood scale and larger). The EPA already defines a collocated scale in its document "Guidance for Network Design and Optimum Site Exposure for $PM_{2.5}$ and PM_{10} (US EPA, 1997). In this document, the EPA defines a collocated scale as 1 to 10 meters. The

EPA believes that almost all agencies would be able to site collocated PM samplers and monitors within 10 meters. Therefore, the EPA proposes to allow waivers, when approved by the EPA Regional Administrator, for collocation of $PM_{2.5}$ samplers and monitors of up to 10 meters so long as the site is at a neighborhood scale or larger. The EPA solicits comment on this proposed change to allow waivers of the maximum allowable distance for collocated $PM_{2.5}$ samplers and monitors.

5. Proposed Probe and Monitoring Path Siting Criteria

a. Near-road Component to the $PM_{2.5}$ Monitoring Network

The EPA proposes that the probe and siting criteria for the near-road component to the $PM_{2.5}$ monitoring network design follow the same probe and siting criteria as the NO_2 near-road monitoring sites. These requirements would provide that the monitoring probe be sited "…as near as practicable to the outside nearest edge of the traffic lanes of the target road segments; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment" (section 6.4 of appendix E to 40 CFR part 58). The EPA solicits comment on this proposed probe and siting criteria for the proposed near-road component to the $PM_{2.5}$ monitoring network design.

b. CSN Network

The EPA proposes to extend the existing probe and monitoring path siting criteria described in appendix E to 40 CFR part 58 for $PM_{2.5}$ FRMs and FEMs to the CSN measurements. The EPA believes that monitoring agencies are already following the probe and siting criteria for $PM_{2.5}$ when conducting CSN measurements; that is, at neighborhood, urban, and regional scale sites the probe height must be 2 to 15 meters above ground level. All other aspects of the existing $PM_{2.5}$ probe and siting criteria would also apply including minimum distances from horizontal supporting structures (i.e., greater than 2 meters) and minimum distance to the drip-line of a tree (i.e., greater than 10 meters). The IMPROVE program SOP (IMPROVE, 1996) on site selection already provides for meeting probe and siting criteria described in Appendix E. The EPA solicits comment on extending the existing probe and siting criteria

for PM to the speciation measurements used to support the proposed new secondary $PM_{2.5}$ visibility index standard.

c. Reinsertion of Table E-1 to Appendix E

The EPA is proposing to reinsert table E-1 to appendix E of 40 CFR part 58. This table presents the minimum separation distance between roadways and probes or monitoring paths for monitoring neighborhood and urban scale ozone (O_3) and oxides of nitrogen (NO, NO_2, NO_x, NO_y). This table was inadvertently removed during a previous CFR revision process. The EPA is utilizing this proposed rule to reinsert this table, unchanged from its prior iteration, back into the CFR.

6. Additional Ambient Air Monitoring Topics

a. Annual Monitoring Network Plan and Periodic Assessment

In October of 2006, the EPA finalized new requirements for each state, or where applicable, local agency to perform and submit to their EPA Regional Offices an Assessment of the Air Quality Surveillance System (40 CFR 58.10). This assessment is required every five years. The first required five year assessments were submitted to EPA Regional Offices on or before July 1, 2010. The assessments are intended to provide a comprehensive look at each monitoring agencies ambient air monitoring network to ensure that the network is meeting the minimum monitoring objectives defined in appendix D to 40 CFR part 58, whether new sites are needed, whether existing sites are no longer needed and can be terminated, and whether new technologies are appropriate for incorporation into the ambient air monitoring network.[207]

Since each state has completed their first required five-year assessment, and several monitoring rule requirements have either been added or changed since this requirement was added in 2006, the EPA thinks it is appropriate to review this requirement and solicit comment on any possible changes the EPA

[207] The EPA provides a link to these assessments on EPA's website 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.

should consider that may improve the usefulness of the assessments. Specifically, the EPA solicits comment on ways to either streamline or add additional criteria for future assessments. Even if no changes to the requirements are recommended by any commenters, the EPA is especially interested in learning from monitoring agencies that may have ideas on how to improve future assessments. Such ideas may not necessarily have to be incorporated into regulation, but could be referred to in our guidance on network assessments (US EPA, 2007b).

The EPA proposes to remove references to "community monitoring zones" and "spatial averaging" in the annual monitoring network plans due to EPA Regional Offices by July 1 of each year. The Agency proposes to remove these references since, as discussed in section VII.A.2 above, the EPA is proposing to remove all references to the spatial averaging option throughout 40 CFR part 50 appendix N. Consistent with these changes, the EPA also proposes to remove references to community monitoring zones under the annual monitoring network plans described in 40 CFR 58.10.

b. Operating Schedules

The EPA generally requires $PM_{2.5}$ SLAMS to operate on at least a 1-day-in-3 sampling schedule, unless a reduced sampling frequency is approved such as might be the case with a site that has a collocated continuous operating $PM_{2.5}$ monitor.[208] However, in the 2006 monitoring rule amendments, the EPA finalized a new requirement for the operating schedule of $PM_{2.5}$ SLAMS sites (40 CFR 58.12). The new requirement stated that sites with a design value within plus or minus five percent of the 24-hour $PM_{2.5}$ NAAQS must have an FRM or FEM operating on a daily sampling schedule. This requirement was included to minimize any statistical error associated with the form of the 24-hour $PM_{2.5}$ NAAQS (i.e., the 98th percentile). In section III.F, the Administrator is proposing to revise the level of the primary annual $PM_{2.5}$ NAAQS. Accordingly, she is now considering whether this proposed change should result in any changes to sampling frequency requirements.

[208] All NCore stations must operate on at least a one-in-three day sample frequency for filter-based PM sampling.

The EPA had previously considered how sample frequency affects the Data Quality Objectives in a consultation with the CASAC AAMMS in September of 2005 (70 FR 51353 to 51354, August 30, 2005). As a result of that consultation, the EPA proposed (71 FR 2710 to 2808, January 17, 2006) and finalized (71 FR 61236 to 61328, October 17, 2006) changes to the sample frequency requirements as part of the monitoring rule changes in 2006. In that work, the EPA demonstrated that having a higher sample count is generally more useful to minimize uncertainty for a percentile standard than an annual average. Given the proposed strengthening of the primary annual $PM_{2.5}$ NAAQS and the known burden of performing daily sampling using the filter-based samplers that are still a mainstay in monitoring agency networks, the issue of needing daily sampling for sites that have design values close to the level of the 24-hour $PM_{2.5}$ standard should be reconsidered if the site already has a design value above the level of the primary annual $PM_{2.5}$ NAAQS.

In a related issue, since the EPA finalized the requirement for daily sampling at sites within 5 percent of the 24-hour $PM_{2.5}$ NAAQS in 2006, there has been confusion over the procedures for adjusting sample frequencies, where necessary, to account for variations in year-to-year design values. Therefore, the EPA proposes to revise this requirement in the following ways: (1) The EPA proposes that monitors would only be required to operate on a daily schedule if their 24-hour design values are within five percent of the 24-hour $PM_{2.5}$ NAAQS and the site has a design value that is not above the level of the annual $PM_{2.5}$ NAAQS. (2) The EPA proposes that review of data for purposes of determining applicability of this requirement at a minimum be included in each agency's annual monitoring network plan described in 40 CFR 58.10 based on the three most recent years of ambient data that were certified as of the May 1 deadline. However, monitoring agencies may request changes to sample frequency at any time of the year by submitting such a request to their applicable EPA Regional Office. Changes in sampling frequency are expected to take place by January 1 of the following year. Increased sampling is expected to be conducted for at least three years, unless a reduction in sampling frequency has been approved in a subsequent annual monitoring network plan or otherwise approved by

the Regional Administrator. The EPA solicits comment on these proposed changes to the required operating schedule for $PM_{2.5}$ SLAMS.

c. Data Reporting and Certification for CSN and IMPROVE Data

The EPA solicits comment on minor changes to reporting and certification of data associated with CSN and IMPROVE data. The chemical analyses of filters associated with CSN measurements results in reporting of data that are usually within three months of the sample collection. This fits within the existing reporting requirements for most ambient air measurements that data be reported within 90 days past the end of the previous quarterly reporting period (40 CFR 58.15). However, some agencies also use IMPROVE or their own internal laboratory for processing of chemical analyses. IMPROVE is known to validate and report its data on a schedule that is approximately 12 to 18 months after sample collection. At least one state laboratory continues to provide chemical analysis of filters associated with sites that are not NCore (note: all NCore stations use either IMPROVE or the CSN National Laboratory contractor for their speciation laboratory analysis). Therefore, the EPA solicits comment on including the existing reporting requirements when reporting CSN measurements. In addition, the EPA also solicits comment on a longer reporting and certification[209] schedule specifically for CSN and IMPROVE that appropriately balances having sufficient time to analyze, validate, and report data with the need to have the data in sufficient time to use in assessments including calculating the proposed $PM_{2.5}$ visibility index values discussed in section VII.A.5 above. Since 2010, the EPA has required states to certify their data by May 1 of each year. Since in some cases chemical speciation data may not be fully validated and submitted to EPA by May 1 of a given year, the EPA solicits comment on having data certification of these speciation measurements take place by May 1 of the following year. For example, if the fourth quarter chemical speciation data were not fully available to certify by May 1 of the following year, it would be certified another 12 months after that. The EPA solicits comment on the reporting and certification schedules for chemical speciation data.

[209] Data certification requirements are described in 40 CFR 58.15.

d. Requirements for Archiving Filters

The EPA proposes to extend the requirement for archival of $PM_{2.5}$, PM_{10}, and $PM_{10-2.5}$ filters from manual low-volume samplers (samplers with a flow rate of less than 200 liters/minute) at SLAMS from one year after data collection to five years after data collection. The archive of low-volume PM filters is an important tool for on-going research and development of emission control strategies and for use in health and epidemiology research. During a workshop on Ambient Air Quality Monitoring and Health Research in 2008, retaining filters for laboratory analysis was identified as a key recommendation to provide daily measurements of metals and elements (US EPA, 2008d, pp. 17 to 21). The EPA's current requirement of one-year is not sufficiently long for retrospective analysis of important episodes and for use in long-term epidemiology research. Since first requiring filter archival of low-volume PM filters in 1997, the EPA has always recommended longer filters archives and most agencies are already doing so. However, a small number of agencies have reported discarding older filters, despite the minimal cost of storing these filters. Since cold storage of a large number of filters may be cost prohibitive and of little benefit in retaining key aerosol species in the x-ray fluorescence (XRF) analyses, the EPA proposes to minimize the costs of retaining filters by only requiring cold storage during the first year after sample collection. Therefore, the EPA solicits comment on this proposal to extend the filter archival requirement from one to five years, but only require cold storage during the first year.

IX. Clean Air Act Implementation Requirements for the PM NAAQS

The proposed revisions to the primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS discussed in sections III.F and VI.F above, if finalized, would trigger a process under which states[210] will make recommendations to the Administrator regarding area designations, and the EPA will take final action on these designations. States will also be required to review, modify, and

[210] This and all subsequent references to "state" are meant to include state, local and tribal agencies responsible for the implementation of a $PM_{2.5}$ control program.

supplement their existing implementation plans. The proposed PM NAAQS revisions would also affect the applicable air permitting requirements and the transportation conformity and general conformity processes. This section provides background information for understanding the possible implications of the proposed NAAQS changes, and describes the EPA's plans for providing states necessary guidance or rules in a timely manner to clarify how they are affected and to assist their implementation efforts. This section also describes existing EPA interpretations of CAA requirements and other EPA guidance relevant to implementation of new or revised NAAQS. Relevant CAA provisions that provide potential flexibility with regard to meeting implementation timelines are also discussed.

This section also contains a discussion of several requirements of the stationary source construction permit programs under the CAA that may be affected by the proposed revisions of the PM NAAQS. These are the PSD and Nonattainment New Source Review (NNSR) programs. To facilitate implementation of the PSD requirements, which would be the first of the implementation requirements to become applicable upon the effective date of the final NAAQS rule, the EPA proposes as part of this rulemaking to add a grandfathering provision to its regulations that would apply to certain PSD permit applications that are pending on the effective date of the revised PM NAAQS. If the proposed NAAQS revisions are finalized, this rule could be finalized at the same time as the revised NAAQS. This section also discusses other possible actions under consideration to facilitate implementation of the PSD and NNSR programs (see section IX.F).

The EPA intends to propose additional appropriate regulations or issue guidance related to the implementation requirements for the revised PM NAAQS at a later date or dates. These may include additional revisions to both the PSD and NNSR regulations, as well as the promulgation of rules or development of guidance related to NAAQS implementation. These actions will be taken on a schedule that provides timely assistance to responsible states. Accordingly, in this section, the EPA solicits comment on several issues that the Agency anticipates will need to be addressed in future guidance or regulatory actions. Because these issues are not relevant to the establishment of the NAAQS, the EPA

does not expect to respond, nor is the Agency required to respond, to these comments in the final action on this proposal, but the EPA expects these comments will be helpful as future guidance and regulations are developed.

A. Designation of Areas

After the EPA establishes or revises a NAAQS, the CAA requires the EPA and the states to take steps to ensure that the new or revised NAAQS is met. The first step, known as the initial area designations, involves identifying areas of the country that either meet or do not meet the new or revised NAAQS along with the nearby areas contributing to violations.

Section 107(d)(1) of the CAA states that, "By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109, the Governor of each state shall … submit to the Administrator a list of all areas (or portions thereof) in the State" that designates those areas as nonattainment, attainment, or unclassifiable.[211] Section 107(d)(1)(B)(i) further provides, "Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) … as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations." The term "promulgation" has been interpreted by the courts with respect to the NAAQS to be signature and widespread dissemination of a rule. By no later than 120 days prior to promulgating designations, the EPA is required to notify states of any intended modifications to their boundaries as the EPA may deem necessary. States then have an opportunity to comment on the EPA's tentative decision. Whether or not a state provides a recommendation, the EPA must timely promulgate the designation that it deems appropriate. While section 107 of the CAA specifically addresses states, the EPA intends to follow the same process for

[211] While the CAA says "designating" with respect to the Governor's letter, in the full context of the CAA section it is clear that the Governor actually makes a recommendation to which the EPA must respond via a specified process if the EPA does not accept it.

tribes to the extent practicable, pursuant to section 301(d) of the CAA regarding tribal authority, and the Tribal Authority Rule (63 FR 7254; February 12, 1998). To provide clarity and consistency in doing so, the EPA issued a 2011 guidance memorandum on working with tribes during the designations process (Page, 2011).

Monitoring data are currently available from numerous existing $PM_{2.5}$ mass and $PM_{2.5}$ speciation sites to determine compliance with the proposed revised primary annual $PM_{2.5}$ NAAQS and with the proposed $PM_{2.5}$ visibility index NAAQS. As discussed in sections III and VI above, the EPA is proposing to: (1) revise the form and level of the primary annual $PM_{2.5}$ standard and retain the current primary 24-hour $PM_{2.5}$ standard (section III.F); (2) retain the current secondary 24-hour $PM_{2.5}$ standard and revise the form and retain the level of the secondary annual $PM_{2.5}$ standard for non-visibility-related welfare protection (section VI.F); and (3) establish a distinct secondary $PM_{2.5}$ visibility index standard (section VI.F). The EPA's examination of air quality monitoring data current at the time of this proposal indicates that, for the proposed levels for primary standards and the secondary $PM_{2.5}$ visibility index standard, it is likely that the vast majority of monitors violating this secondary standard would overlap with monitors violating the primary standards. Since the same types of emissions sources contribute to concentrations affecting attainment status for both the proposed primary and secondary NAAQS, the EPA expects that the nonattainment area boundaries in locations with such overlap would be identical. The EPA will, consistent with previous area designations, use area-specific factor analysis[212] to support area boundary decisions for both the primary and secondary standards. The EPA intends to more fully address issues affecting area designations in designations guidance that will be issued around the same time as any revised $PM_{2.5}$ NAAQS are finalized. The EPA solicits comment related to establishing nonattainment area boundaries for the proposed revised primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS, including any relevant technical information that should be

[212] The EPA has used area-specific factor analyses to support boundary determinations by evaluating factors such as air quality data, emissions data, population density and degree of urbanization, traffic and commuting patterns, meteorology, and geography/topography.

considered by the EPA, and any input on the extent to which different considerations may be relevant to establishing boundaries for a secondary $PM_{2.5}$ NAAQS.

For the reasons stated above, upon promulgation of the revised NAAQS, the EPA currently intends to move forward on the same schedule with the initial area designations for both the revised primary annual $PM_{2.5}$ standard and the secondary $PM_{2.5}$ visibility index standard. The EPA notes that promulgating initial area designations for these standards on the same schedule will provide early regulatory certainty for states. The EPA intends to promulgate the revised PM NAAQS in December 2012 and complete initial designations for both the revised primary annual $PM_{2.5}$ NAAQS and the secondary $PM_{2.5}$ visibility index NAAQS by December 2014 using available air quality data from the current $PM_{2.5}$ and speciation monitoring networks. These designations would follow the standard 2-year process described previously and would be based on 3 consecutive years of certified air quality monitoring data from the years 2010 to 2012, or 2011 to 2013. (Note, as discussed in sections IV.F and VI.F above, the EPA is proposing to retain the current primary 24-hour PM_{10} standard and to revise the form of the secondary annual $PM_{2.5}$ standard to remove the option for spatial averaging and to retain all other elements of the current suite of secondary PM standards to address non-visibility welfare effects. A new round of mandatory designations for these standards would occur only if these standards change.[213])

In today's action, as discussed in section VIII.B.3.b.i above, the EPA is proposing to add requirements for establishing near-road $PM_{2.5}$ monitors in certain cities. If these requirements are finalized, the EPA anticipates that it will take up to 3 years to establish new monitoring sites for $PM_{2.5}$ mass, plus an additional 3 years of monitoring thereafter to determine compliance with the mass-based primary and secondary $PM_{2.5}$ NAAQS based on these new monitors. This means that a complete set of

[213] As discussed in section in VII.A.2 above, the EPA is proposing to remove the option for spatial averaging from the form of the secondary annual $PM_{2.5}$ NAAQS consistent with the proposed change in the form of the primary annual $PM_{2.5}$ standard. The EPA does not consider this change to trigger a new round of non-discretionary designations for this standard.

air quality data for use in designations from any near-road monitoring sites would not be available until 2018. Also, as discussed in section VIII.B.3.d above, the EPA is proposing that each state with a CBSA over 1 million in population would need to have a CSN (or IMPROVE) monitoring site in at least one of its CBSAs to collect speciated $PM_{2.5}$ data to support implementation of the proposed secondary standard to address visibility impairment. This proposal may require the addition of new monitors, or the relocation of existing monitors, in some CBSAs. The EPA is also proposing in today's action to extend the data certification period for speciation measurements by 12 months. Thus, even if EPA were to consider taking an additional year to complete the designations process (i.e., in December 2015 instead of in December 2014), data from new $PM_{2.5}$ near-road monitoring sites would not be available prior to the extended CAA designation deadline; and data from certain CSN (or IMPROVE) monitors also may not be available prior to the extended CAA designation deadline. For these reasons, the EPA does not currently intend to delay designations based on unavailability of data for either the revised primary or distinct secondary standards in order to be able to include data from these new monitors. Initial area designations would not take into account monitoring data from any newly established near-road monitoring sites, nor from newly established speciation monitoring sites.

The EPA recognizes that the number of $PM_{2.5}$ speciation monitoring sites available to support the state Governors' designation recommendations and EPA's decisions for the proposed secondary $PM_{2.5}$ visibility index NAAQS will be much smaller than the number of $PM_{2.5}$ FRM/FEM/ARM sites available to support designation recommendations and decisions for the revised annual primary $PM_{2.5}$ NAAQS. Therefore, it may well be that more areas of the nation are designated unclassifiable (or unclassifiable/attainment) for the proposed $PM_{2.5}$ visibility index NAAQS than for the proposed revised primary annual $PM_{2.5}$ NAAQS, if finalized. At this time the EPA does not believe that taking an additional year to complete designations for the secondary $PM_{2.5}$ visibility index NAAQS would change this outlook. However, the EPA intends to remain flexible with regard to the designation schedule for the proposed revised $PM_{2.5}$ NAAQS and will reassess the potential need for an extended schedule upon

issuance of the final NAAQS rule and thereafter.

In summary, the EPA intends to provide designation guidance to the states at the time of the promulgation of revised NAAQS or very shortly thereafter, to assist them in formulating these recommendations. In accordance with section 107(d)(4) of the CAA, the EPA currently believes that state Governors (and tribes, if they choose) should submit their initial designation recommendations for both the revised primary annual $PM_{2.5}$ NAAQS and the distinct secondary $PM_{2.5}$ visibility index NAAQS to the EPA no later than 1 year following promulgation of any revised NAAQS (e.g., in December 2013 assuming promulgation of the revised PM NAAQS in December 2012). If the Administrator intends to modify any state area recommendation, the EPA would notify the appropriate state Governor no later than 120 days prior to making final designation decisions. A state that believes the Administrator's modification is inappropriate would have an opportunity to demonstrate to EPA why it believes its original recommendation (or a revised recommendation) is more appropriate before designations are promulgated. The Administrator would take any additional input from the state into account in making final designation decisions.

As previously stated, the EPA plans to issue guidance regarding designations for the revised $PM_{2.5}$ NAAQS at or very shortly after the time of their final promulgation. The EPA invites preliminary comment on all aspects of the designation process at this time, which the Agency will consider in developing that guidance.

B. Section 110(a)(2) Infrastructure SIP Requirements

The CAA directs states to address basic SIP requirements to implement, maintain, and enforce the standards. States are to develop and maintain an air quality management infrastructure that includes enforceable emission limitations, a permitting program, an ambient monitoring program, an enforcement program, air quality modeling capabilities, and adequate personnel, resources, and legal authority. Under CAA sections 110(a)(1) and 110(a)(2), states are to submit these SIPs within 3 years after promulgation of a new or revised primary standard. While the CAA allows the EPA to set a shorter time for

submission of these SIPs, the EPA does not currently intend to do so. Section 110(b) of the CAA provides that the EPA may extend the deadline for the "infrastructure" SIP submission for a new secondary standard by up to 18 months beyond the initial 3 years. If both the revised primary annual $PM_{2.5}$ NAAQS and the distinct secondary $PM_{2.5}$ visibility index NAAQS are finalized, the EPA currently believes it would be more efficient for states and the EPA if each affected state submits a single section 110 infrastructure SIP that addresses both standards at the same time (i.e., within 3 years of promulgation of any revisions to the NAAQS for PM), because the EPA does not at present discern any need for there to be any substantive difference in the infrastructure SIPs for the two standards. However, the EPA also recognizes that states may prefer the flexibility to submit the secondary NAAQS infrastructure SIP at a later date. The EPA solicits comment on these infrastructure SIP submittal timing considerations. The EPA intends to provide guidance regarding the required date(s) for submission of infrastructure SIPs at the same time as or very shortly after promulgation of the revised NAAQS.

Section 110(a)(2) of the CAA includes the following paragraphs describing specific requirements of infrastructure SIPs: (A) Emission limits and other control measures, (B) Ambient air quality monitoring/data system, (C) Programs for enforcement of control measures and for construction or modification of stationary sources, (D)(i) Interstate pollution transport and (D)(ii) Interstate and international pollution abatement, (E) Adequate resources and authority, conflict of interest, and oversight of local governments and regional agencies, (F) Stationary source monitoring and reporting, (G) Emergency episodes, (H) SIP revisions, (I) Plan revisions for nonattainment areas, (J) Consultation with government officials, public notification, PSD and visibility protection, (K) Air quality modeling and submission of modeling data, (L) Permitting fees, and (M) Consultation and participation by affected local entities.

The EPA interprets the CAA such that for two of the section 110(a)(2) elements, both of which pertain to nonattainment area requirements in part D, title I of the CAA, the required submittal date should not be governed by the 3-year submission deadline of section 110(a)(1). Therefore, for the

reasons explained below, the following section 110(a)(2) elements are considered by EPA to be outside the scope of infrastructure SIP actions: (1) section 110(a)(2)(C) to the extent it refers to permit programs (known as "nonattainment new source review") under part D; and (2) section 110(a)(2)(I) (plan revisions for nonattainment areas) in its entirety. The EPA does not expect infrastructure SIP submittals to include regulations or emission limits developed specifically for attaining the relevant standard in areas designated nonattainment for the proposed revised $PM_{2.5}$ NAAQS. Infrastructure SIPs for any final revised $PM_{2.5}$ NAAQS will be due before $PM_{2.5}$ SIPs are due to demonstrate attainment with the same NAAQS. (New emissions limitations and other control measures to attain a revised $PM_{2.5}$ NAAQS will be due 3 years from the effective date of nonattainment area designation as required under CAA section 172(c) and will be reviewed and acted upon through a separate process.) For this reason, the EPA does not expect infrastructure SIP submissions to identify new nonattainment area emissions controls.

It is the responsibility of each state to review its air quality management program's infrastructure SIP provisions in light of each revised NAAQS. Most states have revised and updated their infrastructure SIPs in recent years to address requirements associated with revised NAAQS. It may be the case that for a number of infrastructure elements, the state may believe it has adequate state regulations already adopted and approved into the SIP to address a particular requirement with respect to the revised PM NAAQS. For such portions of the state’s infrastructure SIP submittal, the state may provide a “certification” specifying that certain existing provisions in the SIP are adequate. Although the term "certification" does not appear in the CAA as a type of infrastructure SIP submittal, the EPA sometimes uses the term in the context of infrastructure SIPs, by policy and convention, to refer to a state's minimal SIP submittal (e.g., in the form of a letter to the EPA from the state Governor or her/his designee).

If a state determines that its existing SIP-approved provisions are adequate in light of the revised PM NAAQS with respect to a given infrastructure SIP element (or sub-element), then the state may make a "certification" that the existing SIP contains provisions that address those requirements of the

specific section 110(a)(2) infrastructure elements. In the case of a certification, the submittal does not have to include a copy of the relevant provision (e.g., rule or statute) itself. Rather, the submittal may provide citations to the SIP-approved state statutes, regulations, or non-regulatory measures, as appropriate, which meet the relevant CAA requirement. Like any other SIP submittal, such certification can be made only after the state has provided reasonable notice and opportunity for public hearing. This "reasonable notice and opportunity for public hearing" requirement for infrastructure SIP submittals appears at section 110(a), and it comports with the more general SIP requirement at section 110(l) of the CAA. Under the EPA's regulations at 40 CFR part 51, if a public hearing is held, an infrastructure SIP submittal must include a certification by the state that the public hearing was held in accordance with the EPA's procedural requirements for public hearings. See 40 CFR part 51, appendix V, paragraph 2.1(g), and 40 CFR 51.102.

In consultation with its EPA Regional Office, a state should follow applicable EPA regulations governing infrastructure SIP submittals in 40 CFR part 51 - e.g., subpart I (Review of New Sources and Modifications), subpart J (Ambient Air Quality Surveillance), subpart K (Source Surveillance), subpart L (Legal Authority), subpart M (Intergovernmental Consultation), subpart O (Miscellaneous Plan Content Requirements), subpart P (Protection of Visibility), and subpart Q (Reports). For the EPA's general criteria for infrastructure SIP submittals, refer to 40 CFR part 51, appendix V, Criteria for Determining the Completeness of Plan Submissions. A recent EPA guidance memorandum identifies a number of alternatives that are available to states to reduce the administrative burden, cost, and time required to complete the CAA-required steps that are part of submitting infrastructure and other SIP revisions to EPA (McCabe, 2011). The EPA also notes that many of the infrastructure SIP provisions are not NAAQS-specific, and therefore are likely to have been approved as part of SIP actions associated with other recently promulgated NAAQS (e.g., 2006 $PM_{2.5}$ and 2008 lead NAAQS).

The EPA intends to issue a separate guidance document on section 110 infrastructure SIP requirements for any revised PM NAAQS. The target date for issuing such guidance would be no later

than 1 year after the revised PM NAAQS are finalized (2 years before state submittals are due). The EPA invites preliminary comment on all aspects of infrastructure SIPs at this time, which the Agency will consider in developing future guidance.

C. Implementing the Proposed Revised Primary Annual $PM_{2.5}$ NAAQS in Nonattainment Areas

Part D of the CAA describes the various program requirements that apply to nonattainment areas for different NAAQS. Section 172 (found in subpart 1 of part D) includes the general SIP requirements that govern the $PM_{2.5}$ program. Under section 172, states are required to submit SIPs within 3 years of the effective date of area designations by the EPA. These plans need to show how the nonattainment area will attain the primary $PM_{2.5}$ standards "as expeditiously as practicable," but presumptively no later than within 5 years from the effective date of designations. However, in certain cases, the EPA can approve attainment dates up to 10 years from the effective date of designations, as appropriate, considering the severity of the air quality concentrations in the area, and the availability and feasibility of emission control measures per section 172(a)(2)(C).

Section 172(a)(1) of the CAA authorizes the EPA to establish classification categories for areas designated nonattainment for the primary or secondary PM NAAQS, but does not require the EPA to do so. The implementation program for the 1997 and 2006 primary and secondary $PM_{2.5}$ standards did not include a tiered classification system. This provided a relatively simple implementation structure and flexibility for states to implement control programs tailored to the specific nature of the problem and source mix in each area. For this same reason, the EPA also does not intend to establish classifications for nonattainment areas for the proposed revised primary annual $PM_{2.5}$ standard (or for a revised primary 24-hour standard if one is promulgated). However, the EPA solicits comment on whether a classification system would be appropriate and how a classification system could be designed.

In April 2007, the EPA issued a detailed $PM_{2.5}$ implementation rule (72 FR 20586; April 25, 2007) to provide guidance to states regarding development of SIPs to attain the 1997 $PM_{2.5}$ NAAQS. The EPA believes that the overall framework and policy approach of the implementation rule for the

1997 $PM_{2.5}$ NAAQS provides effective and appropriate guidance on the general approach for states to follow in planning for attainment of the revised primary annual $PM_{2.5}$ standard. The EPA intends to develop and propose a revised implementation rule that will address any new implementation requirements as a result of the proposed revised primary annual $PM_{2.5}$ NAAQS and the proposed revised monitoring regulations. The EPA intends to propose this implementation rule within 1 year after the revised PM NAAQS are promulgated, and finalize the implementation rule by no later than the time the area designations process is finalized (approximately 1 year later). The EPA believes that for many issues, regulatory text similar to that of the existing implementation rule for the 1997 $PM_{2.5}$ NAAQS can be included in this new implementation rule. In the implementation rule for the 1997 $PM_{2.5}$ NAAQS, there are a few specific references to the 1997 annual $PM_{2.5}$ NAAQS or associated implementation dates; in a proposed implementation rule for any revised $PM_{2.5}$ NAAQS, such references would be updated as appropriate. In addition, the EPA expects to consider options for potentially updating certain policies in the existing implementation rule based on new information or implementation experience. The EPA solicits preliminary comment on the implementation issues that the Agency should consider for updating.

Under the approach outlined in the implementation rule for the 1997 $PM_{2.5}$ NAAQS, the state begins the development of an attainment demonstration with the evaluation of the air quality improvements the nonattainment area can expect in the future due to "on the books" existing federal, state, and local emission reduction measures. The state then must conduct a further assessment of emission sources in the nonattainment area, and the additional reasonably available control measures (RACM) and reasonably available control technology (RACT) that can be implemented by these sources, in determining how soon the area can attain the standard. (Under the current implementation rule, the sources for consideration would be those emitting SO_2, direct $PM_{2.5}$, and presumptively NOx. Sources of the other $PM_{2.5}$ precursors, VOC and ammonia, presumptively do not need to be evaluated for control measures unless demonstrated by the state or the EPA as significant contributors to $PM_{2.5}$

concentrations in the relevant nonattainment area.) Under section 172 of the CAA as interpreted by the EPA, attainment demonstrations must include a RACM analysis showing that no additional reasonably available measures could be adopted and implemented such that the SIP could specify an attainment date that is 1 or more years earlier.

The evaluation of these potential emission reductions and associated air quality improvement is commonly performed with sophisticated air quality modeling tools. Given that fine particle concentrations are affected both by regionally-transported pollutants (e.g., SO_2 and NO_x emissions from power plants) and emissions of direct $PM_{2.5}$ from local sources in the nonattainment area (e.g., steel mills, rail yards, and highway mobile sources), the EPA recommends the use of regional grid-based models (such as CMAQ and CAMx) in combination with source-oriented dispersion models (such as AERMOD) to develop $PM_{2.5}$ attainment strategies for the revised annual primary NAAQS. Although the EPA projects significant improvements in $PM_{2.5}$ concentrations regionally from a number of recently promulgated rules such as the Cross State Air Pollution Rule (76 FR 48208, August 8, 2011) and the Mercury and Air Toxics Standards rule (77 FR 9304, February 16, 2012) that will result in SO_2 and NO_x reductions from many geographically dispersed sources, local reductions of direct $PM_{2.5}$ emissions also result in important health benefits. On a per ton basis, reductions of direct $PM_{2.5}$ emissions are more effective in reducing $PM_{2.5}$ concentrations than reductions of precursor emissions. Therefore, reductions of direct $PM_{2.5}$ emissions should play a key role in attainment planning as well.

Each nonattainment area needs to ensure that it will make "reasonable further progress" (RFP) in accordance with section 172(c)(2) of the CAA from the time of SIP submittal to its attainment date. Under the approach outlined in the implementation rule for the 1997 $PM_{2.5}$ NAAQS, for an area that can demonstrate it will attain the standard within the presumptive 5-year period from designation, its attainment demonstration will be considered to meet the RFP requirement. The EPA believes it is appropriate to apply this same approach for the revised annual primary $PM_{2.5}$ standard. The EPA believes there should be no additional RFP requirements for such an area because the SIP and attainment

demonstration would be due 3 years after designations and its attainment date will be only 2 years after that date. An area that cannot demonstrate attainment within the presumptive 5 year period would be required to provide a separate RFP plan showing that the area will achieve emission reductions by certain interim milestone dates which provide for "generally linear" progress over the course of the implementation period. All $PM_{2.5}$ attainment plans must also include contingency measures which would apply without significant delay in the event the area fails to attain by its attainment date.

The EPA expects that the same general approach for determining attainment of the 1997 $PM_{2.5}$ primary standard by the attainment deadline would be followed for determining attainment with any primary $PM_{2.5}$ standard. Attainment would be evaluated based on the 3 most recent years of certified, complete, and quality-assured air quality data in the nonattainment area. The EPA also would expect to include similar flexibility provisions for an area to be able to obtain two 1-year attainment date extensions under certain circumstances. In the 1997 $PM_{2.5}$ NAAQS implementation rule, an area whose design value based on the most recent 3 years of data exceeds the standard could receive a 1-year attainment date extension if the air quality concentration for the third year alone does not exceed the level of the standard. Similarly, an area that has received a 1-year extension could receive a second 1-year extension if the average of the area's air quality concentration in the "extension year" and the previous year does not exceed the level of the standard.

The EPA notes that in other sections of today's proposal, the EPA describes new requirements for deploying near-road monitors and clarifies certain existing monitoring provisions. As discussed in the designations section, the EPA would not expect that data from any new near-road $PM_{2.5}$ monitors would be available in time to consider during the initial area designations process, and therefore such monitoring data would not be the basis for designating a new nonattainment area at the time of initial designations. The EPA plans to address any potential implications of the proposed monitoring changes on attainment planning and development of attainment demonstrations by states in the future implementation rule. The EPA requests comment on any specific attainment planning considerations for

future SIPs that may be associated with today's proposed changes to monitoring provisions.

With regard to implementation of the pre-existing standards for $PM_{2.5}$, the EPA's current opinion is that the changes in the monitoring regulations, if finalized, should not result in any new requirements with respect to attainment plans or maintenance plans for the 1997 or the 2006 $PM_{2.5}$ NAAQS during some specified transition period.[214] For example, if the proposed PM NAAQS revisions and revised monitoring regulations are finalized in December 2012, many states will have recently submitted, or will be close to submitting their implementation plans to attain the 2006 24-hour $PM_{2.5}$ NAAQS (also due in December 2012). In addition, state and EPA actions are still under way with regard to adopting and approving certain attainment plans and maintenance plans for nonattainment areas under the 1997 $PM_{2.5}$ standards. The EPA does not believe it would be reasonable for requirements applicable to such attainment plans and maintenance plans to change beginning immediately upon any revision of the monitoring regulations. It could be very burdensome on state air quality programs to revise SIPs that have already been submitted to EPA or that have been under development for some time and are about to be submitted. The EPA believes that a more reasonable approach would be to provide for a transition period before the revised monitoring network and data comparability provisions would affect implementation plan and maintenance plan requirements. The EPA believes it would be important for the transition period to provide enough time for the EPA to complete action on attainment and maintenance SIPs for the 1997 or 2006 $PM_{2.5}$ NAAQS that were initiated and completed (or that are close to completion) by states before finalization of the proposed changes to the monitoring regulations. The EPA believes that if a SIP for the 1997 or 2006 $PM_{2.5}$ NAAQS has been approved during the transition period, the state would not be under an obligation to revise it unless the EPA has made a SIP call. The EPA invites preliminary comment on this transition period concept, and on an appropriate date by which the transition period should be concluded.

[214] For example, it may be possible that a new near-road monitoring site has collected 3 years of data and shown a violation before final EPA action has been taken on an attainment plan or maintenance plan for the 1997 or 2006 NAAQS.

D. Implementing the Primary and Secondary PM_{10} NAAQS

As summarized in sections IV.F and VI.F above, the EPA is proposing to retain the current primary and secondary 24-hour PM_{10} standards to protect against the health effects associated with short-term exposures to thoracic coarse particles and against welfare effects. If this approach is finalized, the EPA would retain the existing implementation strategy for meeting the CAA requirements for PM_{10}. States and emission sources would continue to follow the existing guidance and regulations for implementing the current standards.

E. Implementing the Proposed Secondary $PM_{2.5}$ Visibility Index NAAQS in Nonattainment Areas

In past actions, the EPA has set the secondary PM standards identical to the primary PM standards. In this action, as summarized in section VI.F above, the EPA is proposing a distinct secondary $PM_{2.5}$ visibility index NAAQS. In addition, as also summarized in section VI.F above, the EPA is proposing to retain the current annual and 24-hour secondary $PM_{2.5}$ standards to provide protection against non-visibility welfare effects. Although the proposed secondary $PM_{2.5}$ visibility index NAAQS would differ from the primary $PM_{2.5}$ NAAQS (and existing secondary $PM_{2.5}$ NAAQS) with respect to indicator/index, statistical form, and level, attainment of this standard would, like the $PM_{2.5}$ mass-based standards, depend on ambient measurements (i.e., specifically speciated $PM_{2.5}$ mass concentrations). The EPA expects that implementation of emission reduction measures that will help to achieve the mass-based 1997 and 2006 primary and secondary $PM_{2.5}$ standards and the proposed revised primary annual $PM_{2.5}$ standard will also provide important improvements in visibility and substantial progress toward meeting the proposed secondary $PM_{2.5}$ visibility index standard because these emission reduction measures will address the same sources and pollutants which also contribute to PM-related visibility impairment. In fact, as discussed below in section IX.F.1, an analysis of the relationships between recent design values for the proposed primary (annual and 24-hour) $PM_{2.5}$ standards and coincident design values for the proposed $PM_{2.5}$ visibility index standard indicates that all or nearly all areas in attainment of the proposed primary $PM_{2.5}$ standards would also likely be in attainment of the

proposed secondary $PM_{2.5}$ visibility index standard (Kelly, et al. 2012).[215]

Section 172(a)(1) of the CAA authorizes the EPA to establish classification categories for areas designated nonattainment for the primary or secondary PM NAAQS, but does not require the EPA to do so. The implementation program for the 1997 and 2006 primary and secondary $PM_{2.5}$ standards did not include a tiered classification system. This provided a relatively simple implementation structure and flexibility for states to implement control programs tailored to the specific nature of the problem and source mix in each area. For this same reason, the EPA also does not intend to establish classifications for nonattainment areas for the proposed secondary $PM_{2.5}$ visibility index standard.

Section 172(a)(2) of the CAA provides the same statutory framework for implementing secondary standards in nonattainment areas as it does for primary standards, except that it provides different attainment date requirements for secondary standards. The attainment date for the proposed revised primary annual $PM_{2.5}$ standard is as expeditiously as practicable, but presumptively within 5 years of the date of designation, with the possibility of an attainment date of up to 10 years for certain areas with more severe air quality problems. For secondary NAAQS, however, section 172(a)(2)(B) defines the attainment date for an area designated nonattainment as "the date by which attainment can be achieved as expeditiously as practicable" but with no maximum limitation. Thus, it is possible for the EPA to approve an implementation plan that provides for attainment of the secondary standards by a date more than 10 years after the date of designation with an appropriate demonstration.

As noted in the above section on implementing the primary $PM_{2.5}$ standard, the EPA expects that the same general approach for providing two possible 1-year extensions to the attainment date would also apply to any revised secondary $PM_{2.5}$ standard. Attainment would be evaluated based on the 3 most

[215] This analysis was based on 2008 to 2010 air quality data and for illustrative purposes used an alternative standard level of 12 $\mu g/m^3$ for the primary annual $PM_{2.5}$ standard and the proposed level of 35 $\mu g/m^3$ level for the primary 24-hour $PM_{2.5}$ standard together with the proposed levels of 30 and 28 dv in conjunction with a 24-hour averaging time and a 90th percentile form for the secondary $PM_{2.5}$ visibility index standard. The relationships between design values as characterized here are dependent upon the specific level and form of each of the standards.

recent years of certified, complete, and quality-assured air quality data in the nonattainment area. The EPA also would expect to include similar flexibility provisions for an area to be able to obtain two 1-year attainment date extensions under certain circumstances. An area whose design value based on the most recent 3 years of data exceeds the standard could receive a 1-year attainment date extension if the deciview index for the third year alone does not exceed the level of the standard. Similarly, an area that has received a 1-year extension could receive a second 1-year extension if the average of the area's deciview index in the "extension year" and the previous year does not exceed the level of the standard.

As noted previously, the EPA expects that implementation of control measures to achieve the 1997 and 2006 primary annual and 24-hour $PM_{2.5}$ standards and the proposed revised primary annual $PM_{2.5}$ standard will address the same sources and pollutants that contribute to PM-related visibility impairment, and, thus, great progress can be achieved toward attaining the proposed secondary $PM_{2.5}$ visibility index standard as a result of clean air programs designed principally to improve public health by attaining the primary $PM_{2.5}$ standards. However, because the proposed secondary $PM_{2.5}$ standard is based on a visibility index rather than a mass concentration, implementation can be expected to present new challenges when developing part D SIPs. For example, while the proposed revision to the level and form of the primary annual $PM_{2.5}$ standard does not pose any new issues with respect to air quality modeling methods, the speciated nature of the index for the proposed secondary $PM_{2.5}$ visibility index standard does pose new modeling issues. For this reason, the EPA invites commenters to present information concerning air quality modeling and other issues that are expected to be unique to implementing the proposed secondary $PM_{2.5}$ visibility index standard in nonattainment areas and that should be considered by EPA in the development of the future implementation rule and related guidance. The EPA particularly seeks input on how implementation planning for the proposed secondary $PM_{2.5}$ visibility index standard can be integrated as much as possible with implementation planning for the proposed revised primary annual $PM_{2.5}$ standard to increase the efficiency of the process and reduce administrative burden on state agencies and stakeholders. The EPA will consider these comments in

developing a proposed implementation rule and related guidance for the revised standards.

F. Prevention of Significant Deterioration and Nonattainment New Source Review Programs for the Proposed Revised Primary Annual $PM_{2.5}$ NAAQS and the Proposed Secondary $PM_{2.5}$ Visibility Index NAAQS

The CAA requires states to include SIP provisions that address the preconstruction review of new stationary sources and the modification of existing sources. The preconstruction review of each new and modified source generally applies on a pollutant-specific basis and the requirements for each pollutant vary depending on whether the area is designated attainment or nonattainment for that pollutant. Parts C and D of title I of the CAA contain specific requirements for the preconstruction review and permitting of new major stationary sources and major modifications, referred to as the PSD program and the NNSR program, respectively. Collectively, those permit requirements are commonly referred to as the "major NSR program."

The proposed revised primary annual $PM_{2.5}$ NAAQS and proposed secondary $PM_{2.5}$ visibility index NAAQS, if finalized, would affect certain PSD permitting actions as of the effective date for those NAAQS and would affect certain NNSR permitting actions on and after the effective date of an area designation as "nonattainment" for $PM_{2.5}$. In order to minimize the potential for disruption to NSR permitting, the EPA is proposing, in section IX.F.1.a of this preamble, a grandfathering provision for certain PSD permits that are already in process, and is also proposing, in section IX.F.1.c, a surrogacy approach for implementing PSD permitting requirements for the proposed secondary $PM_{2.5}$ visibility index NAAQS. These provisions will assure that NSR permitting will be able to continue using provisions and processes virtually identical to those already in place for the existing $PM_{2.5}$ NAAQS, except that, in evaluating whether a source causes or contributes to a NAAQS violation, an applicant would need to compare the source's impacts to a different level and form of the primary annual standard, if finalized as proposed. As discussed in more detail in the following sections, the EPA is not now proposing to change the $PM_{2.5}$ increments, nor are we proposing to revise screening tools that are now used to implement PSD for $PM_{2.5}$, such as the significant emission rate, used as a threshold for

determining whether a given project is subject to major NSR permitting requirements under both PSD and NNSR; the significant impact levels, used to determine the scope of the required air quality analysis that must be carried out in order to demonstrate that the source's emissions will not cause or contribute to a violation of any NAAQS or increment under the PSD program; or the significant monitoring concentration, a screening tool used to determine whether it may be appropriate to exempt a proposed source from the requirement to collect pre-construction ambient monitoring data as part of the required air quality analysis.

1. Prevention of Significant Deterioration

The PSD requirements set forth under part C (sections 160 through 169) of the CAA apply to new major stationary sources and major modifications locating in areas designated as "attainment" or "unclassifiable" with respect to the NAAQS for a particular pollutant. The EPA regulations addressing the statutory requirements under part C for a PSD permit program can be found at 40 CFR 51.166 (containing the PSD requirements for an approved SIP) and 40 CFR 52.21 (the federal PSD permit program). For PSD, a "major stationary source" is one with the potential to emit 250 tons per year (tpy) or more of any air pollutant, unless the source or modification is classified under a list of 28 source categories contained in the statutory definition of "major emitting facility" in section 169(1) of the CAA. For those 28 source categories, a "major stationary source" is one with the potential to emit 100 tpy or more of any air pollutant. A "major modification" is a physical change or a change in the method of operation of an existing major stationary source that results in a significant emissions increase and a significant net emissions increase of a regulated NSR pollutant. Under PSD, new major sources and major modifications must apply best available control technology (BACT) for each applicable pollutant and conduct an air quality analysis to demonstrate that the proposed construction will not cause or contribute to a violation of any NAAQS or PSD increments (see CAA section 165(a)(3); 40 CFR 51.166(k); 40 CFR 52.21(k)). PSD requirements also include in appropriate cases an analysis of potential adverse impacts on Class I areas (see sections 162 and 165 of the CAA).

PSD permitting requirements first became applicable to $PM_{2.5}$ in 1997 when EPA established a NAAQS for $PM_{2.5}$ (Seitz, 1997). The EPA's regulations define the term "regulated NSR pollutant" to include "[a]ny pollutant for which a national ambient air quality standard has been promulgated and any pollutant identified [in EPA regulations] as a constituent or precursor to such pollutant" (40 CFR 51.166(b)(49); 40 CFR 52.21(b)(50)).[216] In addition, on May 16, 2008, the EPA amended its rules to identify certain $PM_{2.5}$ precursors (SO_2 and NO_x) as regulated NSR pollutants and adopt other provisions, such as a significant emissions rate for $PM_{2.5}$, to facilitate implementation of PSD and NNSR program requirements for $PM_{2.5}$ (73 FR 28321). States were required to revise their SIPs by May 16, 2011 to incorporate the required elements of the 2008 final rule.

On October 20, 2010, the EPA again amended the PSD rules at 40 CFR 51.166 and 52.21 to add PSD increments as well as two screening tools for $PM_{2.5}$ – significant impact levels (SILs) and a significant monitoring concentration (SMC) (75 FR 64864). The October 2010 final rule became effective on December 20, 2010. The EPA indicated that the SILs and SMC for $PM_{2.5}$, while useful tools, are not considered mandatory elements of an approvable SIP; thus, no schedule was imposed on states for addressing those screening tools in their PSD rules. For the portions of the rule that addressed the PSD increments for $PM_{2.5}$, states are required to submit the necessary SIP revisions (at least as stringent as the PSD requirements at 40 CFR 51.166) to EPA for approval within 21 months from the date on which the EPA promulgated the new $PM_{2.5}$ increments – by July 20, 2012. This particular schedule is prescribed by the CAA specifically for the adoption of new PSD increments in state PSD programs. Sources for which PSD permits are issued pursuant to the federal PSD program at 40 CFR 52.21 after October 20, 2011, must determine their impact on the $PM_{2.5}$ increments.

The PSD program currently regulates emissions of PM using several indicators of particles,

[216] Under various provisions of the CAA, PSD requirements are applicable to each pollutant subject to regulation under the CAA, excluding hazardous air pollutants. The definition of "regulated NSR pollutant" also includes pollutants subject to any standard under section 111 of the CAA or any Class I or II substance subject to title VI of the CAA.

including "particulate matter emissions" (as regulated under various new source performance standards under 40 CFR part 60), "PM_{10} emissions," and "$PM_{2.5}$ emissions." The latter two emission indicators are designed to be consistent with the ambient air indicators for PM that the EPA currently uses in the PM NAAQS. As already noted, the PSD program also limits $PM_{2.5}$ concentrations by regulating emissions of gaseous pollutants that result in the secondary formation of particulate matter. Those pollutants, known as $PM_{2.5}$ precursors, generally include SO_2 and NO_x.

In addition to the NAAQS revisions themselves, for which proposed and other possible implementation approaches are described further below, the EPA is proposing certain clarifications to the existing monitoring regulations codified at 40 CFR 58.30 (Special considerations for data comparisons to the NAAQS). These proposed clarifications are presented in detail in section VIII.B.2 of this preamble. The monitoring regulations provide a basis for determining whether specific monitoring sites are comparable to specific NAAQS. By extension, the EPA has used the principles for making these determinations for monitoring sites to also guide permitting authorities in assessing the comparability of specific receptor locations involved in PSD air quality analyses. Receptors are used in PSD modeling analyses to predict potential air quality impacts in the vicinity of the proposed new or modified facility and in some cases also at more distant Class I areas. The EPA will continue to use these principles in guiding PSD modeling analysis design. Accordingly, if the proposed PM NAAQS revisions and monitoring regulation clarifications described previously are finalized, the EPA will advise permitting agencies to qualify or disqualify specific receptor locations used in PSD air quality analyses consistent with those final provisions, and we will do so ourselves when we are the permitting authority.

With regard to the specific revisions being proposed to the PM NAAQS, today's action, if finalized as proposed, would affect sources applying for PSD permits in several ways. We first discuss the implications for PSD with respect to the proposed revised primary annual $PM_{2.5}$ standard (some of which also apply to the proposed secondary $PM_{2.5}$ visibility index standard), and then the unique

implications for PSD with respect to the proposed secondary $PM_{2.5}$ visibility index standard.

a. Grandfathering Provision

As discussed previously in this preamble, the EPA is proposing to revise the level of the primary annual $PM_{2.5}$ NAAQS and establish a secondary $PM_{2.5}$ visibility index NAAQS.[217] Longstanding EPA policy interprets the CAA and EPA regulations at 40 CFR 52.21(k)(1) and 51.166(k)(1) to generally require that PSD permit applications must include a demonstration that new sources and modifications will not cause or contribute to a violation of any NAAQS that is in effect as of the date the PSD permit is issued (Page, 2010a; Seitz, 1997). Thus, if the proposed revision to the primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS are promulgated, any proposed new and modified sources with permits pending at the time those $PM_{2.5}$ NAAQS changes take effect would be expected to demonstrate compliance with them, absent some type of transition provision exempting such applications from the new requirements.

In order to provide for a reasonable transition into the new PSD permitting requirements that will result from the proposed revision of the primary annual NAAQS, the proposed addition of a distinct secondary NAAQS for visibility protection, and the changes to the monitoring requirements discussed earlier, the EPA proposes to add a grandfathering provision to the federal PSD program codified at 40 CFR 52.21 that would apply to certain PSD permit applications that are pending on the effective date of the revised PM NAAQS. The EPA proposes that the grandfathering provision would apply specifically to pending PSD permit applications for which the proposed permit (draft permit or preliminary determination) has been noticed for public comment before the effective date of the revised NAAQS.

The proposed grandfathering provision would not be the first such grandfathering provision adopted by the EPA. The Agency previously recognized that the CAA provides discretion for the EPA to grandfather PSD permit applications from requirements that become applicable while the application

[217] The EPA is also proposing to revise the form of the annual primary standard by removing the option for spatial averaging. However, this provision has played no role in PSD so its removal has no implications for PSD.

is pending (45 FR 52683, Aug. 7, 1980; 52 FR 24672, July 1, 1987; US EPA, 2011c, pp. 54 to 61). As discussed in more detail in these referenced actions, section 165(a)(3) of the CAA requires that a permit applicant demonstrate that its proposed project will not cause or contribute to a violation of any NAAQS. At the same time, section 165(c) of the CAA requires that a PSD permit be granted or denied within 1 year after the permitting authority determines the application for such permit to be complete. In addition, section 301 of the CAA authorizes the Administrator "to prescribe such regulations as are necessary to carry out his functions under this chapter." When read in combination, these three provisions of the CAA provide the EPA with the discretion to promulgate regulations to grandfather pending permit applications from having to address a revised NAAQS where necessary to achieve a balance between the CAA objectives to protect the NAAQS on the one hand, and to avoid delays in processing PSD permit applications on the other. The EPA has also construed section 160(3) of the CAA, which states that a purpose of the PSD program is to "insure that economic growth will occur in a manner consistent with the preservation of existing clean air resources" to call for a balancing of economic growth and protection of air quality (70 FR 59587 to 59588, Oct. 12, 2005). The reasoning of those prior EPA actions is also applicable to the promulgation of revised PM NAAQS.[218]

The CAA provides the EPA with discretion to establish the appropriate milestone within the permitting process for determining that a permit application is eligible for grandfathering (US EPA, 2011c, p. 81). For example, in 1987, the EPA used the date of submittal of a complete permit application as the milestone upon which to base the grandfathering of a source from new permitting requirements associated with the revisions made to the PM NAAQS at that time (52 FR 24672, July 1, 1987 at

[218] In one extraordinary case where the EPA had not previously adopted a grandfathering provision in regulations and had significantly exceeded the deadline in section 165(c) of the CAA, the EPA has taken the position that it may grandfather through adjudication respecting a specific source, thus interpreting its regulations, as well as other authorities, to allow grandfathering in that extraordinary circumstance (US EPA, 2011c, pp. 67 to 71). Although grandfathering without a specific exemption in regulations was justified based on the particular facts in that specific instance, the EPA generally believes the preferred approach is to enable grandfathering through express regulatory exemptions of the type proposed in this action (US EPA, 2011c, p. 68).

24703). In the context of the implementation of the revisions to the PM NAAQS that are being proposed today, the EPA is proposing to use a different milestone to establish the date before which permits may be grandfathered. Accordingly, to avoid unreasonable delays in permit processing and issuance, and based on basic principles of fairness and equity, we believe that it is appropriate to allow pending permit applications that have reached the notice and comment period on a proposed permit (that is, a notice has been issued for public comment on the proposed permit action) by the effective date of the revised PM NAAQS to continue being processed in accordance with the PM NAAQS requirements in place as the time of the public notice on the proposed permit.[219]

Before a proposed permit is issued for public comment, the applicant still has a reasonable opportunity to amend its permit application to address new or revised NAAQS that become effective while the reviewing authority's preliminary consideration of the application is underway. Furthermore, the reviewing authority has the opportunity to review additional material and revise its fact sheet or statement of basis before beginning the public comment period on such a permit. However, if the EPA and other reviewing authorities were to apply new permitting requirements based on the revised PM NAAQS after the public comment period has begun, this would unduly delay the processing of the permit application by potentially requiring an additional public comment period and additional work by the reviewing authority at a time when it should be focused on considering public comments and preparing a final permit decision in order to conclude its review of a permit application in a timely manner. Through this proposal, the EPA is providing notice to current and future permit applicants that they may have to provide an analysis showing that their facility will not cause or contribute to a violation of the revised NAAQS for PM if a proposed permit is not issued for public comment before

[219] There may be proposed permits for which a public notice was issued prior to October 20, 2011, which is the date that $PM_{2.5}$ increments became applicable requirements for any newly issued federal PSD permits under 40 CFR 52.21. It is not the EPA's intention that the grandfathering provision proposed today should relieve such a permit from the requirement to demonstrate compliance with those new $PM_{2.5}$ increments, for which the EPA did not adopt any grandfathering provisions but deferred implementation in accordance with the requirements of the CAA.

such NAAQS become effective.

Accordingly, the EPA proposes to amend the federal PSD regulations at 40 CFR 52.21 to provide a grandfathering provision to allow for the continued review of permits proposed before a revision to the 2006 PM NAAQS under the PM NAAQS that applied at the time of the public notice on the proposed permit. The EPA also proposes that states that issue PSD permits under a SIP-approved PSD permit program should have the discretion to "grandfather" proposed PSD permits in the same manner under these same circumstances. Thus, the EPA also proposes to revise section 40 CFR 51.166 to provide a comparable exemption applicable to SIP-approved PSD programs.

In developing the proposed grandfathering provision, the EPA considered whether such a provision should include a sunset clause. A sunset clause would add a time limit beyond which an otherwise eligible permit action would no longer be grandfathered from PSD permitting requirements associated with a revised PM NAAQS. Consistent with past grandfathering actions described above, the EPA is not proposing to include a sunset clause for the proposed grandfathering provision. Permit applicants and reviewing authorities already have strong incentives to process applications and issue draft permits in a timely manner, and the EPA does not believe that the addition of a sunset clause to the proposed grandfathering provision would add meaningful additional incentive for sources or permitting authorities to expedite permitting processes. Furthermore, the EPA believes that a sunset clause could in fact result in further delays for permit actions that qualify for the proposed grandfathering provision in circumstances where unrelated and not reasonably avoidable factors cause draft permit issuance and public notice to lapse beyond the sunset date. In such cases, the already delayed permit action would be further delayed to address PSD permitting requirements associated with the revised PM NAAQS, potentially triggering a domino effect of newly applicable requirements. As such, the EPA believes a sunset clause would diminish the value of the grandfathering provision and likely introduce additional complexities in relation to specific permit actions. However, the EPA solicits comment on whether a sunset clause would be appropriate under certain circumstances, and if so, what time limits would be

placed on the grandfathering period associated with the revised PM NAAQS.

b. Recent Guidance Applicable to the Proposed Revised Primary Annual $PM_{2.5}$ NAAQS

Today's proposal to revise the level of the primary annual $PM_{2.5}$ NAAQS from 15.0 μg/m^3 to a level within the range of 12.0 and 13 μg/m^3 and to establish a distinct secondary $PM_{2.5}$ visibility index NAAQS generally will require proposed new major stationary sources and modifications to take these changes into account as part of the required air quality analysis to demonstrate that the proposed emissions increase will not cause or contribute to a violation of the PM NAAQS. If the PM NAAQS are revised as proposed, and when effective, proposed sources that are not grandfathered from the new requirements (as described in section IX.F.1.a) would be required to demonstrate compliance with the suite of PM NAAQS, including the revised primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS.

PSD applicants are currently required to demonstrate compliance with the existing primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS and will need to consider their impact on the revised primary annual $PM_{2.5}$ NAAQS, if finalized. To assist sources and permitting authorities in carrying out the required air quality analysis for $PM_{2.5}$ under the existing standards, the EPA issued, on March 23, 2010, a guidance memorandum that recommends certain interim procedures to address the fact that compliance with the 24-hour $PM_{2.5}$ NAAQS is based on a particular statistical form, and that there are technical complications associated with the ability of existing models to estimate the impacts of secondarily formed $PM_{2.5}$ resulting from emissions of $PM_{2.5}$ precursors (Page, 2010b). For the latter issue, the EPA recommended that special attention be given to the evaluation of monitored background air quality data, since such data readily account for the contribution of both primary and secondarily formed $PM_{2.5}$. To provide more detail and to address potential issues associated with the modeling of direct and precursor emissions of $PM_{2.5}$, the EPA is now developing additional permit modeling guidance that will recommend appropriate technical approaches for conducting a $PM_{2.5}$ NAAQS compliance demonstration for the existing $PM_{2.5}$ NAAQS, which includes more adequate accounting for

contributions from secondary formation of ambient $PM_{2.5}$ resulting from a proposed new or modified source's precursor emissions. (As discussed in the next section, these recommended approaches may be extended to the proposed secondary NAAQS as well under a surrogacy approach). To this end, the EPA discussed this draft guidance in March 2012 at the EPA's 10th Modeling Conference.[220] Based on its review of public comments received and further technical analyses, the EPA intends to issue final guidance by the end of calendar year 2012.

c. Surrogacy Approach for the Proposed Secondary $PM_{2.5}$ Visibility Index NAAQS

As summarized in section VI.F of this preamble, the EPA is proposing a distinct secondary NAAQS for $PM_{2.5}$ that will provide protection against visibility impairment, measured in terms of a visibility index using a calculated $PM_{2.5}$ light extinction indicator (see section VI.D.1 above). The $PM_{2.5}$ visibility index values are determined using a six-step procedure involving 24-hour speciated $PM_{2.5}$ concentration data together with climatological relative humidity factors. The EPA plans to calculate design values for the proposed secondary $PM_{2.5}$ visibility index NAAQS using the procedures described in section VII.A.5 above, relying upon ambient $PM_{2.5}$ speciation measurement data available through the CSN or IMPROVE methods and spatial interpolation of historical relative humidity data.

As explained above, the PSD program requires individual new or modified stationary sources to carry out an air quality analysis to demonstrate that their proposed emissions increases will not cause or contribute to a violation of any NAAQS. Such a demonstration for the proposed secondary $PM_{2.5}$ visibility index NAAQS could require each PSD applicant to predict, via air quality modeling, the visibility impairment that will result from its proposed emissions in conjunction with an assessment of existing air quality (visibility impairment) conditions. Under 40 CFR 51.166(l)(1) and 40 CFR 52.21(l)(1), all applications of air quality modeling for purposes of determining whether a new or modified source will cause or contribute to a NAAQS violation, including a violation of the proposed

[220] The presentation on this draft guidance was posted on the EPA website at: http://www.epa.gov/ttn/scram/10thmodconf.htm.

secondary visibility index NAAQS for $PM_{2.5}$, must be based upon air quality models specified in appendix W to 40 CFR part 51. Currently there are no air quality models identified in Appendix W that are recommended for regulatory applications (Appendix W to 40 CFR part 51, Section 3.1.1(b)) for addressing the atmospheric chemistry associated with secondary formation of $PM_{2.5}$. Thus, if this demonstration were to be attempted using the six-step procedure that the EPA is proposing to use for calculating $PM_{2.5}$ visibility index design values, significant technical issues with the modeling procedures could arise. Those technical difficulties include the current limitations on speciated source-specific emissions data for model input; the lack of an EPA-approved air quality model with the capability to address the atmospheric chemistry associated with secondary formation of $PM_{2.5}$; and the lack of PSD screening tools for streamlining the air quality analysis process. In addition, due to the limited monitoring network for speciated $PM_{2.5}$, some sources may not be able to rely on existing speciated monitoring data to adequately represent the background air quality and thereby satisfy preconstruction monitoring requirements. Consequently, those prospective PSD sources could be required to collect new data in order to determine the representative background concentrations of $PM_{2.5}$ species (i.e., those required for calculating the $PM_{2.5}$ visibility index values as described in section VII.A.5 above).

Recognizing these difficult technical issues, the EPA believes that there is an essential need to provide alternative approaches to enable prospective PSD sources to demonstrate that they will not cause or contribute to a violation of the secondary $PM_{2.5}$ visibility index NAAQS, if finalized as proposed. To meet this need, the EPA believes that it is reasonable to allow the use of a surrogacy approach, as discussed below, for at least the interim period while technical issues are being resolved, but which could potentially be continued beyond such time if shown to be appropriate. The EPA is providing notice of its intent to follow such an approach and is asking for comments on the approach as discussed in the remainder of this section. The Agency believes that following this approach will facilitate the transition to a workable PSD permitting approach under the proposed secondary $PM_{2.5}$

visibility index NAAQS.

To support consideration of alternative approaches that could be used by prospective PSD sources, the EPA conducted a two-pronged technical analysis of the relationships between the proposed $PM_{2.5}$ visibility index standard and the 24-hour $PM_{2.5}$ standards (Kelly, et al., 2012). The first prong of the analysis addressed aspects of a PSD significant impact analysis by evaluating whether an individual source's impact resulting in a small increase in $PM_{2.5}$ concentration would produce a comparably small increase in visibility impairment. This analysis included estimates of $PM_{2.5}$ speciation profiles based on direct $PM_{2.5}$ emission profiles for a broad range of source categories and for theoretical upper and lower bound scenarios. The analysis indicated that small increases in $PM_{2.5}$ concentrations caused by individual sources produce similarly small changes in visibility impairment for ambient conditions near the proposed standard level of either 30 dv or 28 dv. The second prong of the analysis addressed aspects of a PSD cumulative impact analysis by exploring the relationship between the 3-year design values for the primary and secondary 24-hour $PM_{2.5}$ standards and coincident design values for the proposed $PM_{2.5}$ visibility index standard based on recent air quality data. This analysis showed that visibility generally decreases when daily $PM_{2.5}$ concentrations increase, and vice versa. This analysis further explored the appropriateness of using a demonstration that a source will not cause or contribute to a violation of the 24-hour $PM_{2.5}$ standards as a surrogate for a demonstration that a source will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index standard. The Kelly, et al. (2012) analysis was based on 2008 to 2010 air quality data and on the proposed retention of the 24-hour $PM_{2.5}$ standards with a level of 35 $\mu g/m^3$ in conjunction with a 98th percentile form (sections III.F and IV.F) and the proposed secondary $PM_{2.5}$ visibility index standard with a level of either 30 dv or 28 dv in conjunction with 24-hour averaging time and a 90th percentile form (see section VI.F).[221] This analysis indicated that all or nearly all areas in attainment of the 24-hour $PM_{2.5}$ standards would also likely be in attainment of the

[221] As identified in section IX.E above, the relationships between design values characterized in the Kelly, et al. (2012) analysis and summarized here are dependent upon the specific level and form of each of these standards.

proposed secondary $PM_{2.5}$ visibility index standard.

The EPA believes that this technical analysis is robust and will have broad national application. Based on this technical analysis, the EPA currently believes that there is sufficient evidence that, for the purposes of making a demonstration under the PSD program that a new or modified source will not cause or contribute to a violation of the proposed secondary 24-hour $PM_{2.5}$ visibility index NAAQS, a demonstration that the source will not cause or contribute to a violation of the mass-based 24-hour $PM_{2.5}$ NAAQS serves as a suitable surrogate. As such, many or all sources undergoing PSD review for $PM_{2.5}$ would be able to rely upon their analysis demonstrating that they will not cause or contribute to a violation of the mass-based 24-hour $PM_{2.5}$ NAAQS to also demonstrate that they will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index NAAQS, if finalized. The described surrogate approach would thus serve to overcome the technical challenges discussed above and minimize otherwise burdensome and costly air quality analyses associated with individual sources being required to perform separate and distinct analyses with regard to the proposed secondary $PM_{2.5}$ visibility index standard. The EPA believes this surrogacy approach is appropriate to fulfill PSD requirements for individual sources in PSD areas, which, by definition, will not have been designated as nonattainment for the $PM_{2.5}$ visibility index NAAQS. However, our proposed surrogacy approach for PSD should not be construed as a proposal to use a surrogacy approach for designating nonattainment areas or for implementing programs to attain the visibility index NAAQS in those areas.

The surrogacy approach is not intended to replace or otherwise undermine the validity of the analytical techniques employed for air quality related value (AQRV) assessments, including visibility, required under 40 CFR 51.166(p) and 40 CFR 52.21(p). The federal land managers (FLM) – federal officials with direct responsibility for management of Federal Class I parks and wilderness areas – have an affirmative responsibility to protect the AQRVs of such lands, and to provide the appropriate procedures and analysis techniques for assessing AQRVs (Appendix W to 40 CFR part 51, Sections 6.1 (b) and 6.2.3(a)). The FLMs have developed specific modeling approaches for AQRV assessments that

are not specifically governed under the requirements set forth in 40 CFR 51.166(l)(1) and 40 CFR 52.21(l)(1), thus the surrogacy approach is not applicable to the AQRV assessments under the PSD program.

The surrogate approach could be incorporated into the PSD program in any of three alternative ways. First, the decision as to whether the surrogate approach is adequate could be handled on a case-by-case basis in consultation with the permitting authority, similar to the existing consultation process under the EPA's Guideline on Air Quality Models for ozone and secondary $PM_{2.5}$ impacts (40 CFR part 51, appendix W, section 5.2.1.c), with no presumption regarding its adequacy. Second, the EPA could establish a rebuttable presumption that the surrogate approach is applicable for all permits through either guidance or a notice-and-comment rulemaking. In either the first or second alternative, there would be a possibility that reliance on a surrogate-based demonstration could be subjected to challenge for any particular permit analysis. Third, the EPA could establish that the surrogate approach is applicable for all permits, also through a notice-and-comment rulemaking. The EPA seeks comment on all of the identified issues and proposed alternative implementation mechanisms associated with the proposed surrogate approach. It is the Agency's intention to issue either guidance or new regulatory provisions as just described for a surrogacy approach by the time any final revisions to the PM NAAQS become effective, so that sources seeking permits will not be unnecessarily delayed.

While noting the importance of the surrogacy approach as an essential initial strategy due to limitations on data and analytical tools, the EPA also notes that when a technically robust surrogate relationship exists there may not be a need to apply an end date for the use of a surrogacy approach. Without an end date, PSD applicants would always have the option of relying upon such a demonstration if they would so choose. This would offer long-term benefits in terms of simplification and resource savings for applicants and reviewing authorities. Accordingly, based on the technical analysis for the standards analyzed (Kelly, et al, 2012) which supports the surrogacy approach for demonstrating that a source will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$

visibility index NAAQS, the EPA may determine that it is not necessary to announce an end date for using it. The EPA invites comment on this aspect of the proposal as well.

For context, the EPA notes that with regard to sources being required to demonstrate that they would not cause or contribute to a violation of the 1997 $PM_{2.5}$ NAAQS, the EPA has previously issued an interim policy (Seitz, 1997). Under the 1997 policy, which is no longer in effect,[222] the EPA stated that demonstrating compliance with the NSR requirements for controlling PM_{10} emissions and for analyzing impacts on PM_{10} air quality could be used to demonstrate compliance with the $PM_{2.5}$ NSR requirements. This approach was designed to control $PM_{2.5}$ emissions and protect $PM_{2.5}$ air quality until certain technical difficulties concerning $PM_{2.5}$ were resolved. At that time, however, we did not support the policy with any technical analysis to show how a demonstration of compliance with the PM_{10} NAAQS would satisfy the $PM_{2.5}$ requirements and support the issuance of a PSD permit. Consequently, the EPA later concluded that, in keeping with numerous court opinions regarding the use of surrogates, PSD applicants and reviewing authorities seeking to rely specifically on the 1997 PM_{10} Surrogate Policy should consider certain overarching legal principles, including that a surrogate may be used only after it has been shown to be reasonable (such as where the surrogate is a reasonable proxy for the pollutant or has a predictable correlation to the pollutant) and that the relationship between the regulated pollutant and the surrogate pollutant can be shown to apply in the specific instance where an applicant or reviewing authority seeks to rely upon it. In keeping with these principles, the Agency believes that the surrogate approach now being proposed for use in demonstrating that a source will not cause or contribute to a violation of the proposed secondary $PM_{2.5}$ visibility index NAAQS is supported by a robust technical analysis. The EPA invites comment on this analysis, which is provided in the docket for this action.

The EPA notes that the analysis supporting the surrogacy approach for the PSD program is distinct from and serves a different purpose than the analyses conducted to inform the Administrator's

[222] The 1997 PM_{10} Surrogate Policy formally ended on May 16, 2011. See 76 FR 28646 (May 18, 2011).

proposed conclusion on the appropriate indicator for a standard intended to protect against PM-related visibility impairment. As discussed in section VI.A above, the EPA has long recognized that the determination of a single, appropriate national level for a secondary standard to address PM-related visibility impairment is complicated by regional differences in several factors that influence visibility, such as background and current $PM_{2.5}$ concentrations, $PM_{2.5}$ composition, and average relative humidity. Variations in these factors across regions could thus result in situations where attaining an appropriately protective concentration of fine particles in one region might or might not provide the appropriate degree of protection in a different region. Although the analysis upon which the surrogacy approach is based (Kelly, et al., 2012) generally shows that daily $PM_{2.5}$ visibility index values decrease when daily $PM_{2.5}$ mass concentrations decrease, and vice versa, there is nonetheless considerable variability in that relationship across the range of ambient fine particle concentrations. As a result, as discussed in section VI.D.1.d above, the Administrator provisionally concludes that a calculated $PM_{2.5}$ light extinction indicator is an appropriate indicator to replace the current $PM_{2.5}$ mass indicator and that such an indicator would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by virtue of directly incorporating the effects of differences in $PM_{2.5}$ composition and relative humidity across the country.

d. PSD Screening Provisions: Significant Emissions Rates, Significant Impact Levels, and Significant Modeling Concentration.

The EPA has historically allowed the use of screening tools to help facilitate the implementation of the NSR program by reducing the permit applicant's burden and streamlining the permitting process for circumstances where emissions or concentrations could be considered de minimis. These screening tools, which all provide de minimis thresholds of some kind, include a significant emissions rate (SER), significant impact levels (SILs), and a significant monitoring concentration (SMC). The EPA promulgated a SER for $PM_{2.5}$ in the 2008 final rule on NSR implementation as part of the first phase of NSR amendments to address $PM_{2.5}$ (74 FR 28333, May 16, 2008). The $PM_{2.5}$ SER is used to determine

whether any proposed major stationary source or major modification will emit sufficient amounts of $PM_{2.5}$ to require review under the PSD program.[223] Under the terms of the existing EPA regulations, the applicable SER for $PM_{2.5}$ is 10 tpy of direct $PM_{2.5}$ emissions (including condensable PM) and, for precursors, 40 tpy of SO_2 and 40 tpy of NO_x emissions. 40 CFR 51.166(b)(23); 40 CFR 52.21(b)(23). This SER applies to permitting requirements based on both the annual and 24-hour $PM_{2.5}$ NAAQS. The SERs are pollutant-specific but not specific to the averaging time of any NAAQS for a particular pollutant. At this time, the EPA is not proposing any change to the existing $PM_{2.5}$ SER as a result of the proposed revisions to the primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS. However, the EPA intends to consider this issue in a subsequent rulemaking that will specifically address various PSD implementation issues that are being described herein. The EPA will solicit comment on any proposed changes to the SERs for $PM_{2.5}$ and its precursors at that time, but also invites preliminary suggestions at this time that we may consider in developing that proposed rulemaking. Until any rulemaking to amend existing regulations is completed, permitting decisions should continue to be based on the SERs for $PM_{2.5}$ and its precursors in existing regulations.

Once it is determined that the proposed new source or modification is significant for $PM_{2.5}$, the permit applicant must complete an air quality analysis. The SIL helps to determine the scope of the required air quality analysis that must be carried out in order to demonstrate that the source's emissions will not cause or contribute to a violation of any NAAQS or increment. The EPA promulgated SILs for $PM_{2.5}$ in 2010 under a final rule that established increments, SILs, and SMC for $PM_{2.5}$ (75 FR 64890 to 64894, October 20, 2010). A separate $PM_{2.5}$ SIL is defined for each averaging period for which $PM_{2.5}$ NAAQS and increments currently exist, as well as for each of the three area classifications, i.e., Class I, II and III, that Congress established in the CAA for PSD purposes.

Historically, sources have been allowed to model their proposed emissions increase to predict

[223] The PSD rules provide that a source that would emit major amounts of any regulated NSR pollutant must undergo review for that pollutant as well as any other regulated NSR pollutant that the source would emit in significant amounts.

ambient impacts associated with that emissions increase, and to compare this predicted ambient concentration of $PM_{2.5}$ to the applicable SIL, which is also expressed as an ambient $PM_{2.5}$ concentration over a prescribed averaging time consistent with the NAAQS and increments. At this time, the EPA is not proposing to revise the annual SIL for $PM_{2.5}$ as a result of the proposed revision to the primary annual $PM_{2.5}$ NAAQS. However, the EPA intends to review this issue and will consider any potential need to revise the existing SIL in a separate rulemaking addressing PSD implementation issues. The EPA welcomes preliminary comments concerning this issue, but will also provide an additional opportunity for comments at a later date in the event that a subsequent proposal is made to revise the annual $PM_{2.5}$ SIL.

While the proposed secondary $PM_{2.5}$ visibility index NAAQS is a 24-hour standard for which no $PM_{2.5}$ SIL is currently defined, there is a question as to whether the existing 24-hour $PM_{2.5}$ SIL, expressed on a $PM_{2.5}$ mass basis ($\mu g/m^3$), would be appropriate for this proposed secondary NAAQS, expressed in terms of a $PM_{2.5}$ visibility index. As discussed in section IX.F.1.c above, the EPA conducted an analysis to evaluate whether an individual source's impact resulting in a small increase in $PM_{2.5}$ concentration would produce a comparably small increase in visibility impairment (Kelly et al., 2012). The analysis indicates that small increases in $PM_{2.5}$ concentrations caused by individual sources produce similarly small changes in visibility impairment for ambient conditions near the proposed standard level of either 30 dv or 28 dv.

The EPA is not proposing any possible alternatives to the existing 24-hour $PM_{2.5}$ SIL in this proposed rule, but instead intends to issue a separate rulemaking to assess this and other related PSD implementation issues. The EPA also wishes to note that the current $PM_{2.5}$ SILs are the subject of a petition that challenges the EPA's legal authority under the CAA to develop and implement those SILs, and also alleges that the existing $PM_{2.5}$ SILs have not been adequately demonstrated to represent *de minimis* values. *Sierra Club v. EPA, No. 10-1413* (D.C. Circuit filed December 17, 2010). In the course of this litigation, the EPA has recognized the need to correct the text of two $PM_{2.5}$ SILs provisions in the

regulations, and the EPA has asked the court to vacate those provisions so that the EPA may correct them. However, the EPA does not believe this corrective action would preclude use of the $PM_{2.5}$ SILs in the interim, and the EPA intends to provide guidance on continued use of the $PM_{2.5}$ SILs (in a manner consistent with principles articulated by the EPA in the rulemaking and litigation) pending this correction of the regulatory text. The proposed revised primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS do not affect the continued used of the $PM_{2.5}$ SILs in accordance with the forthcoming guidance described above. As a separate matter, the EPA intends to consider the need for a new SIL specifically for implementing any secondary $PM_{2.5}$ visibility index NAAQS under the PSD program. In the event that we do proceed, the EPA now welcomes preliminary comments as to how such a SIL could be developed. The EPA will also provide an additional opportunity for comments at a later date in the event that a subsequent proposal is made to establish a separate SIL for the secondary $PM_{2.5}$ visibility index NAAQS, if such a secondary NAAQS is finalized

Finally, the SMC, also measured as an ambient pollutant concentration ($\mu g/m^3$), is a screening tool used to determine whether it may be appropriate to exempt a proposed source from the requirement to collect pre-construction ambient monitoring data as part of the required air quality analysis for a particular pollutant. The EPA promulgated the existing SMC for $PM_{2.5}$ in 2010 on the basis of the defined minimum detection limit for $PM_{2.5}$ and the current information at that time concerning the physical capabilities of the $PM_{2.5}$ FRM samplers. In that rulemaking, the EPA addressed uncertainties introduced into the measurement of $PM_{2.5}$ due to variability in the mechanical performance of the $PM_{2.5}$ samplers and micro-gravimetric analytical balances that weigh filter samples. In a future NSR implementation rulemaking that will follow this rulemaking, the EPA intends to evaluate the types of additional ambient data, if any, that may need to be collected by a proposed source concerning the proposed secondary $PM_{2.5}$ visibility index NAAQS, and the feasibility of individual sources being required to gather such additional information. The EPA welcomes preliminary comments concerning this issue, but will provide additional opportunity for comment when a subsequent NSR implementation

rulemaking is proposed concerning the proposed revisions to the PM NAAQS.

e. PSD Increments

Section 166(a) of the CAA requires the EPA to promulgate "regulations to prevent the significant deterioration of air quality" for pollutants covered by the NAAQS. Among other things, the EPA has implemented this requirement through promulgation of PSD increments. The EPA promulgated $PM_{2.5}$ increments in 2010 to prevent significant air quality deterioration with regard to the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS[224] (75 FR 64864, October 20, 2010). The proposed revision to the primary annual $PM_{2.5}$ NAAQS raises the question of whether the EPA should consider revising the annual $PM_{2.5}$ increments. Similarly, the EPA's proposed action to establish a distinct secondary $PM_{2.5}$ visibility index NAAQS raises the question of whether revisions to the $PM_{2.5}$ increments are appropriate to address public welfare considerations protected by the proposed secondary standard.

In this proposal, the EPA is not proposing to revise the $PM_{2.5}$ increments. The EPA will consider whether it is appropriate to propose such an action in the future, and if so, would undertake the necessary rulemaking. The EPA invites preliminary comments at this time on such a need, and on issues we should consider if we undertake a rule to revise the $PM_{2.5}$ increments. In the meantime, the current $PM_{2.5}$ increments remain in effect, and PSD permitting should continue pursuant to the current increments, with a minimum of disruption to the permitting process when the revised NAAQS take effect.

2. Nonattainment New Source Review

The requirements under part D of the CAA pertain to the preconstruction review and permitting requirements for new major stationary sources and major modifications locating in areas designated "nonattainment" for a particular pollutant. Those requirements are commonly referred to as the NNSR

[224] The primary and secondary NAAQS for $PM_{2.5}$ have been the same up until this time where EPA is proposing a distinct secondary NAAQS for PM-related visibility impairment.

program. The EPA regulations for the NNSR program are contained at 40 CFR 51.165, 52.24 and part 51, appendix S.

For NNSR, "major stationary source" is generally defined as a source with the potential to emit at least 100 tpy or more of a pollutant for which an area has been designated "nonattainment." Thus, the NNSR program applies to pollutants for which the EPA has promulgated NAAQS. Because the EPA has defined the PM NAAQS, and has established area designations for PM, in terms of two separate indicators – PM_{10} and $PM_{2.5}$ – each indicator is regulated separately for purposes of NNSR applicability. That is, for PM_{10}, a "major stationary source" for NNSR applicability generally is a source that is located in a PM_{10} nonattainment area and has the potential to emit at least 100 tpy of PM_{10} emissions.[225] For $PM_{2.5}$, a "major stationary source" for NNSR applicability is a source that is located in a $PM_{2.5}$ nonattainment area and has the potential to emit at least 100 tpy of direct $PM_{2.5}$ ("$PM_{2.5}$ emissions") or a precursor of $PM_{2.5}$.

For a major modification, the NNSR rules rely upon SERs described previously in the PSD discussion in section IX.F.1. For NNSR, a major modification is a physical change or a change in the method of operation of an existing stationary source that is major for the nonattainment pollutant and that results in a significant net emissions increase of that nonattainment pollutant. As described earlier, the EPA will be evaluating the existing SERs for $PM_{2.5}$ and $PM_{2.5}$ precursors, and will determine whether there is any basis for proposing changes to the existing values. Any decision to propose 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

[225] In some cases, however, the CAA and the EPA's regulations define "major stationary source" for nonattainment area NSR in terms of a lower emissions rate dependent on the pollutant. For PM_{10}, for example, a source having the potential to emit at least 70 tpy of PM_{10} is considered "major" if the source is located in a nonattainment area classified as a "Serious Area."

averaging periods. Thus, an area may be nonattainment for the annual standard and unclassifiable/attainment or attainment for the 24-hour standard. While no formal policy has yet been developed to address this situation, the EPA presently believes that it is reasonable to require that only NNSR (and not PSD) applies for $PM_{2.5}$ in any area that is nonattainment for either averaging period.[226] Looking forward, the EPA proposes that areas would be designated for a proposed secondary $PM_{2.5}$ visibility index NAAQS independently of designations for the mass-based annual and 24-hour $PM_{2.5}$ NAAQS. Accordingly, the EPA intends to address this issue in a future NSR rulemaking, but invites comments now on whether it is appropriate to apply the NNSR program requirements for any pollutant that is designated nonattainment for at least one averaging period or at least one primary or secondary NAAQS for a particular pollutant.

New major stationary sources or major modifications based on $PM_{2.5}$ emissions (or emissions of a $PM_{2.5}$ precursor) in a $PM_{2.5}$ nonattainment area, must install technology that meets the lowest achievable emission rate (LAER); secure appropriate emissions reductions to offset the proposed emissions increases; and perform other analyses as required under section 173 of the CAA. Following the promulgation of any revised NAAQS for $PM_{2.5}$, some new nonattainment areas for $PM_{2.5}$ may result. Where a state does not have any NNSR program or the current NNSR program does not apply to $PM_{2.5}$, that state will be required to submit the necessary SIP revisions to ensure that new major stationary sources and major modifications for $PM_{2.5}$ undergo preconstruction review pursuant to the NNSR program. Under section 172(b) of the CAA, the Administrator may provide states up to 3 years from the effective date of nonattainment area designations to submit the necessary SIP revisions meeting the applicable NNSR requirements. Nevertheless, permits issued to sources in nonattainment areas must satisfy the applicable NNSR requirements as of the effective date of the nonattainment designation; therefore states lacking the appropriate NNSR program requirements at that time will be allowed to

[226] However, transportation conformity requirements discussed in section IX.G below are dependent upon the averaging period(s) for which an area is designated nonattainment.

issue such permits during the SIP revision period in accordance with the applicable nonattainment permitting requirements contained in the Emissions Offset Interpretative Ruling at 40 CFR part 51, appendix S, which would apply to the revised PM NAAQS upon their effective date. The EPA is not proposing any type of $PM_{2.5}$ grandfathering provision at this time for purposes of NNSR. The timetable for adopting new provisions under the state NNSR program will not apply with regard to the revised NAAQS for $PM_{2.5}$ until such time that an area is designated nonattainment for a particular standard. Further consideration of the need for a grandfathering provision for purposes of NNSR for the revised NAAQS for $PM_{2.5}$ will be made and addressed in the future, as appropriate.

G. Transportation Conformity Program

Transportation conformity is required under CAA section 176(c) to ensure that transportation plans, transportation improvement programs (TIPs) and federally supported highway and transit projects will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. Transportation conformity applies to areas that are designated nonattainment and maintenance for transportation-related criteria pollutants: carbon monoxide, ozone, NO_2, and $PM_{2.5}$, and PM_{10}. Transportation conformity for any revised NAAQS for $PM_{2.5}$ does not apply until 1 year after the effective date of the nonattainment designation for that NAAQS (See CAA section 176(c)(6) and 40 CFR 93.102(d)). The EPA's Transportation Conformity Rule (40 CFR part 51, subpart T, and 40 CFR part 93, subpart A) establishes the criteria and procedures for determining whether transportation activities conform to the SIP. The EPA is not proposing changes to the transportation conformity rule in this proposed rulemaking. The EPA notes that the transportation conformity rule already addresses the $PM_{2.5}$ and PM_{10} NAAQS. However, in the future, the EPA will review the need to issue or revise guidance describing how the current conformity rule applies in nonattainment and maintenance areas for any revised primary or distinct secondary PM NAAQS, as needed.

As discussed in section VIII above, the EPA is proposing certain clarifying changes to $PM_{2.5}$ air

quality monitoring regulations These proposed changes are designed to align different elements of the monitoring regulations for consistency, which will help facilitate the interpretation of modeling results from quantitative $PM_{2.5}$ conformity hot-spot analyses for the annual standards by clarifying which receptors are comparable to the NAAQS.

If the EPA finalizes these changes to the monitoring regulations, the EPA will update its guidance on quantitative $PM_{2.5}$ hot-spot analyses as appropriate to make it consistent with the revised monitoring requirements (US EPA, 2010j). If the proposed revisions to the monitoring requirements are finalized, the EPA intends that the current quantitative $PM_{2.5}$ hot spot guidance would continue to apply to any quantitative $PM_{2.5}$ hot-spot analysis that was begun before the effective date of these proposed revisions to the monitoring regulations. Revised guidance on receptors to be compared to the annual $PM_{2.5}$ standards for quantitative $PM_{2.5}$ hot-spot analyses would apply to any quantitative $PM_{2.5}$ hot-spot analysis begun after the effective date of the revised monitoring regulations. Nonattainment and maintenance areas are encouraged to use their interagency consultation processes to determine whether an analysis for a given project was started before the effective date of changes to the monitoring requirements. Applying the current guidance regarding whether or not a receptor can be compared to the annual $PM_{2.5}$ NAAQS to analyses that had begun before the effective date of changes to the monitoring regulations is consistent with how the conformity rule and guidance address the transitional period for new emissions factor models or local planning assumptions (40 CFR 93.110(a) and 93.111(b) and (c)). In both of those cases, analyses begun before the new model or data became available can be completed using the data and/or model that were available when the analyses began. The EPA allows this in order to conserve state resources by not making transportation planning agencies redo analyses simply because a model has been revised, new data have become available, or in this case, the EPA has revised its regulations for $PM_{2.5}$ monitoring.

H. General Conformity Program

General conformity is required by CAA section 176(c). This section requires that federal

agencies do not adopt, accept, approve, or fund activities that are not consistent with state air quality goals. General conformity applies to any federal action (e.g., funding, licensing, permitting, or approving), other than projects that are Federal Highway Administration (FHWA)/Federal Transit Administration (FTA) projects as defined in 40 CFR 93.101 (which are covered under transportation conformity described above), if the action takes place in a nonattainment or maintenance area for ozone, PM, NO_2, carbon monoxide, lead, or SO_2. General conformity also applies to a federal highway and transit project if it does not involve either Title 23 or 49 funding, but does involve FHWA or FTA approval such as is required for a connection to an Interstate highway or for a deviation from applicable design standards per 40 CFR 93.101. (The FHWA and FTA actions described here as not subject to general conformity are subject to transportation conformity.) General conformity for any revised PM NAAQS would not apply until 1 year after the effective date of a nonattainment designation for that NAAQS. The EPA's General Conformity Rule (40 CFR 93.150 to 93.165) establishes the criteria and procedures for determining if a federal action conforms to the SIP. With respect to any revision to the primary or secondary standards, a federal agency would be expected to continue to estimate emissions for conformity analyses in the same manner as they are estimated for conformity analyses for the current PM NAAQS. EPA's existing general conformity regulations include the basic requirement that a federal agency's general conformity analysis be based on the latest and most accurate emission estimation techniques available (40 CFR 93.159(b)), and EPA would expect that this same principle would be followed for analyses needed with respect to any revised PM NAAQS. When updated and improved emissions estimation techniques become available, EPA would expect the federal agency to use these techniques. The EPA is not proposing changes to the general conformity rule in this proposed rulemaking. The general conformity rule already addresses the $PM_{2.5}$ and PM_{10} NAAQS. The EPA will review the need to issue guidance describing how the current conformity rule applies in nonattainment and maintenance areas for the final revised primary and secondary PM NAAQS.

X. Statutory and Executive Order Reviews

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

Under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), this action is an "economically significant regulatory action" because it is likely to have an annual effect on the economy of $100 million or more. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations have been documented in the docket for this action.

In addition, the EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in *Regulatory Impact Analysis for the Proposed Revisions to the National Ambient Air Quality Standards for Particulate Matter*, EPA 452/R-12-003. A copy of the analysis is available in Docket No. EPA-HQ-OAR-2010-0955.

The estimates in the RIA are associated with alternative levels (in $\mu g/m^3$) of the primary annual/24-hour $PM_{2.5}$ standards including: 13/35, 12/35, 11/35, and 11/30. Table 4 provides a summary of the estimated costs, monetized benefits, and net benefits associated with full attainment of these alternative standards.

Table 4. Total Costs, Monetized Benefits and Net Benefits in 2020[a] (millions of 2006$)[b]
Full Attainment

Alternate $PM_{2.5}$ Standards (annual/ 24-hour, in µg/m^3)	Total Costs		Monetized Benefits[c]		Net Benefits[c]	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate[d]	7% Discount Rate
13/35	$2.9	$2.9	$88 to $220	$79 to $200	$85 to $220	$76 to $200
12/35	$69	$69	$2,300 to $5,900	$2,100 to $5,400	$2,300 to $5,900	$2,000 to $5,300
11/35	$270	$270	$9,200 to $23,000	$8,300 to $21,000	$8,900 to $2300	$8,000 to $21,000
11/30	$390	$390	$14,000 to $36,000	$13,000 to $33,000	$14,000 to $36,000	$13,000 to $33,000

[a] Values are rounded to two significant figures.
[b] Using a 2010$ year increases estimated costs and benefits by approximately 8%.
[c] The reduction in premature death each year accounts for over 90 percent of total monetized benefits. Mortality risk valuation assumes discounting over the SAB-recommended 20-year segmented lag structure. Not all possible benefits or disbenefits are quantified and monetized in this analysis. B is the sum of all unquantified benefits. Data limitations prevented us from quantifying these endpoints, and as such, these benefits are inherently more uncertain than those benefits that we were able to quantify.
[d] Due to data limitations, we were unable to discount compliance costs for all sectors at 3%. As a result, the net benefit calculations at 3% were computed by subtracting the monetized benefits at 3% minus the costs at 7%.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.S. 3501 et seq. Burden is defined at 5 CFR 1320.3(b). There are no information collection requirements directly associated with revisions to a NAAQS under section 109 of the CAA.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) a small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of particulate matter in ambient air as required by section 109 of the CAA. *See also American Trucking Associations v. EPA*. 175 F.3d at 1044-45 (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

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

This action is also not subject to the requirements section 205 of the UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This action imposes no new expenditure or enforceable duty on any state, local, or tribal governments or the private sector, and the EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

Furthermore, in setting a NAAQS, the EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of state plans to implement the standards. *See also American Trucking Associations v. EPA*, 175 F. 3d at 1043 (noting that because the EPA is precluded from considering costs of implementation in establishing NAAQS, preparation of a Regulatory Impact Analysis pursuant to the Unfunded Mandates Reform Act would not furnish any information which the court could consider in reviewing the NAAQS). The EPA acknowledges, however, that any corresponding revisions to associated SIP requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively, might result in such effects. Accordingly, the EPA will address, as appropriate, unfunded mandates if and when it proposes any revisions to 40 CFR parts 51 or 58.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order

13132. The rule does not alter the relationship between the Federal government and the states regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, the EPA is mandated to establish and review NAAQS; however, CAA section 116 preserves the rights of states to establish more stringent requirements if deemed necessary by a state. Furthermore, this proposed rule does not impact CAA section 107 which establishes that the states have primary responsibility for implementation of the NAAQS. Finally, as noted in section D (above) on UMRA, this rule does not impose significant costs on state, local, or Tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this action.

However, as also noted in section D (above) on UMRA, the EPA recognizes that states will have a substantial interest in this rule and any corresponding revisions to associated air quality surveillance requirements, 40 CFR part 58. Therefore, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between the EPA and state and local governments, the EPA specifically solicits comment on this proposed rule from state and local officials.

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

The action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It does not have a substantial direct effect on one or more Indian Tribes, since Tribes are not obligated to adopt or implement any NAAQS. The Tribal Authority Rule gives Tribes the opportunity to develop and implement CAA programs such as the PM NAAQS, but it leaves to the discretion of the Tribe whether to develop these programs and which programs, or appropriate elements of a program, they will adopt. Thus, Executive Order 13175 does not apply to this rule.

Although Executive Order 13175 does not apply to this rule, the EPA consulted with tribal officials or other representatives of tribal governments in developing this action.

The EPA specifically solicits additional comments on this proposed rule from tribal officials.

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

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of PM exposures on children. The protection offered by these standards may be especially important for children because childhood represents a lifestage associated with increased susceptibility to PM-related health effects. Because children have been identified as a susceptible population, we have carefully evaluated the environmental health effects of exposure to PM pollution among children. Discussions of the results of the evaluation of the scientific evidence and policy considerations pertaining to children are contained in sections III.B, III.D, IV.B, and IV.C of this preamble. A listing of documents that contain the evaluation of scientific evidence and policy considerations that pertain to children is found in the section on Children's Environmental Health in the Supplementary Information section of this preamble, and a copy of all documents have been placed in the public docket for this action.

The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of early life exposure to PM.

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

This action is not a "significant energy action" as defined in Executive Order 13211, (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this action concerns the review of the NAAQS for PM. The action does not prescribe specific pollution control strategies by which these ambient standards will be met. Such strategies are developed by states on a case-by-case basis, and the EPA cannot predict whether the control options selected by states will include regulations on energy suppliers, distributors, or users.

I. National Technology Transfer and Advancement Act

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

This proposed rulemaking involves technical standards for environmental monitoring and measurement. Specifically, the EPA proposes to retain the indicators for fine ($PM_{2.5}$) and coarse (PM_{10}) particles. The indicator for fine particles is measured using the Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere (appendix L to 40 CFR part 50), which is known as the $PM_{2.5}$ FRM, and the indicator for coarse particles is measured using the Reference Method for the Determination of Particulate Matter as PM_{10} in the Atmosphere (appendix J to 40 CFR part 50), which is known as the PM_{10} FRM. The EPA also proposes to add a distinct secondary standard for $PM_{2.5}$ defined in terms of a calculated $PM_{2.5}$ light extinction indicator, which would use $PM_{2.5}$ mass species and relative humidity data to calculate $PM_{2.5}$ light extinction.

To the extent feasible, the EPA employs a Performance-Based Measurement System (PBMS), which does not require the use of specific, prescribed analytic methods. The PBMS is defined as a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner. It is intended to be more flexible and cost effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. Though the FRM defines the particular specifications for ambient monitors, there is some variability with regard to how monitors measure PM, depending on the type and size of PM and environmental conditions. Therefore, it is not

practically possible to fully define the FRM in performance terms to account for this variability. Nevertheless, our approach in the past has resulted in multiple brands of monitors being approved as FRM for PM, and we expect this to continue. Also, the FRMs described in 40 CFR part 50 and the equivalency criteria described in 40 CFR part 53, constitute a performance-based measurement system for PM, since methods that meet the field testing and performance criteria can be approved as FEMs. Since finalized in 2006 (71 FR, 61236, October 17, 2006) the new field and performance criteria for approval of $PM_{2.5}$ continuous FEMs has resulted in the approval of six approved FEMs.[227] In summary, for measurement of $PM_{2.5}$ and PM_{10}, the EPA relies on both FRMs and FEMs, with FEMs relying on a PBMS approach for their approval. The EPA is not precluding the use of any other method, whether it constitutes a voluntary consensus standard or not, as long as it meets the specified performance criteria.

For the proposed secondary standard defined in terms of a calculated $PM_{2.5}$ light extinction indicator, the EPA proposes to use existing monitoring technologies that are already deployed in the CSN and IMPROVE monitoring programs as well as relative humidity data from sensors already deployed at routine weather stations. The sampling and analysis protocols in use in the CSN program are the result of substantial input and recommendations from CASAC both during their initial deployment about ten years ago, and during the more recent transition to carbon sampling that is consistent with IMPROVE protocols (Henderson 2005c). Monitoring agencies also played a strong role in directing the sampling technologies used in the CSN. During the first few years of implementing the CSN there were up to four different sampling approaches used in the network. Over time as monitoring agencies shared their experiences and data with each other, several agencies shifted their network operations to the sampling technology used today. By 2008, the EPA was working closely with all remaining monitoring agencies to transition to the current CSN sampling for ions and elements. All carbon sampling was fully transitioned to the current method by October of 2009 for consistency with the IMPROVE program.

[227] A list of designated reference and equivalent methods is available on EPA's website at: http://www.epa.gov/ttn/amtic/criteria.html.

Therefore, while the current CSN sampling methods were not developed or adopted by a voluntary consensus standard body, they are the result of harmonizing the network by monitoring agency users and EPA. The CSN network and methods are described in more detail in the Policy Assessment (US EPA, 2011a, Appendix B, section B.1.3).

The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable voluntary consensus standards for any of the proposed indicators with an explanation as to why such standards should be used in this regulation.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

The EPA maintains an ongoing commitment to ensure environmental justice for all people, regardless of race, color, national origin, or income. Ensuring environmental justice means not only protecting human health and the environment for everyone, but also ensuring that all people are treated fairly and are given the opportunity to participate meaningfully in the development, implementation, and enforcement of environmental laws, regulations, and policies. The EPA has identified potential disproportionately high and adverse effects on minority and/or low-income populations from this proposed rule.

The EPA has identified persons from lower socioeconomic strata as a susceptible population for PM-related health effects. As a result, the EPA has carefully evaluated the potential impacts on low-income and minority populations as discussed in section III.E.3.a of this preamble. The Agency expects

this proposed rule would lead to the establishment of uniform NAAQS for PM. The Integrated Science Assessment and Policy Assessment contain the evaluation of the scientific evidence and policy considerations that pertain to these populations. These documents are available as described in the Supplementary Information section of this preamble and copies of all documents have been placed in the public docket for this action.

The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of PM on low-income populations and minority populations.

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List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 51

Environmental protection, Administrative practices and procedures, Air pollution control, Intergovernmental relations

40 CFR Part 52

Environmental protection, Administrative practices and procedures, Air pollution control, Intergovernmental relations

40 CFR Part 53

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements

Dated: June 14, 2012

Lisa P. Jackson,
Administrator.

For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 50 – NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

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

2. Table 1 in §50.14(c)(2)(vi) is revised to read as follows:

§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.

* * * * *

(c) ***

(2) ***

(vi) ***

Table 1 Special Schedules for Exceptional Event Flagging and Documentation Submission for Data to be Used in Initial Designations for New or Revised NAAQS

NAAQS pollutant/ standard/(level)/ promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
$PM_{2.5}$/24-Hr Standard (35 µg/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	2008	October 1, 2010	June 1, 2011

ppb) Promulgated June 22, 2010	2009	October 1, 2010	June 1, 2011
	2010	June 1, 2011	June 1, 2011
	2011	60 days after the end of the calendar quarter in which the event occurred or March 31, 2012, whichever date occurs first.	60 days after the end of the calendar quarter in which the event occurred or March 31, 2012, whichever date occurs first.
$PM_{2.5}$/ 24-Hour Standard (final level and promulgation date TBD)	2010 to 2011	July 1, 2013	December 12, 2013
	2012	July 1, 2013[a]	December 12, 2013
	2013	July 1, 2014[a]	August 1, 2014
$PM_{2.5}$/ Annual Standard (final level and promulgation date TBD)	2010 to 2011	July 1, 2013	December 12, 2013
	2012	July 1, 2013[a]	December 12, 2013
	2013	July 1, 2014[a]	August 1, 2014
$PM_{2.5}$ Visibility Index (final level and promulgation date TBD)	2010 to 2011	July 1, 2013	December 12, 2013
	2012	July 1, 2013[a]	December 12, 2013
	2013	July 1, 2014[a]	August 1, 2014

[a] This date is the same as the general schedule in 40 CFR 50.14.
Note: The table of revised deadlines only applies to data EPA will use to establish the final initial area designations for new NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment. TBD = to be determined.
*****

3. Add §50.18 to read as follows:

§50.18 National primary ambient air quality standards for $PM_{2.5}$.

(a) The national primary ambient air quality standards for $PM_{2.5}$ are [12.0 to 13.0] micrograms per cubic meter ($\mu g/m^3$) annual arithmetic mean concentration and 35 $\mu g/m^3$ 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 of this part and designated in accordance with part 53 of this chapter; or

(2) An equivalent method designated in accordance with part 53 of this chapter.

(b) The primary annual $PM_{2.5}$ standard is met when the annual arithmetic mean concentration, as determined in accordance with appendix N of this part, is less than or equal to [12.0 to 13.0] $\mu g/m^3$.

(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 $\mu g/m^3$.

4. Add §50.19 to read as follows:

§50.19 National secondary ambient air quality standard for $PM_{2.5}$

(a) The following national secondary ambient air quality standard for PM is in addition to the national secondary ambient air quality standards for PM_{10} specified in §50.6 and for $PM_{2.5}$ specified in §50.13.

(1) [30 or 28] deciviews (dv), 24-hour average concentration, based on a calculated $PM_{2.5}$ visibility index using methods based on appendix C of part 58 of this chapter.

(2) [Reserved].

(b) The 24-hour secondary $PM_{2.5}$ visibility index standard is met when the 90th percentile 24-hour calculated $PM_{2.5}$ visibility index, as determined in accordance with appendix N of this part, is less than or equal to [30 or 28] dv.

5. Appendix N to part 50 is revised to read as follows:

Appendix N to Part 50—Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$

1.0 General

(a) This appendix explains the data handling conventions and computations necessary for determining when the national ambient air quality standards (NAAQS) for $PM_{2.5}$ are met, including the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS specified in §50.7, 50.13, and 50.18, and the secondary $PM_{2.5}$ visibility index NAAQS specified in §50.19. $PM_{2.5}$ is defined, in general terms, as particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers. $PM_{2.5}$ mass concentrations are measured in the ambient air by a Federal Reference Method (FRM) based on appendix L of this part, as

applicable, and designated in accordance with part 53 of this chapter; or by a Federal Equivalent Method (FEM) designated in accordance with part 53 of this chapter; or by an Approved Regional Method (ARM) designated in accordance with part 58 of this chapter. Only those FRM, FEM, and ARM measurements that are derived in accordance with part 58 of this chapter (i.e., that are deemed "suitable") shall be used in comparisons with the $PM_{2.5}$ NAAQS. Chemically speciated $PM_{2.5}$ mass concentrations are derived from ambient air measurements using the methods specified in appendix C of part 58 of this chapter. The data handling and computation procedures to be used to construct annual and 24-hour NAAQS metrics from reported $PM_{2.5}$ mass concentrations, and the associated instructions for comparing these calculated metrics to the levels of the $PM_{2.5}$ NAAQS, are specified in sections 2.0, 3.0, and 4.0 of this appendix. The data handling and computation procedures to be used to construct the $PM_{2.5}$ visibility index metric from reported speciated $PM_{2.5}$ concentrations (and related climatological relative humidity hygroscopic growth factors), and the associated instructions for comparing these computed metrics to the level of the $PM_{2.5}$ visibility index NAAQS, are specified in sections 2.0, 3.0, and 5.0 of this appendix.

(b) Decisions to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, are made according to the requirements and process deadlines specified in §§50.1, 50.14, and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

Annual mean refers to a weighted arithmetic mean, based on quarterly means, as defined in section 4.4 of this appendix.

The Air Quality System (AQS) is EPA's official repository of ambient air data.

Collocated monitors refers to two or more air measurement instruments for the same parameter (e.g., $PM_{2.5}$ mass) operated at the same site location, and whose placement is consistent with §53.1 of this chapter. For purposes of considering a combined site record in this appendix, when two or more monitors are operated at the same site, one monitor is designated as the "primary" monitor with any

additional monitors designated as "collocated." It is implicit in these appendix procedures that the primary monitor and collocated monitor(s) are all deemed suitable for the applicable NAAQS comparison; however, it is not a requirement that the primary and monitors utilize the same specific sampling and analysis method.

The collocated PM_{10} data substitution test substitutes reported same-day PM_{10} FRM/FEM daily values from the same site for missing scheduled $PM_{2.5}$ samples in data capture deficient quarters.

Combined site data record is the data set used for performing calculations in appendix N. It represents data for the primary monitors augmented with data from collocated monitors according to the procedure specified in 3.0(d) of this appendix.

Creditable samples are daily values in the combined site record that are given credit for data completeness. The number of creditable samples (cn) for a given year also governs which value in the sorted series of daily values represents the 98th or 90th percentile for that year. Creditable samples include daily values collected on scheduled sampling days and valid make-up samples taken for missed or invalidated samples on scheduled sampling days.

Daily values for the annual and 24-hour $PM_{2.5}$ NAAQS refer to the 24-hour average concentrations of $PM_{2.5}$ mass measured (or averaged from hourly measurements in AQS) from midnight to midnight (local standard time) from suitable monitors. Daily values for the $PM_{2.5}$ visibility index NAAQS refer to the 24-hour average $PM_{2.5}$ visibility index values derived from reported speciated $PM_{2.5}$ measurements and corresponding f(RH) factors using the formulae specified in section 5.0 of this appendix.

Data substitution tests are diagnostic evaluations performed on an annual $PM_{2.5}$ NAAQS design value (DV) or a 24-hour $PM_{2.5}$ NAAQS DV to determine if that metric, which is otherwise judged incomplete (via the applicable 75 percent data capture or 11 creditable samples per quarter minimum data completeness options), shall nevertheless be deemed complete and valid for NAAQS comparisons, or alternatively, shall still be considered incomplete and not valid for NAAQS comparisons. There are three data substitution tests, the "maximum quarterly value" test, the "minimum quarterly value" test,

and the "collocated PM_{10}" test. Only one of the three tests needs to "pass" in order to validate the DV in question. These tests substitute actual same-site extreme daily values for missing data in an incomplete year(s), calculate a revised "test DV" using the original plus substituted data, and, if the test DV relays the same NAAQS status (i.e., meets or not meets) as the original (otherwise incomplete) DV, the test is deemed to have "passed" and since only one passing test is needed, the original DV (without the diagnostic data substitutions) is then considered complete and valid for NAAQS comparisons. If the test DV relays a different NAAQS status as the original (otherwise incomplete) DV, the test is deemed to have "failed", and if all applicable substitution tests are "failed" then the original DV will still be considered incomplete and not valid for NAAQS comparisons.

Deciview is the unit of measure for the level of the secondary $PM_{2.5}$ visibility index NAAQS. This metric describes changes in uniform light extinction that can be perceived by a human observer. One deciview represents the minimal perceptible change in visibility to the human eye. Daily calculated $PM_{2.5}$ light extinction values in units of Mm^{-1} are translated to $PM_{2.5}$ visibility index values in terms of deciviews according to equation 7 in section 5(d)(3) of this appendix.

Design values (DVs) are the 3-year average NAAQS metrics that are compared to the NAAQS levels to determine when a monitoring site meets or does not meet the NAAQS, calculated as shown in sections 4.0 and 5.0 of this appendix. There are three separate DVs specified in this appendix:

(1) The 3-year average of $PM_{2.5}$ annual mean mass concentrations for each eligible monitoring site is referred to as the "annual $PM_{2.5}$ NAAQS DV".

(2) The 3-year average of annual 98th percentile 24-hour average $PM_{2.5}$ mass concentration values recorded at each eligible monitoring site is referred to as the "24-hour (or daily) $PM_{2.5}$ NAAQS DV".

(3) The 3-year average of annual 90th percentile 24-hour average $PM_{2.5}$ visibility index values calculated for each eligible monitoring site is referred to as the "$PM_{2.5}$ visibility index NAAQS DV".

Elemental carbon (EC) is the reported concentration of $PM_{2.5}$ elemental carbon from the speciation methods identified in appendix C to part 58 of this chapter.

Eligible sites are monitoring stations that meet the criteria specified in §58.11 and §58.30 of this chapter, and thus are approved for comparison to the annual $PM_{2.5}$ NAAQS. For the 24-hour $PM_{2.5}$ NAAQS and the $PM_{2.5}$ visibility index NAAQS, all site locations that meet the criteria specified in §58.11 are approved (i.e., eligible) for NAAQS comparisons.

Extra samples are non-creditable samples. They are daily values that do not occur on scheduled sampling days and that cannot be used as make-up samples for missed or invalidated scheduled samples. Extra samples are used in mean calculations and are included in the series of all daily values subject to selection as a 98th or 90th percentile value, but are not used to determine which value in the sorted list represents the 98th or 90th percentile.

Fine soil (FS) is the calculated measure of $PM_{2.5}$ crustal material. It is derived from the reported speciated $PM_{2.5}$ concentrations of aluminum (Al), silicon (Si), calcium (Ca), iron (Fe), and titanium (Ti) using formula 5d in 5(d)(1) of this appendix. FS data is generated from the speciation methods identified in appendix C to part 58 of this chapter.

f(RH) is a unitless water growth factor used to relate a given relative humidity (RH) to its impact on $PM_{2.5}$ light-scattering.

Make-up samples are samples collected to take the place of missed or invalidated required scheduled samples. Make-up samples can be made by either the primary or the collocated monitor. Make-up samples are either taken before the next required sampling day or exactly one week after the missed (or voided) sampling day.

The maximum quarterly value data substitution test substitutes actual "high" reported daily $PM_{2.5}$ values from the same site (specifically, the highest reported non-excluded quarterly values (year non-specific) contained in the combined site record for the evaluated 3-year period) for missing daily values.

The minimum quarterly value data substitution test substitutes actual "low" reported daily $PM_{2.5}$ values from the same site (specifically, the lowest reported quarterly values (year non-specific) contained in the combined site record for the evaluated 3-year period) for missing daily values.

98th percentile [90th percentile] is the smallest daily value out of a year of $PM_{2.5}$ mass monitoring data [$PM_{2.5}$-related visibility indices] below which no more than 98 [90] percent of all daily values fall using the ranking and selection method specified in section 4.5(a) [5.0(d)(4)] of this appendix.

Nitrate is the fully neutralized $PM_{2.5}$ nitrate ion (NO_3^-) concentration. It is the reported concentration of NO_3^- multiplied by a factor (1.29) to account for full neutralization with ammonium. See equation 5b in 5(d)(1) of this appendix. Nitrate data is generated from the speciation methods identified in appendix C to part 58 of this chapter.

Organic mass (OM) is the concentration of $PM_{2.5}$ organic carbon ($PM_{2.5}$ OC) multiplied by a factor (1.4) to adjust the OC for other elements (e.g., hydrogen and oxygen) assumed to be associated with the $PM_{2.5}$ OC. See equation 5c in 5(d)(1) of this appendix. Organic mass data is generated from the speciation methods identified in appendix C to part 58 of this chapter.

$PM_{2.5}$ b_{ext} is a calculated measure of the total fraction of light that is attenuated by $PM_{2.5}$ particles per unit distance (e.g., per inverse megameter, Mm^{-1}). The estimate is derived from daily average speciated $PM_{2.5}$ mass concentrations and climatological monthly average relative humidity data via equation 6 in 5(d)(2) of this appendix.

$PM_{2.5}$ organic carbon ($PM_{2.5}$ OC) refers to the measured organic carbon with an adjustment for adsorbed organic vapors (known as the organic carbon artifact). $PM_{2.5}$ organic carbon data is generated from the speciation methods identified in Appendix C to Part 58.

$PM_{2.5}$ visibility index is the indicator used for the secondary $PM_{2.5}$ visibility index NAAQS. The index is computed on a 24-hour average basis from $PM_{2.5}$ b_{ext} using equation 7 in 5(d)(3) of this appendix.

Primary monitors are suitable monitors designated by a state or local agency in their annual network plan (and in AQS) to be the default data source for creating a combined site record for purposes of NAAQS comparisons. If there is only one suitable monitor at a particular site location, then it is presumed to be a primary monitor.

Quarter refers to a calendar quarter (e.g., January through March).

Quarterly data capture rate is the percentage of scheduled samples in a calendar quarter that have corresponding valid reported sample values. Quarterly data capture rates are specifically calculated as the number of creditable samples for the quarter divided by the number of scheduled samples for the quarter, the result then multiplied by 100 and rounded to the nearest integer.

Scheduled $PM_{2.5}$ samples refers to those reported daily values which are consistent with the required sampling frequency (per §58.12 of this chapter) for the primary monitor, or those that meet the special exception noted in 3.0(e).

Seasonal sampling is the practice of collecting data at a reduced frequency during a season of expected low concentrations.

Speciation methods refer to the $PM_{2.5}$ chemical speciation methods identified in section 2.9.2 of appendix C to part 58 of this chapter which include those used by the Chemical Speciation Network (CSN) and the Interagency Monitoring of Protected Visual Environment (IMPROVE) network.

Suitable monitors are instruments that use sampling and analysis methods approved for NAAQS comparisons. For the annual and 24-hour $PM_{2.5}$ NAAQS, suitable monitors include all FRMs, and all FEMs/ARMs except those specific continuous FEMs/ARMs disqualified by a particular monitoring agency network per §58.11 of this chapter. For the $PM_{2.5}$ visibility index NAAQS, suitable monitors include the speciation methods specified in section 2.9.2 of appendix C of part 58 of this chapter which include those used by the CSN and the IMPROVE network.

Sulfate is the fully neutralized $PM_{2.5}$ sulfate ion (SO_4^{2-}) concentration. It is the reported concentration of SO_4^{2-} multiplied by a factor (1.375) to account for full neutralization with ammonium. See equation 5a in 5(d)(1) of this appendix. Sulfate data are generated from the speciation methods identified in appendix C to part 58 of this chapter.

Year refers to a calendar year.

2.0 Monitoring Considerations

(a) Section 58.30 of this chapter provides special considerations for data comparisons to the annual $PM_{2.5}$ NAAQS.

(b) Monitors meeting the network technical requirements detailed in §58.11 of this chapter are suitable for comparison with the NAAQS for $PM_{2.5}$. All speciation samplers using the speciation methods specified in section 2.9.2 of appendix C of part 58 of this chapter are deemed suitable for comparisons to the $PM_{2.5}$ visibility index NAAQS.

(c) Section 58.12 of this chapter specifies the required minimum frequency of sampling for $PM_{2.5}$. Exceptions to the specified sampling frequencies, such as seasonal sampling, are subject to the approval of the EPA Regional Administrator and must be documented in the state or local agency Annual Monitoring Network Plan as required in §58.10 of this chapter and also in AQS.

3.0 Requirements for Data Use and Data Reporting for Comparisons with the NAAQS for $PM_{2.5}$

(a) Except as otherwise provided in this appendix, all valid FRM/FEM/ARM $PM_{2.5}$ mass concentration data and speciated $PM_{2.5}$ mass concentration data produced by suitable monitors that are required to be submitted to AQS, or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in the DV calculations. Generally, EPA will only use such data if they have been certified by the reporting organization (as prescribed by §58.15 of this chapter); however, data not certified by the reporting organization can nevertheless be used, if the deadline for certification has passed and EPA judges the data to be complete and accurate.

(b) $PM_{2.5}$ mass concentration data (typically collected hourly for continuous instruments and daily for filter-based instruments) shall be reported to AQS in micrograms per cubic meter ($\mu g/m^3$) to at least one decimal place, with additional digits to the right being truncated. If concentrations are reported to AQS with more than one decimal place, AQS will truncate the value to one decimal place for NAAQS usage (i.e., for implementing the procedures in this appendix). In situations where $PM_{2.5}$ mass data are submitted to AQS with less precision than specified above, these data shall nevertheless still be deemed

appropriate for NAAQS usage. For the purpose of calculating $PM_{2.5}$ visibility index values, the speciated $PM_{2.5}$ component concentrations of sulfate, nitrate, $PM_{2.5}$ OC, EC, Al, Si, Ca, Fe, and Ti, the AQS will convert (if necessary) reported concentrations into units of $\mu g/m^3$ rounded to four decimal places (0.xxxx5 rounds up), or three significant digits when the concentration value is 0.1 or more. In situations where fewer decimal places or significant digits than specified above are reported to AQS, such data shall nevertheless still be deemed appropriate for NAAQS usage.

(c) Block 24-hour average concentrations will be computed in AQS from submitted hourly $PM_{2.5}$ concentration data (mass or species) for each corresponding day of the year and the result will be stored in the first, or start, hour (i.e., midnight, hour '0') of the 24-hour period. A 24-hour average concentration shall be considered valid if at least 75 percent of the hourly averages (i.e., 18 hourly values) for the 24-hour period are available. In the event that less than all 24 hourly average concentrations are available (i.e., less than 24, but at least 18), the 24-hour average concentration shall be computed on the basis of the hours available using the number of available hours within the 24-hour period as the divisor (e.g., 19, if 19 hourly values are available). For $PM_{2.5}$ mass concentrations, 24-hour periods with seven or more missing hours shall be considered valid if, after substituting zero for all missing hourly concentrations, the resulting 24-hour average daily value is greater than the level of the 24-hour $PM_{2.5}$ NAAQS (i.e., greater than or equal to 35.5 $\mu g/m^3$). Twenty-four hour average $PM_{2.5}$ mass concentrations that are averaged in AQS from hourly values will be truncated to one decimal place, consistent with the data handling procedure for the reported hourly (and also 24-hour filter-based) data; twenty-four-hour average $PM_{2.5}$ speciated mass concentrations that are averaged in AQS from hourly values will be rounded to four decimal places (or three significant digits if the average is greater than 0.1), consistent with the data handling procedures for the reported hourly (and also 24-hour filter-based) data.

(d) All calculations shown in this appendix shall be implemented on a site-level basis. Site level concentration data shall be processed as follows:

(1) The default dataset for $PM_{2.5}$ mass and speciated concentrations for a site shall consist of the measured concentrations recorded from the designated primary monitor(s). All daily values produced by the primary monitor are considered part of the site record; this includes all creditable samples and all extra samples.

(2) Data for the primary monitors shall be augmented as much as possible with data from collocated monitors. If a daily value is not produced by the primary monitor for a particular day (scheduled or otherwise), but a value is available from a collocated monitor, then that collocated value shall be considered part of the combined site data record. If more than one collocated daily value is available, the average of those valid collocated values shall be used as the daily value. The data record resulting from this procedure is referred to as the "combined site data record."

(e) All daily values in a combined site data record are used in the calculations specified in this appendix, however, not all daily values are given credit towards data completeness requirements. Only creditable samples are given credit for data completeness. Creditable samples include daily values in the combined site record that are collected on scheduled sampling days and valid make-up samples taken for missed or invalidated samples on scheduled sampling days. Days are considered scheduled according to the required sampling frequency of the designated primary monitor with one exception for aggregated $PM_{2.5}$ mass. The exception is, if a collocated continuous FEM monitor has a more intensive sampling frequency than the primary FRM monitor, then samples contributed to the combined site record from that continuous FEM/ARM are always considered scheduled and, hence, also creditable. Daily values in the combined site data record that are reported for nonscheduled days, but that are not valid make-up samples are referred to as extra samples. For the $PM_{2.5}$ visibility index NAAQS, creditable samples are based on daily values of $PM_{2.5}$ b_{ext} (which essentially require non-missing values for the nine required input speciated $PM_{2.5}$ parameters, all reported on the same scheduled sampling days). Section 5.0 of this appendix specifies in further detail the procedure for calculating $PM_{2.5}$ visibility index values and the ensuing determination of whether they are creditable or not.

4.0 Comparisons with the Annual and 24-Hour $PM_{2.5}$ NAAQS

4.1 Annual $PM_{2.5}$ NAAQS

(a) The primary annual $PM_{2.5}$ NAAQS is met when the annual $PM_{2.5}$ NAAQS DV is less than or equal to [12.0 to 13.0] $\mu g/m^3$ at each eligible monitoring site. The secondary annual $PM_{2.5}$ NAAQS is met when the annual $PM_{2.5}$ NAAQS DV is less than or equal to 15.0 $\mu g/m^3$ at each eligible monitoring site.

(b) Three years of valid annual means are required to produce a valid annual $PM_{2.5}$ NAAQS DV. A year meets data completeness requirements when quarterly data capture rates for all four quarters are at least 75 percent. However, years with at least 11 creditable samples in each quarter shall also be considered valid if the resulting annual mean or resulting annual $PM_{2.5}$ NAAQS DV (rounded according to the conventions of section 4.3 of this appendix) is greater than the level of the applicable primary or secondary annual $PM_{2.5}$ NAAQS. Furthermore, where the explicit 75 percent data capture and/or 11 sample minimum requirements are not met, the 3-year annual $PM_{2.5}$ NAAQS DV shall still be considered valid (and complete) if it passes at least one of the three data substitution tests stipulated below.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 4.1(b) of this appendix and thus would normally not be useable for the calculation of a valid annual $PM_{2.5}$ NAAQS DV, the annual $PM_{2.5}$ NAAQS DV shall nevertheless be considered valid (and complete) if one (or more) of the test conditions specified in 4.1(c)(i), 4.1(c)(ii), and 4.1(c)(iii) is met.

(1) An annual $PM_{2.5}$ NAAQS DV that is above the level of the NAAQS can be validated if it passes the minimum quarterly value data substitution test. This type of data substitution is permitted only if there are at least 30 days across the three matching quarters of the three years under consideration (e.g., collectively, quarter 1 of year 1, quarter 1 of year 2 and quarter 1 of year 3) from which to select the quarter-specific low value. Data substitution will be performed in all quarter periods that have less than 11 creditable samples.

<u>Procedure</u>: Identify for each deficient quarter (i.e., those with less than 11 creditable samples) the lowest

reported daily value for that quarter, looking across those three months of all three years under consideration. If after substituting the lowest reported daily value for a quarter for (11- cn) daily values in the matching deficient quarter(s) (i.e., to bring the creditable number for those quarters up to 11), the procedure yields a recalculated annual $PM_{2.5}$ NAAQS test DV that is greater than the level of the standard, then the annual $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the annual $PM_{2.5}$ NAAQS is deemed to have been exceeded in that 3-year period.

(2) An annual $PM_{2.5}$ NAAQS DV that is equal to or below the level of the NAAQS can be validated if it passes the maximum quarterly value data substitution test. This type of data substitution is permitted only if there are at least 30 days across the three matching quarters of the three years under consideration from which to select the quarter-specific high value. Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture. If any quarter has less than 50 percent data capture then this substitution test cannot be used.

Procedure: Identify for each deficient quarter (i.e., those with less than 75 percent data capture) the highest reported daily value for that quarter, excluding state-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, looking across those three months of all three years under consideration. If after substituting the highest reported daily $PM_{2.5}$ value for a quarter for all missing daily data in the matching deficient quarter(s) (i.e., to make those quarters 100 percent complete), the procedure yields a recalculated annual $PM_{2.5}$ NAAQS test DV that is less than or equal to the level of the standard, then the annual $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the annual $PM_{2.5}$ NAAQS is deemed to have been met in that 3-year period.

(3) An annual $PM_{2.5}$ NAAQS DV that is equal to or below the level of the NAAQS can be validated if it passes the collocated PM_{10} data substitution test. Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture. If any quarter has less than 50 percent data capture then this substitution test cannot be used.

Procedure: Identify for each deficient quarter (i.e., those with less than 75 percent data capture),

available collocated FRM/FEM PM_{10} values reported for each $PM_{2.5}$ scheduled day that is missing a valid daily $PM_{2.5}$ value. If there is more than one collocated daily PM_{10} value present for a particular day (that is scheduled for measuring $PM_{2.5}$ but does not have a corresponding valid daily $PM_{2.5}$ value), then the highest of those multiple daily PM_{10} values will be used as the substituted value. If, after substituting the available collocated daily PM_{10} values for as many as possible missing daily $PM_{2.5}$ values in the deficient quarter(s), the procedure yields recalculated data capture rates of 75 percent or more, and a recalculated annual $PM_{2.5}$ NAAQS test DV less than or equal to the level of the standard, then the annual $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the annual $PM_{2.5}$ NAAQS is deemed to have been met in that 3-year period.

(d) An annual $PM_{2.5}$ NAAQS DV based on data that do not meet the completeness criteria stated in 4(b) and also do not satisfy the test conditions specified in section 4(c), may also be considered valid with the approval of, or at the initiative of, the EPA Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the daily values that are available, and nearby concentrations in determining whether to use such data.

(e) The equations for calculating the annual $PM_{2.5}$ NAAQS DVs are given in section 4.4 of this appendix.

4.2 Twenty-four-hour $PM_{2.5}$ NAAQS

(a) The primary and secondary 24-hour $PM_{2.5}$ NAAQS are met when the 24-hour $PM_{2.5}$ NAAQS DV at each eligible monitoring site is less than or equal to 35 $\mu g/m^3$.

(b) Three years of valid annual $PM_{2.5}$ 98th percentile mass concentrations are required to produce a valid 24-hour $PM_{2.5}$ NAAQS DV. A year meets data completeness requirements when quarterly data capture rates for all four quarters are at least 75 percent. However, years shall be considered valid, notwithstanding quarters with less than complete data (even quarters with less than 11 creditable samples, but at least one creditable sample must be present for the year), if the resulting annual 98th percentile value or resulting 24-hour NAAQS DV (rounded according to the conventions of section 4.3

of this appendix) is greater than the level of the standard. Furthermore, where the explicit 75 percent data capture requirement is not met, the 24-hour $PM_{2.5}$ NAAQS DV shall still be considered valid (and complete) if it passes one (or both) of two applicable data substitution tests (i.e., the maximum quarterly value or collocated PM_{10} data substitution tests).

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 4.2(b) of this appendix and thus would normally not be useable for the calculation of a valid 24-hour $PM_{2.5}$ NAAQS DV, the 24-hour $PM_{2.5}$ NAAQS DV shall nevertheless be considered "complete and valid" if either of the test conditions specified in 4.2(c)(i) or 4.2(c)(ii) are met.

(1) A $PM_{2.5}$ 24-hour mass NAAQS DV that is equal to or below the level of the NAAQS can be validated if it passes the maximum quarterly value data substitution test. This type of data substitution is permitted only if there are at least 30 days across the three matching quarters of the three years under consideration from which to select the quarter-specific high value.

Procedure: Identify for each deficient quarter (i.e., those with less than 75 percent data capture) the highest reported daily $PM_{2.5}$ value for that quarter, excluding state-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, looking across those three months of all three years under consideration. If, after substituting the highest reported daily maximum $PM_{2.5}$ value for a quarter for all missing daily data in the matching deficient quarter(s) (i.e., to make those quarters 100 percent complete), the procedure yields a recalculated 3-year 24-hour NAAQS test DV less than or equal to the level of the standard, then the 24-hour $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the 24-hour $PM_{2.5}$ NAAQS is deemed to have been met in that 3-year period.

(2) A 24-hour $PM_{2.5}$ NAAQS DV that is equal to or below the level of the NAAQS can be validated if it passes the collocated PM_{10} data substitution test. Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture. If any quarter has less than 50 percent data capture then this substitution test cannot be used.

Procedure: Identify for each deficient quarter, available collocated FRM/FEM daily PM_{10} values reported for each $PM_{2.5}$ scheduled day that is missing a valid daily $PM_{2.5}$ value. If there is more than one collocated daily PM_{10} value present for a particular day (that is scheduled for measuring $PM_{2.5}$ but doesn't have a corresponding valid daily $PM_{2.5}$ value), then the highest of those daily PM_{10} values will be used as the substituted daily $PM_{2.5}$ value. If, after substituting the available collocated daily PM_{10} values for as many as possible missing daily $PM_{2.5}$ values in the deficient quarter(s), the procedure yields recalculated data capture rates of 75 percent or more, and a recalculated 24-hour $PM_{2.5}$ NAAQS test DV less than or equal to the level of the standard, then the 24-hour $PM_{2.5}$ NAAQS DV is deemed to have passed the diagnostic test and is valid, and the 24-hour $PM_{2.5}$ NAAQS is deemed to have been met in that 3-year period.

(d) A 24-hour $PM_{2.5}$ NAAQS DV based on data that do not meet the completeness criteria stated in 4(b) and also do not satisfy the test conditions specified in section 4(c), may also be considered valid with the approval of, or at the initiative of, the EPA Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the daily values that are available, and nearby concentrations in determining whether to use such data.

(e) The procedures and equations for calculating the 24-hour $PM_{2.5}$ NAAQS DVs are given in section 4.5 of this appendix.

4.3 Rounding Conventions. For the purposes of comparing calculated $PM_{2.5}$ NAAQS DVs to the applicable level of the standard, it is necessary to round the final results of the calculations described in sections 4.4 and 4.5 of this appendix. Results for all intermediate calculations shall not be rounded.

(a) Annual $PM_{2.5}$ NAAQS DVs shall be rounded to the nearest tenth of a $\mu g/m^3$ (decimals x.x5 and greater are rounded up to the next tenth, and any decimal lower than x.x5 is rounded down to the nearest tenth).

(b) Twenty-four-hour $PM_{2.5}$ NAAQS DVs shall be rounded to the nearest 1 $\mu g/m^3$ (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to

the nearest whole number).

4.4 Equations for the Annual $PM_{2.5}$ NAAQS.

(a) An annual mean value for $PM_{2.5}$ is determined by first averaging the daily values of a calendar quarter using equation 1 of this appendix:

Equation 1

$$\overline{X}_{q,y} = \frac{1}{n_q} \sum_{i=1}^{n_q} X_{i,q,y}$$

Where:

$\overline{X}_{q,y}$ = the mean for quarter q of the year y;
n_q = the number of daily values in the quarter; and
$x_{i\ q,y}$ = the ith value in quarter q for year y.

(b) Equation 2 of this appendix is then used to calculate the site annual mean:

Equation 2

$$\overline{X}_y = \frac{1}{4} \sum_{q=1}^{4} \overline{X}_{q,y}$$

Where:

$\overline{X}_y$ = the annual mean concentration for year *y* (*y* = 1, 2, or 3); and

$\overline{X}_{q,y}$ = 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:

$\overline{X}$ = the annual $PM_{2.5}$ NAAQS DV; and

$\overline{X}_y$ = 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.

<u>Procedure</u>: Sort all the daily values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 98th percentile value is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range for the annual creditable number of samples for year y (cn_y) (e.g., for 120 creditable samples per year, the appropriate range would be 101 to 150). The corresponding "n" value in the right column identifies the rank of the annual 98th percentile value in the descending sorted list of site specific daily values for year y (e.g., for the range of 101 to 150, n would be 3). Thus, $P_{0.98,\,y}$ = the nth largest value (e.g., for the range of 101 to 150, the 98th percentile value would be the third highest value in the sorted series of daily values.

Table 1

Annual number of creditable samples for year *y* (cn_y)	P 0.98, y is the nth maximum for the year where *n* is the listed number
1 to 50	1
51 to 100	2
101 to 150	3
151 to 200	4
201 to 250	5
251 to 300	6
301 to 350	7
351 to 366	8

(b) The 24-hour $PM_{2.5}$ NAAQS DV is then calculated by averaging the annual 98th percentiles using equation 4 of this appendix:

Equation 4

$$\overline{P}_{0.98} = \frac{1}{3}\sum_{y=1}^{3} P_{0.98_y}$$

Where

$\overline{P}_{0.98}$ = the 24-hour $PM_{2.5}$ NAAQS DV; and

$P_{0.98\,y}$ = the annual 98th percentile for year *y*

(c) The 24-hour $PM_{2.5}$ NAAQS DV is rounded according to the conventions in section 4.3 of this appendix before a comparison with the level of the primary and secondary 24-hour NAAQS are made.

5.0 Comparisons with the Secondary $PM_{2.5}$ Visibility Index NAAQS

(a) The secondary $PM_{2.5}$ visibility index NAAQS is met when the $PM_{2.5}$ visibility index NAAQS DV at each eligible monitoring site is less than or equal to [30 or 28] deciviews.

(b) Three years of valid annual 90th percentile concentrations of 24-hour average $PM_{2.5}$ visibility index values are required to produce a valid $PM_{2.5}$ visibility index NAAQS DV. A year meets data completeness requirements when there are at least 11 creditable daily values of $PM_{2.5}$ visibility indices

in each quarter (all four of the year); a daily value is defined as one that contains valid estimates for all five major speciation $PM_{2.5}$ components: sulfate, nitrate, OM, EC, and FS. In order to derive these five major components, 24-hour average concentrations are needed for the following nine parameters: SO_4^{2-}, NO_3^-, EC, Al, Si, Ca, Fe, and Ti, and $PM_{2.5}$ OC. Years with less than 11 creditable samples in each quarter shall still be considered complete and the corresponding identified 90th percentile deemed valid, if the 90th percentile value for that year or a resulting 3-year average 90th percentile value (i.e., a $PM_{2.5}$ visibility index NAAQS DV) encompassing that annual value exceeds the NAAQS level (i.e., [30 or 28] deciviews). The use of less than complete data (i.e., data not meeting the criteria stated in this subsection) is subject to the approval of the EPA Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

(c) Rounding Conventions: For the purposes of calculating $PM_{2.5}$ visibility index NAAQS DVs to compare to the level of the standard, it is necessary to round the final results of the calculations described in sections 5 (d) of this appendix as noted below. Results for all intermediate calculations shall not be rounded unless otherwise specified.

(1) Daily deciview values shall be rounded to the nearest 0.1 deciview (decimals 0.x5 and greater are rounded up to the next tenth, and any decimal lower than 0.x5 is rounded down to the stated tenth).

(2) The $PM_{2.5}$ visibility index NAAQS DV shall be rounded to the nearest 1 deciview (decimal values x.5 and greater are rounded up to the nearest whole number, and any decimal values lower than x.5 are rounded down to the nearest whole number).

(d) Procedures and Equations for the Secondary $PM_{2.5}$ Visibility Index NAAQS

(1) The five major speciation components (Sulfate, Nitrate, OM, EC, and FS) are derived from reported concentrations of SO_4^{2-}, NO_3^-, EC, Al, Si, Ca, Fe, and Ti, and reported/adjusted concentrations of $PM_{2.5}$ OC, according to the equations below:

Equation 5a

$$Sulfate_i = SO_{4\,i\,i}^{2-} \times 1.375$$

Where:

$Sulfate_i$ = ammonium sulfate for day *i*; and

$SO_{4\,i}^{2-}$ = the reported sulfate ion concentration (SO_4^{2-}) for day *i*

Equation 5b

$$Nitrate_i = NO_{3\,i}^{-} \times 1.29$$

Where:

$Nitrate_i$ = ammonium nitrate for day *i*; and

$NO_{3\,i}^{-}$ = the reported nitrate ion concentration (NO_3^-) for day *i*

Equation 5c

$$OM_i = (PM_{2.5}OC_i) \times 1.4$$

Where:

OM_i = organic mass for day *i*; and

$PM_{2.5}\,OC_i$ = measured organic carbon with an adjustment for adsorbed organic vapors

Equation 5d

$$FS_i = (Al_i \times 2.20) + (Si_i \times 2.49) + (Ca_i \times 1.63) + (Fe_i \times 2.42) + (Ti_i \times 1.94)$$

Where:

FS_i = fine soil for day i; and

Al_i = the reported aluminum concentration for day i; and

Si_i = the reported silicon concentration for day i; and

Ca_i = the reported calcium concentration for day i; and

Fe_i = the reported iron concentration for day i; and

Ti_i = the reported titanium concentration for day i

(2) Daily estimates of $PM_{2.5}$-related calculated light-extinction, $PM_{2.5}$ b_{ext} (expressed in units of inverse

megameters (Mm^{-1})), are derived by equation 6. The components sulfate, nitrate, OM, and FS are derived using formulae, 5a, 5b, 5c, and 5d. The component EC is the reported concentration of $PM_{2.5}$ elemental carbon. The *f*(RH*)* value corresponding to each site-day shall be identified from the most recent 10-year average climatological database. This database contains spatially gridded monthly values of *f*(RH). The database record for the grid-point closest in distance to the monitoring site shall be selected for utilization in calculating $PM_{2.5}$ b_{ext}. The monthly value identified from the database record for the selected grid location will be the one corresponding to the sample month of the reported input speciation concentrations.

Equation 6:

$$PM_{2.5}\ b_{ext:i} = (3 \times Sulfate_i \times f(RH)_{m,gp}) + (3 \times Nitrate_i \times f(RH)_{m,gp}) + (4 \times OM_i) + (10 \times EC_i) + (FS_i)$$

Where:

$PM_{2.5}\ b_{ext:i}$	=	$PM_{2.5}$-related light extinction in Mm^{-1} for day i; and
Sulfate $_i$	=	ammonium sulfate for day i; and
Nitrate $_i$	=	ammonium nitrate for day; and
OM $_i$	=	organic mass for day; and
EC $_i$	=	the reported concentration of elemental carbon for day i; and
FS $_i$	=	fine soil for day i; and
$f(RH)_{m,gp}$	=	the RH hygroscopic growth factor determined from the EPA "climatological *f*(RH) database" corresponding to month m for day i for the grid point gp closest in distance to the monitoring site

(3) Daily estimates of $PM_{2.5}$ b_{ext}, in units of Mm^{-1}, are converted to $PM_{2.5}$ visibility index values, in units of deciviews, according to equation 7.

Equation 7:

$$PM_{2.5}_visibility_index_i = 10 \times \ln\left(\frac{(PM_{2.5}_b_{ext_i} + 10)}{10}\right)$$

Where:

$PM_{2.5}$_visibility_index$_i$	=	$PM_{2.5}$ visibility index value (in deciview units) for day *i*; and
$PM_{2.5}_b_{ext_i}$	=	$PM_{2.5}$-related light extinction (in Mm^{-1} units) for day *i*

(4) Identification of annual 90th percentile $PM_{2.5}$ visibility index values is accomplished by the steps

provided in this subsection. Table 2 of this appendix shall be used to identify annual 90th percentile values according to the creditable number of 24-hour $PM_{2.5}$ visibility index values calculated for the year.

Procedure: Sort all the daily $PM_{2.5}$ visibility index values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 90th percentile is determined from this sorted series of values which is ordered from the highest to the lowest number. Using the left column of Table 2, determine the appropriate range for the annual creditable number of samples for year y (n_y) (e.g., for 35 creditable samples in a year, the appropriate range would be 31 to 40). The corresponding "nth" value in the right column identifies the rank of the annual 90th percentile value in the descending sorted list of $PM_{2.5}$ visibility index values for year y (e.g., for the range of 31 to 40, n is equal to 4). Thus, $P_{0.90,\,y}$ = the nth largest value (e.g.., for the range of 31 to 40, the 90th percentile value would be the fourth highest value in the sorted series of $PM_{2.5}$ visibility index values).

(5) The $PM_{2.5}$ visibility index NAAQS DV is then calculated by averaging the annual 90th percentile $PM_{2.5}$ visibility index values for three consecutive years using equation 8 of this appendix:

Equation 8

$$\overline{P}_{0.90} = \frac{1}{3}\sum_{y=1}^{3} P_{0.90:y}$$

Where:
$\overline{P}_{0.90}$ = the $PM_{2.5}$ visibility index NAAQS DV; and
$P_{0.90:y}$ = the annual 90th percentile $PM_{2.5}$ visibility index value for year y

Table 2

Annual number of creditable samples for year "y" (cn_y)	P 0.90, y is the nth maximum for the year where n is the listed number
1 to 10	1

11 to 20	2
21 to 30	3
31 to 40	4
41 to 50	5
51 to 60	6
61 to 70	7
71 to 80	8
81 to 90	9
91 to 100	10
101 to 110	11
111 to120	12
121 to 130	13
131 to 140	14
141 to 150	15
151 to 160	16
161 to 170	17
171 to 180	18
181 to 190	19
191 to 200	20
201 to 210	21
211 to 220	22
221 to 230	23
231 to 240	24
241 to 250	25
251 to 260	26
261 to 270	27
271 to 280	28
281 to 290	29
291 to 300	30
301 to 310	31
311 to 320	32
321 to 330	33
331 to 340	34
341 to 350	35
351 to 360	36
361 to 366	37

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

6. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401-7671q.

Subpart I – [Amended]

7. In §51.166, add paragraph (i)(10) to read as follows:

§51.166 Prevention of significant deterioration of air quality

* * * * *

(i) Exemptions. * * *

(10) The plan may provide that the requirements of paragraph (k)(1) of this section shall not apply to a stationary source or modification with respect to the national ambient air quality standards for $PM_{2.5}$ as in effect on [EFFECTIVE DATE OF FINAL RULE] if the reviewing authority has first published before that date public notice that a preliminary determination for the permit subject to this section has been issued. Instead, the requirements in paragraph (k)(1) shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ as in effect at the time of the public notice on the proposed permit.

* * * * *

PART 52—APPROVAL AND PROMULGATIONS OF IMPLEMENTATION PLANS

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

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

9. In §52.21, add paragraph (i)(11) to read as follows:

§52.21 Prevention of significant deterioration of air quality.

* * * * *

(i) * * *

(11) The requirements of paragraph (k)(1) of this section shall not apply to a stationary source or modification with respect to the national ambient air quality standards for $PM_{2.5}$ as in effect on [EFFECTIVE DATE OF FINAL RULE] if the Administrator has first published before that date a public notice that a draft permit subject to this section has been prepared. Instead, the requirements in paragraph (k)(1) shall apply with respect to the national ambient air quality standards for $PM_{2.5}$ as in effect on the date the Administrator first published a public notice that a draft permit has been prepared.

* * * * *

PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

10. The authority citation for part 53 continues to read as follows:

Authority: Section 301(a) of the Clean Air Act (42 U.S.C. sec. 1857 g(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 $PM_{10-2.5}$ sampler offered for sale as part of an FRM or FEM shall function within the limits of the performance specifications referred to in §53.20(a), §53.30(a), §53.35, §53.50, or §53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in §53.4(b)(3).

* * * * *

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

12. The authority citation of part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7405, 7410, 7414, 7601, 7611, 7614, and 7619.

13. Section 58.1 is amended by adding in alphabetical order a definition for "Area-wide" and by removing the definition for "Community monitoring zone (CMZ)".

The addition reads as follows:

§58.1 Definitions.

* * * * *

Area-wide means all monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro-or middle scale that are representative of many such locations in the same CBSA.

* * * * *

14. Section 58.10 is amended as follows:

a. By adding paragraph (a)(8).

b. By adding paragraph (b)(13).

c. By revising paragraph (c).

d. By revising paragraph (d).

The additions and revisions read as follows:

§58.10 Annual monitoring network plan and periodic network assessment.

(a) * * *

(8) A plan for establishing near-road $PM_{2.5}$ monitoring sites in accordance with the requirements of appendix D to this part shall be submitted to the Regional Administrator by July 1, 2014. The plan shall provide for all required monitoring stations to be operational by January 1, 2015.

(b) * * *

(13) The identification of any $PM_{2.5}$ FEMs and/or ARMs used in the monitoring agency's network where the data are not of sufficient quality such that data collected for the period of time that the plan covers (i.e., the next 18 months or until a new plan is submitted addressing this issue) are not to be compared to the NAAQS. For required SLAMS where the agency identifies that the $PM_{2.5}$ Class III FEM or ARM does not produce data of sufficient quality for comparison to the NAAQS, the monitoring agency must ensure that an operating FRM or filter-based FEM meeting the sample frequency requirements described in §58.10 or other Class III $PM_{2.5}$ FEM or ARM with data of sufficient quality is operating and reporting data to meet the network design criteria described in appendix D to this part.

(c) The annual monitoring network plan must document how state and local agencies provide for the review of changes to a $PM_{2.5}$ monitoring network that impact the location of a violating $PM_{2.5}$ monitor. The affected state or local agency must document the process for obtaining public comment and include any comments received through the public notification process within their submitted plan.

(d) The state, or where applicable local, agency shall perform and submit to the EPA Regional

Administrator an assessment of the air quality surveillance system every 5 years to determine, at a minimum, if the network meets the monitoring objectives defined in appendix D to this part, whether new sites are needed, whether existing sites are no longer needed and can be terminated, and whether new technologies are appropriate for incorporation into the ambient air monitoring network. The network assessment must consider the ability of existing and proposed sites to support air quality characterization for areas with relatively high populations of susceptible individuals (e.g., children with asthma), and, for any sites that are being proposed for discontinuance, the effect on data users other than the agency itself, such as nearby states and tribes or health effects studies. The state, or where applicable local, agency must submit a copy of this 5-year assessment, along with a revised annual network plan, to the Regional Administrator. The assessments are due every five years beginning July 1, 2010.

* * * * *

15. Section 58.11 is amended by adding paragraph (e) to read as follows:

§58.11 Network technical requirements.

* * * * *

(e) State and local governments must assess data from Class III $PM_{2.5}$ FEM and ARM monitors operated within their network using the performance criteria described in table C-4 to subpart C of part 53, for any case where the data are identified as not of sufficient comparability to a collocated FRM, such that the FEM or ARM should not be used in comparison to the NAAQS. These assessments are required in the monitoring agency's annual monitoring network plan described in §58.10(b)(13) for any case where the FEM or ARM is identified as not of sufficient comparability to a collocated FRM. The performance criteria apply with the following provisions to accommodate how monitoring agencies operate their collocated $PM_{2.5}$ methods:

(1) The acceptable concentration range (Rj), $\mu g/m^3$ may include values down to 0 $\mu g/m^3$.

(2) The minimum number of test sites shall be at least one; however, the number of test sites will generally include all locations within an agency's network with collocated FRMs and FEMs or ARMs.

(3) The minimum number of methods shall include at least one FRM and at least one FEM or ARM.

(4) Since multiple FRMs and FEMs may not apply; the precision statistic requirement does not apply, even if precision data are available.

(5) All seasons must be covered with no more than three years in total aggregated together.

16. Section 58.12 is amended by revising paragraph (d)(1)(iii) and by removing and reserving paragraph (f)(2).

The revision reads as follows:

§ 58.12 Operating schedules.

* * * * *

(d) * * *

(1) ***

(iii) Required SLAMS stations whose measurements determine the design value for their area and that are within plus or minus 5 percent of the 24-hour $PM_{2.5}$ NAAQS must have an FRM or FEM operate on a daily schedule if the design value for the annual NAAQS is less than the level of the annual $PM_{2.5}$ standard. A continuously operating FEM or ARM $PM_{2.5}$ monitor satisfies this requirement unless it is identified in the monitoring agency's annual monitoring network plan as not appropriate for comparison to the NAAQS.

* * * * *

17. Section 58.13 is amended by adding paragraphs (f) and (g) to read as follows:

§58.13 Monitoring network completion.

* * * * *

(f) $PM_{2.5}$ monitors required in near-road environments as described in appendix D to this part, must be physically established no later than January 1, 2015, and at that time, must be operating under all of the requirements of this part, including the requirements of appendices A, C, D, and E to this part.

(g) CSN (or IMPROVE) monitoring stations required as described in appendix D to this part not already

operational, must be physically established no later than January 1, 2015, and at that time must be operating under all of the requirements of this part, including the requirements of appendices A, C, D, and E to this part.

18. Section 58.16 is amended by revising paragraphs (a) and (f) to read as follows:

§58.16 Data submittal and archiving requirements.

(a) The state, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO_2; CO; O_3; NO_2; NO; NOy; NO_x; Pb–TSP mass concentration; Pb–PM_{10} mass concentration; PM_{10} mass concentration; $PM_{2.5}$ mass concentration; for filter-based $PM_{2.5}$ FRM/FEM the field blank mass, sampler-generated average daily temperature, and sampler-generated average daily pressure; chemically speciated $PM_{2.5}$ mass concentration data; $PM_{10\text{-}2.5}$ mass concentration; meteorological data from NCore and PAMS sites; average daily temperature and average daily pressure for Pb sites if not already reported from sampler generated records; and metadata records and information specified by the AQS Data Coding Manual (http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm). The state, or where appropriate, local agency, may report site specific meteorological measurements generated by onsite equipment (meteorological instruments, or sampler generated) or measurements from the nearest airport reporting ambient pressure and temperature. Such air quality data and information must be submitted directly to the AQS via electronic transmission on the specified quarterly schedule described in paragraph (b) of this section.

* * * * *

(f) The state, or where applicable, local agency shall archive all $PM_{2.5}$, PM_{10}, and $PM_{10–2.5}$ filters from manual low-volume samplers (samplers having flow rates less than 200 liters/minute) from all SLAMS sites for a minimum period of 5 years after collection. These filters shall be made available for supplemental analyses at the request of EPA or to provide information to state and local agencies on particulate matter composition. Other Federal agencies may request access to filters for purposes of

supporting air quality management or community health—such as biological assay—through the applicable EPA Regional Administrator. The filters shall be archived according to procedures approved by the Administrator, which shall include cold storage of filters after post-sampling laboratory analyses for at least 12 months following field sampling. The EPA recommends that particulate matter filters be archived for longer periods, especially for key sites in making NAAQS-related decisions or for supporting health-related air pollution studies.

* * * * *

Subpart C—Special Purpose Monitors

19. Section 58.20 is amended by revising paragraph (c) to read as follows:

§58.20 Special purpose monitors (SPM).

* * * * *

(c) All data from an SPM using an FRM, FEM, or ARM which has operated for more than 24 months are eligible for comparison to the relevant NAAQS, subject to the conditions of §§58.11(e) and 58.30, unless the air monitoring agency demonstrates that the data came from a particular period during which the requirements of appendix A, appendix C, or appendix E to this part were not met, subject to review and EPA Regional Office approval as part of the annual monitoring network plan described in §58.10.

* * * * *

Subpart D—Comparability of Ambient Data to the NAAQS

20. The heading for Subpart D is revised to read as set forth above.

21. Section 58.30 is amended by revising paragraph (a) to read as follows:

§58.30 Special considerations for data comparisons to the NAAQS.

(a) *Comparability of $PM_{2.5}$ data*. The primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS are described in part 50 of this chapter. Monitors that follow the network technical requirements specified in §58.11 are eligible for comparison to the NAAQS.

(1) $PM_{2.5}$ measurement data from all eligible monitors are compared to the 24-hour $PM_{2.5}$ NAAQS.

(2) $PM_{2.5}$ measurement data from all eligible monitors that are representative of area-wide air quality are compared to the annual $PM_{2.5}$ NAAQS. Area-wide means all monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro- or middle-scale that are representative of many such locations in the same CBSA. As specified in appendix D to this part, section 4.7.1, when micro- or middle-scale $PM_{2.5}$ monitoring sites are presumed to collectively identify a larger region of localized high ambient $PM_{2.5}$ concentrations; for example, a $PM_{2.5}$ monitoring site located in a near-road environment where there are many other similar locations in the same CBSA, these sites would be considered representative of an area-wide location and, therefore, eligible for comparison to the annual $PM_{2.5}$ NAAQS. $PM_{2.5}$ measurement data from monitors that are not representative of area-wide air quality but rather of relatively unique micro-scale, or localized hot spot, or relatively unique middle-scale impact sites are not eligible for comparison to the annual $PM_{2.5}$ NAAQS. As specified in §58.30(a)(1), $PM_{2.5}$ measurement data from these monitors are eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. For example, if a micro- or middle-scale $PM_{2.5}$ monitoring site is adjacent to a unique dominating local $PM_{2.5}$ source, then the $PM_{2.5}$ measurement data from such a site would only be eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. Approval of sites that are suitable and sites that are not suitable for comparison with the annual $PM_{2.5}$ NAAQS is provided for as part of the annual monitoring network plan described in §58.10.

* * * * *

22. Appendix A to part 58 is amended as follows:

a. By redesignating the existing introductory paragraph in section 1 as paragraph (c) in section 1 and revising it.

b. By adding paragraph (a) to section 1.

c. By adding paragraph (b) to section 1.

d. By revising paragraph 1.1.3.

e. By revising paragraphs 3.2.3, 3.2.4, 3.2.5.6, and 3.2.6.3.

f. By adding paragraph 3.2.9.

g. By revising paragraphs 3.3.2 and 3.3.3.

h. By adding paragraph 3.3.9.

i. By revising paragraphs (b) and (c) in section 4.

j. By adding paragraph (c)(6) in section 4.

k. By revising paragraph 4.3 and 4.3.1.

l. By revising Tables A-1 and A-2.

The revisions and additions read as follows:

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *

1. * * *

(a) For this Appendix, the term "$PM_{2.5}$" refers to $PM_{2.5}$ mass measurements used in determining whether areas meet the primary and secondary $PM_{2.5}$ standards and "$PM_{2.5}$ CSN" refers to the chemically speciated $PM_{2.5}$ mass measurements used to calculate $PM_{2.5}$ light extinction to determine if areas meet the secondary PM standard to address visibility impairment.

(b) Each monitoring organization is required to implement a quality system that provides sufficient information to assess the quality of the monitoring data. The quality system must, at a minimum, include the specific requirements described in this appendix of this subpart. Failure to conduct or pass a required check or procedure, or a series of required checks or procedures, does not by itself invalidate data for regulatory decision making. Rather, the checks and procedures required in this appendix shall be used in combination with other data quality information, reports, and similar documents showing overall compliance with part 58 by the monitoring agencies and by EPA, and using a "weight of evidence" approach when determining the suitability of data for regulatory decisions. The EPA reserves the authority to use or not use monitoring data submitted by a monitoring organization when making

regulatory decisions based on the EPA's assessment of the quality of the data. Generally, consensus built validation templates or validation criteria already approved in Quality Assurance Project Plans (QAPPs) should be used as the basis for the weight of evidence approach.

(c) This appendix specifies the minimum quality system requirements applicable to SLAMS air monitoring data and PSD data for the pollutants SO_2, NO_2, O_3, CO, Pb, $PM_{2.5}$, $PM_{2.5}$ CSN, PM_{10} and $PM_{10\ 2.5}$ submitted to EPA. This appendix also applies to all SPM stations using FRM, FEM, or ARM methods which also meet the requirements of appendix E of this part, unless alternatives to this appendix for SPMs have been approved in accordance with §58.11(a)(2). Monitoring organizations are encouraged to develop and maintain quality systems more extensive than the required minimums. The permit-granting authority for PSD may require more frequent or more stringent requirements. Monitoring organizations may, based on their quality objectives, develop and maintain quality systems beyond the required minimum. Additional guidance for the requirements reflected in this appendix can be found in the "Quality Assurance Handbook for Air Pollution Measurement Systems", volume II, part 1 (see reference 10 of this appendix) and at a national level in references 1, 2, and 3 of this appendix.

* * * * *

1.1.3 The requirements for precision assessment for the automated methods are the same for both SLAMS and PSD. However, for manual methods, only one collocated site is required for PSD. $PM_{2.5}$ CSN collocation is not required for PSD sites.

* * * * *

3. * * *

3.2 * * *

3.2.3 Flow Rate Verification for Particulate Matter. A one-point flow rate verification check must be performed at least once every month on each automated analyzer used to measure PM_{10}, $PM_{10-2.5}$, $PM_{2.5}$, and $PM_{2.5}$ CSN. The verification is made by checking the operational flow rate of the analyzer. If the verification is made in conjunction with a flow rate adjustment, it must be made prior to such flow rate

adjustment. Randomization of the flow rate verification with respect to time of day, day of week, and routine service and adjustments is encouraged where possible. For the standard procedure, use a flow rate transfer standard certified in accordance with section 2.6 of this appendix to check the analyzer's normal flow rate. Care should be used in selecting and using the flow rate measurement device such that it does not alter the normal operating flow rate of the analyzer. Report the flow rate of the transfer standard and the corresponding flow rate measured by the analyzer. The percent differences between the audit and measured flow rates are used to assess the bias of the monitoring data as described in section 4.2.2 of this appendix (using flow rates in lieu of concentrations).

3.2.4 Semi-Annual Flow Rate Audit for Particulate Matter. Every 6 months, audit the flow rate of the PM_{10}, $PM_{10-2.5}$, $PM_{2.5}$, and $PM_{2.5}$ CSN particulate analyzers. Where possible, EPA strongly encourages more frequent auditing. The audit should (preferably) be conducted by a trained experienced technician other than the routine site operator. The audit is made by measuring the analyzer's normal operating flow rate using a flow rate transfer standard certified in accordance with section 2.6 of this appendix. The flow rate standard used for auditing must not be the same flow rate standard used to calibrate the analyzer. However, both the calibration standard and the audit standard may be referenced to the same primary flow rate or volume standard. Great care must be used in auditing the flow rate to be certain that the flow measurement device does not alter the normal operating flow rate of the analyzer. Report the audit flow rate of the transfer standard and the corresponding flow rate measured (indicated) by the analyzer. The percent differences between these flow rates described in section 4.2.3 of this appendix are used to validate the one-point flow rate verification checks described in section 4.2.2 of this appendix.

3.2.5 * * *

3.2.5.6 The two collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference. A waiver of up to 10 meters between a primary and

collocated sampler may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation. Calibration, sampling, and analysis must be the same for all the collocated samplers in each agency's network.

* * * * *

3.2.6* * *

3.2.6.3 The two collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference. A waiver of up to 10 meters between a primary and a collocated sampler may be approved by the Regional Administrator for sites at a neighborhood or larger scale of representation taking into consideration safety, logistics, and space availability. Calibration, sampling, and analysis must be the same for all the collocated samplers in each agency's network.

* * * * *

3.2.9 Collocated Sampling Procedures for $PM_{2.5}$ CSN. $PM_{2.5}$ CSN Collocation is not required for PSD sites. A minimum of six collocated sites are required nationally for the CSN monitoring network. Sites selected for collocation should reflect spatial, temporal, and constituent variability of the chemical speciation network. Collocated sites may be rotated within the network at 3 year intervals. Decisions on rotations will be made by the Regional Administrator taking into consideration geographic coverage, chemical species, and capabilities of the monitoring agency. Data from the collocated sites will be used to estimate precision of the secondary PM standard to address visibility impairment. For each pair of collocated monitors, designate one sampler as the primary monitor whose concentrations will be used to report air quality for the site, and designate the other as the audit monitor.

3.2.9.1 The two collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference. Calibration, sampling, and analysis must be the same for all the collocated samplers in each agency's network.

3.2.9.2 Sample the collocated audit monitor on a 12-day schedule. Report the measurements from both primary and collocated audit monitors at each collocated sampling site. The calculations for evaluating precision between the two collocated monitors are described in section 4.3.1 of this appendix.

3.3* * *

3.3.2 Flow Rate Verification for Particulate Matter. Follow the same procedure as described in section 3.2.3 of this appendix for $PM_{2.5}$, $PM_{2.5}$ CSN, PM_{10} (low-volume instruments), and $PM_{10-2.5}$. High-volume PM_{10} and TSP instruments can also follow the procedure in section 3.2.3 but the audits are required to be conducted quarterly. The percent differences between the audit and measured flow rates are used to assess the bias of the monitoring data as described in section 4.2.2 of this appendix.

3.3.3 Semi-Annual Flow Rate Audit for Particulate Matter. Follow the same procedure as described in section 3.2.4 of this appendix for $PM_{2.5}$, $PM_{2.5}$ CSN, PM_{10}, $PM_{10-2.5}$ and TSP instruments. The percent differences between these flow rates described in section 4.2.3 of this appendix are used to validate the one-point flow rate verification checks described in section 4.2.2 of this appendix.

Great care must be used in auditing high-volume particulate matter samplers having flow regulators because the introduction of resistance plates in the audit flow standard device can cause abnormal flow patterns at the point of flow sensing. For this reason, the flow audit standard should be used with a normal filter in place and without resistance plates in auditing flow-regulated high-volume samplers, or other steps should be taken to assure that flow patterns are not perturbed at the point of flow sensing.

* * * * *

3.3.9 Collocated Sampling Procedures for $PM_{2.5}$ CSN. $PM_{2.5}$ CSN Collocation is not required for PSD sites. Follow the same procedure as described in Section 3.2.9

4. * * *

(b) The EPA will provide annual assessments of data quality aggregated by site and primary quality assurance organization for SO_2, NO_2, O_3 and CO; by primary quality assurance organization for PM_{10}, $PM_{2.5}$, and Pb; and by primary quality assurance organization and nationally for $PM_{10-2.5}$, Pb at NCore,

and $PM_{2.5}$ CSN.

(c) At low concentrations, agreement between values (measurements or calculations) of collocated samplers, expressed as relative percent difference or percent difference, may be relatively poor. For this reason, collocated pairs are selected for use in the precision and bias calculations only when both values are equal to or above the following limits:

* * * * *

(6) $PM_{2.5}$ CSN: 5 deciviews

* * * * *

4.3 Statistics for the Assessment of $PM_{2.5}$, $PM_{2.5}$ CSN, and $PM_{10-2.5}$.

4.3.1 Precision Estimate. Precision for collocated instruments for $PM_{2.5}$, $PM_{2.5}$ CSN, and $PM_{10-2.5}$ may be estimated where both the primary and collocated instruments are the same method designation and when the method designations are not similar. Follow the procedure described in section 4.2.1 of this appendix. In addition, one may want to perform an estimate of bias when the primary monitor is an FEM and the collocated monitor is an FRM. Follow the procedure described in section 4.1.3 of this appendix in order to provide an estimate of bias using the collocated data.

* * * * *

Table A–1 of Appendix A to Part 58—Difference and Similarities Between SLAMS and PSD Requirements

Topic	SLAMS	PSD
Requirements	1. The development, documentation, and implementation of an approved quality system 2. The assessment of data quality 3. The use of reference, equivalent, or approved methods 4. The use of calibration standards traceable to NIST or other primary standard 5. The participation in EPA performance evaluations and the permission for EPA to conduct system audits	Same as SLAMS

Monitoring and QA Responsibility	State/local agency via the "primary quality assurance organization"	Source owner/operator.
Monitoring Duration	Indefinitely	Usually up to 12 months.
Annual Performance Evaluation (PE)	Standards and equipment different from those used for spanning, calibration, and verifications. Prefer different personnel	Personnel, standards and equipment different from those used for spanning, calibration, and verifications.
PE audit rate:		
—Automated	100% per year	100% per quarter.
—Manual	Varies depending on pollutant. See Table A–2 of this appendix	100% per quarter.
Precision Assessment:		
—Automated	One-point QC check biweekly but data quality dependent	One point QC check biweekly.
—Manual	Varies depending on pollutant. See Table A–2 of this appendix	One site: 1 every 6 days or every third day for daily monitoring (TSP and Pb).
Reporting		
—Automated	By site—EPA performs calculations annually	By site—source owner/operator performs calculations each sampling quarter.
—Manual	By reporting organization—EPA performs calculations annually	By site—source owner/operator performs calculations each sampling quarter.

Table A–2 of Appendix A to Part 58—Minimum Data Assessment Requirements for SLAMS Sites

Method	Assessment method	Coverage	Minimum Frequency	Parameters reported
Automated Methods				
1-Point QC for SO_2, NO_2, O_3, CO	Response check at concentration 0.01–0.1 ppm SO_2, NO_2, O_3, and 1–10 ppm CO	Each analyzer	Once per 2 weeks	Audit concentration[1] and measured concentration[2]
Annual performance evaluation for SO_2, NO_2, O_3, CO	See section 3.2.2 of this appendix	Each analyzer	Once per year	Audit concentration[1] and measured concentration[2] for each level.

Flow rate verification PM_{10},$PM_{2.5}$, $PM_{2.5}$ CSN $PM_{10–2.5}$	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM_{10},$PM_{2.5}$, $PM_{2.5}$ CSN $PM_{10–2.5}$	Check of sampler flow rate using independent standard	Each sampler	Once every 6 months	Audit flow rate and measured flow rate indicated by the sampler.
Collocated sampling $PM_{2.5}$,$PM_{10–2.5}$	Collocated samplers	15%	Every 12 days	Primary sampler concentration and duplicate sampler concentration.
$PM_{2.5}$ CSN	Collocated samplers	6 per national network	Every 12 days	Primary sampler concentration and duplicate sampler concentration.
Performance evaluation program $PM_{2.5}$,$PM_{10–2.5}$	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites 2. 8 valid audits for primary QA orgs, with >5 sites 3. All samplers in 6 years	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Manual Methods				
Collocated sampling PM_{10},TSP, $PM_{10–2.5}$, $PM_{2.5}$, Pb-TSP, Pb-PM_{10}	Collocated samplers	15%	Every 12 days PSD—every 6 days	Primary sampler concentration and duplicate sampler concentration.
$PM_{2.5}$ CSN	Collocated samplers	6 per network	Every 12 days	Primary sampler concentration and duplicate sampler concentration.
Flow rate verification PM_{10} (low-vol), $PM_{10-2.5}$, $PM_{2.5}$, $PM_{2.5}$ CSN, Pb-PM_{10}	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.
Flow rate verification PM_{10}	Check of sampler flow rate	Each sampler	Once every quarter	Audit flow rate and measured flow rate

(high-vol), TSP, Pb-TSP				indicated by the sampler.
Semi-annual flow rate audit PM_{10}, TSP, $PM_{10-2.5}$, $PM_{2.5}$, $PM_{2.5}$ CSN, Pb-TSP, Pb-PM_{10}	Check of sampler flow rate using independent standard	Each sampler, all locations	Once every 6 months	Audit flow rate and measured flow rate indicated by the sampler.
Pb audit strips Pb-TSP, Pb-PM_{10}	Check of analytical system with Pb audit strips	Analytical	Each quarter	Actual concentration and audit concentration.
Performance evaluation program $PM_{2.5}$, $PM_{10-2.5}$	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites 2. 8 valid audits for primary QA orgs, with >5 sites 3. All samplers in 6 years	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Performance evaluation program Pb-TSP, Pb-PM_{10}	Collocated samplers	1. 1 valid audit and 4 collocated samples for primary QA orgs, with >5 sites 2. 2 valid audits and 6 collocated samples for primary QA orgs, with >5 sites	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration. Primary sampler concentration and duplicate sampler concentration.

[1]Effective concentration for open path analyzers.
[2]Corrected concentration, if applicable, for open path analyzers.

* * * * *

23. Appendix C to part 58 is amended as follows:

a. By revising paragraph 2.9.

b. In section 6.0 by adding references 8 through 13.

Appendix C to Part 58—Ambient Air Quality Monitoring Methodology

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2.9 Use of Chemical Speciation Methods at SLAMS

$PM_{2.5}$ chemical speciation network (CSN) stations include analysis for elements, selected anions and cations, and carbon. Descriptions of the CSN standard operating procedures and QAPP are available in references 10 and 11. Interagency Monitoring of Protected Visual Environments (IMPROVE) station methods also provide analysis for elements, selected anions and cations, and carbon, and in addition include a PM_{10} mass channel. Descriptions of the IMPROVE samplers and the data they collect are available in references 4, 5, and 6 of this appendix. The CSN Quality Assurance Project Plan (QAPP) (which include field SOPs), and laboratory SOPs are available in references 8 through 13.

2.9.1 Use of IMPROVE Samplers at a SLAMS Site. IMPROVE samplers may be used in SLAMS for monitoring of regional background and regional transport concentrations of fine particulate matter. The IMPROVE samplers were developed for use in the IMPROVE network to characterize all of the major components and many trace constituents of the particulate matter that impair visibility in Federal Class I Areas.

2.9.2 Use of CSN or IMPROVE sampling methods at a SLAMS site to provide chemical species data used in the $PM_{2.5}$ light extinction calculation. Chemical species data resulting from CSN or IMPROVE sampling methods used at SLAMS are eligible for use in the $PM_{2.5}$ light extinction calculation defined in Appendix N to 40 CFR Part 50.

* * * * *

6.0 References

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8. Quality Assurance Project Plan: $PM_{2.5}$ Chemical Speciation Sampling at Trends, NCore, Supplemental and Tribal Sites. Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711. EPA-454/B-12-003. June 2012.

9. Standard Operating Procedure for the X-Ray Fluorescence Analysis of Particulate Matter Deposits on Teflon Filters, RTI International, Research Triangle Park, NC. August 19, 2009.

10. Standard Operating Procedure for $PM_{2.5}$ Cation Analysis, RTI International, Research Triangle Park, NC. August 25, 2009.

11. Standard Operating Procedure for $PM_{2.5}$ Anion Analysis, RTI International, Research Triangle Park, NC. August 26, 2009.

12. Standard Operating Procedure for Cleaning Nylon Filters Used for the Collection of $PM_{2.5}$ Material, RTI International, Research Triangle Park, NC. August 25, 2009.

13. DRI Standard Operating Procedure #2-216r2 – DRI Model 2001 Thermal/Optical Carbon Analysis (TOR/TOT) of Aerosol Filter Samples – Method IMPROVE_A, Reno, NC, Revised July 2008.

24. Appendix D to part 58 is amended as follows:

a. By revising paragraphs 4.7.1(b), 4.7.1(c)(1), and 4.7.4

b. By removing paragraph 4.7.5

c. By removing and reserving paragraph 4.8.2

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

4. * * *

4.7 * * *

4.7.1* * *

(b) Specific Design Criteria for $PM_{2.5}$. The required monitoring stations or sites must be sited to represent area-wide air quality. These sites can include sites collocated at PAMS. These monitoring stations will typically be at neighborhood or urban-scale; however, micro-or middle-scale $PM_{2.5}$ monitoring sites that represent many such locations throughout a metropolitan area are considered to represent area-wide air quality.

(1) At least one monitoring station is to be sited in an area of expected maximum concentration.

(2) For MSAs with a population over 1,000,000, at least one $PM_{2.5}$ FRM, FEM, or ARM is to be collocated at a near-road NO_2 station described in section 4.3.2(a) of this appendix.

(3) For areas with additional required SLAMS, a monitoring station is to be sited in an area of poor air quality.

(4) Additional technical guidance for siting $PM_{2.5}$ monitors is provided in references 6 and 7 of this appendix.

(c) ***

(1) *Micro-scale*. This scale would typify areas such as downtown street canyons and traffic corridors where the general public would be exposed to maximum concentrations from mobile sources. In some circumstances, the micro-scale is appropriate for particulate sites. SLAMS sites measured at the micro-scale level should, however, be limited to urban sites that are representative of long-term human exposure and of many such microenvironments in the area. In general, micro-scale particulate matter sites should be located near inhabited buildings or locations where the general public can be expected to be exposed to the concentration measured. Emissions from stationary sources such as primary and secondary smelters, power plants, and other large industrial processes may, under certain plume conditions, likewise result in high ground level concentrations at the micro-scale. In the latter case, the micro-scale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Data collected at micro-scale sites provide information for evaluating and developing hot spot control measures.

* * * * *

4.7.4 $PM_{2.5}$ Chemical Speciation Site Requirements.

(a) Each state shall continue to conduct chemical speciation monitoring and analysis at sites designated to be part of the $PM_{2.5}$ Speciation Trends Network (STN). The selection and modification of these STN sites must be approved by the Administrator. The $PM_{2.5}$ chemical speciation urban trends sites shall include analysis for elements, selected anions and cations, and carbon. Samples must be collected using the monitoring methods and the sampling schedules approved by the Administrator. Chemical speciation is encouraged at additional sites where the chemically resolved data would be useful in developing state

implementation plans and supporting atmospheric or health effects related studies.

(b) For purposes of supplying chemical species data for use in the calculated $PM_{2.5}$ light extinction indicator, states shall be required to operate CSN or IMPROVE monitoring stations at SLAMS under the following provisions:

(1) Operation of CSN or IMPROVE measurements is only required in states having at least one CBSA with a population of 1,000,000 or more people; however, multiple CBSAs with a population of 1,000,000 or more people in the same state are not each required to have CSN or IMPROVE methods operating at SLAMS unless specified below.

(2) The requirement to operate at least one CSN or IMPROVE monitoring station in a CBSA at a SLAMS shall be considered met by any approved NCore or STN station operating in a CBSA within the state.

(3) All CBSAs with a population of 2,500,000 or more people shall be required to have at least one CSN or IMPROVE monitoring station at a SLAMS within the CBSA; alternatively, the CSN or IMPROVE monitoring station may be sited in another CBSA adjacent to or downwind of the CBSA with a population of 2,500,000 or more people, when the alternative CBSA is expected to have a higher design value for the secondary PM NAAQS for visibility impairment.

(4) When siting additional CSN or IMPROVE monitoring equipment at SLAMS, the location of the monitoring site can be either a representative area-wide location for the CBSA or in an area-wide location of expected maximum concentration.

* * * * *

25. Appendix E to part 58 is amended as follows:

a. By adding paragraph (d) to section 1.

b. By adding table E-1 to section 6 after paragraph (c) introductory text.

c. By revising table E-4 in section 11.

Appendix E to Part 58—Probe and Monitoring Path Siting Criteria for Ambient Air Quality

Monitoring

* * * * *

1. * * *

(d) $PM_{2.5}$ CSN measurement equipment sited at SLAMS to provide data for use in the calculation for comparison to the secondary PM standard to address visibility impairment follow the same probe and siting criteria as prescribed for PM samplers in this appendix.

* * * * *

6. * * *

Table E-1 to Appendix E of Part 58. Minimum Separation Distance Between Roadways and Probes or Monitoring Paths for Monitoring Neighborhood and Urban Scale Ozone (O_3) and Oxides of Nitrogen (NO, NO_2, NO_X, NO_Y)

Roadway average daily traffic, vehicles per day	Minimum distance [1] (meters)	Minimum distance[1,2] (meters)
≤ 1,000 …….	10	10
10,000 ……..	10	20
15,000 ……..	20	30
20,000 ……..	30	40
40,000 ……..	50	60
70,000 ……..	100	100
≥ 110,000 ……	250	250

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2] Applicable for ozone monitors whose placement has not already been approved as of December 18, 2006.

* * * * *

11. * * *

Table E–4 of Appendix E to Part 58—Summary of Probe and Monitoring Path Siting Criteria

Pollutant	Scale (maximum monitoring path length, meters)	Height from ground to probe, inlet or 80% of monitoring path[1] (meters)	Horizontal and vertical distance from supporting structures[2] to probe, inlet or 90% of monitoring path[1] (meters)	Distance from trees to probe, inlet or 90% of monitoring path[1] (meters)	Distance from roadways to probe, inlet or monitoring path[1] (meters)
SO_2[3,4,5,6]	Middle (300 m) Neighborhood Urban, and Regional (1 km)	2–15	>1	>10	N/A
CO[4,5,7]	Micro, middle (300 m), Neighborhood (1 km)	3 1/2: 2–15	>1	>10	2–10; *see* Table E–2 of this appendix for middle and neighborhood scales.
O_3[3,4,5]	Middle (300 m) Neighborhood, Urban, and Regional (1 km)	2–15	>1	>10	*See* Table E–1 of this appendix for all scales.
NO_2[3,4,5]	Micro (Near-road [50–300 m])	2–7 (micro);	>1	>10	≤50 meters for near-road micro-scale.
	Middle (300 m)	2–15 (all other scales)			
	Neighborhood, Urban, and Regional (1 km)				*See* Table E–1 of this appendix for all other scales
Ozone precursors (for PAMS)[345]	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	>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

		scales)			

N/A—Not applicable.
[1]Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring, middle, neighborhood, urban, and regional scale NO_2 monitoring, and all applicable scales for monitoring SO_2,O_3, and O_3 precursors.
[2]When probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.
[3]Should be greater than 20 meters from the dripline of tree(s) and must be 10 meters from the dripline when the tree(s) act as an obstruction.
[4]Distance from sampler, probe, or 90 percent of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the sampler, probe, or monitoring path. Sites not meeting this criterion may be classified as middle scale (*see* text).
[5]Must have unrestricted airflow 270 degrees around the probe or sampler; 180 degrees if the probe is on the side of a building or a wall.
[6]The probe, sampler, or monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.
[7]For micro-scale CO monitoring sites, the probe must be >10 meters from a street intersection and preferably at a midblock location.
[8]Collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference, unless a waiver is in place as approved by the Regional Administrator.

26. Appendix G to Part 58 is amended:

a. By revising sections 9 and 10.

b. By revising paragraph 12.i.a and table 2 in 12.i.d..

c. By revising section 13.

The revisions read as follows:

Appendix G to Part 58 - Uniform Air Quality Index (AQI) and Daily Reporting

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9. *How Does the AQI Relate to Air Pollution Levels?*

For each pollutant, the AQI transforms ambient concentrations to a scale from 0 to 500. The AQI is keyed as appropriate to the national ambient air quality standards (NAAQS) for each pollutant. In most cases, the index value of 100 is associated with the numerical level of the short-term standard (i.e.,

averaging time of 24-hours or less) for each pollutant. The index value of 50 is associated with the numerical level of the annual standard for a pollutant, if there is one, at one-half the level of the short-term standard for the pollutant, or at the level at which it is appropriate to begin to provide guidance on cautionary language. Higher categories of the index are based on increasingly serious health effects and increasing proportions of the population that are likely to be affected. The index is related to other air pollution concentrations through linear interpolation based on these levels. The AQI is equal to the highest of the numbers corresponding to each pollutant. For the purposes of reporting the AQI, the sub-indexes for PM_{10} and $PM_{2.5}$ are to be considered separately. The pollutant responsible for the highest index value (the reported AQI) is called the "critical" pollutant.

10. *What Monitors Should I Use to Get the Pollutant Concentrations For Calculating the AQI?*

You must use concentration data from State/Local Air Monitoring Station (SLAMS) or parts of the SLAMS required by 40 CFR 58.10 for each pollutant except PM. For PM, calculate and report the AQI on days for which you have measured air quality data (e.g., from continuous $PM_{2.5}$ monitors required in Appendix D to this part). You may use PM measurements from monitors that are not reference or equivalent methods (for example, continuous PM_{10} or $PM_{2.5}$ monitors). Detailed guidance for relating non-approved measurements to approved methods by statistical linear regression is referenced in section 13 of this appendix.

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12. * * *

i. * * *

a. Identify the highest concentration among all of the monitors within each reporting area and truncate as follows:

(1) Ozone – truncate to 3 decimal places

$PM_{2.5}$ – truncate to 1 decimal place

PM_{10} – truncate to integer

CO – truncate to 1 decimal place

SO_2 – truncate to integer

NO_2 – truncate to integer

d. * * *

Table 2.—Breakpoints For The AQI

These breakpoints							Equal these AQI's	
O_3 (ppm) 8-hour	**O_3 (ppm) 1-hour[1]**	**$PM_{2.5}$ (µg/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 -13.0)	0-54	0.0-4.4	0-35	0-53	0-50	Good
0.060-0.075	.....	(12.1 – 13.1) – 35.4	55-154	4.5-9.4	36-75	54-100	51-100	Moderate
0.076-0.095	0.125-0.164	35.5 – 55.4	155-254	9.5-12.4	76-185	101-360	101-150	Unhealthy for Sensitive Groups
0.096-0.115	0.165-0.204	55.5 - 150.4	255-354	12.5-15.4	186-304	361-649	151-200	Unhealthy
0.116-0.374	0.205-0.404	150.5 - 250.4	355-424	15.5-30.4	305-604	650-1249	201-300	Very Unhealthy
([2]).....	0.405-0.504	250.5 - 350.4	425-504	30.5-40.4	605-804	1250-1649	301-400	Hazardous.
([2]).....	0.505-0.604	350.5 - 500.4	505-604	40.5-50.4	805-1004	1650-2049	401-500	

[1] Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI based on 1-hour ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index value may be calculated, and the maximum of the two values reported.

[2] 8-hour O_3 values do not define higher AQI values (≥ 301). AQI values of 301 or greater are calculated with 1-hour O_3 concentrations.

13. *What Additional Information Should I Know?*

The EPA has developed a computer program to calculate the AQI for you. The program prompts for inputs, and it displays all the pertinent information for the AQI (the index value, color, category, sensitive group, health effects, and cautionary language). The EPA has also prepared a brochure on the AQI that explains the index in detail (The Air Quality Index), Reporting Guidance (Technical Assistance Document for the Reporting of Daily Air Quality –the Air Quality Index (AQI)) that provides associated health effects and cautionary statements, and Forecasting Guidance (Guideline for Developing an Ozone Forecasting Program) that explains the steps necessary to start an air pollution forecasting program. You can download the program and the guidance documents at www.airnow.gov. Reference for relating non-approved PM measurements to approved methods (Eberly, S., T. Fitz-Simons, T. Hanley, L. Weinstock., T. Tamanini, G. Denniston, B. Lambeth, E. Michel, S. Bortnick. Data Quality Objectives (DQOs) For Relating Federal Reference Method (FRM) and Continuous $PM_{2.5}$ Measurements to Report an Air Quality Index (AQI). U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-454/B-02-002, November 2002) can be found on the Ambient Monitoring Technology Information Center (AMTIC) website, http://www.epa.gov/ttnamti1/.

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